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*Status: Point in time view as at 21/03/2024.*

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## STATUTORY INSTRUMENTS

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# 2002 No. 618

## CONSUMER PROTECTION

### The Medical Devices Regulations 2002

*Made* - - - - 20th May 2002  
*Laid before Parliament* 21st May 2002  
*Coming into force* - - 13th June 2002

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972<sup>M1</sup> in relation to measures relating to medical devices<sup>M2</sup>, in exercise of the powers conferred by the said section 2(2), in exercise, with the consent of the Treasury, of the powers conferred by section 56(1) and (2) of the Finance Act 1973<sup>M3</sup>, in exercise of the powers conferred by sections 11 and 27(2) of the Consumer Protection Act 1987<sup>M4</sup>, and in exercise of all other powers enabling him in that behalf, after consultation in accordance with section 11(5) of the Consumer Protection Act 1987 with organisations appearing to him to be representative of interests substantially affected by these Regulations, with such other persons considered by him appropriate and with the Health and Safety Commission, hereby makes the following Regulations:—

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#### **Modifications etc. (not altering text)**

**C1** [Regulations](#): power to amend conferred (11.2.2021) by [Medicines and Medical Devices Act 2021](#) (c. 3), [ss. 15\(1\)](#), [50\(1\)\(f\)](#)

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#### **Marginal Citations**

**M1** [1972 c. 68](#).

**M2** The Secretary of State was designated in relation to measures relating to active implantable medical devices in [S.I. 1991/2289](#), and in relation to measures relating to medical devices other than active implantable medical devices in [S.I. 1993/2661](#).

**M3** [1973 c. 51](#).

**M4** [1987 c. 43](#).

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## PART I

### *Introductory Provisions Relating to all Medical Devices*

#### **Citation and commencement**

1. These Regulations may be cited as the Medical Devices Regulations 2002 and shall come into force 13th June 2002.

#### **Expiry of certain provisions in these Regulations**

[<sup>F1</sup>1ZA.—(1) Subject to paragraph (3), regulations 19B and 30A cease to have effect at 23:59 on 30 June 2028.

(2) Subject to paragraph (3), regulations 19C, 44ZA and 44ZB cease to have effect at 23:59 on 30 June 2030.

(3) The following cease to have effect at 23:59 on 30 June 2023—

- (a) regulation 19B(4), (5), (8) and (9);
- (b) regulation 19C(8) and (9);
- (c) regulation 30A(4) to (7);
- (d) regulation 44ZA(4) and (5);
- (e) regulation 44ZB(4) and (5).]

#### **Textual Amendments**

**F1** Reg. 1ZA substituted (30.6.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(1), 4

#### **[<sup>F2</sup>Schedules**

1A. Schedules 2 and 2A have effect.]

#### **Textual Amendments**

**F2** Regs. 1ZA, 1A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(2)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, 3); 2020 c. 1, **Sch. 5 para. 1(1)**

#### **Interpretation** **E+W+S**

2.—(1) <sup>F3</sup>... In these Regulations <sup>F4</sup>...—

<sup>F5</sup>...

“active implantable medical device” means a medical device which—

- (a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and
- (b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to

remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product;

F6  
...

[<sup>F7</sup>“approved body” is to be construed in accordance with regulation A45;]

F8  
...

F9  
...

“CE marking” means a conformity marking consisting of the initials “CE”;

F10  
...

[<sup>F11</sup>“clinical data” means the safety or performance information that is generated from the use of a device, derived from—

- (a) clinical investigations of the device concerned; or
- (b) clinical investigations or other studies reported in scientific literature of a similar device for which equivalence to the device in question can be demonstrated; or
- (c) published or unpublished reports on other clinical experiences of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;]

[<sup>F12</sup>“coronavirus test device” means an *in vitro* diagnostic medical device for the detection of the presence of a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);]

[<sup>F13</sup>“designated standard” has the meaning given in regulation 3A;]

“device for performance evaluation” means a product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises;

[<sup>F14</sup>“Directive 90/385” means Council Directive [90/385/EEC](#) of 20 June 1990 on the approximation of the laws of Member States relating to active implantable devices [<sup>F15</sup>as it had effect immediately before IP completion day];]

[<sup>F16</sup>“Directive 93/42” means Council Directive [93/42/EEC](#) of 14 June 1993 concerning medical devices [<sup>F17</sup>as it had effect immediately before IP completion day];]

[<sup>F18</sup>“Directive 98/79” means Directive [98/79/EC](#) of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices [<sup>F19</sup>as it had effect immediately before IP completion day];]

F20  
...

[<sup>F21</sup>“Directive 2003/12” means Commission Directive 2003/12 of 3rd February 2003 on the reclassification of breast implants in the framework of Directive [93/42/EEC](#) concerning medical devices;]

F22  
...

[<sup>F23</sup>“Directive 2005/50” means Commission Directive [2005/50/EC](#) of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive [93/42/EEC](#) concerning medical devices;]

[<sup>F24</sup>“Directive 2007/47” means Directive [2007/47/EC](#) of the European Parliament and of the Council amending Council Directive [90/385/EEC](#) on the approximation of the laws of the

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Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market;]

F25  
...

“<sup>F26</sup>... CAB” shall be construed in accordance with regulation 48(1);

F27  
...

F28  
...

F29  
...

[<sup>F30</sup>“hazard” means a potential source of injury or damage to health;]

[<sup>F31</sup>“hip, knee or shoulder replacement” means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint, other than ancillary components (screws, wedges, plates and instruments);]

[<sup>F32</sup>“intended for clinical investigation” means—

- (a) intended for use by a registered medical practitioner when conducting investigations of that device in an adequate human clinical environment; or
- (b) intended for use by any other person in [<sup>F33</sup>Great Britain] who, by virtue of their professional qualification, is authorised to carry out investigations of that device in an adequate human clinical environment;]

“intended purpose” means—

- (a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;
- (b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials;

“*in vitro* diagnostic medical device” means a medical device which—

- (a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
- (b) is intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—
  - (i) concerning a physiological or pathological state,
  - (ii) concerning a congenital abnormality,
  - (iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
  - (iv) to monitor therapeutic measures,
 and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination;

[<sup>F34</sup>“machinery” has the meaning given to it by [<sup>F35</sup>regulation 4 of the Supply of Machinery (Safety) Regulations 2008];]

“manufacturer” means—

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- (a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or
- (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient;

“medical device” means [<sup>F36</sup>any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application,] which—

- (a) is intended by the manufacturer to be used for human beings for the purpose of-
  - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
  - (iv) control of conception; and
- (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

“the Medical Devices Directives” means Directive 90/385, Directive 93/42, [<sup>F37</sup>both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012] and Directive 98/79;

<sup>F38</sup> ...

“medicinal product” has the meaning given in [<sup>F39</sup>regulation 2(1) of the Human Medicines Regulations 2012];

[<sup>F40</sup>“mutual recognition agreement” means an agreement that—

- (a) is between the United Kingdom and a country listed in Schedule 2, and
- (b) covers matters including the conditions under which the United Kingdom and [<sup>F41</sup>that country] will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies;]

<sup>F42</sup> ...

<sup>F43</sup> ...

<sup>F44</sup> ...

“placing on the market” means, in relation to a medical device, the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on the [<sup>F45</sup>Great Britain] market [<sup>F46</sup>and related expressions must be construed accordingly];

“putting into service” means—

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- (a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation;
- (b) in relation to any other medical device, the first making available of the device in <sup>[F47]</sup>Great Britain] to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

<sup>[F48]</sup>“Regulation (EU) No 207/2012” means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices;<sup>[F49]</sup>(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)]

“Regulation (EU) No 722/2012” means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives [90/385/EEC](#) and [93/42/EEC](#) with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin; <sup>[F50]</sup>(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)]

<sup>[F51]</sup>“Regulation (EU) 2017/745” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending [Directive 2001/83/EC](#), Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives [90/385/EEC](#) and [93/42/EEC](#);

<sup>[F51]</sup>“Regulation (EU) 2017/746” means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing [Directive 98/79/EC](#) and Commission [Decision 2010/227/EU](#);

<sup>[F52]</sup>“Regulation (EU) 2022/1107” means Commission Implementing [Regulation \(EU\) 2022/1107](#) of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council;

“relevant essential requirements”, in relation to a medical device, means the essential requirements set out in Annex 1 of Directive 90/385, Annex I of Directive 93/42 or Annex I of Directive 98/79 which apply to it, but not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation;

“specimen receptacle” means a medical device which (whether vacuum-type or not) is specifically intended by its manufacturer to be used for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination;

“stable derivatives device” means a medical device that contains human blood, blood products, plasma or blood cells of human origin, and which incorporates, as an integral part, a substance which—

- (a) if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of <sup>[F53]</sup>regulation 2(2) of the Human Medicines Regulations 2012]; and
- (b) is liable to act upon the human body with action ancillary to that of the device;

<sup>[F54]</sup>“*statistical review*” means a review of the statistical sections of the written notice which a manufacturer or their UK responsible person submits to the Secretary of State pursuant to regulation 16(1) or 29(1) in respect of an intended clinical investigation of a relevant device;]

“supply”, in relation to a medical device, means—

- (a) the supply of, or the offer or agreement to supply, the device; or

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(b) the exposure or possession for supply of the device;

[<sup>F55</sup>“third country conformity assessment body” means a body established in a country which is listed in Schedule 2 and designated in accordance with a relevant mutual recognition agreement to carry out conformity assessment procedures for the purposes of these Regulations;]

F56 ...

[<sup>F57</sup>“UK marking” has the meaning given in Article 2(22) of Regulation (EC) No 765/2008;] and

F58 ...

[<sup>F59</sup>“UK responsible person” means a person established in any part of the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations.]

[<sup>F60</sup>(1A) In these Regulations, any reference to Annexes 1 to 7 to Directive 90/385, Annexes I to X to Directive 93/42 or Annex I to X to Directive 98/79 is to be construed as a reference to those Annexes [<sup>F61</sup>as they applied immediately before IP completion day and as modified by Schedule 2A.]]

[<sup>F62</sup>(1B) In these Regulations, any reference to Annex 1 to Directive 90/385 or to Annex I to Directive 93/42 is to that Annex read with Regulation (EU) No 207/2012.]

(2) In these Regulations, unless the context otherwise requires, a reference—

- (a) to a numbered regulation, Part or Schedule is to the regulation or Part of, or the Schedule to, these Regulations bearing that number;
- (b) in a regulation to a numbered or lettered paragraph is to the paragraph of that regulation bearing that number or letter; and
- (c) in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph in that paragraph bearing that number or letter.

### Extent Information

**E1** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

**F3** Words in [reg. 2\(1\)](#) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021](#) (S.I. 2021/873), [reg. 1\(1\)](#), [Sch. 1 para. 1\(a\)](#)

**F4** Words in [reg. 2\(1\)](#) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003](#) (S.I. 2003/1697), [regs. 1\(1\)\(a\)](#), [2\(a\)](#)

**F5** Words in [reg. 2\(1\)](#) omitted (26.5.2021) by virtue of [Medicines and Medical Devices Act 2021](#) (c. 3), [ss. 41\(4\)](#), [50\(3\)](#) (with [s. 41\(8\)](#)); S.I. 2021/610, [reg. 2\(c\)](#) (with [reg. 3](#))

**F6** Words in [reg. 2\(1\)](#) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), [regs. 1\(2\)](#), [2\(2\)\(a\)](#)

**F7** Words in [reg. 2](#) inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), [regs. 1\(1\)](#), [3\(3\)\(aa\)](#) (as amended by S.I. 2020/1478, [regs. 1\(3\)](#), [Sch. 2 paras. 2](#), [4\(a\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F8** Words in [reg. 2](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), [regs. 1\(1\)](#), [3\(3\)\(b\)](#) (as amended by S.I. 2020/1478, [regs. 1\(3\)](#), [Sch. 2 para. 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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- F9** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F10** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(da)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F11** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(c)**
- F12** Words in reg. 2 inserted (28.7.2021) by The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (S.I. 2021/910), regs. 1(1), **3**
- F13** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(d)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(i)**
- F15** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(e)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(d)**); 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(ii)**
- F17** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(f)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(e)**); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(iii)**
- F19** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(g)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(f)**); 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(h)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in reg. 2(1) inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **2(c)**
- F22** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(b)**
- F23** Words in reg. 2(1) inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **2(a)**
- F24** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(d)**
- F25** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Word in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(j)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(c)**
- F28** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(ia)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(g)(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F29** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(k)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)



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- F30** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(e)**
- F31** Words in reg. 2(1) inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **2(b)**
- F32** Words in reg. 2(1) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(f)**
- F33** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(l)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(i)**); 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(g)**
- F35** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(m)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F36** Words in reg. 2(1) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(h)**
- F37** Words in reg. 2(1) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(4)**
- F38** Words in reg. 2(1) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(i)**
- F39** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(n)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(o)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F41** Words in reg. 2(1) substituted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 1(b)**
- F42** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(p)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F43** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(d)**
- F44** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(q)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(j)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F45** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(r)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(k)**); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(r)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(s)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(l)**); 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in reg. 2(1) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(5)**
- F49** Words in reg. 2(1) inserted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 1(c)**
- F50** Words in reg. 2(1) inserted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 1(d)**
- F51** Words in reg. 2(1) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **5**

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- F52** Words in reg. 2(1) inserted (E.W.S.) (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **9**
- F53** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(t)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in reg. 2(1) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **4**
- F55** Words in reg. 2 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(u)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F56** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(e)**
- F57** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(ua)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 paras. 24(m)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F58** Words in reg. 2 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(v)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(n)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F59** Words in reg. 2 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(3)(w)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **4(o)**); 2020 c. 1, Sch. 5 para. 1(1)
- F60** Reg. 2(1A) inserted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(b)**
- F61** Words in reg. 2(1A) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(4)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **5**); 2020 c. 1, Sch. 5 para. 1(1)
- F62** Reg. 2(1B) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(6)**

## Interpretation **N.I.**

2.—(1) In these Regulations<sup>F543</sup> ...—

<sup>F5</sup> ...

“active implantable medical device” means a medical device which—

- (a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and
- (b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product;

<sup>F544</sup> ...

“Association Agreement” means an Agreement, listed in Schedule 1, establishing an Association between the European Communities and their Member States, on the one part, and another State on the other part (referred to in these Regulations as a “State which is a Party to an Association Agreement”) on Conformity Assessment and Acceptance of Industrial Products;

<sup>F545</sup> “authorised representative” means a person established within a relevant state, explicitly designated by the manufacturer who is not a person established in a relevant state, who acts for

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the manufacturer and may be addressed by authorities and bodies in a relevant state instead of the manufacturer with regard to the latter's obligation under Directive 90/385, Directive 93/42 and Directive 98/79;]

“CE marking” means a conformity marking consisting of the initials “CE”;

“the Community” means—

- (a) in the context of any requirement relating to an *in vitro* diagnostic medical device, the [<sup>F546</sup>European Union];
- (b) in the context of any requirement relating to any other medical device, the European Economic Area;

[<sup>F547</sup>“clinical data” means the safety or performance information that is generated from the use of a device, derived from—

- (a) clinical investigations of the device concerned; or
- (b) clinical investigations or other studies reported in scientific literature of a similar device for which equivalence to the device in question can be demonstrated; or
- (c) published or unpublished reports on other clinical experiences of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;]

[<sup>F12</sup>“coronavirus test device” means an *in vitro* diagnostic medical device for the detection of the presence of a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);]

“device for performance evaluation” means a product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises;

[<sup>F548</sup>“Directive 90/385” means Council Directive [90/385/EEC](#) of 20 June 1990 on the approximation of the laws of Member States relating to active implantable devices;]

[<sup>F549</sup>“Directive 93/42” means Council Directive [93/42/EEC](#) of 14 June 1993 concerning medical devices;]

[<sup>F550</sup>“Directive 98/79” means Directive [98/79/EC](#) of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices;]

“Directive 2001/83” means Directive [2001/83/EC](#) of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to medicinal products for human use [<sup>F551</sup> [<sup>F552</sup> as amended by Directive [2002/98/EC](#) of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive [2003/63/EC](#) amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use, Directive [2004/24/EC](#) of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use and Directive [2004/27/EC](#) of the European Parliament and of the Council amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use];

[<sup>F553</sup>“Directive 2003/12” means Commission Directive 2003/12 of 3rd February 2003 on the reclassification of breast implants in the framework of Directive [93/42/EEC](#) concerning medical devices;]

<sup>F554</sup> ...

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[<sup>F555</sup>“Directive 2005/50” means Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices;]

[<sup>F556</sup>“Directive 2007/47” means Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market;

“Directive 2006/42/EC” means Directive 2006/42/EC of the European Parliament and of the Council on machinery;]

“<sup>F557</sup>... CAB” shall be construed in accordance with regulation 48(1);

<sup>F558</sup>  
...

[<sup>F559</sup>“European Economic Area” means the European Economic Area created by the EEA Agreement;]

“harmonised standard” means—

- (a) a technical specification adopted, on a mandate from the European Commission, by the European Committee for Standardisation or the European Committee for Electrotechnical Standardisation, or by both of those bodies, in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations <sup>F560</sup>, pursuant to the general guidelines on co-operation between the Commission and the said Committees signed on 13th November 1984; or
- (b) a monograph of the European Pharmacopoeia (in particular any monograph on surgical sutures and the interaction between medicinal products and materials used in medical devices containing medicinal products),

the reference number of which has been published in the Official Journal of the [<sup>F546</sup>European Union];

[<sup>F561</sup>“hazard” means a potential source of injury or damage to health;]

[<sup>F562</sup>“hip, knee or shoulder replacement” means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint, other than ancillary components (screws, wedges, plates and instruments);]

[<sup>F563</sup>“intended for clinical investigation” means—

- (a) intended for use by a registered medical practitioner when conducting investigations of that device in an adequate human clinical environment; or
- (b) intended for use by any other person in a [<sup>F564</sup>relevant state] who, by virtue of their professional qualification, is authorised to carry out investigations of that device in an adequate human clinical environment;]

“intended purpose” means—

- (a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;
- (b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials;

“*in vitro* diagnostic medical device” means a medical device which—

- (a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
- (b) is intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—
  - (i) concerning a physiological or pathological state,
  - (ii) concerning a congenital abnormality,
  - (iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
  - (iv) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination;

[<sup>F565</sup>“machinery” has the meaning given to it by Article 2(a) of Directive 2006/42;]

“manufacturer” means—

- (a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or
- (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient;

[<sup>F566</sup>“medical device” has the meaning given in Article 2(1) of Regulation (EU) 2017/745 and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;]

“the Medical Devices Directives” means Directive 90/385, Directive 93/42, [<sup>F567</sup>both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012] and Directive 98/79;

<sup>F568</sup> ...

“medicinal product” has the meaning given in article 1.2 of Directive 2001/83;

“Mutual Recognition Agreements” means the agreements, listed in Schedule 2, concluded between the European Community and States which are not part of the European Community on matters including the conditions under which each Party will accept or recognise the results of the conformity assessment procedures undertaken by the other Party’s designated bodies;

“national standard” means a technical specification adopted by [<sup>F569</sup>a relevant state] which transposes, and corresponds to, a harmonised standard;

<sup>F570</sup> ...

“notified body” means a body authorised in accordance with [<sup>F571</sup>Part V or] the Medical Devices Directives to carry out tasks of a notified body or the importing Party under the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure;

“placing on the market” means, in relation to a medical device, the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device

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intended for clinical investigation, with a view to distribution, use, or both, on [<sup>F572</sup>a relevant state] market;

“putting into service” means—

- (a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation;
- (b) in relation to any other medical device, the first making available of the device in [<sup>F573</sup>a relevant state] to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

[<sup>F574</sup>“Regulation (EU) No 207/2012” means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices;

“Regulation (EU) No 722/2012” means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives [90/385/EEC](#) and [93/42/EEC](#) with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin;]

[<sup>F575</sup>“Regulation (EU) 2017/745” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending [Directive 2001/83/EC](#), Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives [90/385/EEC](#) and [93/42/EEC](#);]

[<sup>F576</sup>“Regulation (EU) 2017/746” means [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing [Directive 98/79/EC](#) and Commission [Decision 2010/227/EU](#);

“Regulation (EU) 2022/1107” means Commission Implementing [Regulation \(EU\) 2022/1107](#) of 4 July 2022 laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council];

“relevant essential requirements”, in relation to a medical device, means the essential requirements set out in Annex 1 of Directive [90/385](#), Annex I of Directive [93/42](#) or Annex I of Directive [98/79](#) which apply to it, but not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation;

[<sup>F577</sup>“relevant market” means a market of a relevant state;

“relevant state” means—

- (a) in relation to any requirement relating to an *in vitro* diagnostic medical device, Northern Ireland or a Member State of the European Union;
- (b) in relation to any requirement relating to any other medical device, Northern Ireland or a state in the European Economic Area;
- (c) a State other than a Member State of the European Union which is a Party to an Association Agreement (where applicable under that Association Agreement);]

“specimen receptacle” means a medical device which (whether vacuum-type or not) is specifically intended by its manufacturer to be used for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination;

“stable derivatives device” means a medical device that contains human blood, blood products, plasma or blood cells of human origin, and which incorporates, as an integral part, a substance which—

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(a) if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of article 1.10 of Directive 2001/83; and

(b) is liable to act upon the human body with action ancillary to that of the device;

“supply”, in relation to a medical device, means—

(a) the supply of, or the offer or agreement to supply, the device; or

(b) the exposure or possession for supply of the device;

“third country conformity assessment body” means a body in a State which is not part of the Community that is designated in accordance with the Mutual Recognition Agreements to carry out tasks of a notified body under the conformity assessment procedures set out in the Medical Devices Directives;

F578  
...

[<sup>F577</sup>“UK mutual recognition agreement” means an agreement between the United Kingdom and another country that covers matters including the conditions under which the United Kingdom and that country will accept or recognise the results of the conformity assessment procedures undertaken by each other’s designated bodies;

“UK(NI) indication” means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020;]

“UK notified body” shall be construed in accordance with regulation 45; and

[<sup>F577</sup>“UK responsible person” is to be construed in accordance with regulation 19B(2) for the purposes of Part II, regulation 21C(2) for the purposes of Part III and regulation 44A(2) for the purposes of part IV.]

[<sup>F579</sup>(1A) In these Regulations, any reference to Annexes 1 to 7 to Directive 90/385, Annexes I to X to Directive 93/42 or Annex I to X to Directive 98/79 is to be construed as a reference to those Annexes as amended from time to time.]

[<sup>F580</sup>(1B) In these Regulations, any reference to Annex 1 to Directive 90/385 or to Annex I to Directive 93/42 is to that Annex read with Regulation (EU) No 207/2012.]

(2) In these Regulations, unless the context otherwise requires, a reference—

(a) to a numbered regulation, Part or Schedule is to the regulation or Part of, or the Schedule to, these Regulations bearing that number;

(b) in a regulation to a numbered or lettered paragraph is to the paragraph of that regulation bearing that number or letter; and

(c) in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph in that paragraph bearing that number or letter.

#### Extent Information

**E49** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F5** Words in [reg. 2\(1\)](#) omitted (26.5.2021) by virtue of [Medicines and Medical Devices Act 2021 \(c. 3\)](#), [ss. 41\(4\)](#), [50\(3\)](#) (with [s. 41\(8\)](#)); [S.I. 2021/610](#), [reg. 2\(c\)](#) (with [reg. 3](#))

**F12** Words in [reg. 2](#) inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), [regs. 1\(1\)](#), [3](#)

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- F543** Words in reg. 2(1) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **2(a)**
- F544** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(a)**
- F545** Words in reg. 2 substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 2(a)**
- F546** Words in Regulations substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **4** (with art. 3(3))
- F547** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(c)**
- F548** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(i)**
- F549** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(ii)**
- F550** Words in reg. 2(1) substituted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(a)(iii)**
- F551** OJ No. L 311, 28.11.2001, p.67.
- F552** Words in reg. 2(1) inserted (30.10.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(a), **Sch. para. 10**
- F553** Words in reg. 2(1) inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **2(c)**
- F554** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(b)**
- F555** Words in reg. 2(1) inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **2(a)**
- F556** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(d)**
- F557** Word in reg. 2 omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 2(b)**
- F558** Words in reg. 2(1) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(c)**
- F559** Words in reg. 2(1) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(3)**
- F560** OJ No. L 204, 21.7.1998, p.37; amended by Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).
- F561** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(e)**
- F562** Words in reg. 2(1) inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **2(b)**
- F563** Words in reg. 2(1) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(f)**
- F564** Words in reg. 2 substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 2(c)**
- F565** Words in reg. 2(1) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(g)**
- F566** Words in reg. 2(1) substituted (N.I.) (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **30(a)**
- F567** Words in reg. 2(1) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(4)**
- F568** Words in reg. 2(1) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **2(i)**
- F569** Words in reg. 2 substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 2(d)**



- F570** Words in [reg. 2\(1\)](#) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **2(2)(d)**
- F571** Words in [reg. 2\(1\)](#) substituted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), [regs. 1\(1\)\(a\)](#), **2(f)**
- F572** Words in [reg. 2](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), **Sch. 1 para. 2(e)**
- F573** Words in [reg. 2](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), **Sch. 1 para. 2(f)**
- F574** Words in [reg. 2\(1\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **2(5)**
- F575** Words in [reg. 2\(1\)](#) inserted (N.I.) (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), [regs. 1\(2\)](#), **30(b)**
- F576** Words in [reg. 2\(1\)](#) inserted (N.I.) (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), [regs. 1\(2\)](#), **10**
- F577** Words in [reg. 2](#) inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), **Sch. 1 para. 2(g)**
- F578** Words in [reg. 2\(1\)](#) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **2(2)(e)**
- F579** [Reg. 2\(1A\)](#) inserted (1.7.2012) by [The Medical Devices \(Amendment\) Regulations 2012 \(S.I. 2012/1426\)](#), [regs. 1\(1\)](#), **2(b)**
- F580** [Reg. 2\(1B\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **2(6)**

### **[<sup>F63</sup>Medical devices which are qualifying Northern Ireland goods**

**2A.—(1)** [<sup>F64</sup>Subject to paragraph (1A),] notwithstanding the effect of regulations 19B, 19C, 30A, 44ZA and 44ZB and the expiry of the period during which those regulations apply by virtue of regulation 1ZA, any medical device—

- [<sup>F65</sup>(a) which meets the requirements of—
- (i) these Regulations as they apply in Northern Ireland;
  - (ii) [Regulation \(EU\) 2017/745](#); or
  - (iii) [Regulation \(EU\) 2017/746](#); and]
- (b) which is a qualifying Northern Ireland good,

may be placed on the Great Britain market as if it meets the requirements of these Regulations as they apply in Great Britain.

[  
<sup>F66</sup>(1A) Before 25 July 2024, paragraph (1) only applies to a coronavirus test device that meets the requirements of [Regulation \(EU\) 2017/746](#) if the device also meets the requirements of—

- (a) regulation 34A (approval requirement for coronavirus test devices); or
- (b) the common specifications set out in Annex I and XIII to [Regulation \(EU\) 2022/1107](#).]

(2) In this regulation,

[  
<sup>F67</sup>(a)] “qualifying Northern Ireland good” has the meaning given in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

[  
<sup>F68</sup>(b)] “Regulation (EU) 2017/745” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending [Directive 2001/83/EC](#), [Regulation \(EC\) No 178/2002](#) and [Regulation \(EC\) No 1223/2009](#) and repealing Council Directives [90/385/EEC](#) and [93/42/EEC](#).]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**Textual Amendments**

- F63** Reg. 2A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(4A)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F64** Words in reg. 2A(1) inserted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **11(a)(i)**
- F65** Reg. 2A(1)(a) substituted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **11(a)(ii)**
- F66** Reg. 2A(1A) inserted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **11(b)**
- F67** Words in reg. 2A(2) renumbered as reg. 2A(2)(a) (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **31(b)(i)**
- F68** Reg. 2A(2)(b) inserted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **31(b)(ii)**

**Scope of these Regulations** E+W+S

3. These Regulations shall not apply to—
- (a) medicinal products governed by [<sup>F69</sup>the Human Medicines Regulations 2012] (including medicinal products derived from human blood or human plasma <sup>F70</sup>...);
  - (b) human blood, human blood products, plasma or blood cells of human origin;
  - (c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for [<sup>F71</sup>—
    - (i) stable derivatives devices,
    - (ii) active implantable medical devices and accessories to such devices, and
    - (iii) *in vitro* diagnostic medical devices and accessories to such devices,];
  - (d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin [<sup>F72</sup>, except for <sup>F73</sup>..., *in vitro* diagnostic medical devices and accessories to such devices][<sup>F74</sup>save where medicinal products are incorporated as ancillary to the device];
  - [<sup>F75</sup>(e) transplants or tissues or cells of animal origin, unless—
    - (i) a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue, or
    - (ii) a product is <sup>F76</sup>... an *in vitro* diagnostic medical device, or an accessory to such a device;]
  - (f) cosmetic products governed by [<sup>F77</sup>Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products;] or
  - [<sup>F78</sup>(g) .....

**Extent Information**

- E2** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

- F69** Words in reg. 3(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(5)(c)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F70** Words in reg. 3(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(5)(c)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F71** Words in reg. 3(c) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(a)**
- F72** Words in reg. 3(d) inserted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(b)**
- F73** Words in reg. 3(d) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(a)**
- F74** Words in reg. 3(d) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(b)**
- F75** Reg. 3(e) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(c)**
- F76** Words in reg. 3(e)(ii) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(c)**
- F77** Words in reg. 3(f) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(5)(d)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F78** Reg. 3(g) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(d)**

### Scope of these Regulations **N.I.**

3. These Regulations shall not apply to—
- (a) medicinal products governed by Directive 2001/83 (including medicinal products derived from human blood or human plasma governed by Title X of Directive 2001/83);
  - (b) human blood, human blood products, plasma or blood cells of human origin;
  - (c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for <sup>F581</sup>—
    - (i) stable derivatives devices,
    - (ii) active implantable medical devices and accessories to such devices, and
    - (iii) *in vitro* diagnostic medical devices and accessories to such devices,];
  - (d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin <sup>F582</sup>, except for <sup>F583</sup> ..., *in vitro* diagnostic medical devices and accessories to such devices<sup>F584</sup> save where medicinal products are incorporated as ancillary to the device];
  - <sup>F585</sup>(e) transplants or tissues or cells of animal origin, unless—
    - (i) a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue, or
    - (ii) a product is <sup>F586</sup> ... an *in vitro* diagnostic medical device, or an accessory to such a device;]
  - (f) cosmetic products governed by Council Directive [76/768/EEC](#) <sup>F587</sup>, as amended <sup>F588</sup>, or
  - <sup>F589</sup>(g) .....

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

**E50** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

- F581** Words in reg. 3(c) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(a)**
- F582** Words in reg. 3(d) inserted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(b)**
- F583** Words in reg. 3(d) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(a)**
- F584** Words in reg. 3(d) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(b)**
- F585** Reg. 3(e) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(c)**
- F586** Words in reg. 3(e)(ii) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(c)**
- F587** OJ No. L 262, 27.9.1976, p.169.
- F588** Council Directive 76/768/EEC was amended for the twenty-sixth time by Commission Directive 2000/41/EC (OJ No. L 145, 20.6.2000, p.25).
- F589** Reg. 3(g) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(d)**

### [<sup>F79</sup>Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 <sup>F80</sup>and Regulation (EU) 2017/746]

**3ZA.**—[<sup>F81</sup>(1) Subject to paragraph (2), Parts 2 to 7 only apply in Northern Ireland for the purpose of regulating qualifying devices.]

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph <sup>F82</sup>...—

- [<sup>F83</sup>(a) for the purposes of the registration of medical devices (whether or not they are qualifying devices) and persons placing medical devices on the market in Northern Ireland—
- (i) regulation 19 (registration of persons placing general medical devices on the market),
  - (ii) regulation 21B (registration of persons placing active implantable medical devices on the market),
  - (iii) regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation), and
  - (iv) regulation 53 (fees in connection with the registration of devices and changes to registration details),
- only apply until the date which is 24 months after the date of publication of the notice referred to in Article 34(3) of [Regulation \(EU\) 2017/745](#);
- (aa) regulations 34A to 34D, 38A to 38C, 39A, 56A, 59 and 61 continue to apply in relation to coronavirus test devices whether or not they are qualifying devices;]
- (b) Parts 5 to 7 [<sup>F84</sup>also] apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

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- (3) <sup>F85</sup>For the purposes of this regulation], a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745 <sup>F86</sup>or Article 110 of Regulation (EU) 2017/746]—
- (a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of <sup>F87</sup>Directive 90/385, Directive 93/42 or Directive 98/79, rather than Regulation (EU) 2017/745 or Regulation (EU) 2017/746; and]
  - (b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2 <sup>F88</sup>... to 7.]

#### Textual Amendments

- F79** Reg. 3ZA inserted (N.I.) (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **32**
- F80** Words in reg. 3ZA heading inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(a)**
- F81** Reg. 3ZA(1) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(b)**
- F82** Words in reg. 3ZA(2) omitted (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(i)**
- F83** Reg. 3ZA(2)(a)(aa) substituted for reg. 3ZA(2)(a) (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(ii)**
- F84** Word in reg. 3ZA(2)(b) inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(iii)**
- F85** Words in reg. 3ZA(3) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(i)**
- F86** Words in reg. 3ZA(3) inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(ii)**
- F87** Words in reg. 3ZA(3)(a) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(iii)**
- F88** Words in reg. 3ZA(3)(b) omitted (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(iv)**

#### <sup>F89</sup>Designated standard

- 3A.—(1)** In Parts II, III and IV of these Regulations, a “designated standard” means—
- (a) a technical specification which is—
    - (i) adopted by a recognised standardisation body <sup>F90</sup>or an international standardising body], for repeated or continuous application with which compliance is not compulsory; and
    - (ii) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate; or
  - (b) a monograph of the European Pharmacopoeia (in particular on surgical sutures and on the interaction between medicinal products and materials used in devices containing medicinal products) which has been published in the Official Journal of the European Union.
- (2) For the purposes of paragraph (1), a “technical specification” means a document which prescribes technical requirements to be fulfilled by a device, process, service or system (“the product”) and which lays down—

*Status: Point in time view as at 21/03/2024.*

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- (a) the characteristics required of a product, including levels of quality, performance, interoperability, environmental protection, health and safety and dimensions;
  - (b) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
  - (c) the production methods and processes relating to the product, where these have an effect on its characteristics.
- (3) For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—
- (a) the European Committee for Standardisation (CEN);
  - (b) the European Committee for Electrotechnical Standardisation (CENELEC);
  - (c) the British Standards Institute (BSI).
- [<sup>F91</sup>(3A) In this regulation “international standardising body” has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]
- (4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.
- (5) Before publishing the reference to a standard in relation to a technical specification which has been adopted by BSI, the Secretary of State must have regard to whether the technical specification is consistent with [<sup>F92</sup>such] technical specifications adopted by the other recognised standardisation bodies [<sup>F93</sup>or by international standardising bodies as the Secretary of State considers to be relevant.]
- (6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).
- (7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.
- (8) In this regulation—
- (a) a reference to a “device” is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply;
  - (b) a reference to “the European Pharmacopoeia” is a reference to the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.

#### Textual Amendments

- F89** Regs. 3A, 3B inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(6)** (as amended by [S.I. 2019/1385](#), reg. 1, **Sch. 2 para. 2** and [S.I. 2020/1478](#), regs. 1(2)(3), 4(2), Sch. 2 paras. 2, **8**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F90** Words in [reg. 3A\(1\)\(a\)\(i\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 1(a)**; [S.I. 2020/1662](#), reg. 2(ee)
- F91** [Reg. 3A\(3A\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 1(b)**; [S.I. 2020/1662](#), reg. 2(ee)
- F92** Word in [reg. 3A\(5\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 1(c)(i)**; [S.I. 2020/1662](#), reg. 2(ee)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F93** Words in [reg. 3A\(5\)](#) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), [Sch. 4 para. 1\(c\)\(ii\)](#); S.I. 2020/1662, [reg. 2\(ee\)](#)

## Confidentiality

**F94** 3B. .... ]

### Textual Amendments

- F89** Regs. 3A, 3B inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\), 3\(6\)](#) (as amended by [S.I. 2019/1385](#), [reg. 1](#), [Sch. 2 para. 2](#) and [S.I. 2020/1478](#), [regs. 1\(2\)\(3\), 4\(2\)](#), [Sch. 2 paras. 2, 8](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F94** [Reg. 3B](#) omitted (26.5.2021) by virtue of [Medicines and Medical Devices Act 2021 \(c. 3\)](#), [ss. 41\(5\), 50\(3\)](#); S.I. 2021/610, [reg. 2\(c\)](#) (with [reg. 3](#))

## Transitional provisions

4.—(1) Part II shall not be applied before 1st July 2004 in respect of a device which has been subjected to EEC pattern approval before 1st January 1995 in accordance with the Clinical Thermometers (EEC Requirements) Regulations 1993 <sup>M5</sup>.

(2) Part II shall not be applied—

- (a) before 10th January 2007 in respect of a stable derivatives device placed on the market without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002; or
- (b) before 10th January 2009 in respect of a stable derivatives device put into service without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002.

(3) Part IV shall not be applied before 7th December 2003 in respect of a device placed on the market which is—

- (a) *anin vitro* diagnostic medical device without a CE marking; or
- (b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 7th December 1998.

(4) Part IV shall not be applied before 7th December 2005 in respect of a device put into service which is—

- (a) *anin vitro* diagnostic medical device without a CE marking; or
- (b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 7th December 1998.

[<sup>F95</sup>(5) Regulation 13(4) shall not be applied before 1st March 2004 in respect of breast implants which—

- (a) bore a CE marking before 1st September 2003; and

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) satisfy the requirements in respect of relevant devices falling within Class IIb set out in regulation 13(3).]

[<sup>F96</sup>(6) Regulation 19A shall not be applied before 1st October 2004 in respect of a device placed on the market before 1st April 2004.]

#### Textual Amendments

- F95** Reg. 4(5) inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **3(a)**
- F96** Reg. 4(6) added (1.4.2004) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(b), **3(b)**

#### Marginal Citations

- M5** [S.I. 1993/2360](#).

### [<sup>F97</sup>Transitional provisions for hip, knee and shoulder replacements

- 4A.**—(1) This regulation applies to hip, knee or shoulder replacements.
- (2) Regulation 13(4) shall not apply in respect of a replacement—
- (a) whose manufacturer or his authorised representative has before 1st September 2007—
- (i) fulfilled the applicable obligations imposed by Annex II, excluding Section 4 of that Annex,
  - (ii) declared, in accordance with a declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it, and
  - (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and
- (b) in respect of which an examination under Section 4 of Annex II has been carried out and an EC design-examination certificate under that Section has been issued before 1st September 2009.
- (3) Regulation 13(4) shall not apply before 1st September 2009 in respect of a replacement—
- (a) whose manufacturer or his authorised representative has—
- (i) fulfilled the applicable obligations imposed by Annex II, excluding Section 4 of that Annex,
  - (ii) declared, in accordance with a declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it, and
  - (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and
- (b) which is covered by the decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex II before 1st September 2007.
- (4) Regulation 13(4) shall not apply before 1st September 2010 in respect of replacement—
- (a) whose manufacturer or his authorised representative has—
- (i) fulfilled the applicable obligations imposed by Annex III together with Annex VI,
  - (ii) declared, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it, and
  - (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and



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- (b) which is covered by the decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex VI before 1st September 2007.
- (5) Regulation 13(4) shall not apply in respect of a replacement which—
  - (a) satisfies the conditions set out in paragraph (4)(a) and (b);
  - (b) has been placed on the market before 1st September 2010; and
  - (b) is put into service on or after that date.]

#### Textual Amendments

**F97** Reg. 4A inserted (1.9.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(b), 4

#### [<sup>F98</sup>Revocations, transitional and saving provisions in respect of the new national registration requirements

**4D.**—(1) Regulation 19 is revoked on the day that is 4 months after IP completion day (which is when regulation 7A comes into force).

(2) Regulation 7A does not apply until the day that is 8 months after IP completion day in respect of a device or accessory—

- (a) that is a relevant device for the purposes of Part II; and
- (b) that is classified as belonging to—
  - (i) Class IIa, as referred to in regulation 7, or
  - (ii) Class IIb, as referred to in regulation 7, and is also a Group A device (within the meaning given in regulation 52(1)).

(3) Regulation 7A does not apply until the day that is 12 months after IP completion day in respect of a device or accessory—

- (a) that is a relevant device for the purposes of Part II; and
- (b) that is classified as belonging to Class I, as referred to in regulation 7.

(4) Where regulation 7A does not apply in respect of a device or accessory by virtue of paragraph (2) or (3), regulation 19 continues to have effect after its revocation in respect of that device or accessory.

(6) Regulation 30(3) is revoked on the day that is 4 months after IP completion day (which is when regulation 21A comes into force).

(8) Regulation 44 is revoked on the day that is 4 months after IP completion day (which is when regulation 33A comes into force).

(9) Regulation 33A does not apply until the day that is 8 months after IP completion day in respect of a device or accessory—

- (a) that is a relevant device for the purposes of Part IV, or
- (b) that is—
  - (i) referred to in List B, mentioned in regulation 40(4), or
  - (ii) a device for self-testing (as defined in relation 32(1)).

(10) Regulation 33A does not apply until the day that is 12 months after IP completion day in respect of a device or accessory that is a relevant device for the purposes of Part IV which follows the procedure in regulation 40(1).

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(11) Where regulation 33A does not apply in respect of a device or accessory by virtue of paragraph (9), regulation 44 continues to have effect after its revocation in respect of that device or accessory.

#### Textual Amendments

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **9**); 2020 c. 1, Sch. 5 para. 1(1)

#### Revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date

**4H.**—(1) Commission Decision [2002/364/EC](#) of 7 May 2002 on the common specifications for in vitro diagnostic medical devices <sup>F99</sup>... is revoked on 26th May 2025.

<sup>F100</sup>(2) .....

#### Textual Amendments

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **9**); 2020 c. 1, Sch. 5 para. 1(1)

**F99** Words in reg. 4H(1) omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 2(a)**

**F100** Reg. 4H(2) omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 2(b)**

#### Revocation of Commission Decision 2010/227

**4I.** Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) is revoked.

#### Textual Amendments

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **9**); 2020 c. 1, Sch. 5 para. 1(1)

#### [<sup>F101</sup>Revocation of [Commission Regulation \(EU\) No 207/2012](#) on 26th May 2025

**4J.** [Commission Regulation \(EU\) No 207/2012](#) is revoked on 25th May 2025.]

#### Textual Amendments

**F101** Reg. 4J substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 3**

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

<sup>F102</sup>**Revocation of Regulation (EU) No 722/2012 on 26th May 2025**

**4K.** Regulation (EU) No 722/2012 is revoked on 26th May 2025.]

**Textual Amendments**

**F102** Reg. 4K substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 4**

**Revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date**

**4L.**—(1) Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of [<sup>F103</sup>approved] bodies under Council Directive [90/385/EEC](#) on active implantable medical devices and Council Directive [93/42/EEC](#) on medical devices (“Regulation (EU) No 920/2013”) (insofar as it is retained EU law) is revoked on 26th May 2025.

<sup>F104</sup>(4) .....

<sup>F105</sup>(5) .....

**Textual Amendments**

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 paras. 2, 9**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F103** Word in reg. 4L(1) substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 5(a)**

**F104** Reg. 4L(4) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 5(b)**

**F105** Reg. 4L(5) omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 5(b)**

**Revocation of Regulation (EU) No 2017/2185 and saving provision**

**4M.**—(1) Insofar as it is retained EU law, Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council (“Regulation (EU) No 2017/2185”) is revoked.

**Textual Amendments**

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 paras. 2, 9**); 2020 c. 1, **Sch. 5 para. 1(1)**

**The classification criteria in Directives 2003/12 and 2005/50**

<sup>F106</sup>**4N.** .....

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**Textual Amendments**

**F106** Reg. 4N omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 6**

**Revocation of Regulation (EU) 2017/745**

**4O.**—(1) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive [2001/83/EC](#), Regulation [\(EC\) No 178/2002](#) and Regulation [\(EC\) No 1223/2009](#) and repealing Council Directives [90/385/EEC](#) and [93/42/EEC](#) (“the Medical Devices Regulation”) (insofar as it is retained EU law) is revoked.

**Textual Amendments**

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 paras. 2, 9**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Revocation of Regulation (EU) 2017/746**

**4P.**—(1) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive [98/79/EC](#) and Commission Decision 2010/227/EU (“the in vitro diagnostic medical devices Regulation”) (insofar as it is retained EU law) is revoked.

**Textual Amendments**

**F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 paras. 2, 9**); 2020 c. 1, **Sch. 5 para. 1(1)**

**References in other legislation to Directives 90/385, 93/42 and 98/79**

**4T.**—<sup>F107</sup>(1) .....

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016 (fee for advice for other purposes)—

- (a) the reference to the expression “medical device” having the meaning given in Article 1(2) (a) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to having the meaning given in regulation 2; and

<sup>F108</sup>(b) .....

[ the reference to the expression “[Directive 93/42/EEC](#)” is to be construed, to the extent

<sup>F109</sup>(c) necessary for the practical application of that expression, as a reference also or instead to Part II of the Medical Devices Regulations 2002;

- (d) the references to “paragraph 4.3 of Annex II to [Directive 93/42/EEC](#)” and “paragraph 5 of Annex III to [Directive 93/42/EEC](#)” are to be construed, to the extent necessary for the practical application of those provisions, as references also or instead to those paragraphs

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and those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A.]

(3) In Schedule 1 to the Pressure Equipment (Safety) Regulations 2016 (excluded pressure equipment and assemblies), the reference in paragraph 1(f)(iv) to not being covered by Directive 93/42 is to be construed, to the extent necessary for the practical application of that provision, as a reference also or instead to not being covered by Part II.

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013 (interpretation)—

- (a) the reference to the expression “active implantable medical device” having the meaning given in Article 1(2)(c) of Directive 90/385 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to it having the meaning given in regulation 2<sup>F110</sup> ...;
- (b) the reference to the expression “medical device” having the meaning given in Article 1(2)(a) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference to it also or instead having the meaning given to it in regulation 2;
- (c) the reference to the expression “accessory” having the meaning given in Article 1(2)(b) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as also or instead having the meaning given to “accessory” in regulation 5;
- (d) the reference to the expression “in vitro diagnostic medical device” having the meaning given in Article 1(2)(b) of Directive 98/79 is to be construed, to the extent necessary for the practical application of that definition, as having the meaning given to it in regulation 2;
- (e) the reference to the expression “accessory” having the meaning given in Article 1(2)(c) of Directive 98/79 is to be construed, to the extent necessary for the practical application of that definition, as also or instead having the meaning given to “accessory” in regulation 32.

(5) These Regulations are an enactment implementing a relevant Community Directive for the purposes of regulation 4 of the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993 (provision of personal protective equipment).

(6) These Regulations are also an enactment implementing a relevant Community Directive for the purposes of regulation 4(5)(a) of the Personal Protective Equipment at Work Regulations 1992 (provision of personal protective equipment).]

#### Textual Amendments

- F98** Regs. 4D, 4H-4P, 4T inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **9**); 2020 c. 1, Sch. 5 para. 1(1)
- F107** Reg. 4T(1) omitted (21.3.2024) by virtue of [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024](#) (S.I. 2024/221), regs. 1(2), **13**
- F108** Reg. 4T(2)(b) omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021](#) (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 7(a)(i)**
- F109** Reg. 4T(2)(c)(d) inserted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021](#) (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 7(a)(ii)**
- F110** Words in reg. 4T(4)(a) omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021](#) (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 7(b)**

**Status:** Point in time view as at 21/03/2024.

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## PART II

### General Medical Devices

#### Interpretation of Part II

5.—(1) In this Part <sup>F111</sup>...—

“accessory” means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;

“custom-made device” means a relevant device that is—

(a) manufactured specifically in accordance with a written prescription of a [<sup>F112</sup>registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification,] which gives, under his responsibility, specific characteristics as to its design; and

(b) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

“relevant device” shall be construed in accordance with regulation 6;

“single-use combination product” means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and

“system or procedure pack” has the same meaning as in article 12 of Directive 93/42.

(2) In this Part <sup>F111</sup>..., a reference to a numbered article or Annex is to the article or Annex of Directive 93/42 bearing that number.

#### Textual Amendments

**F111** Words in reg. 5(1)(2) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), 4

**F112** Words in reg. 5(1) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), 4

#### Scope of Part II

6. The requirements of this Part in respect of relevant devices apply in respect of medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than—

(a) active implantable medical devices and accessories to such devices; [<sup>F113</sup>and]

(b) *in vitro* diagnostic medical devices and accessories to such devices; [<sup>F114</sup>and]

(c) [<sup>F115</sup>devices that come within the scope of Directive 93/42 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.]

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### Textual Amendments

- F113** Word in reg. 6(a) inserted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 8(a)**
- F114** Word in reg. 6(b) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 8(b)**
- F115** Reg. 6(c) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 8(c)**

### Classification of general medical devices **E+W+S**

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42 [F116, read with Directive 2003/12][F117 and Directive 2005/50].

(2) In the event of a dispute between a manufacturer and [F118 an approved body] over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42 [F116, read with Directive 2003/12][F117 and Directive 2005/50].

### Extent Information

- E3** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F116** Words in reg. 7 inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **5**
- F117** Words in reg. 7 inserted (1.9.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(b), **5**
- F118** Words in reg. 7(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(3)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **11**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Classification of general medical devices **N.I.**

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42 [F590, read with Directive 2003/12][F591 and Directive 2005/50].

(2) In the event of a dispute between a manufacturer and a notified body over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42 [F590, read with Directive 2003/12][F591 and Directive 2005/50].

### Extent Information

- E51** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F590** Words in reg. 7 inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), 5

**F591** Words in reg. 7 inserted (1.9.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(b), 5

### [<sup>F119</sup>Registration of persons placing general medical devices on the market

**7A.—(1)** No person may place a relevant device on the market in accordance with this Part unless that person—

- (a) is established in Great Britain; and
- (b) has complied with paragraph (2).

(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

- (a) where—
  - (i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;
  - (ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer’s authority to act as their UK responsible person; or
  - (iii) that person is not the manufacturer of the device, the address of that person’s registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;
- (b) that person supplies the Secretary of State with a description of the relevant device; and
- (c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.

(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.

- (3) The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—
  - (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
  - (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
  - (d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;
  - (e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;
  - (f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;



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- (g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;
- (h) if the manufacturer acts contrary to its obligations under these Regulations—
  - (i) terminate the legal relationship with the manufacturer; and
  - (ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.
- (4) In this regulation—
  - (a) the references to “technical documentation” are to be construed in accordance with Annex II, III or VII;
  - (b) the references to “declaration of conformity” are to be construed in accordance with Annexes II, IV, V, VI and VII.]

#### Textual Amendments

**F119** Reg. 7A inserted (E.W.S.) (30.4.2021) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(2)(a), **4(4)** (as amended by [S.I. 2019/1385](#), reg. 1, **Sch. 2 para. 3** and [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **12**); 2020 c. 1, Sch. 5 para. 1(1)

#### Essential requirements for general medical devices **E+W+S**

**8.—**(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it [<sup>F120</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

(2) Subject to regulation 12, no person shall supply a relevant device—

- (a) if that supply is also a placing on the market or putting into service of that device; or
- (b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it [<sup>F121</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

[<sup>F122</sup>(3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in [<sup>F123</sup>Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008] to the extent to which those essential health and safety requirements are more specific than the essential requirements to Directive 93/42.]

#### Extent Information

**E4** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F120** Words in [reg. 8\(1\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **3**

**F121** Words in [reg. 8\(2\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **3**

**F122** [Reg. 8\(3\)](#) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **5**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F123** Words in [reg. 8\(3\)](#) substituted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\), 4\(5\)](#) (as amended by [S.I. 2020/1478](#), [regs. 1\(3\), Sch. 2 para. 2](#)); [2020 c. 1, Sch. 5 para. 1\(1\)](#)

## Essential requirements for general medical devices **N.I.**

**8.—(1)** Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it [<sup>F592</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

(2) Subject to regulation 12, no person shall supply a relevant device—

- (a) if that supply is also a placing on the market or putting into service of that device; or
- (b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it [<sup>F593</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

[<sup>F594</sup>(3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to Directive 2006/42 to the extent to which those essential health and safety requirements are more specific than the essential requirements to Directive 93/42.]

### Extent Information

**E52** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

**F592** Words in [reg. 8\(1\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\), 3](#)

**F593** Words in [reg. 8\(2\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\), 3](#)

**F594** [Reg. 8\(3\)](#) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\), 5](#)

## Determining compliance of general medical devices with relevant essential requirements **E+W+S**

**9.—(1)** In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

- (a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and
- (b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

- (i) such instructions are in English <sup>F124</sup>...

<sup>F125</sup>(ii) .....

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant [<sup>F126</sup>designated standard], unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

- (a) in respect of which the conditions specified in Annex VIII are satisfied; and
- (b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[<sup>F127</sup>(5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

- (a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and
- (b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.]

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or [<sup>F128</sup>their UK responsible person], has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

- (a) the conditions specified in Annex VIII are satisfied;
- (b) notice has been given under regulation 16(1); and
- (c) either—
  - (i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or
  - (ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I <sup>F129</sup>... that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[<sup>F130</sup>(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in [<sup>F131</sup>Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC] and Directive 93/42, the relevant basic health and safety requirements of [<sup>F132</sup>Regulation (EU) 2016/425] shall also be fulfilled.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

- E5** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F124** Words in reg. 9(3)(b)(i) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(a\)\(i\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F125** Reg. 9(3)(b)(ii) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(a\)\(ii\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F126** Words in reg. 9(4) substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 9](#)
- F127** Reg. 9(5A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), [6\(a\)](#)
- F128** Words in reg. 9(6) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(aa\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [13](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F129** Words in reg. 9(8) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(ab\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [13](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F130** Reg. 9(9) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), [6\(b\)](#)
- F131** Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(b\)\(i\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F132** Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(6\)\(b\)\(ii\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

### Determining compliance of general medical devices with relevant essential requirements **N.I.**

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

- (a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and
- (b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—
  - (i) such instructions are in English or another Community language, and
  - (ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

- (a) in respect of which the conditions specified in Annex VIII are satisfied; and
- (b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[<sup>F595</sup>(5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

- (a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and
- (b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.]

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or his authorised representative, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

- (a) the conditions specified in Annex VIII are satisfied;
- (b) notice has been given under regulation 16(1); and
- (c) either—
  - (i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or
  - (ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I of Directive 93/42 that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[<sup>F596</sup>(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in Council Directive 89/686/EEC on the approximation or the laws of the Member States relating to personal protective equipment and Directive 93/42, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.]

#### Extent Information

**E53** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F595** Reg. 9(5A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(a)**

**F596** Reg. 9(9) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(b)**

### [<sup>F133</sup>UK marking] of general medical devices **E+W+S**

**10.**—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a [<sup>F134</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F135</sup>Annex 2 of Regulation (EC) No 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F136</sup>approved body] or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a [<sup>F137</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F138</sup>Annex 2 of Regulation (EC) No 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F139</sup>approved body] or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless [<sup>F140</sup>a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008], appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for the device,

and that [<sup>F141</sup>UK marking] is accompanied by any relevant [<sup>F142</sup>approved body] or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless [<sup>F143</sup>a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008], appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for the device,

and that [<sup>F144</sup>UK marking] is accompanied by any relevant [<sup>F145</sup>approved body] or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device or its sterile pack;
- (b) the instructions for use for a relevant device; or
- (c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the [F146UK marking] or which reduces the visibility or the legibility of the [F146UK marking].

[F147(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

- (a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and
- (b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).]

### Extent Information

- E6** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F133** Words in reg. 10 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F134** Words in reg. 10(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(b\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F135** Words in reg. 10(1)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(b\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F136** Words in reg. 10(1)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(b\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F137** Words in reg. 10(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(c\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F138** Words in reg. 10(2)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(c\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F139** Words in reg. 10(2)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(c\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F140** Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(d\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F141** Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(d\)\(ii\)\(aa\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F142** Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(d\)\(ii\)\(bb\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F143** Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(e\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [14](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F144** Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(e\)\(i\)\(aa\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 14); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F145** Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(e\)\(ii\)\(bb\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 14); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F146** Words in reg. 10(5) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(6A\)\(f\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 14); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F147** [Reg. 10\(6\)](#) inserted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021](#) (S.I. 2021/873), reg. 1(1), [Sch. 1 para. 10](#)

## CE marking of general medical devices **N.I.**

**10.**—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

- (a) meets the requirements set out in Annex XII;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

- (a) meets the requirements set out in Annex XII;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device or its sterile pack;



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- (b) the instructions for use for a relevant device; or
- (c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

#### Extent Information

**E54** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### [<sup>F148</sup>UK(NI) indication: general medical devices

**10A.**—(1) Where the CE marking referred to in regulation 10 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

- (a) visibly, legibly and indelibly; and
- (b) before a relevant device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever such marking is affixed in accordance with regulation 13.

[<sup>F149</sup>(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.]

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.]

#### Textual Amendments

**F148** Reg. 10A inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 3**

**F149** Reg. 10A(3A) inserted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **33**

#### [<sup>F150</sup> UK marking of general medical devices that come within the scope of this Part and other legislation **E+W+S**

**11.** Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation (“the other legislation”) a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

#### Extent Information

- E7** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F150** Reg. 11 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(6B)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **15**); 2020 c. 1, **Sch. 5 para. 1(1)**

### CE marking of general medical devices that come within the scope of more than one Directive **N.I.**

**11.** Where a relevant device comes within the scope of Directive 93/42 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

- (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;
- (b) the manufacturer chooses to follow the set of arrangements in Directive 93/42;
- (c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and
- (d) the particulars of Directive 93/42, as published in the Official Journal of the <sup>F597</sup>European Union], are given in the documents, notices or instructions accompanying the device.

#### Extent Information

- E55** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F597** Words in Regulations substituted (22.4.2011) by [The Treaty of Lisbon \(Changes in Terminology\) Order 2011 \(S.I. 2011/1043\)](#), arts. 2, 4 (with art. 3(3))

### Exemptions from regulations 8 and 10 **E+W+S**

**12.—(1)** A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of <sup>F151</sup>... these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

- (a) the system or procedure pack incorporates a medical device which does not bear a <sup>F152</sup>UK marking]; or
- (b) the chosen combination of medical devices is not compatible in view of their original intended use.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a [<sup>F153</sup>UK marking], where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[<sup>F154</sup>(6) Regulations 8 and 10 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards, or which is marked other than with a UK marking, which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 8 and 10, may be placed on the market.

( 7) In paragraph (6), the Secretary of State, in determining whether another standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 8 and 10, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.]

#### Extent Information

**E8** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F151** Words in reg. 12(1) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [16](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F152** Words in reg. 12(3)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [16](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F153** Words in reg. 12(5) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7\)\(c\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [16](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F154** Reg. 12(6)(7) inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7\)\(d\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [16](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Exemptions from regulations 8 and 10 **N.I.**

**12.—(1)** A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 93/42 or these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

(a) the system or procedure pack incorporates a medical device which does not bear a CE marking; or

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

#### Extent Information

**E56** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Procedures for affixing a [F<sup>155</sup>UK marking] to general medical devices **E+W+S**

**13.—**(1) A relevant device falling within Class I may bear a [F<sup>156</sup>UK marking] only if its manufacturer or [F<sup>157</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by Annex VII;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it.

(2) A relevant device falling within Class IIa may bear a [F<sup>156</sup>UK marking] only if its manufacturer or [F<sup>157</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex VII, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it.

(3) A relevant device falling within Class IIb may bear a [F<sup>156</sup>UK marking] only if its manufacturer or [F<sup>157</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex III, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F<sup>158</sup>this Part] which apply to it.

(4) A relevant device falling within Class III may bear a [F<sup>156</sup>UK marking] only if its manufacturer or [F<sup>157</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (i) Annex II, or
- (ii) Annex III, together with Annex IV or V;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [<sup>F158</sup>this Part] which apply to it; <sup>F159</sup> ...
- (c) ensures that the device meets the provisions of [<sup>F158</sup>this Part] which apply to it; [<sup>F160</sup>and]
- [<sup>F161</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]
- <sup>F162</sup>(5) .....
- <sup>F162</sup>(6) .....

#### Extent Information

**E9** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F155** Words in reg. 13 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(a\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F156** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(c\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F157** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(d\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F158** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(b\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F159** Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(a\)](#)
- F160** Word in reg. 13(4)(c) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(b\)](#)
- F161** Reg. 13(4)(d) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(c\)](#)
- F162** Reg. 13(5)(6) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(3\)](#)

#### Procedures for affixing a CE marking to general medical devices **N.I.**

**13.—(1)** A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by Annex VII;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

**(2)** A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (i) Annex II, excluding Section 4 of that Annex, or
- (ii) Annex VII, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.
- (3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—
  - (a) fulfils the applicable obligations imposed by—
    - (i) Annex II, excluding Section 4 of that Annex, or
    - (ii) Annex III, together with Annex IV, V or VI;
  - (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
  - (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.
  - (4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—
    - (a) fulfils the applicable obligations imposed by—
      - (i) Annex II, or
      - (ii) Annex III, together with Annex IV or V;
    - (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; <sup>F598</sup> ...
    - (c) ensures that the device meets the provisions of Directive 93/42 which apply to it; <sup>F599</sup> and
    - <sup>F600</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]
    - <sup>F601</sup>(5) .....
    - <sup>F601</sup>(6) .....

**Extent Information**

**E57** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Textual Amendments**

- F598** Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(a)**
- F599** Word in reg. 13(4)(c) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(b)**
- F600** Reg. 13(4)(d) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(c)**
- F601** Reg. 13(5)(6) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(3)**

## Procedures for systems and procedure packs, and for devices to be sterilised before use **E** **+W+S**

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

- (a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;
- (b) the person who places or has placed it on the market has drawn up a declaration that—
  - (i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,
  - (ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and
  - (iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

- (a) a system or procedure pack which was sterilised before being placed on the market; or
- (b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

- <sup>[F163]</sup>(a) follow the procedures referred to in either Annex II or IV that relate to obtaining sterility; and
- (b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

<sup>[F164]</sup>(4A) The application of Annex II or IV and the intervention of the <sup>[F165]</sup>approved body] are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.]

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

- (a) no person shall affix a <sup>[F166]</sup>UK marking] to that device as a result of that procedure; and
- (b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

- E10** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F163** Reg. 14(4)(a) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(a)**
- F164** Reg. 14(4A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(b)**
- F165** Words in reg. 14(4A) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(7B)(a)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F166** Words in reg. 14(5)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(7B)(b)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Procedures for systems and procedure packs, and for devices to be sterilised before use **N.I.**

**14.—**(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

- (a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;
- (b) the person who places or has placed it on the market has drawn up a declaration that—
  - (i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,
  - (ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and
  - (iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

- (a) a system or procedure pack which was sterilised before being placed on the market; or
- (b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

- <sup>F602</sup>(a) follow the procedures referred to in either Annex II or IV that relate to obtaining sterility; and]



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

[<sup>F603</sup>(4A) The application of Annex II or IV and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.]

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

- (a) no person shall affix a CE marking to that device as a result of that procedure; and  
 (b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

#### Extent Information

**E58** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F602** Reg. 14(4)(a) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(a)**

**F603** Reg. 14(4A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(b)**

### Procedures for custom-made general medical devices **E+W+S**

**15.** No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or [<sup>F167</sup>their UK responsible person]—

- (a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII [<sup>F168</sup>, read with Regulation (EU) No 722/2012];  
 (b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and  
 (c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII; <sup>F169</sup> ...  
 (d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b) [<sup>F170</sup>; and  
 (e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

#### Extent Information

- E11** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F167** Words in reg. 15 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **4(7C)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F168** Words in reg. 15(a) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), **5**
- F169** Word in reg. 15(c) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), **8(1)**
- F170** Reg. 15(e) and word inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), **8(2)**

#### Procedures for custom-made general medical devices **N.I.**

**15.** No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

- (a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII <sup>F604</sup>, read with Regulation (EU) No 722/2012];
- (b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and
- (c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII; <sup>F605</sup> ...
- (d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b) <sup>F606</sup>; and
- (e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.]

#### Extent Information

- E59** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F604** Words in reg. 15(a) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), **5**
- F605** Word in reg. 15(c) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), **8(1)**
- F606** Reg. 15(e) and word inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), **8(2)**

## Procedures for general medical devices for clinical investigations **E+W+S**

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in <sup>[F171]</sup>Great Britain unless, before he does so, the manufacturer of the device or <sup>[F172]</sup>their UK responsible person] has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (3), the statement required by <sup>[F173]</sup>Sections 1 and 2.2] of Annex VIII <sup>[F174]</sup>, read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

<sup>[F175]</sup>(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

- (a) obtain advice on regulatory requirements relating to an intended clinical investigation; or
- (b) obtain a statistical review in relation to an intended clinical investigation.]

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a <sup>[F176]</sup>UK marking] otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was <sup>[F177]</sup>UK marked] in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or <sup>[F172]</sup>their UK responsible person] as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer <sup>[F178]</sup>or UK responsible person] (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or <sup>[F172]</sup>their UK responsible person] pursuant to paragraph (1), give written notice to the manufacturer or <sup>[F172]</sup>their UK responsible person]—

- (a) that the relevant device may be made available for the purposes of the intended investigation; or
- (b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;
- (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) further clinical use of the relevant device in the investigation is prohibited; and
- (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or [<sup>F172</sup>their UK responsible person], shall—

- (a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;
- (b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and
- (c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

- (a) the manufacturer or [<sup>F172</sup>their UK responsible person] does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or
- (b) the manufacturer or [<sup>F172</sup>their UK responsible person] does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

(10) No person shall conduct a clinical investigation of a relevant device—

- (a) otherwise than in accordance with Annex X; and
- (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or [<sup>F172</sup>their UK responsible person] shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

[<sup>F179</sup>(11) The manufacturer, or their [<sup>F180</sup>single UK responsible person], shall—

- (a) notify the Secretary of State of the end of the clinical investigation; and
- (b) provide justification where premature termination has resulted.]

#### Extent Information

**E12** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F171** Words in reg. 16(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7D\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F172** Words in reg. 16 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(7D\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [20](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F173** Words in reg. 16(1)(a) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(a)**
- F174** Words in reg. 16(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **6**
- F175** Reg. 16(1A) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **5**
- F176** Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F177** Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F178** Words in reg. 16(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F179** Reg. 16(11) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(b)**
- F180** Words in reg. 16(11) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(e)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

## Procedures for general medical devices for clinical investigations **N.I.**

**16.**—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in [<sup>F607</sup>Northern Ireland] unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (3), the statement required by [<sup>F608</sup>Sections 1 and 2.2] of Annex VIII [<sup>F609</sup>, read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a CE marking otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was CE marked in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) that the relevant device may be made available for the purposes of the intended investigation; or
  - (b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.
- (6) A written notice pursuant to paragraph (5) may—
- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;
  - (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.
- (7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—
- (a) further clinical use of the relevant device in the investigation is prohibited; and
  - (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),
- unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.
- (8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—
- (a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;
  - (b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and
  - (c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.
- (9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—
- (a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or
  - (b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).
- (10) No person shall conduct a clinical investigation of a relevant device—
- (a) otherwise than in accordance with Annex X; and
  - (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),
- and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.
- [<sup>F610</sup>(11) The manufacturer, or their single authorised representative, shall—
- (a) notify the Secretary of State of the end of the clinical investigation; and
  - (b) provide justification where premature termination has resulted.]

**Extent Information**

**E60** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Textual Amendments**

**F607** Words in [reg. 16\(1\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 4](#)

**F608** Words in [reg. 16\(1\)\(a\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), [9\(a\)](#)

**F609** Words in [reg. 16\(1\)\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), [6](#)

**F610** [Reg. 16\(11\)](#) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), [9\(b\)](#)

**Manufacturers etc. and conformity assessment procedures for general medical devices** **E**  
**+W+S**

17.—(1) A manufacturer of a relevant device or, where applicable, [<sup>F181</sup>their UK responsible person] who is required to follow, or follows or has followed a conformity assessment procedure set out in [<sup>F182</sup>this Part] shall observe the manufacturer’s obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, [<sup>F181</sup>their UK responsible person] shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with [<sup>F182</sup>this Part] at an intermediate stage of manufacture of the device.

<sup>F183</sup>(3) .....

<sup>F184</sup>(4) .....

<sup>F184</sup>(5) .....

**Extent Information**

**E13** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Textual Amendments**

**F181** Words in [reg. 17](#) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\)](#), [4\(8\)\(a\)](#) (as amended by [S.I. 2020/1478](#), [reg. 1\(3\)](#), [Sch. 2 paras. 2, 21](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

**F182** Words in [reg. 17](#) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\)](#), [4\(8\)\(b\)](#) (as amended by [S.I. 2020/1478](#), [reg. 1\(3\)](#), [Sch. 2 paras. 2, 21](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

**F183** [Reg. 17\(3\)](#) omitted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\)](#), [4\(8\)\(c\)](#) (as amended by [S.I. 2020/1478](#), [reg. 1\(3\)](#), [Sch. 2 paras. 2, 21](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

**F184** [Reg. 17\(4\)\(5\)](#) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), [7](#)

Status: Point in time view as at 21/03/2024.

Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**Manufacturers etc. and conformity assessment procedures for general medical devices** **N.I.**

17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer’s obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device.

- F611(3) .....
- F612(4) .....
- F612(5) .....

**Extent Information**

**E61** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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**Textual Amendments**

**F611** Reg. 17(3) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 5**

**F612** Reg. 17(4)(5) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), 7

**[F185 Approved bodies] and the conformity assessment procedures for general medical devices** **E+W+S**

18.—(1) [F186An approved body] which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out <sup>F187</sup>... at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, <sup>F188</sup>...; and
- (c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where [F189an approved body] takes a decision in accordance with [F190Annex II, III, V or VI,] they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where [F191an approved body] and a manufacturer or [F192the manufacturer’s UK responsible person] have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or [F192the manufacturer’s UK responsible person], extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

- F193(4) .....



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

- E14** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F185** Words in reg. 18 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F186** Words in reg. 18(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(b\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F187** Words in reg. 18(1)(a) omitted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(b\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F188** Words in reg. 18(1)(b) omitted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(b\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F189** Words in reg. 18(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(c\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F190** Words in [reg. 18\(2\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), [10](#)
- F191** Words in reg. 18(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(d\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F192** Words in reg. 18(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(d\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F193** Reg. 18(4) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [4\(9\)\(e\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### UK notified bodies and the conformity assessment procedures for general medical devices **N.I.**

**18.—(1)** A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any [<sup>F613</sup>EEA State]; and
- (c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(2) Where a UK notified body takes a decision in accordance with [<sup>F614</sup>Annex II, III, V or VI,] they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

[<sup>F615</sup>(4) Decisions taken by UK notified bodies before 1st September 2003 in accordance with Annex II in respect of breast implants may not be extended.]

**Extent Information**

**E62** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Textual Amendments**

**F613** Words in [reg. 18\(1\)\(b\)](#) substituted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **8**

**F614** Words in [reg. 18\(2\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), **10**

**F615** [Reg. 18\(4\)](#) added (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), [regs. 1\(1\)\(a\)](#), **8**

[<sup>F194</sup> [<sup>F195</sup> **Registration of persons placing general medical devices on the market**

**19.**—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are neither Class I devices nor custom-made devices, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any general medical device of any class, other than a system or procedure pack which is not CE marked;

[<sup>F196</sup>(ii) . . . . .

(iii) a manufacturer’s authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to Class I devices [<sup>F197</sup>that are not custom-made devices], to—

(i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland;

(c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State’s functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of their address and registered place of business;

(b) supply the Secretary of State with a description of each category of device concerned;

<sup>F198</sup>(c) .....

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;

(b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;

(c) in the case of a device that is a Class IIa or Class IIb non-implantable device, on 1st September 2021.

<sup>F199</sup>(5) .....

<sup>F200</sup>(6) .....]]

**Textual Amendments**

- F194** Reg. 19 revoked (E.W.S) (30.4.2021) by S.I. 2002/618, **reg. 4D(1)** (as inserted by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F195** Reg. 19 substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 6**
- F196** Reg. 19(1)(a)(ii) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(a)**
- F197** Words in reg. 19(1)(b) substituted (N.I.) (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(b)**
- F198** Reg. 19(2)(c) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(c)**
- F199** Reg. 19(5) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(d)**
- F200** Reg. 19(6) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(e)**

**Additional requirements relating to use of animal tissues**

<sup>F201</sup>**19A.** .....

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F201** Reg. 19A omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), 9

### <sup>F202</sup><sup>F203</sup> **Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42**

**19B.**—(1) In this regulation—

- (a) “the Directive” means Directive 93/42 <sup>F204</sup>as it had effect on 25 May 2021] and any reference to an Article or Annex is a reference to that Article or Annex in the Directive <sup>F205</sup>...;
- (b) “Regulation 722/2012” means Commission Regulation (EU) 722/2012 as it has effect in EU law;
- (c) “CE marking” means the CE marking required by Article 17 and shown in Annex XII;
- (d) “harmonised standard” is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 8, 9, 10(1) to (4), 11 and 13 are treated as being satisfied.

(3) <sup>F206</sup>Subject to paragraph (3A),] this paragraph applies where, before placing a relevant device other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—

- (a) ensures—
  - (i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation 722/2012, which apply to it; or
  - (ii) that paragraph (10) and (11) apply;
- (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 11;
  - [ ensures that any certificate issued by a notified body in connection with that conformity
- <sup>F207</sup>(ba) assessment procedure is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;]
- (c) ensures that the documentation required by the conformity assessment procedure is drawn up;
- (d) ensures that the technical and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;
- (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes II, III, IV, V, VI or VII;
- (f) <sup>F208</sup>has drawn up before 26 May 2021] an EU declaration of conformity in accordance with Article 11; and
- (g) ensures that the declaration of conformity is prepared in or translated into English.

<sup>F209</sup>[ (3A) Paragraph (3) only applies to a class I device under the Directive if—

- (a) the conformity assessment procedure under Article 11 required the involvement of a notified body; or

- (b) the conformity assessment procedure for that device under Article 52 of Regulation (EU) 2017/745 would require the involvement of a notified body (if it were to be assessed under that regulation).]
- (4) Where paragraph (5) applies, regulations 8 and 15 are treated as being satisfied.
- (5) This paragraph applies where, before a custom-made device is placed on the market, the manufacturer—
- (a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex VIII, read with Regulation 722/2012;
  - (b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow an assessment of conformity of the device with the requirements of the Directive;
  - (c) undertakes to the Secretary of State—
    - (i) to comply with Section 3.1 of Annex VIII;
    - (ii) to keep all documentation required by Annex VIII available in accordance with Section 4 of Annex VIII; and
    - (iii) to pass the statement mentioned in subparagraph (a) on with the custom-made device so that it may be made available to the patient on request.
- (6) Where paragraph (7) applies, regulations 8 and 14 are treated as being satisfied.
- (7) This paragraph applies where before a system or procedure pack is placed on the market, the manufacturer—
- (a) has complied with Article 12(2);
  - (b) has complied with Article 12(3) and with the procedure in Annex II or V;
    - [ ensures that any certificate in relation to the system or procedure pack or a device within it
  - <sup>F210</sup>(ba) that was issued by a notified body under the Directive is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;
  - (bb) ensures that the declarations required by Article 12 were drawn up before 26 May 2021;]
  - (c) undertakes to keep the declarations required by Article 12 for the period specified in Article 12(4); <sup>F211</sup> ...
  - (d) ensures that the system or procedure pack is accompanied by the information referred to in point 13 of Annex I which must be in [<sup>F212</sup>English; and]
    - [ ensures that the system or procedure pack does not contain a class I device under the
  - <sup>F213</sup>(e) Directive for which—
    - (i) the conformity assessment procedure under Article 11 did not require the involvement of a notified body; and
    - (ii) the conformity assessment procedure under Article 52 of Regulation (EU) 2017/745 would not require the involvement of a notified body (if it were to be assessed under that regulation).]
- (8) Where paragraph (9) applies, regulations 8 and 16 are treated as being satisfied.
- (9) This paragraph applies where before a relevant device intended for clinical investigation is made available in Great Britain for the purpose of a clinical investigation, the manufacturer—
- (a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the Statement required by Sections 1 and 2.2 of Annex VIII;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) undertakes to keep available the documentation referred to in Section 3.2 of Annex VIII for the period specified in Section 4 of that Annex; and
- (c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of paragraph 3.1 of Annex VIII.
- (10) Where paragraph (11) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).
- (11) This paragraph applies where a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard.
- (12) For the purpose of this regulation in regulations 10(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

#### Textual Amendments

- F202** Reg. 19B omitted (N.I.) (21.3.2024) by virtue of [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **14**
- F203** Regs. 19B, 19C inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F204** Words in reg. 19B(1)(a) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(2)(a)**
- F205** Words in reg. 19B(1)(a) omitted (E.W.S.) (1.7.2023) by virtue of [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(2)(b)**
- F206** Words in reg. 19B(3) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(3)(a)**
- F207** Reg. 19B(3)(ba) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(3)(b)**
- F208** Words in reg. 19B(3)(f) substituted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(3)(c)**
- F209** Reg. 19B(3A) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(4)**
- F210** Reg. 19B(7)(ba)(bb) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(5)(a)**
- F211** Word in reg. 19B(7)(c) omitted (E.W.S.) (1.7.2023) by virtue of [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(5)(b)**
- F212** Words in reg. 19B(7)(d) substituted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(5)(c)**
- F213** Reg. 19B(7)(e) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **6(5)(d)**

#### Obligations in Part II and III of these Regulations which are met by complying with obligations in Regulation (EU) 2017/745

**19C.**—(1) In this regulation—

- (a) “the Regulation” means Regulation (EU) 2017/745, as it has effect in EU law, and any reference to an Article or an Annex is a reference to an Article or Annex of the Regulation;
- (b) “CE marking” means the CE marking required by Article 20 and presented in Annex V;
- (c) “harmonised standard” has the meaning given in Article 2(70);

(d) “sponsor” has the meaning given in Article 2(49).

(2) Where paragraph (3) applies, regulations 8, 10(1) to (4), 11, 13, 22, 23, 24 and 27 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device within the meaning of Part II or Part III (as the case may be) other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—

(a) ensures—

(i) that the device meets the general safety and performance requirements in Annex I which apply to it; or

(ii) that paragraphs (10) and (11) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 52;

[ ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn;]

<sup>F214</sup>(ba)

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical documentation required by Annexes II and III and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes IX, X or XI;

(f) draws up an EU declaration of conformity in accordance with Article 19;

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies regulations 8 and 15 (or as the case may be) 22 and 28 are treated as being satisfied.

(5) This paragraph applies where, before a custom-made device is placed on the market, the manufacturer—

(a) has drawn up a statement in English containing the information specified in Section 1 of Annex XIII;

(b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent national authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow assessment of the conformity of the device with the requirements of the Regulation; and

(c) undertakes to comply with Sections 3 (manufacturing), 4 (retention of information) and 5 (review of experience) of Annex XIII.

(6) Where paragraph (7) applies, regulations 8 and 14 are treated as being satisfied.

[<sup>F215</sup>(7) This paragraph applies where, before a system or procedure pack is placed on the market, the person responsible for combining devices to produce that system or procedure pack—

(a) has complied with the relevant requirements of Article 22 including where that Article requires a conformity assessment in accordance with Annex IX or XI; and

(b) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(8) Where paragraph (9) applies, regulations 8 and 16(1) or (as the case may be) 22 and 29(1) are treated as being satisfied.

(9) This paragraph applies where, before a relevant device intended for clinical investigation is made available in Great Britain for the purpose of a clinical investigation, the manufacturer—

- (a) has provided the Secretary of State with the required notice in the form of the application required by Article 70 in English; and
- (b) has provided the Secretary of State with an undertaking to keep available documentation contained in the application in accordance with Section 3 of Chapter III of Annex XV.

(10) Where paragraph (11) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4) or regulation 23(4) (as the case may be).

(11) This paragraph applies where a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard.

(12) For the purpose of this regulation in regulations 10(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

#### Textual Amendments

- F203** Regs. 19B, 19C inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **4(11)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F214** Reg. 19C(3)(ba) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **7(2)**
- F215** Reg. 19C(7) substituted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **7(3)**

## PART III

### *Active Implantable Medical Devices*

#### Interpretation of Part III

**20.**—(1) In this Part<sup>F216</sup>...—

“custom-made device” means an active implantable medical device that is—

- (a) manufactured specifically in accordance with a medical specialist’s written prescription which gives, under his responsibility, specific characteristics as to its design; and
- (b) intended to be used only for a particular patient; and

“relevant device” shall be construed in accordance with regulation 21.

(2) In this Part<sup>F216</sup>..., a reference to a numbered<sup>F217</sup>... Annex is to the<sup>F217</sup>... Annex of Directive 90/385 bearing that number.

#### Textual Amendments

- F216** Words in reg. 20(1)(2) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **10(a)**



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F217** Words in reg. 20(2) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **10(b)**

### Scope of Part III **E+W+S**

**21.**—<sup>F218</sup>(1) The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, <sup>F219</sup>...

<sup>F220</sup>(2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in [<sup>F221</sup>Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008] to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to Directive 90/385.

<sup>F222</sup>(3) Where an active implantable device is intended to administer a medicinal product, that device must be governed by this Part without prejudice to the provisions of the Human Medicines Regulations 2012.]]

<sup>F223</sup>(4) .....

#### Extent Information

**E15** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F218** Reg. 21 renumbered as reg. 21(1) (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **12(a)**

**F219** Words in reg. 21(1) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 11(a)**

**F220** Reg. 21(2)(3) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **12(b)**

**F221** Words in reg. 21(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(2)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

**F222** Reg. 21(3) substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 11(b)**

**F223** Reg. 21(4) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 11(c)**

### Scope of Part III **N.I.**

**21.**—<sup>F616</sup>(1) The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, except for devices that come within the scope of Directive 90/385 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, and

- (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it; and
- (b) the manufacturer chooses to follow the set of arrangements in the other Directive.

<sup>F617</sup>(2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to Directive 90/385.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(3) Where an active implantable medical device is intended to administer a medicinal product, that device shall be governed by Directive 90/385 without prejudice to the provisions of Directive 2001/83/EC.]

#### Extent Information

**E63** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F616** Reg. 21 renumbered as reg. 21(1) (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **12(a)**

**F617** Reg. 21(2)(3) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **12(b)**

### [<sup>F224</sup>Registration of persons placing active implantable medical devices on the market

**21A.—(1)** No person may place a relevant device on the market in accordance with this Part unless that person—

- (a) is established in Great Britain; and
- (b) has complied with paragraph (2).

(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

- (a) where—
  - (i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;
  - (ii) that person is the manufacturer of that device and is based outside the United Kingdom, and the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or
  - (iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;
- (b) that person supplies the Secretary of State with a description of the relevant device; and
- (c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.

(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.

- (3) The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—
  - (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (b) keep available to the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
  - (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;
  - (e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;
  - (f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
  - (g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;
  - (h) if the manufacturer acts contrary to its obligations under these Regulations—
    - (i) terminate the legal relationship with the manufacturer; and
    - (ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.
- (4) In this regulation—
- (a) the references to “technical documentation” are to be construed in accordance with Annex 2, 3 or 5;
  - (b) the references to “declaration of conformity” are to be construed in accordance with Annexes 2, 3 and 5.]

**Textual Amendments**

**F224** Reg. 21A inserted (E.W.S.) (30.4.2021) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(2)(b), **5(3)** (as amended by [S.I. 2019/1385](#), reg. 1, **Sch. 2 para. 4** and [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 paras. 2, 25**); 2020 c. 1, **Sch. 5 para. 1(1)**

**[<sup>F225</sup>Registration of persons placing active implantable medical devices on the market**

**21B.**—(1) Paragraph (2) applies—

- (a) in relation to relevant devices other than custom-made devices, to—
  - (i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any relevant device;
  - <sup>F226</sup>(ii) . . . . .
  - (iii) a manufacturer’s authorised representative who has a registered place of business in Northern Ireland;
  - (iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

<sup>F227</sup>(b) . . . . .

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State’s functions under these Regulations, any person to whom this paragraph applies must—

- (a) inform the Secretary of State of the address of their registered place of business; and
- (b) supply the Secretary of State with a description of each category of device concerned;

<sup>F228</sup>(c) . . . . .

- (d) in the case of an authorised representative, supply the Secretary of State with—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (i) written evidence that they have been designated as an authorised representative;
  - (ii) details of the person who has so designated them; and
  - (iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;
- (e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.
- (3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of the date specified in paragraph (4).
- (4) The obligations in paragraph (2) begin to apply on 1st May 2021.
- <sup>F229</sup>(5) .....
- <sup>F230</sup>(6) .....]

**Textual Amendments**

**F225** Regs. 21B, 21C inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 8**

**F226** Reg. 21B(1)(a)(ii) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **35(a)**

**F227** Reg. 21B(1)(b) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **35(b)**

**F228** Reg. 21B(2)(c) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **35(c)**

**F229** Reg. 21B(5) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **35(d)**

**F230** Reg. 21B(6) omitted (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **35(e)**

**Requirement to appoint a UK responsible person for active implantable medical devices**

<sup>F231</sup>21C. ....

**Textual Amendments**

**F231** Reg. 21C omitted (21.3.2024) by virtue of [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **15**

**Essential requirements for active implantable medical devices**

22.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex 1 which apply to it [<sup>F232</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

- (2) Subject to regulation 26, no person shall supply a relevant device—
  - (a) if that supply is also a placing on the market or putting into service of that device; or
  - (b) in circumstances where that device has also been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex 1 which apply to it [<sup>F233</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

**Textual Amendments**

- F232** Words in reg. 22(1) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **10**
- F233** Words in reg. 22(2) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **10**

**Determining compliance of active implantable medical devices with relevant essential requirements** **E+W+S**

**23.**—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Any—

- (a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and
- (b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

(3) In the case of a relevant device which is being or has been put into service—

- (a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and
- (b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—

(i) the instructions are in English <sup>F234</sup>...

<sup>F235</sup>(ii) .....

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant [<sup>F236</sup>designated standard], unless there are reasonable grounds for suspecting that the device does not comply with that requirement.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(6) A device intended for clinical investigation in respect of which—

- (a) the conditions specified in Annex 7 are satisfied;
- (b) notice has been given under regulation 29(1); and
- (c) either—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or
  - (ii) notice has been given under regulation 29(4),
- shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

#### Extent Information

**E16** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F234** Words in reg. 23(3)(b)(i) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(4)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

**F235** Reg. 23(3)(b)(ii) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(4)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

**F236** Words in reg. 23(4) substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 12**

### Determining compliance of active implantable medical devices with relevant essential requirements **N.I.**

**23.—(1)** In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Any—

- (a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and
- (b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

(3) In the case of a relevant device which is being or has been put into service—

- (a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and
- (b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—
  - (i) the instructions are in English or another Community language, and
  - (ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national Standard, unless there are reasonable grounds for suspecting that the device does not comply with that requirement.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(6) A device intended for clinical investigation in respect of which—

- (a) the conditions specified in Annex 7 are satisfied;
- (b) notice has been given under regulation 29(1); and
- (c) either—

(i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 29(4),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

#### Extent Information

**E64** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### [<sup>F237</sup>UK marking] of active implantable medical devices **E+W+S**

24.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a [<sup>F238</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F239</sup>Annex 2 of Regulation 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F240</sup>approved body] or conformity assessment body identification number for that device.

(2) Subject to regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a [<sup>F238</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F239</sup>Annex 2 of Regulation 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F241</sup>approved body] or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless a [<sup>F238</sup>UK marking], meeting the requirements set out in [<sup>F239</sup>Annex 2 of Regulation 765/2008], appears on—

- (a) where appropriate, any sales packaging for that device; and
- (b) the instructions for use for the device,

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

and that [<sup>F238</sup>UK marking] is accompanied by any relevant [<sup>F242</sup>approved body] or conformity assessment body identification number for that device.

(4) Subject to regulation 26, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a [<sup>F238</sup>UK marking], meeting the requirements set out in [<sup>F239</sup>Annex 2 of Regulation 765/2008], appears on—

- (a) where appropriate, any sales packaging for that device; and
- (b) the instructions for use for the device,

and that [<sup>F238</sup>UK marking] is accompanied by any relevant [<sup>F243</sup>approved body] or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device or its sterile pack;
- (b) the instructions for use for a relevant device; or
- (c) where appropriate, any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the [<sup>F238</sup>UK marking] or which reduces the visibility or the legibility of the [<sup>F238</sup>UK marking].

[<sup>F244</sup>(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of [Regulation \(EU\) No 765/2008](#), the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

- (a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and
- (b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).]

#### Extent Information

**E17** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F237** Words in reg. 24 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(4A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F238** Words in reg. 24 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(4A)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F239** Words in reg. 24 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(4A)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F240** Words in reg. 24(1)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(4A)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F241** Words in reg. 24(2)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(4A)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F242** Words in reg. 24(3)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [5\(4A\)\(d\)\(ii\)](#) (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, [26](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F243** Words in reg. 24(4)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [5\(4A\)\(d\)\(ii\)](#) (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, [26](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F244** [Reg. 24\(6\)](#) inserted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 13](#)

## CE marking of active implantable medical devices **N.I.**

**24.**—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a CE marking which—

- (a) meets the requirements set out in Annex 9;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a CE marking which—

- (a) meets the requirements set out in Annex 9;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex 9, appears on—

- (a) where appropriate, any sales packaging for that device; and
- (b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulation 26, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex 9, appears on—

- (a) where appropriate, any sales packaging for that device; and
- (b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device or its sterile pack;
- (b) the instructions for use for a relevant device; or
- (c) where appropriate, any sales packaging for a relevant device,

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

#### Extent Information

**E65** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### [<sup>F245</sup>UK(NI) indication: active implantable medical devices

**24A.**—(1) Where the CE marking referred to in regulation 24 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 27.

[<sup>F246</sup>(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.]

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service”;

#### Textual Amendments

**F245** Reg. 24A inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 9**

**F246** Reg. 24A(3A) inserted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **36**

#### [<sup>F247</sup>UK marking of active implantable medical devices that come within the scope of this Part and other legislation **E+W+S**

**25.** Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation (“the other legislation”) a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.]

#### Extent Information

**E18** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F247** Reg. 25 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(4B)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

## CE marking of active implantable medical devices that come within the scope of more than one Directive **N.I.**

**25.** Where a relevant device comes within the scope of Directive 90/385 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

- (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;
- (b) the manufacturer chooses to follow the set of arrangements in Directive 90/385;
- (c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and
- (d) the particulars of Directive 90/385, as published in the Official Journal of the [<sup>F618</sup>European Union], are given in the documents, notices or instructions accompanying the device, and in a manner in which those particulars are accessible without it being necessary to destroy the packaging which keeps the device sterile.

### Extent Information

**E66** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

**F618** Words in Regulations substituted (22.4.2011) by [The Treaty of Lisbon \(Changes in Terminology\) Order 2011 \(S.I. 2011/1043\)](#), arts. 2, 4 (with art. 3(3))

## Exemptions from regulations 22 and 24 **E+W+S**

**26.—(1)** A relevant device being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of <sup>F248</sup>... these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a [<sup>F249</sup>UK marking], where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[<sup>F250</sup>(4) Regulations 22 and 24 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 22 and 24, may be placed on the market.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(5) In paragraph (4), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 22 and 24, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.]

#### Extent Information

**E19** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F248** Words in reg. 26(1) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(5)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F249** Words in reg. 26(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(5)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F250** Reg. 26(4)(5) inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **5(5)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### Exemptions from regulations 22 and 24 **N.I.**

**26.**—(1) A relevant device being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 90/385 or these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

#### Extent Information

**E67** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Procedures for affixing a [<sup>F251</sup>UK marking] to active implantable medical devices **E+W+S**

**27.** A relevant device may bear a [<sup>F252</sup>UK marking] only if its manufacturer or [<sup>F253</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex 2, or
  - (ii) Annex 3, together with Annex 4 or 5;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [<sup>F254</sup>this Part] that apply to it; <sup>F255</sup>...

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (c) ensures that the device meets the provisions of [<sup>F254</sup>this Part] which apply to it; [<sup>F256</sup>and] [<sup>F257</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]

#### Extent Information

**E20** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F251** Words in reg. 27 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(5A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F252** Words in reg. 27 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(5A)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F253** Words in reg. 27 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(5A)(b)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F254** Words in reg. 27(b)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(5A)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F255** Word in reg. 27(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **11(a)**
- F256** Word in reg. 27(c) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **11(b)**
- F257** Reg. 27(d) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **11(c)**

### Procedures for affixing a CE marking to active implantable medical devices **N.I.**

27. A relevant device may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
- (i) Annex 2, or
  - (ii) Annex 3, together with Annex 4 or 5;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 90/385 that apply to it; <sup>F619</sup> ...
- (c) ensures that the device meets the provisions of Directive 90/385 which apply to it; [<sup>F620</sup>and] [<sup>F621</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]

#### Extent Information

**E68** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F619** Word in reg. 27(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **11(a)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F620** Word in [reg. 27\(c\)](#) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **11(b)**
- F621** [Reg. 27\(d\)](#) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **11(c)**

### Procedures for custom-made active implantable medical devices **E+W+S**

**28.** No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or [<sup>F258</sup>their UK responsible person]—

- (a) has drawn up the statement containing the information required by Section 2.1 of Annex 6<sup>F259</sup>, read with Regulation (EU) No 722/2012];
- (b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;
- (c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex 6; and
- (d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

#### Extent Information

**E21** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F258** Words in [reg. 28](#) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [regs. 1\(1\)](#), **5(5B)** (as amended by [S.I. 2020/1478](#), [regs. 1\(3\)](#), [Sch. 2 paras. 2](#), **30**); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)
- F259** Words in [reg. 28\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **12**

### Procedures for custom-made active implantable medical devices **N.I.**

**28.** No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

- (a) has drawn up the statement containing the information required by Section 2.1 of Annex 6<sup>F622</sup>, read with Regulation (EU) No 722/2012];
- (b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;
- (c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex 6; and
- (d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

**E69** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

**F622** Words in [reg. 28\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), [regs. 1\(2\), 12](#)

## Procedures for active implantable medical devices for clinical investigations **E+W+S**

**29.**—(1) No person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in [<sup>F260</sup>Great Britain] unless, before he does so, the manufacturer of the device or [<sup>F261</sup>their UK responsible person] has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (2), the statement required by Section 2.2 of Annex 6 [<sup>F262</sup>, read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.1 and 3.2 of Annex 6.

[<sup>F263</sup>(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

- (a) obtain advice on regulatory requirements relating to an intended clinical investigation; or
- (b) obtain a statistical review in relation to an intended clinical investigation.]

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or [<sup>F261</sup>their UK responsible person] as soon as it becomes available.

(3) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer [<sup>F264</sup>or UK responsible person] (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(4) The Secretary of State may, in respect of notice in writing given by a manufacturer or [<sup>F261</sup>their UK responsible person] pursuant to paragraph (1), give written notice to the manufacturer or [<sup>F261</sup>their UK responsible person]—

- (a) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, that the relevant device may be made available for the purposes of the intended investigation; or
  - (b) if the ethics committee opinion required under Section 2.2 of Annex 6 is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.
- (5) A written notice pursuant to paragraph (4) may—
- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.
- (6) Where a written notice pursuant to paragraph (4) in respect of a relevant device has been withdrawn by the Secretary of State—
- (a) further clinical use of the relevant device in the investigation is prohibited; and
  - (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),
- unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.
- (7) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or [<sup>F261</sup>their UK responsible person], shall—
- (a) take all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1, and the first paragraph of Section 3.2, of Annex 6;
  - (b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and
  - (c) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation.
- (8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(b) are met, amongst other reasons, if—
- (a) the manufacturer or [<sup>F261</sup>their UK responsible person] does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (7); or
  - (b) the manufacturer or [<sup>F261</sup>their UK responsible person] does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1).
- (9) No person shall conduct a clinical investigation of a relevant device—
- (a) otherwise than in accordance with Annex 7; and
  - (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(a),
- and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or [<sup>F261</sup>their UK responsible person] shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex 7.
- [<sup>F265</sup>(10) The manufacturer, or their [<sup>F266</sup>single UK responsible person], shall—
- (a) notify the Secretary of State of the end of the clinical investigation; and
  - (b) provide justification where premature termination has resulted.]

#### Extent Information

**E22** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F260** Words in reg. 29(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(5C)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F261** Words in reg. 29 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5C)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F262** Words in reg. 29(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **13**
- F263** Reg. 29(1A) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **6**
- F264** Words in reg. 29(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5C)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F265** Reg. 29(10) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **13**
- F266** Words in reg. 29(10) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5C)(d)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**

## Procedures for active implantable medical devices for clinical investigations **N.I.**

**29.**—(1) No person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in [<sup>F623</sup>Northern Ireland] unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

- (a) subject to paragraph (2), the statement required by Section 2.2 of Annex 6 [<sup>F624</sup>, read with Regulation (EU) No 722/2012]; and
- (b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(3) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(4) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

- (a) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, that the relevant device may be made available for the purposes of the intended investigation; or
- (b) if the ethics committee opinion required under Section 2.2 of Annex 6 is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(5) A written notice pursuant to paragraph (4) may—

- (a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.
- (6) Where a written notice pursuant to paragraph (4) in respect of a relevant device has been withdrawn by the Secretary of State—
- (a) further clinical use of the relevant device in the investigation is prohibited; and
  - (b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),
- unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.
- (7) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—
- (a) take all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1, and the first paragraph of Section 3.2, of Annex 6;
  - (b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and
  - (c) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation.
- (8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(b) are met, amongst other reasons, if—
- (a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (7); or
  - (b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1).
- (9) No person shall conduct a clinical investigation of a relevant device—
- (a) otherwise than in accordance with Annex 7; and
  - (b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(a),
- and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex 7.
- [<sup>F625</sup>(10) The manufacturer, or their single authorised representative, shall—
- (a) notify the Secretary of State of the end of the clinical investigation; and
  - (b) provide justification where premature termination has resulted.]

#### Extent Information

**E70** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F623** Words in [reg. 29\(1\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 10](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F624** Words in reg. 29(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **13**

**F625** Reg. 29(10) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **13**

## Manufacturers etc. and conformity assessment procedures for active implantable medical devices **E+W+S**

**30.**—(1) A manufacturer of a relevant device or, where applicable, [<sup>F267</sup>their UK responsible person] who is required to follow, or follows or has followed a conformity assessment procedure [<sup>F268</sup>in the Annexes referred to in regulation 27(a)] shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, [<sup>F269</sup>their UK responsible person] shall, when following a conformity assessment procedure [<sup>F270</sup>in the Annexes referred to in regulation 27(a)], take account of the results of any assessment or verification operations which have been carried out <sup>F271</sup>... at an intermediate stage of manufacture of the device.

<sup>F272</sup>(3) .....

<sup>F273</sup>(4) .....

<sup>F273</sup>(5) .....

### Extent Information

**E23** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

**F267** Words in reg. 30(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(6)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F268** Words in reg. 30(1) substituted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 14(a)**

**F269** Words in reg. 30(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(6)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F270** Words in reg. 30(2) inserted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 14(b)(i)**

**F271** Words in reg. 30(2) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 14(b)(ii)**

**F272** Reg. 30(3) revoked (E.W.S.) (30.4.2021) by S.I. 2002/618, **reg. 4D(6)** (as inserted (E.W.S.) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)

**F273** Reg. 30(4)(5) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(6)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

## Manufacturers etc. and conformity assessment procedures for active implantable medical devices **N.I.**

**30.**—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 90/385 shall observe the manufacturer’s obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 90/385 at an intermediate stage of manufacture of the device.

[<sup>F626</sup>(3) Except as provided in paragraphs (4) and (5), the manufacturer of a relevant device, who under their own name places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, shall provide the Secretary of State with—

- (a) the address of their registered place of business;
- (b) a description of the devices concerned; and
- (c) details of the label and instructions for use that accompany each device.

(4) Where the manufacturer of a relevant device places a device on the market under their own name, but does not have a registered place of business in [<sup>F627</sup>a relevant state], the manufacturer shall—

- (a) designate a single authorised representative; and
- (b) ensure that the authorised representative has a registered place of business in [<sup>F627</sup>a relevant state].

(5) The authorised representative referred to in paragraph (4) shall provide the competent authority of [<sup>F628</sup>the relevant state] in which they have their registered place of business with the information referred to in paragraph (3) above.]

### Extent Information

**E71** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

**F626** Reg. 30(3)-(5) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **14**

**F627** Words in reg. 30(4) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 11(a)**

**F628** Words in reg. 30(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 11(b)**

## [<sup>F274</sup>Obligations in Part III which are met by complying with obligations in Directive 90/385

**30A.**—(1) In this regulation—

- (a) “the Directive” means Directive 90/385 [<sup>F275</sup>as it had effect on 25 May 2021] and any reference to an Article or Annex is a reference to that Article or Annex in the Directive

<sup>F276</sup> ...;

- (b) “Regulation 722/2012” means Commission Regulation (EU) 722/2012 as it has effect in EU Law;
  - (c) “CE marking” means the CE marking required by Article 12 and shown in Annex 9;
  - (d) “harmonised standard” is to be construed in accordance with Article 5.
- (2) Where paragraph (3) applies regulations 22, 24(1) to (4), 25 and 27 are treated as being satisfied.
- (3) This paragraph applies where, before placing a relevant device other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—
- (a) ensures—
    - (i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or
    - (ii) that paragraphs (8) and (9) apply;
  - (b) ensures that the relevant conformity assessment procedure that applies to the device, where the device is a device other than those which are custom-made or intended for clinical investigations, has been carried out in accordance with Article 9;
    - [ ensures that the certificate issued by a notified body in connection with that conformity
    - <sup>F277</sup>(ba) assessment procedure is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;]
  - (c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;
  - (d) ensures that the technical and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;
  - (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes 2, 3, 4 or 5;
  - (f) [<sup>F278</sup> has drawn up before 26 May 2021] an EU Declaration of Conformity in accordance with Article 9; and
  - (g) ensures that the declaration of conformity is prepared in or translated into English.
- (4) Where paragraph (5) applies, regulations 25 and 28 are treated as being satisfied.
- (5) This paragraph applies where, before a custom-made device is placed on the market, the manufacturer—
- (a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex 6, read with Regulation 722/2012;
  - (b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow an assessment of conformity of the device with the requirements of the Directive;
  - (c) undertakes to the Secretary of State—
    - (i) to comply with Section 3.1 of Annex 6;
    - (ii) to keep all documentation required by Annex 6 for the period specified in Section 4 of Annex 6; and
    - (iii) to pass on the statement mentioned in sub-paragraph (a) with the custom-made device so that it may be made available to the patient on request.
- (6) Where paragraph (7) applies, regulations, 22 and 29 are treated as being satisfied.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(7) This paragraph applies where, before a relevant device intended for clinical investigation is made available in Great Britain for the purpose of a clinical investigation, the manufacturer—

- (a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the statement required by Section 2.2 of Annex 6;
- (b) has provided an undertaking to keep available for five years the documentation referred to in Section 3.1 and 3.2 of Annex 6; and
- (c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in Section 3.2 of Annex 6.

(8) Where paragraph (9) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).

(9) This paragraph applies where a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard.

(10) For the purpose of this regulation in regulations 24(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

#### Textual Amendments

- F274** Reg. 30A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(8)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **34**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F275** Words in reg. 30A(1)(a) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **8(2)(a)**
- F276** Words in reg. 30A(1)(a) omitted (1.7.2023) by virtue of [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **8(2)(b)**
- F277** Reg. 30A(3)(ba) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **8(3)(a)**
- F278** Words in reg. 30A(3)(f) substituted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **8(3)(b)**

#### <sup>F279</sup> **Approved bodies] and the conformity assessment procedures for active implantable medical devices** **E+W+S**

**31.**—(1) [<sup>F280</sup>An approved body] which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out in accordance with [<sup>F281</sup>this Part] at an intermediate stage of manufacture of the device; and
- (b) lay down, by common accord with the manufacturer or [<sup>F282</sup>their UK responsible person], the time limits for completion of the assessment and verification operations referred to in Annex 2 or 3.

(2) Where [<sup>F283</sup>an approved body] takes a decision in accordance with [<sup>F284</sup>Annex 2, 3 or 5], they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) [<sup>F285</sup>Where an approved body and a manufacturer or the manufacturer’s UK responsible person] have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application

from and with the agreement of the manufacturer or [<sup>F286</sup>the manufacturer's UK responsible person], extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

#### Extent Information

**E24** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F279** Words in reg. 31 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F280** Words in reg. 31(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F281** Words in reg. 31(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(b)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F282** Words in reg. 31(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(b)(iii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F283** Words in reg. 31(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F284** Words in reg. 31(2) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **15**

**F285** Words in reg. 31(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F286** Words in reg. 31(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **5(7)(d)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

### UK notified bodies and the conformity assessment procedures for active implantable medical devices **N.I.**

**31.—(1)** A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 90/385 at an intermediate stage of manufacture of the device; and
- (b) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex 2 or 3.

(2) Where a UK notified body takes a decision in accordance with [<sup>F629</sup>Annex 2, 3 or 5], they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

#### Extent Information

**E72** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F629** Words in [reg. 31\(2\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), [15](#)

## PART IV

### *In Vitro Diagnostic Medical Devices*

#### Interpretation of Part IV **E+W+S**

**32.**—(1) In this Part <sup>F287</sup>...—

“accessory” means an article intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

- (a) itself an *in vitro* diagnostic medical device;
- (b) an invasive sampling medical device; or
- (c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

“calibration and control material” means any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device;

[<sup>F288</sup>“common technical specification” means a technical specification set out in the Annex to Commission [Decision 2002/364/EC](#) (as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act) for a relevant device referred to in a list in Annex II;]

“device for self-testing” means an *in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment; and

“relevant device” shall be construed in accordance with regulation 33(1);

(2) In this Part <sup>F287</sup>..., a reference to a numbered article or Annex is to the article or Annex of Directive 98/79 bearing that number.

#### Extent Information

**E25** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F287** Words in reg. 32(1)(2) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **11**

**F288** Words in reg. 32 substituted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 15**

### Interpretation of Part IV **N.I.**

**32.**—(1) In this Part <sup>F630</sup>...—

“accessory” means an article intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

- (a) itself an *in vitro* diagnostic medical device;
- (b) an invasive sampling medical device; or
- (c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

“calibration and control material” means any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device;

“common technical specification” means a technical specification for a relevant device referred to in a list in Annex II which has been adopted in accordance with the procedure set out in article 7(2) and published in the Official Journal of the [<sup>F631</sup>European Union];

“device for self-testing” means an *in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment; and

“relevant device” shall be construed in accordance with regulation 33(1);

(2) In this Part <sup>F630</sup>..., a reference to a numbered article or Annex is to the article or Annex of Directive 98/79 bearing that number.

### Extent Information

**E73** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

**F630** Words in reg. 32(1)(2) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **11**

**F631** Words in Regulations substituted (22.4.2011) by [The Treaty of Lisbon \(Changes in Terminology\) Order 2011 \(S.I. 2011/1043\)](#), arts. 2, 4 (with art. 3(3))

### Scope of Part IV

**33.**—(1) The requirements of this Part in respect of relevant devices apply in respect of *in vitro* diagnostic medical devices [<sup>F289</sup>(including coronavirus test devices)] and accessories to such devices, except for—

- (a) products manufactured and used within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; [<sup>F290</sup>and]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) <sup>F291</sup> devices that come within the scope of Directive 98/79 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, and
- (i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and
  - (ii) the manufacturer chooses to follow the set of arrangements in the other Directive.]
- (2) The requirements of this Part in respect of devices for performance evaluation do not apply in respect of—
- (a) products manufactured and used only within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; <sup>F292</sup>and]
  - (b) <sup>F293</sup> devices that come within the scope of Directive 98/79 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, and
    - (i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and
    - (ii) the manufacturer chooses to follow the set of arrangements in the other Directive.]

#### Textual Amendments

- F289** Words in reg. 33(1) inserted (28.7.2021) by The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (S.I. 2021/910), regs. 1(1), 4
- F290** Word in reg. 33(1)(a) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 16(a)(i)**
- F291** Reg. 33(1)(b) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 16(a)(ii)**
- F292** Word in reg. 33(2)(a) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 16(b)(i)**
- F293** Reg. 33(2)(b) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 16(b)(ii)**

#### <sup>F294</sup>Registration etc. of persons placing in vitro diagnostic medical devices on the market

**33A.**—(1) No person may place a relevant device on the market in accordance with this Part unless that person—

- (a) is established in Great Britain; and
- (b) has complied with paragraph (2).

(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

- (a) where—
  - (i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;
  - (ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer’s authority to act as their UK responsible person; or

- (iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;
  - (b) that person supplies the Secretary of State with—
    - (i) a description of the relevant device; and
    - (ii) the relevant information in paragraph (4); and
  - (c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.
- (2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.
- (3) The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—
- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
  - (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
  - (d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;
  - (e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;
  - (f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
  - (g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;
  - (h) if the manufacturer acts contrary to its obligations under these Regulations—
    - (i) terminate the legal relationship with the manufacturer; and
    - (ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.
- (4) In this regulation “relevant information” means—
- (a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;
  - (b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;
  - (c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;
  - (d) in relation to devices in a list in Annex II and devices for self-testing—
    - (i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;
  - (e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.
- (5) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.
- (6) In this regulation a device is a “new relevant device” if—
- (a) there has been no such device continuously available on the United Kingdom or EEA market during the previous three years for the relevant analyte or other parameter; or
  - (b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or EEA market during the previous three years.
- (7) In paragraph (3)—
- (a) the references to “technical documentation” are to be construed in accordance with Annexes III to VIII;
  - (b) the references to “declaration of conformity” are to be construed in accordance with Annexes III, IV, V and VII.]

#### Textual Amendments

**F294** Reg. 33A inserted (E.W.S.) (30.4.2021) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(2)(c), **6(3)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 5** and S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **36**); 2020 c. 1, Sch. 5 para. 1(1)

#### Essential requirements for *in vitro* diagnostic medical devices

**34.**—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

- (2) Subject to regulation 39, no person shall supply a relevant device—
- (a) if that supply is also a placing on the market or putting into service of that device; or
  - (b) in circumstances where that device has been placed on the market or put into service, unless that device meets those essential requirements set out in Annex I which apply to it.

#### [<sup>F295</sup> Approval requirement for coronavirus test devices

**34A.**—(1) Subject to regulations [<sup>F296</sup>34B to 34D], 39(1) and 39A, no person other than the Secretary of State may place on the market or put into service a coronavirus test device, unless—

- (a) the Secretary of State has approved it in accordance with regulation 38A(5); and
- (b) the approval remains valid in accordance with regulation 38A(6).

(2) Subject to regulations [<sup>F297</sup>34B to 34D], 39(1) and 39A, no person other than the Secretary of State may supply a coronavirus test device—

- (a) if that supply is also a placing on the market or putting into service of that device; or
- (b) in circumstances where that device has been placed on the market or put into service,

unless the Secretary of State has approved it in accordance with regulation 38A(5) and the approval remains valid in accordance with regulation 38A(6).

(3) The requirements in paragraphs (1) and (2) are without prejudice to the other requirements of this Part.

#### Textual Amendments

**F295** Regs. 34A-34C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), **5**

**F296** Words in reg. 34A(1) substituted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **16**

**F297** Words in reg. 34A(2) substituted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **16**

#### Public sector use of coronavirus test devices

**34B.**—(1) Regulation 34A(1) does not apply in relation to a coronavirus test device that is placed on the market or put into service only for use by—

- (a) the Secretary of State;
- (b) a devolved public health body; or
- (c) a health service body supplied pursuant to an existing contract.

(2) Regulation 34A(2) does not apply in relation to a coronavirus test device that is supplied to—

- (a) the Secretary of State;
- (b) a devolved public health body; or
- (c) a health service body pursuant to an existing contract.

(3) In this regulation—

“a devolved public health body” is—

- (a) in Wales, Welsh Ministers or Public Health Wales National Health Service Trust;
- (b) in Scotland, Scottish Ministers;
- (c) in Northern Ireland, the Department of Health in Northern Ireland;

“an existing contract” is a contract entered into before the coming into force of regulation 34A;

“a health service body” is—

- (a) an NHS body as defined in section 275 of the National Health Service Act 2006 or in section 206 of the National Health Service (Wales) Act 2006;
- (b) a body listed in section 17A(2)(a) to (c) or (e) of the National Health Service (Scotland) Act 1978; or
- (c) a health and social care body as defined in section 1(5)(a) to (e) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.

#### Textual Amendments

**F295** Regs. 34A-34C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), **5**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Transitional provisions for coronavirus test devices

**34C.**—(1) The requirements in regulation 34A do not apply in respect of any period before 1st September 2021.

(2) A person may place on the market, put into service or supply a coronavirus test device from 1st September 2021 until the end of 31st October 2021 if—

- (a) that person has made an application to the Secretary of State in respect of that device, in accordance with regulation 38A; or
- (b) that person is not—
  - (i) the manufacturer of the device,
  - (ii) a person acting as the manufacturer’s UK responsible person appointed for the purposes of regulation 33A or under regulation 44A, or
  - (iii) a person acting as the manufacturer’s authorised representative in Northern Ireland in accordance with regulation 44.]

#### Textual Amendments

**F295** Regs. 34A-34C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), 5

### [<sup>F298</sup>Exemption for coronavirus test devices in conformity with [Regulation \(EU\) 2017/746](#) and [Regulation \(EU\) 2022/1107](#)

**34D.** Regulation 34A does not apply in Northern Ireland—

- (a) in relation to a coronavirus test device that is in conformity with [Regulation \(EU\) 2017/746](#) and the common specifications set out in Annex I and XIII to [Regulation \(EU\) 2022/1107](#);
- (b) after 24 July 2024, in relation to a coronavirus test device that is in conformity with [Regulation \(EU\) 2017/746](#).]

#### Textual Amendments

**F298** Reg. 34D inserted (21.3.2024) by [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), 17

### Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements **E+W+S**

**35.**—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English <sup>F299</sup>... .

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant [<sup>F300</sup>designated standard].

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

#### Extent Information

**E26** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F299** Words in reg. 35(2) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(4)(a)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **37**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F300** Words in reg. 35(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(4)(b)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **37**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements **N.I.**

**35.**—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English if the device may reach a final user in [<sup>F632</sup>Northern Ireland], unless—

- (a) the Secretary of State, to the extent that Directive 98/79 allows him to do so, has authorised the use of another Community language or more than one other Community language; or
- (b) the relevant device is a device for self-testing, in which case the instructions for use and the label must include a translation into the official language of any member State of the Community in which the device reaches a final user.

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant national standard.

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.

#### Extent Information

**E74** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F632** Words in [reg. 35\(2\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 12**

### [<sup>F301</sup>UK marking] of *in vitro* diagnostic medical devices **E+W+S**

**36.**—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device bears a [<sup>F302</sup>UK marking] which—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) meets the requirements set out in [<sup>F303</sup>Annex 2 of Regulation 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F304</sup>approved body] or conformity assessment body identification number for that device.

(2) Subject to regulation 39, no person shall supply a relevant device unless, where practical and appropriate, that device bears a [<sup>F302</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F303</sup>Annex 2 of Regulation 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F304</sup>approved body] or conformity assessment body identification number for that device,

if that supply is also placing on the market or putting into service or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless a [<sup>F302</sup>UK marking], meeting the requirements set out in [<sup>F303</sup>Annex 2 of Regulation 765/2008], appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for that device,

and that [<sup>F302</sup>UK marking] is accompanied by any relevant [<sup>F304</sup>approved body] or conformity assessment body identification number for that device.

(4) Subject to regulation 39, no person shall supply a relevant device (if that supply is also placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a [<sup>F302</sup>UK marking], meeting the requirements set out in [<sup>F303</sup>Annex 2 of Regulation 765/2008], appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for that device,

and that [<sup>F302</sup>UK marking] is accompanied by any relevant [<sup>F304</sup>approved body] or conformity assessment body identification number for that device.

(5) Subject to regulation 39, no person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device;
- (b) the instructions for use for a relevant device; or
- (c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the [<sup>F302</sup>UK marking] or which reduces the visibility or the legibility of the [<sup>F302</sup>UK marking].

[<sup>F305</sup>(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of [Regulation \(EU\) No 765/2008](#), the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

- (a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and
- (b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).]



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

- E27** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F301** Words in reg. 36 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [6\(4A\)\(a\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, [38](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F302** Words in reg. 36 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [6\(4A\)\(b\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, [38](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F303** Words in reg. 36 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [6\(4A\)\(c\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, [38](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F304** Words in reg. 36 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [6\(4A\)\(d\)](#) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, [38](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F305** [Reg. 36\(6\)](#) inserted (E.W.S.) (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 17](#)

### CE marking of *in vitro* diagnostic medical devices **N.I.**

**36.**—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device bears a CE marking which—

- (a) meets the requirements set out in Annex X;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulation 39, no person shall supply a relevant device unless, where practical and appropriate, that device bears a CE marking which—

- (a) meets the requirements set out in Annex X;
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex X, appears on—

- (a) any sales packaging for that device; and
- (b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulation 39, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex X, appears on—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) any sales packaging for that device; and
- (b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) Subject to regulation 39, no person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

- (a) a relevant device;
- (b) the instructions for use for a relevant device; or
- (c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

#### Extent Information

**E75** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### [<sup>F306</sup>UK(NI) indication: *in vitro* diagnostic medical devices

**36A.**—(1) Where the CE marking referred to in regulation 36 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

- (a) visibly, legibly and indelibly; and
- (b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 36.

[<sup>F307</sup>(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.]

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.]

#### Textual Amendments

**F306** Reg. 36A inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), [Sch. 1 para. 13](#)

**F307** Reg. 36A(3A) inserted (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), [37](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### [<sup>F308</sup>UK marking of *in vitro* diagnostic devices that come within the scope of this Part and other legislation **E+W+S**

**37.** Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation (“the other legislation”) a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.]

#### Extent Information

**E28** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F308** Reg. 37 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(4B)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, **39**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive **N.I.**

**37.** Where a relevant device comes within the scope of Directive 98/79 and another Directive (“the other Directive”) issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are satisfied, except where—

- (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;
- (b) the manufacturer chooses to follow the set of arrangements in Directive 98/79;
- (c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and
- (d) the particulars of Directive 98/79, as published in the Official Journal of the [<sup>F633</sup>European Union], are given in the documents, notices or instructions accompanying the device.

#### Extent Information

**E76** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F633** Words in Regulations substituted (22.4.2011) by [The Treaty of Lisbon \(Changes in Terminology\) Order 2011 \(S.I. 2011/1043\)](#), arts. 2, **4** (with art. 3(3))

### *In vitro* diagnostic medical devices not ready for use

**38.** Subject to regulation 39, no person shall—

- (a) put into service a relevant device;
- (b) supply a relevant device—
  - (i) if that supply is also a putting into service of that device, or
  - (ii) in circumstances where that device has been placed on the market or put into service,

*Status: Point in time view as at 21/03/2024.*

*Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

which is not ready for use.

### **[<sup>F309</sup> Applications for approval of coronavirus test devices**

**38A.**—(1) A person may make an application to the Secretary of State under this regulation for approval of a coronavirus test device.

(2) An application must include such information as the Secretary of State may require for the purposes of exercising their functions under—

- (a) paragraph (5); and
- (b) regulation 38C.

(3) An application must be made through the gov.uk website.

(4) The Secretary of State may treat an application made before the coming into force of this regulation as an application made under this regulation, if it meets the requirements of paragraph (2).

(5) The Secretary of State must approve a coronavirus test device if the Secretary of State is satisfied on the basis of the information contained in the application that the coronavirus test device meets the requirements of regulation 38B.

(6) An approval granted under paragraph (5) is valid for a period of 5 years, beginning with the day on which it is granted.

(7) Nothing in this regulation shall be taken to prevent—

- (a) the Secretary of State;
- (b) a weights and measures authority in Great Britain; or
- (c) a district council in Northern Ireland,

from exercising a duty under regulation 61 to enforce these Regulations.

#### **Textual Amendments**

**F309** Regs. 38A-38C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), 6

### **Performance requirements for coronavirus test devices**

**38B.**—(1) The requirements that a coronavirus test device must meet for the purposes of regulation 38A(5) are set out in paragraphs (2) to (6).

(2) A coronavirus test device must be able to be put into service in accordance with this Part.

(3) A coronavirus test device that is an antigen test must have—

- (a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 60%;
- (b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 93%.

(4) A coronavirus test device that is a direct molecular test must have—

- (a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 70%;
- (b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 93%.

(5) A coronavirus test device that is an extracted molecular test must have—

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 93%;
  - (b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 97%.
- (6) Where a coronavirus test device is also intended to detect the presence of anything other than a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the requirements in paragraphs (2) to (5) apply only in relation to its performance in detecting the presence of that viral antigen or viral ribonucleic acid (RNA).

(7) In this regulation and in regulation 38C—

“antigen test” means an *in vitro* diagnostic medical device for the detection of the presence of a viral antigen specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

“direct molecular test” means an *in vitro* diagnostic medical device which—

- (a) is for the detection of the presence of viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and
- (b) does not use a preliminary step of purification and concentration;

“extracted molecular test” means an *in vitro* diagnostic medical device which—

- (a) is for the detection of the presence of viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and
- (b) uses a preliminary step of purification and concentration;

“sensitivity”, in relation to a coronavirus test device, means the proportion of true positives that are correctly identified by the test, calculated using the equation—

$$\text{Sensitivity} = \frac{\text{True Positives}}{\text{True Positives} + \text{False Negatives}}$$

“specificity”, in relation to a coronavirus test device, means the proportion of true negatives that are correctly identified by the test, calculated using the equation—

$$\text{Specificity} = \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Positives}}$$

#### Textual Amendments

**F309** Regs. 38A-38C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), 6

#### Register of approved coronavirus test devices

**38C.**—(1) The Secretary of State must establish a register of coronavirus test devices which the Secretary of State has approved in accordance with regulation 38A.

(2) The Secretary of State must publish the register on the gov.uk website.

(3) The register must contain the following information in respect of each coronavirus test device—

- (a) the name and address of the registered place of business of the person who made the application under regulation 38A;
- (b) if the person who made the application was not the manufacturer, the name and address of the registered place of business of the manufacturer;
- (c) the country in which the manufacturer is established;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (d) the name and address of the registered place of business of the UK responsible person or the manufacturer’s authorised representative having a registered place of business in Northern Ireland, if there is one in respect of the device;
  - (e) the name and description of the coronavirus test device;
  - (f) the date and version number of the instructions for use included in the application;
  - (g) whether the coronavirus test device is an antigen test, a direct molecular test, or an extracted molecular test;
  - (h) the date on which the coronavirus test device was approved in accordance with regulation 38A and the date on which that approval ceases to be valid.
- (4) The register may contain such other information relating to the coronavirus test device and its intended use as the Secretary of State considers appropriate.]

#### Textual Amendments

**F309** Regs. 38A-38C inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), 6

#### Exemptions from <sup>F310</sup>this Part] **E+W+S**

**39.**—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

- (a) the device is not used on any specimen taken from the participants; and
- (b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of <sup>F311</sup>... these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a <sup>F312</sup>UK marking], where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

<sup>F313</sup>(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.]

#### Extent Information

**E29** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F310** Words in [reg. 39](#) heading substituted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), 7

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F311** Words in reg. 39(1)(b) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(5)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F312** Words in reg. 39(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(5)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F313** Reg. 39(3)(4) inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(5)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Exemptions from regulations 34, 36 and 38 **N.I.**

**39.**—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

- (a) the device is not used on any specimen taken from the participants; and
- (b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of Directive 98/79 or these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

#### Extent Information

- E77** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### [<sup>F314</sup>Exemptions for coronavirus test devices

**39A.**—(1) Regulation 34A does not apply where, in circumstances which give rise to a need to protect the public from a risk of serious harm to health, the Secretary of State—

- (a) has decided to permit, where appropriate for a specified period, the placing on the market or putting into service of a particular coronavirus test device or coronavirus test devices of a particular class or description that has not been approved under regulation 38A(5); and
- (b) has not withdrawn that permission.

(2) The Secretary of State may give permission under paragraph (1) subject to such conditions as are set out in a protocol published by the Secretary of State.

(3) If the Secretary of State publishes a protocol for the purpose of paragraph (2), the protocol must specify the period of time for which it has effect.

(4) The Secretary of State may withdraw or amend a protocol published under paragraph (2).]

#### Textual Amendments

- F314** [Reg. 39A](#) inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), **8**

*Status: Point in time view as at 21/03/2024.*

*Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

## Procedures for affixing a <sup>F315</sup>UK marking] to *in vitro* diagnostic medical devices **E+W+S**

**40.**—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a <sup>F316</sup>UK marking] only if its manufacturer or <sup>F317</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of <sup>F318</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of <sup>F318</sup>this Part] which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a <sup>F316</sup>UK marking] only if its manufacturer or <sup>F317</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Sections 1 to 6 of Annex III,
  - (ii) Annex IV, or
  - (iii) Annex V and either Annex VI or Annex VII;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of <sup>F318</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of <sup>F318</sup>this Part] which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a <sup>F316</sup>UK marking] only if its manufacturer or <sup>F317</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex IV, or
  - (ii) Annexes V and VII;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of <sup>F318</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of <sup>F318</sup>this Part] which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a <sup>F316</sup>UK marking] only if its manufacturer or <sup>F317</sup>their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex IV,
  - (ii) Annexes V and VI, or
  - (iii) Annexes V and VII;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of <sup>F318</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of <sup>F318</sup>this Part] which apply to it.

### Extent Information

**E30** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

- F315** Words in reg. 40 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(5A\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 41); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F316** Words in reg. 40 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(5A\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 41); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F317** Words in reg. 40 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(5A\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 41); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F318** Words in reg. 40 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(5A\)\(c\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 41); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Procedures for affixing a CE marking to *in vitro* diagnostic medical devices **N.I.**

**40.**—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 98/79 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Sections 1 to 6 of Annex III,
  - (ii) Annex IV, or
  - (iii) Annex V and either Annex VI or Annex VII;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex IV, or
  - (ii) Annexes V and VII;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex IV,
  - (ii) Annexes V and VI, or
  - (iii) Annexes V and VII;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

**Extent Information**

**E78** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices E+W+S**

41.—(1) A manufacturer of a relevant device or, where applicable, [<sup>F319</sup>their UK responsible person] who is required to follow, or follows or has followed a conformity assessment procedure set out in [<sup>F320</sup>this Part] shall observe the manufacturer’s obligations set out in that procedure [<sup>F321</sup>that apply to the manufacturer or, as the case may be, their UK responsible person].

(2) A manufacturer of a relevant device or, where applicable, [<sup>F319</sup>their UK responsible person] shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with [<sup>F320</sup>this Part] at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, [<sup>F319</sup>their UK responsible person] shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

- (a) the declaration of conformity for that device;
- (b) the technical documentation referred to in Annexes III to VIII relating to that device; and
- (c) the decisions, reports and certificates of [<sup>F322</sup>approved bodies] relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine <sup>M6</sup>.

<sup>F323</sup>(5) .....

**Extent Information**

**E31** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Textual Amendments**

**F319** Words in reg. 41 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(6\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 42); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F320** Words in reg. 41 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), [reg. 6\(6\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 42); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F321** Words in reg. 41(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), **reg. 6(6)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 42); 2020 c. 1, **Sch. 5 para. 1(1)**
- F322** Words in reg. 41(3)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), **reg. 6(6)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 42); 2020 c. 1, **Sch. 5 para. 1(1)**
- F323** Reg. 41(5) omitted (E.W.S.) (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 18**

#### Marginal Citations

- M6** Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

### Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices **N.I.**

**41.—(1)** A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 98/79 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

- (a) the declaration of conformity for that device;
- (b) the technical documentation referred to in Annexes III to VIII relating to that device; and
- (c) the decisions, reports and certificates of notified bodies relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine<sup>M18</sup>.

(5) Until the European databank referred to in article 12 has been established, the manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market [<sup>F634</sup>in Northern Ireland], provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

#### Extent Information

- E79** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F634** Words in [reg. 41\(5\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 14**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Marginal Citations

**M18** Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

### <sup>F324</sup>Approved bodies] and the conformity assessment procedures for *in vitro* diagnostic medical devices **E+W+S**

42.—(1) <sup>F325</sup>An approved body] which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out <sup>F326</sup>... at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, <sup>F327</sup>...; and
- (c) lay down, by common accord with the manufacturer or <sup>F328</sup>their UK responsible person], the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

(2) Where <sup>F329</sup>an approved body] takes a decision in accordance with Annex III, IV, or V, they shall specify the period of validity of the decision, which, initially, shall be a period of not more than 5 years.

(3) Where <sup>F330</sup>an approved body] and a manufacturer or <sup>F331</sup>their UK responsible person] have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or <sup>F331</sup>their UK responsible person], extend the period of validity of the decision for further periods of up to 5 years, each such period commencing on the expiry of the previous period.

### Textual Amendments

**F324** Words in reg. 42 heading substituted (E.W.S.) (31.12.2020) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F325** Words in reg. 42(1) substituted (E.W.S.) (31.12.2020) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F326** Words in reg. 42(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F327** Words in reg. 42(1)(b) omitted (E.W.S.) (31.12.2020) by virtue of *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F328** Words in reg. 42(1)(c) substituted (E.W.S.) (31.12.2020) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(b)(iv)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F329** Words in reg. 42(2) substituted (E.W.S.) (31.12.2020) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F330** Words in reg. 42(3) substituted (E.W.S.) (31.12.2020) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **6(7)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F331** Words in reg. 42(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **6(7)(d)(ii)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

## UK notified bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices **N.I.**

**42.**—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out before 7th June 2000; and
- (c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

(2) Where a UK notified body takes a decision in accordance with Annex III, IV, or V, they shall specify the period of validity of the decision, which, initially, shall be a period of not more than 5 years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to 5 years, each such period commencing on the expiry of the previous period.

## Devices for performance evaluation **E+W+S**

**43.** No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or <sup>F332</sup>their UK responsible person—

- (a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;
- (b) ensures that—
  - (i) the device conforms with the documentation mentioned in the said section 2, and
  - (ii) the relevant requirements of <sup>F333</sup>these Regulations] are complied with as respects that device; and
- (c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations.

### Extent Information

**E32** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

- F332** Words in reg. 43 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **6(8)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **44**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F333** Words in reg. 43(b)(ii) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **6(8)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **44**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Devices for performance evaluation **N.I.**

**43.** No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or his authorised representative—

- (a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;
- (b) ensures that—
  - (i) the device conforms with the documentation mentioned in the said section 2, and
  - (ii) the relevant requirements of the Directive are complied with as respects that device; and
- (c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations.

### Extent Information

- E80** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### <sup>F334</sup><sup>F335</sup> **Registration of persons placing *in vitro* diagnostic medical devices on the market or for performance evaluation**

**44.**—(1) Paragraph (2) applies—

- (a) in relation to relevant devices that are Annex II devices or devices for self-testing, to—
  - (i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland, or makes available for performance evaluation, any relevant device;
  - <sup>F336</sup>(ii) .....
  - (iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;
  - (iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;
- (b) in relation to relevant devices other than Annex II devices or devices for self-testing, to—
  - (i) a manufacturer who places a device on the Northern Ireland market, or makes such a device available for performance evaluation, and has a registered place of business in Northern Ireland;

- (ii) an authorised representative with a registered place of business in Northern Ireland.
- (2) For the purpose of enabling the Secretary of State to exercise the Secretary of State’s functions under these Regulations, any person to whom this paragraph applies must—
  - (a) inform the Secretary of State of the address of their registered place of business; and
  - (b) supply the Secretary of State with—
    - (i) a description of each category of device concerned;
    - (ii) the relevant information in paragraph (7);
  - <sup>F337</sup>(c) .....
  - (d) in the case of an authorised representative, supply the Secretary of State with—
    - (i) written evidence that they have been designated as an authorised representative;
    - (ii) details of the person who has so designated them; and
    - (iii) where the person placing the devices concerned on the market, or making them available for performance evaluation, is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market, or making them available for performance evaluation;
  - (e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.
- (3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.
- (4) The obligations in paragraph (2) begin to apply—
  - (a) where a device is being placed on the market by a manufacturer with a registered place of business in Northern Ireland or by a person who has designated an authorised representative with a registered place of business in Northern Ireland, on 1st January 2021;
  - (b) in circumstances other than those described in sub-paragraph (a)—
    - (i) in the case of a relevant device that is a List A device, on 1st May 2021;
    - (ii) in the case of a relevant device that is a device for self-testing, on 1st September 2021; and
    - (iii) in the case of a relevant device that is a List B device, on 1st September 2021.
- <sup>F338</sup>(5) .....
- <sup>F339</sup>(6) .....
- (7) In this regulation “relevant information” means—
  - (a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;
  - (b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;
  - (c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;
  - (d) in relation to devices in a list in Annex II and devices for self-testing—
    - (i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;
  - (e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.
- (8) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.
- (9) In paragraphs (7) and (8) a device is a “new relevant device” if—
- (a) there has been no such device continuously available on the United Kingdom or EEA market during the previous three years for the relevant analyte or other parameter; or
  - (b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or EEA market during the previous three years.]]

#### Textual Amendments

- F334** Reg. 44 revoked (E.W.S.) (30.4.2021) by S.I. 2002/618, **reg. 4D(8)** (as inserted by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F335** Regs. 44, 44ZA substituted for reg. 44 (N.I.) (31.12.2020 immediately before IP completion day) by *The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020* (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 15**
- F336** Reg. 44(1)(a)(ii) omitted (21.3.2024) by virtue of *The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024* (S.I. 2024/221), regs. 1(2), **18(a)**
- F337** Reg. 44(2)(c) omitted (21.3.2024) by virtue of *The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024* (S.I. 2024/221), regs. 1(2), **18(b)**
- F338** Reg. 44(5) omitted (21.3.2024) by virtue of *The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024* (S.I. 2024/221), regs. 1(2), **18(c)**
- F339** Reg. 44(6) omitted (21.3.2024) by virtue of *The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024* (S.I. 2024/221), regs. 1(2), **18(d)**

#### <sup>F340</sup><sup>F341</sup> Obligations in Part IV which are met by complying with obligations in Directive 98/79

**44ZA.**—(1) In this regulation—

- (a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79 as <sup>F342</sup>it had effect on 25 May 2022];
- (b) “Regulation 722/2012” means Commission Regulation (EU) 722/2012 as it applies in the European Union;
- (c) “CE marking” means the CE marking required by Article 16 and shown in Annex X;
- (d) “harmonised standard” is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) <sup>F343</sup>Subject to paragraph (3A),] this paragraph applies where, before placing a relevant device on the market, the manufacturer—



- (a) ensures—
    - (i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or
    - (ii) that paragraphs (6) and (7) apply;
  - (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 9;
    - [ ensures that any certificate issued by a notified body in connection with that conformity
  - <sup>F344</sup>(ba) assessment procedure is valid by virtue of Article 110(2) of Regulation (EU) 2017/746;]
  - (c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;
  - (d) ensures that the technical and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;
  - (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes III, IV, V, VI or VII;
  - (f) [<sup>F345</sup>has drawn up before 26 May 2022] an EU Declaration of Conformity in accordance with Article 9;
  - (g) ensures that the declaration of conformity is prepared in or translated into English.
- [
- <sup>F346</sup>(3A) Paragraph (3) only applies to a relevant device for which the conformity assessment procedure under Article 9 did not require the involvement of a notified body, if the conformity assessment procedure for that device under Article 48 of Regulation (EU) 2017/746 would require the involvement of a notified body.]
- (4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.
  - (5) This paragraph applies where before a relevant device intended for performance evaluation is made available in Great Britain for the purpose of a performance evaluation, the manufacturer—
    - (a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;
    - (b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;
    - (c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of Section 3 of Annex VIII.
  - (6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).
  - (7) This paragraph applies where—
    - (a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or
    - (b) a relevant device is in conformity with a common technical specification.
  - (8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

- F340** Reg. 44ZA omitted (N.I.) (21.3.2024) by virtue of [The Medical Devices \(In Vitro Diagnostic Devices etc.\) \(Amendment\) Regulations 2024 \(S.I. 2024/221\)](#), regs. 1(2), **19**
- F341** Regs. 44ZA, 44ZB inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(10)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **46**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F342** Words in reg. 44ZA(1)(a) substituted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **9(2)**
- F343** Words in reg. 44ZA(3) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **9(3)(a)**
- F344** Reg. 44ZA(3)(ba) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **9(3)(b)**
- F345** Words in reg. 44ZA(3)(f) substituted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **9(3)(c)**
- F346** Reg. 44ZA(3A) inserted (E.W.S.) (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023 \(S.I. 2023/627\)](#), regs. 2(2), **9(4)**

### <sup>F341</sup>**Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746**

**44ZB.**—(1) In this regulation—

- (a) any reference to an Article or Annex is a reference to that Article or Annex in Regulation (EU) 2017/746 as it has effect in EU law;
- (b) “CE marking” means the CE marking required by Article 18 and presented in Annex V;
- (c) “harmonised standard” has the meaning given in Article 2(73);
- (d) “sponsor” has the meaning given in Article 2(57).

(2) Where paragraph (3) applies, regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

- (a) ensures—
  - (i) that the device meets the general safety and performance requirements in Annex I which apply to it; or
  - (ii) that paragraphs (6) and (7) apply;
- (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 48;
 

[ ensures that any certificate issued by a notified body in connection with that conformity

<sup>F347</sup>(ba) assessment procedure has not expired or been withdrawn;]
- (c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;
- (d) ensures that the technical documentation required by Annexes II and III and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;
- (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedures set out in Annexes IX, X and XI;

- (f) draws up an EU declaration of conformity in accordance with Article 17; and
  - (g) ensures that the declaration of conformity is prepared in or translated into English.
- (4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.
- (5) This paragraph applies where, before a person supplies or makes available a device falling within Part IV for the purposes of performance evaluation, the sponsor of the performance evaluation—
- (a) has been able to provide the Secretary of State with the required notice in the form of the application required by Chapter I of Annex XIV in English;
  - (b) has been able to provide the Secretary of State with an undertaking to keep available information contained in the application in accordance with Chapter II of Annex XIV.
- (6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).
- (7) This paragraph applies where—
- (a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or
  - (b) a relevant device is in conformity with a common technical specification.
- (8) For the purpose of this regulation, in regulations 36(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

#### Textual Amendments

- F341** Regs. 44ZA, 44ZB inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **6(10)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **46**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F347** Reg. 44ZB(3)(ba) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **10**

## PART V

### *[<sup>F348</sup>Notified Bodies][<sup>F348</sup>Approved Bodies], Conformity Assessment Bodies and Marking of Products*

#### Textual Amendments

- F348** Words in Pt. 5 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(2)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### <sup>F349</sup>Interpretation of Part V

**44A.** In this Part, “medical device” means a device that is a “relevant device” for the purposes of Part II, III or IV.]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Textual Amendments

**F349** Reg. 44A inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **12**

### [<sup>F350</sup>Meaning of approved body and UK notified body

**A45.**—(1) An approved body is a conformity assessment body which—

- (a) has been designated by the Secretary of State pursuant to the procedure set out in regulation 45 (designation etc. of approved bodies); or
- (b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 45(5) to withdraw a designation.

(2) In this regulation—

“UK notified body” means a body which the Secretary of State had before IP completion day notified to the European Commission in accordance with Article 3(7) of Commission Implementing Regulation (EU) 920/2013 or under Article 15 of Directive 98/79.”]

### Textual Amendments

**F350** Reg. A45 inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(3)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Designation etc. of [<sup>F351</sup>approved bodies] **E+W+S**

**45.**—(1) The Secretary of State may designate for the purposes of [<sup>F352</sup>these Regulations] any corporate or other body as a body which is to carry out any of the tasks of [<sup>F353</sup>an approved body], and, if he so designates a body (referred to in these Regulations as [<sup>F354</sup>an “approved body”]), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of [<sup>F355</sup>an approved body] only if—

- (a) in so far as it is to be designated as a body which is to carry out tasks included in [<sup>F356</sup>Part III], it is a body in respect of which the criteria for the designation of [<sup>F357</sup>approved bodies set out in Annex 8 of Directive 90/385][<sup>F358</sup>, read with Regulation (EU) No 722/2012,] are met;
- (b) in so far as it is to be designated as a body which is to carry out tasks included in [<sup>F359</sup>Part II], it is a body in respect of which the criteria for the designation of [<sup>F360</sup>approved bodies set out in Annex XI of Directive 93/42][<sup>F361</sup>, read with [<sup>F362</sup>Regulation (EU) No 722/2012,] are met;
- (c) in so far as it is to be designated as a body which is to carry out tasks included in [<sup>F363</sup>Part IV], it is a body in respect of which the criteria for the designation of [<sup>F364</sup>approved bodies set out in Annex IX of Directive 98/79] are met; and
- (d) in so far as it needs to be able to fulfil the functions of an importing Party arising out of [<sup>F365</sup>a mutual recognition agreement], it is able to do so.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that [F366an approved body] may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

- (a) the body so requests;
- (b) he considers that it is no longer a body in respect of which the applicable criteria for designation set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [F367both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met; or
- (c) he considers that the body is not capable of fulfilling the functions of an importing Party arising out of [F368a mutual recognition agreement] which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

- (a) effecting a variation under paragraph (4); or
- (b) restricting or withdrawing a designation under paragraph (5),

otherwise than at [F369the approved body's request], the Secretary of State shall give to the [F370approved body] an opportunity to make representations to him in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [F371both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met as respects the tasks which the body wants to carry out, or carries out, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of [F372a mutual recognition agreement] which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or
- (b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that [F373an approved body] supply to him any or all relevant information and documents, including budgetary documents, necessary—

- (a) to enable him to verify that the body meets the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [F374both read with Regulation (EU) No 722/2012], or Annex IX of Directive 98/79; or
- (b) for the purposes of deciding whether or not the body is capable of fulfilling the functions of an importing Party arising out of [F375a mutual recognition agreement] which it needs to be able to fulfil,

and the body shall supply to him any and all relevant information or documents so requested.

#### Extent Information

**E33** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

## Textual Amendments

- F351** Words in reg. 45 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F352** Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(b\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F353** Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(b\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F354** Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(b\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F355** Words in reg. 45(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(c\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F356** Word in reg. 45(2)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(d\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F357** Words in reg. 45(2)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(d\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F358** Words in reg. 45(2)(a) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [14\(2\)](#)
- F359** Words in reg. 45(2)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(e\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F360** Words in reg. 45(2)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(f\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F361** Words in reg. 45(2)(b) inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), [13\(a\)](#)
- F362** Words in reg. 45(2)(b) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [14\(3\)](#)
- F363** Words in reg. 45(2)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(f\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F364** Words in reg. 45(2)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(f\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F365** Words in reg. 45(2)(d) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(g\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F366** Words in reg. 45(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(h\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F367** Words in reg. 45(5)(b) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [14\(4\)](#)
- F368** Words in reg. 45(5)(c) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F369** Words in reg. 45(6) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(j\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F370** Words in reg. 45(6) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(j\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F371** Words in reg. 45(7) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [14\(4\)](#)
- F372** Words in reg. 45(7) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(k\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F373** Words in reg. 45(8) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(l\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F374** Words in reg. 45(8) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [14\(4\)](#)
- F375** Words in reg. 45(8)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [7\(4\)\(l\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Designation etc. of UK notified bodies **N.I.**

45.—(1) The Secretary of State may designate for the purposes of article 11 of Directive 90/385, article 16 of Directive 93/42 or article 15 of Directive 98/79 any corporate or other body as a body which is to carry out any of the tasks of a notified body [<sup>F635</sup>with respect to devices to be placed on the market in Northern Ireland], and, if he so designates a body (referred to in these Regulations as a “UK notified body”), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of a notified body only if—

- (a) in so far as it is to be designated as a body which is to carry out tasks included in Directive 90/385, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex 8 of that Directive [<sup>F636</sup>, read with Regulation (EU) No 722/2012,] are met;
- (b) in so far as it is to be designated as a body which is to carry out tasks included in Directive 93/42, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex XI of that Directive [<sup>F637</sup>, read with [<sup>F638</sup>Regulation (EU) No 722/2012,] are met;
- (c) in so far as it is to be designated as a body which is to carry out tasks included in Directive 98/79, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex IX of that Directive are met; and
- (d) in so far as it needs to be able to fulfil the functions of an importing Party arising out of the Mutual Recognition Agreements, it is able to do so.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that a UK notified body may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

- (a) the body so requests;

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(b) he considers that it is no longer a body in respect of which the applicable criteria for designation set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [<sup>F639</sup>both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met; or

(c) he considers that the body is not capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

- (a) effecting a variation under paragraph (4); or
- (b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the notified body's request, the Secretary of State shall give to the notified body an opportunity to make representations to him in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [<sup>F640</sup>both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met as respects the tasks which the body wants to carry out, or carries out, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or
- (b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that a UK notified body supply to him any or all relevant information and documents, including budgetary documents, necessary—

- (a) to enable him to verify that the body meets the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [<sup>F641</sup>both read with Regulation (EU) No 722/2012], or Annex IX of Directive 98/79; or
- (b) for the purposes of deciding whether or not the body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the body shall supply to him any and all relevant information or documents so requested.

#### Extent Information

**E81** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F635** Words in [reg. 45\(1\)](#) inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 16](#)

**F636** Words in [reg. 45\(2\)\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), [14\(2\)](#)



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F637** Words in reg. 45(2)(b) inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **13(a)**
- F638** Words in reg. 45(2)(b) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **14(3)**
- F639** Words in reg. 45(5)(b) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **14(4)**
- F640** Words in reg. 45(7) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **14(4)**
- F641** Words in reg. 45(8) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **14(4)**

### [<sup>F376</sup>Choice of approved bodies and conformity assessment bodies] **E+W+S**

**46.** Where a conformity assessment procedure involves the intervention of [<sup>F377</sup>an approved body], including work which may be carried out by a third country conformity assessment body, the manufacturer of a device or [<sup>F378</sup>the manufacturer's UK responsible person] may apply to [<sup>F379</sup>any approved body] or third country conformity assessment body to carry out tasks under that procedure which are within the framework of tasks which the body is designated to carry out.

#### Extent Information

- E34** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F376** Reg. 46 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(5)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F377** Words in reg. 46 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(5)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F378** Words in reg. 46 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(5)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F379** Words in reg. 46 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(5)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

### Choice of notified bodies and conformity assessment bodies **N.I.**

**46.** Where a conformity assessment procedure involves the intervention of a notified body, including work which may be carried out by a third country conformity assessment body, the manufacturer of a device or his authorised representative may apply to any notified body or third country conformity assessment body to carry out tasks under that procedure which are within the framework of tasks which the body is designated to carry out.

#### Extent Information

- E82** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 21/03/2024.

Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**[<sup>F380</sup>General matters relating to approved bodies] E+W+S**

47.—(1) [<sup>F381</sup>An approved body] to which an application has been made by a manufacturer or [<sup>F382</sup>the manufacturer’s UK responsible person] to perform the functions of [<sup>F383</sup>an approved body] under a conformity assessment procedure set out in [<sup>F384</sup>these Regulations] shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or [<sup>F385</sup>the manufacturer’s UK responsible person] has supplied information or data to [<sup>F386</sup>an approved body] in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or [<sup>F387</sup>the manufacturer’s UK responsible person] supplies to an approved body] in the course of a conformity assessment procedure set out in [<sup>F388</sup>these Regulations] shall, <sup>F389</sup> ..., be in English <sup>F390</sup> ....

(4) [<sup>F391</sup>An approved body] shall, as respects a medical device which it has assessed <sup>F392</sup> ..., inform all [<sup>F393</sup>other approved bodies] and the Secretary of State of—

- (a) all certificates suspended or withdrawn; and
- (b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where [<sup>F394</sup>an approved body] finds, as respects a medical device which it has assessed <sup>F392</sup> ..., that—

- (a) the applicable requirements of [<sup>F395</sup>these Regulations] have not been met or are no longer met; or
- (b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the [<sup>F396</sup>approved body] is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the [<sup>F396</sup>approved body] shall inform the Secretary of State thereof.

(6) The Secretary of State may request that [<sup>F397</sup>an approved body] supply to him any information and documents that the Secretary of State may, having regard to the terms of [<sup>F398</sup>a mutual recognition agreement], need to supply to a Party to [<sup>F398</sup>a mutual recognition agreement], and the body shall supply to him any and all information or documents so requested.

(8) [<sup>F399</sup>An approved body] shall provide conformity assessment bodies with all the information it is required to provide to those bodies under [<sup>F400</sup>a mutual recognition agreement].

<sup>F401</sup>(9) .....

<sup>F401</sup>(10) .....

**Extent Information**

**E35** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

*Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

## Textual Amendments

- F380** Reg. 47 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F381** Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(b\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F382** Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(b\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F383** Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(b\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F384** Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(b\)\(iv\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F385** Words in reg. 47(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(c\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F386** Words in reg. 47(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(c\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F387** Words in reg. 47(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(d\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F388** Words in reg. 47(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(d\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F389** Words in reg. 47(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(d\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F390** Words in reg. 47(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(d\)\(iv\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F391** Words in reg. 47(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(e\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F392** Words in reg. 47(4)(5) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), [16](#)
- F393** Words in reg. 47(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(e\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F394** Words in reg. 47(5) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(f\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F395** Words in reg. 47(5)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(f\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F396** Words in reg. 47(5) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(f\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F397** Words in reg. 47(6) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(g\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F398** Words in reg. 47(6) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(g\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F399** Words in reg. 47(8) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(h\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F400** Words in reg. 47(8) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), [7\(6\)\(h\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [47](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F401** Reg. 47(9)(10) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), [15](#)

### General matters relating to UK notified bodies **N.I.**

**47.—(1)** A UK notified body to which an application has been made by a manufacturer or his authorised representative to perform the functions of a notified body under a conformity assessment procedure set out in the Medical Devices Directives shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or his authorised representative has supplied information or data to a UK notified body in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or his authorised representative supplies to a notified body in the course of a conformity assessment procedure set out in the Medical Devices Directives shall, if the notified body is within the United Kingdom, be in English or some other Community language acceptable to the notified body concerned.

(4) A UK notified body shall, as respects a medical device which it has assessed <sup>F642</sup> ..., inform all other notified bodies and the Secretary of State of—

- (a) all certificates suspended or withdrawn; and
- (b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where a UK notified body finds, as respects a medical device which it has assessed <sup>F642</sup> ..., that—

- (a) the applicable requirements of the Medical Devices Directives have not been met or are no longer met; or
- (b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the notified body is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the notified body shall inform the Secretary of State thereof.

(6) The Secretary of State may request that a UK notified body supply to him any information and documents that the Secretary of State may, having regard to the terms of the Mutual Recognition

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Agreements, need to supply to a Party to the Mutual Recognition Agreements, and the body shall supply to him any and all information or documents so requested.

(8) A UK notified body shall provide conformity assessment bodies with all the information it is required to provide to those bodies under the Mutual Recognition Agreements.

<sup>F643</sup>(9) .....

<sup>F643</sup>(10) .....

#### Extent Information

**E83** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F642** Words in reg. 47(4)(5) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **16**

**F643** Reg. 47(9)(10) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **15**

### <sup>F402</sup> Register of approved bodies **E+W+S**

**47A.**—(1) The Secretary of State must ensure that—

- (a) each approved body is assigned an identification number; and
- (b) there is a register of—
  - (i) approved bodies;
  - (ii) their approved body identification number;
  - (iii) the tasks for which they have been designated; and
  - (iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

#### Extent Information

**E36** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F402** Reg. 47A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(7)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**

### <sup>F644</sup> Register of UK notified bodies **N.I.**

**47A.**—(1) The Secretary of State must ensure that—

- (a) each notified body established in the United Kingdom is assigned an identification number; and

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) there is a register of—
- (i) notified bodies established in the United Kingdom;
  - (ii) their notified body identification number;
  - (iii) the tasks for which they have been notified;
  - (iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

#### Extent Information

**E84** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F644** [Reg. 47A](#) inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 17](#)

### Designation etc. of <sup>F403</sup>... conformity assessment bodies **E+W+S**

**48.**—(1) The Secretary of State may designate for the purposes of [<sup>F404</sup>a mutual recognition agreement] any corporate or other body as a body which is to carry out any of the tasks of a <sup>F405</sup>... conformity assessment body, and, if he so designates a body (referred to in these Regulations as [<sup>F406</sup>a “CAB”]), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of [<sup>F407</sup>a CAB] only if the Secretary of State considers that the body is capable of fulfilling the functions of [<sup>F407</sup>a CAB] arising out of [<sup>F408</sup>a mutual recognition agreement] which it needs to be able to fulfil.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that [<sup>F409</sup>a CAB] may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

- (a) the body so requests; or
- (b) he considers that the body is not capable of fulfilling the functions of [<sup>F410</sup>a CAB] arising out of [<sup>F411</sup>a mutual recognition agreement] which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

- (a) effecting a variation under paragraph (4); or
- (b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the <sup>F412</sup>... CAB’s request, the Secretary of State shall give to the <sup>F412</sup>... CAB an opportunity to make representations to him in writing and shall take into account any such representations as are made.

*Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(7) For the purpose of deciding whether or not a body is capable of fulfilling the functions of [F413 a CAB] arising out of [F414 a mutual recognition agreement] which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or
- (b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that [F415 a CAB] supply to him any or all relevant information and documents, including budgetary documents, necessary for the purposes of deciding whether or not the body is capable of fulfilling the functions of [F415 a CAB] arising out of [F416 a mutual recognition agreement] which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

#### Extent Information

**E37** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F403** Word in reg. 48 heading omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F404** Words in reg. 48(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F405** Words in reg. 48(1) omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F406** Words in reg. 48(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F407** Words in reg. 48(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F408** Words in reg. 48(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F409** Words in reg. 48(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F410** Words in reg. 48(5)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F411** Words in reg. 48(5)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **7(8)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F412** Word in reg. 48(6) omitted (E.W.S.) (31.12.2020) by virtue of **The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019** (S.I. 2019/791), regs. 1(1), **7(8)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F413** Words in reg. 48(7) substituted (E.W.S.) (31.12.2020) by **The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019** (S.I. 2019/791), regs. 1(1), **7(8)(g)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F414** Words in reg. 48(7) substituted (E.W.S.) (31.12.2020) by **The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019** (S.I. 2019/791), regs. 1(1), **7(8)(g)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F415** Words in reg. 48(8) substituted (E.W.S.) (31.12.2020) by **The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019** (S.I. 2019/791), regs. 1(1), **7(8)(h)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F416** Words in reg. 48(8) substituted (E.W.S.) (31.12.2020) by **The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019** (S.I. 2019/791), regs. 1(1), **7(8)(h)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

#### Designation etc. of <sup>F645</sup>... conformity assessment bodies **N.I.**

**48.**—(1) The Secretary of State may designate for the purposes of [<sup>F646</sup>a UK mutual recognition agreement] any corporate or other body as a body which is to carry out any of the tasks of a <sup>F647</sup>... conformity assessment body, and, if he so designates a body (referred to in these Regulations as [<sup>F648</sup>a “CAB”]), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of [<sup>F649</sup>a CAB] only if the Secretary of State considers that the body is capable of fulfilling the functions of [<sup>F649</sup>a CAB] arising out of [<sup>F650</sup>a UK mutual recognition agreement] which it needs to be able to fulfil.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that [<sup>F651</sup>a CAB] may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

- (a) the body so requests; or
- (b) he considers that the body is not capable of fulfilling the functions of [<sup>F652</sup>a CAB] arising out of [<sup>F653</sup>a UK mutual recognition agreement] which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

- (a) effecting a variation under paragraph (4); or
- (b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the <sup>F654</sup>... CAB’s request, the Secretary of State shall give to the <sup>F654</sup>... CAB an opportunity to make representations to him in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is capable of fulfilling the functions of [<sup>F655</sup>a CAB] arising out of [<sup>F656</sup>a UK mutual recognition agreement] which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or



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(b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that [<sup>F657</sup>a CAB] supply to him any or all relevant information and documents, including budgetary documents, necessary for the purposes of deciding whether or not the body is capable of fulfilling the functions of [<sup>F657</sup>a CAB] arising out of [<sup>F658</sup>a UK mutual recognition agreement] which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

#### Extent Information

**E85** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F645** Word in reg. 48 heading omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(a)**

**F646** Words in reg. 48(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(i)**

**F647** Words in reg. 48(1) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(ii)**

**F648** Words in reg. 48(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(iii)**

**F649** Words in reg. 48(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(c)(i)**

**F650** Words in reg. 48(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(c)(ii)**

**F651** Words in reg. 48(4) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(d)**

**F652** Words in reg. 48(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(e)(i)**

**F653** Words in reg. 48(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(e)(ii)**

**F654** Words in reg. 48(6) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(f)**

**F655** Words in reg. 48(7) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(g)(i)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F656** Words in reg. 48(7) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 18(g)(ii)**
- F657** Words in reg. 48(8) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 18(h)(i)**
- F658** Words in reg. 48(8) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 18(h)(ii)**

### <sup>F417</sup>**Fees charged by approved bodies and conformity assessment bodies** **E+W+S**

**49.**—(1) <sup>F418</sup>[An approved body or CAB] may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

- <sup>F419</sup>(a) in the case of an approved body, performing the functions of an approved body or an importing Party under these Regulations or a mutual recognition agreement; and
- (b) in the case of <sup>F420</sup>[a CAB], performing the functions of <sup>F420</sup>[a CAB] arising out of <sup>F421</sup>[a mutual recognition agreement] in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the <sup>F422</sup>[approved body or CAB] charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the <sup>F423</sup>[approved body]; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The <sup>F424</sup>[approved body or CAB] may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

#### **Extent Information**

**E38** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### **Textual Amendments**

- F417** Reg. 49 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(a)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F418** Words in reg. 49(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(b)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F419** Reg. 49(1)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(c)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F420** Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(d)(i)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F421** Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F422** Words in reg. 49(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F423** Words in reg. 49(3)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F424** Words in reg. 49(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

### **[<sup>F659</sup>Fees charged by UK notified bodies and conformity assessment bodies] N.I.**

**49.**—(1) A UK notified body or [<sup>F660</sup>CAB] may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

- (a) in the case of a UK notified body, performing the functions of a notified body or an importing Party under [<sup>F661</sup>the Medical Devices Directives or a UK mutual recognition agreement in respect of a conformity assessment procedure set out in the Medical Devices Directives or these Regulations as they apply in Great Britain]; and
- (b) in the case of [<sup>F662</sup>a CAB], performing the functions of [<sup>F662</sup>a CAB] arising out of [<sup>F663</sup>a UK mutual recognition agreement] in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the UK notified body or [<sup>F664</sup>CAB] charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the notified body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The UK notified body or [<sup>F665</sup>CAB] may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

#### **Extent Information**

**E86** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### **Textual Amendments**

- F659** Reg. 49 heading substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(a)**
- F660** Word in reg. 49(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(b)**
- F661** Words in reg. 49(1)(a) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(c)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F662** Words in reg. 49(1)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(d)(i)**
- F663** Words in reg. 49(1)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(d)(ii)**
- F664** Word in reg. 49(3) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(e)**
- F665** Word in reg. 49(4) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 19(f)**

### Products incorrectly marked with <sup>F425</sup>an approved body] or conformity assessment body number **E+W+S**

50.—(1) No person shall—

- (a) affix <sup>F426</sup>an approved body] or conformity assessment body number to a medical device if that body has not carried out an assessment in respect of that device for that person;
- (b) supply a medical device (if that supply is also a placing on the market, or if that supply is of a device which has been placed on the market) which has affixed to it <sup>F426</sup>an approved body] or conformity assessment body number if that body—
  - (i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or
  - (ii) has had its designation as <sup>F426</sup>an approved body] or conformity assessment body withdrawn.

(2) No person shall provide information comprising <sup>F427</sup>an approved body] or conformity assessment body number on a medical device, the instructions for use for a medical device, or the sales packaging for a medical device if that device—

- (a) is being or has been placed on the market; and
- (b) <sup>F428</sup>the approved body] or conformity assessment body—
  - (i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or
  - (ii) has had its designation as <sup>F427</sup>an approved body] or conformity assessment body withdrawn.

(3) Where the sectoral annex on medical devices in a Mutual Recognition Agreement under which a conformity assessment body was designated states that the annex does not apply to devices of a particular class or description, no person may supply a medical device of that class or description bearing the number of that conformity assessment body (if that supply is also a placing on the market or putting into service or is of a device that has been placed on the market or put into service) unless—

- (a) an assessment has been carried out on that device for the person responsible for placing it on the market or putting it into service by <sup>F429</sup>an approved body]; and
- (b) the device bears the <sup>F430</sup>approved body] number of that <sup>F430</sup>approved body].

(4) For the purposes of this regulation, <sup>F431</sup>an approved body] shall be taken to have carried out an assessment in respect of a device if it has endorsed a report prepared by a third country conformity assessment body in respect of that device.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Extent Information

- E39** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F425** Words in reg. 50 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F426** Words in reg. 50(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F427** Words in reg. 50(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F428** Words in reg. 50(2)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F429** Words in reg. 50(3)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F430** Words in reg. 50(3)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(e)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F431** Words in reg. 50(4) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(10)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Products incorrectly marked with a notified body or conformity assessment body number **N.I.**

**50.**—(1) No person shall—

- (a) affix a notified body or conformity assessment body number to a medical device if that body has not carried out an assessment in respect of that device for that person;
- (b) supply a medical device (if that supply is also a placing on the market, or if that supply is of a device which has been placed on the market) which has affixed to it a notified body or conformity assessment body number if that body—
  - (i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or
  - (ii) has had its designation as a notified body or conformity assessment body withdrawn.

(2) No person shall provide information comprising a notified body or conformity assessment body number on a medical device, the instructions for use for a medical device, or the sales packaging for a medical device if that device—

- (a) is being or has been placed on the market; and
- (b) the notified body or conformity assessment body—
  - (i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or
  - (ii) has had its designation as a notified body or conformity assessment body withdrawn.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(3) Where the sectoral annex on medical devices in a Mutual Recognition Agreement under which a conformity assessment body was designated states that the annex does not apply to devices of a particular class or description, no person may supply a medical device of that class or description bearing the number of that conformity assessment body (if that supply is also a placing on the market or putting into service or is of a device that has been placed on the market or put into service) unless—

- (a) an assessment has been carried out on that device for the person responsible for placing it on the market or putting it into service by a notified body; and
- (b) the device bears the notified body number of that notified body.

(4) For the purposes of this regulation, a notified body shall be taken to have carried out an assessment in respect of a device if it has endorsed a report prepared by a third country conformity assessment body in respect of that device.

#### Extent Information

**E87** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Products incorrectly marked with a <sup>F432</sup>UK marking **E+W+S**

51.—(1) No person shall—

- (a) affix the <sup>F433</sup>UK marking] for a medical device to a product which is not a medical device; or
- (b) supply a product (if that supply is also a placing on the market, or if that supply is of a product which has been placed on the market) which has affixed to it the <sup>F433</sup>UK marking] for a medical device if that product is not a medical device.

(2) No person shall provide information comprising a <sup>F433</sup>UK marking] for a medical device on a product, the instructions for use for a product, or the sales packaging for a product if the product is not a medical device.

#### Extent Information

**E40** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F432** Words in reg. 51 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

**F433** Words in reg. 51 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

### Products incorrectly marked with a CE marking **N.I.**

51.—(1) No person shall—

- (a) affix the CE marking for a medical device to a product which is not a medical device; or

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- (b) supply a product (if that supply is also a placing on the market, or if that supply is of a product which has been placed on the market) which has affixed to it the CE marking for a medical device if that product is not a medical device.

(2) No person shall provide information comprising a CE marking for a medical device on a product, the instructions for use for a product, or the sales packaging for a product if the product is not a medical device.

#### Extent Information

**E88** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

## PART VI

### *Fees charged by the Secretary of State*

#### Interpretation of Part VI

52.—(1) In this Part<sup>F434</sup> ...—

[<sup>F435</sup>“approved manufacturer” in relation to a medicinal substance means a manufacturer who—

- (a) holds a manufacturing authorisation which permits the manufacturer to manufacture that substance for inclusion in an authorised medicinal product; or
- (b) holds an examination certificate for a device incorporating that medicinal substance and that certificate was issued by an approved body or notified body after consultation with the Secretary of State in respect of that substance;]

[<sup>F435</sup>“authorised medicinal product” means a medicinal product in respect of which a marketing authorisation has been granted;]

[<sup>F435</sup>“clinical development” means the conduct of studies of a medicinal substance in human subjects in order to—

- (a) discover or verify the effects of such a substance,
- (b) identify any adverse reaction to such a substance, or
- (c) study absorption, distribution, metabolism and excretion of such a substance,

with the object of ascertaining the safety or efficacy of that substance, as required to verify the safety and usefulness of the substance in accordance with section 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385;]

[<sup>F435</sup>“consultation” means a consultation required by—

- (a) section 4.3 of Annex II of Directive 93/42 or Directive 90/385; or
- (b) section 5 of Annex III of Directive 93/42 or Directive 90/385;]

[<sup>F435</sup>“examination certificate” means—

- (a) a design-examination certificate within the meaning of sections 4.3 and 4.4 of Annex II of Directive 93/42 or Directive 90/385, issued by an approved body;
- (b) a type-examination certificate within the meaning of sections 5 and 6 of Annex III of Directive 93/42 or Directive 90/385, issued by an approved body;

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- (c) an EC design-examination certificate within the meaning of sections 4.3 and 4.4 of the version of Annex II of Directive 93/42 or Directive 90/385 that existed immediately before IP completion day, issued by a notified body; or
- (d) an EC type-examination certificate within the meaning of sections 5 and 6 of the version of Annex III of Directive 93/42 or Directive 90/385 that existed immediately before IP completion day), issued by a notified body;]

[<sup>F435</sup>“further consultation” means a consultation by an approved body in relation to any device which—

- (a) may be placed on the market or put into service in accordance with Part 2 or 3 and which is the subject of an examination certificate issued by that approved body after consultation with the Secretary of State;
- (b) is the subject of proposed changes within section 4.4 of Annex II of Directive 93/42 or Directive 90/385 or section 6 of Annex III of Directive 93/42 or Directive 90/385 and if that device is to be placed on the market or put into service, those changes may require a supplement to the examination certificate previously issued by that approved body after consultation with the Secretary of State; or
- (c) is of a similar design or type to a device which has been the subject of an unsuccessful application for an examination certificate where—
  - (i) the person who made that unsuccessful application makes a further application for an examination certificate to the approved body which determined that unsuccessful application; and
  - (ii) within the relevant period that further application becomes the subject of consultation between that approved body and the Secretary of State;]

“Group A device” means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

“Group B device” means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and “half day” means a period of three and a half hours.

[<sup>F435</sup>“incorporates” means incorporates as an integral part;]

[<sup>F435</sup>“marketing authorisation” has the meaning given by regulation 8 of the Human Medicines Regulations 2012;]

[<sup>F435</sup>“medicinal substance” means a substance which, if used separately from a device, may be considered to be a medicinal product, as defined in Schedule 1 to the Medicines (Products for Human Use) Fees Regulations 2016;]

[<sup>F435</sup>“new medicinal substance” means a medicinal substance which is not—

- (a) an authorised medicinal product;
- (b) an ingredient or, as the case may be, the sole active ingredient of such a product; or
- (c) a substance which has been incorporated in a device in respect of which an examination certificate has been issued by an approved body which has consulted the Secretary of State;]

[<sup>F435</sup>“quality development” means the chemical, pharmaceutical and biological testing required in order to verify the quality of a medicinal substance in accordance with paragraph 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385;]

[<sup>F435</sup>“relevant period” means the period of 5 years which starts on the first day on which the Secretary of State was consulted in respect of the unsuccessful application or, if there has been more than one such application in any particular case, in respect of the first of them;]



[<sup>F435</sup>“safety development” means the toxicological and pharmacological testing required in order to verify the safety of a medicinal substance in accordance with paragraph 7.4 of Annex I of Directive 93/42 and section 10 of Annex I of Directive 90/385; and]

[<sup>F435</sup>“scientific advice” means advice in connection with the quality, safety or clinical development for a medicinal substance incorporated, or to be incorporated, in a device.]

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.

#### Textual Amendments

**F434** Words in reg. 52(1) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **15**

**F435** Words in reg. 52(1) inserted (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **7**

### Fees in connection with the registration of devices and changes to registration details **E+W** **+S**

**53.** Any person required to supply the Secretary of State with any information under [<sup>F436</sup>regulation 7A, 19, 21A, 33A or 44] shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of [<sup>F437</sup>£240], and that fee—

- (a) shall be payable when the information is supplied by that person to the Secretary of State; and
- (b) shall accompany that information when it is supplied.

#### Extent Information

**E41** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F436** Words in reg. 53 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **8(2)** (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 48](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

**F437** Sum in reg. 53 substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **8**

### Fees in connection with the registration of devices and changes to registration details **N.I.**

**53.** Any person required to supply the Secretary of State with any information under regulation 19 [<sup>F666</sup>, 21B] or 44 shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of [<sup>F667</sup>£240], and that fee—

- (a) shall be payable when the information is supplied by that person to the Secretary of State; and

*Status: Point in time view as at 21/03/2024.*

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(b) shall accompany that information when it is supplied.

#### Extent Information

**E89** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F666** Word in [reg. 53](#) inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 20](#)
- F667** Sum in [reg. 53](#) substituted (N.I.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), [regs. 1\(2\)](#), [9](#)

#### <sup>F438</sup>Fees payable in connection with the designation of approved bodies] **E+W+S**

**54.**—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 45 as <sup>F439</sup>an approved body] shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of <sup>F440</sup>£8,918]; or
- (b) in all other cases, a fee of <sup>F441</sup>£35,672].

<sup>F442</sup>(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) must, in connection with that application for a variation, pay to the Secretary of State—

- (a) in respect of an extension to the scope of the body's designation to carry out tasks under Part 2, Part 3 or Part 4, which extends the body's designation in relation to a Part under which they have already been designated, a fee of £12,571;
- (b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and where the Secretary of State considers that an additional assessment of the body's procedures is required, a fee of £18,212.]

(3) Where, pursuant to regulation 45(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, <sup>F443</sup>both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of <sup>F444</sup>a mutual recognition agreement] which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- <sup>F445</sup>(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of <sup>F446</sup>£58,341] plus the amounts specified in paragraph (3A);
- <sup>F447</sup>(b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection, a fee of £45,675, plus the amounts specified in paragraph (3A); and]
- (c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of <sup>F448</sup>£10,072] plus the amounts specified in paragraph (3A).]

<sup>F449</sup>(3A) Subject to paragraph (3B), the additional amounts payable in respect of an inspection referred to in paragraph (3) shall be—

- (a) an amount for time spent by a member of staff undertaking a site visit at a rate—

- (i) for the time spent on site, of [<sup>F450</sup>£631] per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and
- (ii) for the time spent travelling to and from the site, of [<sup>F451</sup>£171] per hour;
- (b) the actual costs of travel, accommodation and subsistence; and
- (c) out of pocket expenses.

(3B) Where the Secretary of State conducts an inspection referred to in paragraph (3)(a) on the same date and at the same premises as an inspection pursuant to regulation 48(7)(a)—

- (a) the amount referred to in paragraph (3A)(3) shall include an amount for any time spent on site by a member of staff which is attributable to the conduct of the inspection pursuant to regulation 48(7)(a), at the rate referred to paragraph (3A)(a)(i); and
- (b) the costs and expenses referred to in paragraph (3A)(b) and (c) shall include any additional costs and expenses attributable to the conduct of the inspection pursuant to regulation 48(7)(a).]

[<sup>F452</sup>(3C) [<sup>F453</sup>An approved body] that applies to the Secretary of State for a renewal of its designation pursuant to article 4 of Regulation (EU) No 920/2013 shall pay to the Secretary of State—

- (a) a fee of [<sup>F454</sup>£35,672 ] in respect of the application; and
- (b) where an audit is carried out in connection with the application, a fee of [<sup>F455</sup>£58,341] in respect of the audit [<sup>F456</sup>,

plus the amounts specified in paragraph (3A).]

(3D) Where the Secretary of State conducts an assessment of [<sup>F457</sup>an approved body] pursuant to article 5 of Regulation (EU) No 920/2013, [<sup>F458</sup>the approved body] shall pay to the Secretary of State—

- (a) if the assessment relates to the UK notified body's assessment of clinical data only, a fee of [<sup>F459</sup>£18,583]; or
- (b) in any other case, a fee of [<sup>F460</sup>£22,789][<sup>F461</sup>,

plus the amounts specified in paragraph (3A).]

(3E) [<sup>F462</sup>An approved body] that submits a summary evaluation report to the Secretary of State pursuant to article 5(4) of Regulation (EU) No 722/2012 shall pay to the Secretary of State a fee of [<sup>F463</sup>£1,297].]

[<sup>F464</sup>(3F) Where, pursuant to regulation 45(7)(a) or 45(7)(b), the Secretary of State conducts an on-site assessment of a subsidiary of the body, the body must pay to the Secretary of State a fee of £22,789, plus the costs and expenses referred to in paragraph (3A).]

(4) A fee under this regulation—

- (a) in connection with an application for designation under [<sup>F465</sup>regulation 45(1),] a variation under regulation 45(4)[<sup>F466</sup>, a renewal under Regulation (EU) No 920/2013 (but not any associated audit) or a submission of a summary evaluation report under Regulation (EU) No 722/2012]—
  - (i) shall be payable when the application [<sup>F467</sup>or submission] to the Secretary of State is made, and
  - (ii) shall accompany the application [<sup>F468</sup>or submission] when it is made;

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- (b) in connection with an inspection pursuant to regulation 45(7) <sup>F469</sup> or an audit or assessment pursuant to Regulation (EU) No 920/2013], shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

<sup>F470</sup>(5) In this regulation—

“Regulation (EU) No 920/2013” means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive [90/385/EEC](#) on active implantable medical devices and Council Directive [93/42/EEC](#) on medical devices; and

“subsidiary” is to be construed in accordance with section 1159 of the Companies Act 2006.]

### Extent Information

- E42** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Textual Amendments

- F438** Reg. 54 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **8(3)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F439** Words in reg. 54(1) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **8(3)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F440** Sum in reg. 54(1)(a) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(2)(a)**
- F441** Sum in reg. 54(1)(b) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(2)(b)**
- F442** Reg. 54(2) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(3)**
- F443** Words in reg. 54(3) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), **16**
- F444** Words in reg. 54(3) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **8(3)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F445** Reg. 54(3)(a)-(c) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007](#) (S.I. 2007/803), regs. 1(1)(b), **13(2)(c)**
- F446** Sum in reg. 54(3)(a) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(4)(a)**
- F447** Reg. 54(3)(b) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(4)(b)**
- F448** Sum in reg. 54(3)(c) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(4)(c)**
- F449** Reg. 54(3A)(3B) inserted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007](#) (S.I. 2007/803), regs. 1(1)(b), **13(2)(d)**
- F450** Sum in reg. 54(3A)(a)(i) substituted (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(5)(a)**
- F451** Sum in reg. 54(3A)(a)(ii) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023](#) (S.I. 2023/377), regs. 1(2), **10(5)(b)**
- F452** Reg. 54(3C)-(3E) inserted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017](#) (S.I. 2017/207), regs. 1(1), **3(6)**

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- F453** Words in reg. 54(3C) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F454** Sum in reg. 54(3C)(a) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(6)(a)**
- F455** Sum in reg. 54(3C)(b) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(6)(b)**
- F456** Words in reg. 54(3C) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(6)(c)**
- F457** Words in reg. 54(3D) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F458** Words in reg. 54(3D) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F459** Sum in reg. 54(3D)(a) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(7)(a)**
- F460** Sum in reg. 54(3D)(b) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(7)(b)**
- F461** Words in reg. 54(3D) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(7)(c)**
- F462** Words in reg. 54(3E) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(3)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **48**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F463** Sum in reg. 54(3E) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(8)**
- F464** Reg. 54(3F) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(9)**
- F465** Words in reg. 54(4)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(i)**
- F466** Words in reg. 54(4)(a) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(ii)**
- F467** Words in reg. 54(4)(a)(i) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
- F468** Words in reg. 54(4)(a)(ii) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
- F469** Words in reg. 54(4)(b) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(b)**
- F470** Reg. 54(5) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **10(10)**

### Fees payable in connection with the designation etc. of UK notified bodies **N.I.**

**54.—(1)** A corporate or other body that applies to the Secretary of State for designation under regulation 45 as a notified body shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of [<sup>F668</sup>£2,063]; or
- (b) in all other cases, a fee of [<sup>F669</sup>£8,252].

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of [F670£6,504].

(3) Where, pursuant to regulation 45(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, [F671both read with Regulation (EU) No 722/2012] or Annex IX of Directive 98/79 are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

[F672(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of [F673£15,904] plus the amounts specified in paragraph (3A);

(b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection—

(i) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in all three of the Annexes referred to in this paragraph are met, a fee of [F674£10,160],

(ii) if the inspection is for the purpose of deciding whether or not the body is one in respect of which the criteria set out in only two of the three Annexes referred to in this paragraph are met, a fee of [F674£10,160], or

(iii) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in only one of the Annexes referred to in this paragraph are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, a fee of [F674£10,160],

plus the amounts specified in paragraph (3A); and

(c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of [F675£4,404] plus the amounts specified in paragraph (3A).]

[F676(3A) Subject to paragraph (3B), the additional amounts payable in respect of an inspection referred to in paragraph (3) shall be—

(a) an amount for time spent by a member of staff undertaking a site visit at a rate—

(i) for the time spent on site, of [F677£361.20] per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and

(ii) for the time spent travelling to and from the site, of [F678£90.30] per hour;

(b) the actual costs of travel, accommodation and subsistence; and

(c) out of pocket expenses.

(3B) Where the Secretary of State conducts an inspection referred to in paragraph (3)(a) on the same date and at the same premises as an inspection pursuant to regulation 48(7)(a)—

(a) the amount referred to in paragraph (3A)(3) shall include an amount for any time spent on site by a member of staff which is attributable to the conduct of the inspection pursuant to regulation 48(7)(a), at the rate referred to paragraph (3A)(a)(i); and

(b) the costs and expenses referred to in paragraph (3A)(b) and (c) shall include any additional costs and expenses attributable to the conduct of the inspection pursuant to regulation 48(7)(a).]

[F679(3C) A UK notified body that applies to the Secretary of State for a renewal of its designation pursuant to article 4 of Regulation (EU) No 920/2013 shall pay to the Secretary of State—

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) a fee of £8,252 in respect of the application; and
  - (b) where an audit is carried out in connection with the application, a fee of £15,904 in respect of the audit.
- (3D) Where the Secretary of State conducts an assessment of a UK notified body pursuant to article 5 of Regulation (EU) No 920/2013, the UK notified body shall pay to the Secretary of State—
- (a) if the assessment relates to the UK notified body’s assessment of clinical data only, a fee of £2,586; or
  - (b) in any other case, a fee of £3,876.
- (3E) A UK notified body that submits a summary evaluation report to the Secretary of State pursuant to article 5(4) of Regulation (EU) No 722/2012 shall pay to the Secretary of State a fee of £532.]
- (4) A fee under this regulation—
- (a) in connection with an application for designation under [<sup>F680</sup>regulation 45(1),] a variation under regulation 45(4)[<sup>F681</sup>, a renewal under Regulation (EU) No 920/2013 (but not any associated audit) or a submission of a summary evaluation report under Regulation (EU) No 722/2012]—
    - (i) shall be payable when the application [<sup>F682</sup>or submission] to the Secretary of State is made, and
    - (ii) shall accompany the application [<sup>F683</sup>or submission] when it is made;
  - (b) in connection with an inspection pursuant to regulation 45(7) [<sup>F684</sup>or an audit or assessment pursuant to Regulation (EU) No 920/2013], shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.
- [<sup>F685</sup>(5) In this regulation, “Regulation (EU) No 920/2013” means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices.]

#### Extent Information

**E90** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F668** Sum in reg. 54(1)(a) substituted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **3(2)(a)**
- F669** Sum in reg. 54(1)(b) substituted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **3(2)(b)**
- F670** Sum in reg. 54(2) substituted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **3(3)**
- F671** Words in reg. 54(3) substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **16**
- F672** Reg. 54(3)(a)-(c) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(c)**
- F673** Sum in reg. 54(3)(a) substituted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **3(4)(a)**
- F674** Sum in reg. 54(3)(b) substituted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **3(4)(b)**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F675** Sum in reg. 54(3)(c) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(4)(c)**
- F676** Reg. 54(3A)(3B) inserted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(2)(d)**
- F677** Sum in reg. 54(3A)(a)(i) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(a)**
- F678** Sum in reg. 54(3A)(a)(ii) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(5)(b)**
- F679** Reg. 54(3C)-(3E) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(6)**
- F680** Words in reg. 54(4)(a) substituted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(i)**
- F681** Words in reg. 54(4)(a) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(ii)**
- F682** Words in reg. 54(4)(a)(i) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
- F683** Words in reg. 54(4)(a)(ii) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(a)(iii)**
- F684** Words in reg. 54(4)(b) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(7)(b)**
- F685** Reg. 54(5) inserted (1.4.2017) by The Medical Devices (Fees Amendment) Regulations 2017 (S.I. 2017/207), regs. 1(1), **3(8)**

#### <sup>F471</sup> **Fees payable in connection with the designation etc. of ... conformity assessment bodies** **E+W+S**

**55.**—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as [<sup>F472</sup>a CAB] shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of [<sup>F473</sup>£8,918]; or
- (b) in all other cases, a fee of [<sup>F474</sup>£35,672].

[<sup>F475</sup>(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) must, in connection with that application for a variation, pay to the Secretary of State—

- (a) in respect of an extension to the scope of the body's designation to carry out tasks arising out of a mutual recognition agreement that were not previously within the scope of the body's designation, a fee of £12,571; or
- (b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and which requires the Secretary of State to undertake an additional assessment of the body's procedures, a fee of £18,212.]

(3) [<sup>F476</sup>Subject to paragraphs (3A) to (3C)] where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of [<sup>F477</sup>a CAB] arising out of [<sup>F478</sup>a mutual recognition agreement] which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- [<sup>F479</sup>(a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of [<sup>F480</sup>£58,341] plus the amounts specified in paragraph (3D);



- (b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of [<sup>F481</sup>£10,072] plus the amounts specified in paragraph (3D);
- (c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of [<sup>F482</sup>£1,880];
- (d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of [<sup>F483</sup>£10,072 ] plus the amounts specified in paragraph (3D).]

[<sup>F484</sup>(3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be [<sup>F485</sup>£58,341] plus—

- (a) [<sup>F486</sup>£1,880] for each additional inspection; and
- (b) the amounts specified in paragraph (3D).

(3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be [<sup>F487</sup>£10,072 ] plus—

- (a) [<sup>F488</sup>£1,880] for each additional inspection; and
- (b) the amounts specified in paragraph (3D)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3)(c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be [<sup>F489</sup>£1,880] for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) shall be—

- (a) an amount for time spent by a member of staff undertaking a site visit at a rate—
  - (i) for the time spent on site, of [<sup>F490</sup>£631] per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and
  - (ii) for the time spent travelling to and from the site, of [<sup>F491</sup>£171] per hour;
- (b) the actual costs of travel, accommodation and subsistence, and
- (c) out of pocket expenses.]

(4) A fee under this regulation—

- (a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(4)—
  - (i) shall be payable when the application to the Secretary of State is made, and
  - (ii) shall accompany the application when it is made;
- (b) in connection with an inspection pursuant to regulation 48(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

#### Extent Information

**E43** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

*Status: Point in time view as at 21/03/2024.*

*Changes to legislation: The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

### Textual Amendments

- F471** Word in reg. 55 heading omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(a)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F472** Words in reg. 55(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(b)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F473** Sum in reg. 55(1)(a) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(2)(a)**
- F474** Sum in reg. 55(1)(b) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(2)(b)**
- F475** Reg. 55(2) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(3)**
- F476** Words in reg. 55(3) inserted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(3)(c)(i)**
- F477** Words in reg. 55(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(c)(i)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F478** Words in reg. 55(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **8(4)(c)(ii)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 7** and S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F479** Reg. 55(3)(a)-(d) substituted for reg. 55(3)(a)-(c) (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(3)(c)(ii)**
- F480** Sum in reg. 55(3)(a) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(4)(a)**
- F481** Sum in reg. 55(3)(b) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(4)(b)**
- F482** Sum in reg. 55(3)(c) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(c)(iii)**
- F483** Sum in reg. 55(3)(d) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(4)(b)**
- F484** Reg. 55(3A)-(3D) inserted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(3)(d)**
- F485** Sum in reg. 55(3A) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(5)**
- F486** Sums in reg. 55(3A) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(d)**
- F487** Sum in reg. 55(3B) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(6)**
- F488** Sums in reg. 55(3B) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(e)**
- F489** Sum in reg. 55(3C) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(f)**
- F490** Sum in reg. 55(3D)(a)(i) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(7)(a)**
- F491** Sum in reg. 55(3D)(a)(ii) substituted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **11(7)(b)**

<sup>F686</sup> **Fees payable in connection with the designation etc. of ... conformity assessment bodies** **N.I.**

55.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as [<sup>F687</sup>a CAB] shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of [<sup>F688</sup>£8,918]; or
- (b) in all other cases, a fee of [<sup>F689</sup>£35,672].

[<sup>F690</sup>(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) must, in connection with that application for a variation, pay to the Secretary of State—

- (a) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out tasks arising out of a UK mutual recognition agreement that were not previously within the scope of the body's designation, a fee of £12,571; or
- (b) in respect of an extension to the scope of the body's designation, which extends the body's designation to carry out certain tasks that were not previously within the scope of the body's designation and which requires the Secretary of State to undertake an additional assessment of the body's procedures, a fee of £18,212.]

(3) [<sup>F691</sup>Subject to paragraphs (3A) to (3C)] where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of [<sup>F692</sup>a CAB] arising out of [<sup>F693</sup>a UK mutual recognition agreement] which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- [<sup>F694</sup>(a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of [<sup>F695</sup>£58,341] plus the amounts specified in paragraph (3D);
- (b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of [<sup>F696</sup>£10,072 ] plus the amounts specified in paragraph (3D);
- (c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of [<sup>F697</sup>£1,880];
- (d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of [<sup>F698</sup>£10,072] plus the amounts specified in paragraph (3D).]

[<sup>F699</sup>(3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be [<sup>F700</sup>£58,341] plus—

- (a) [<sup>F701</sup>£1,880] for each additional inspection; and
- (b) the amounts specified in paragraph (3D).

(3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7) (a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be [<sup>F702</sup>£10,072] plus—

- (a) [<sup>F703</sup>£1,880] for each additional inspection; and
- (b) the amounts specified in paragraph (3D)

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3) (c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be [<sup>F704</sup>£1,880] for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) shall be—

- (a) an amount for time spent by a member of staff undertaking a site visit at a rate—
    - (i) for the time spent on site, of [<sup>F705</sup>£631] per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and
    - (ii) for the time spent travelling to and from the site, of [<sup>F706</sup>£171] per hour;
  - (b) the actual costs of travel, accommodation and subsistence, and
  - (c) out of pocket expenses.]
- (4) A fee under this regulation—
- (a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(4)—
    - (i) shall be payable when the application to the Secretary of State is made, and
    - (ii) shall accompany the application when it is made;
  - (b) in connection with an inspection pursuant to regulation 48(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

#### Extent Information

**E91** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F686** Word in [reg. 55](#) heading omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 21\(a\)](#)

**F687** Words in [reg. 55\(1\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 21\(b\)](#)

**F688** Sum in [reg. 55\(1\)\(a\)](#) substituted (N.I.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), [regs. 1\(2\)](#), [12\(2\)\(a\)](#)

**F689** Sum in [reg. 55\(1\)\(b\)](#) substituted (N.I.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), [regs. 1\(2\)](#), [12\(2\)\(b\)](#)

**F690** [Reg. 55\(2\)](#) substituted (N.I.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), [regs. 1\(2\)](#), [12\(3\)](#)

**F691** Words in [reg. 55\(3\)](#) inserted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), [regs. 1\(1\)\(b\)](#), [13\(3\)\(e\)\(i\)](#)

**F692** Words in [reg. 55\(3\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 21\(c\)\(i\)](#)

**F693** Words in [reg. 55\(3\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), [reg. 1\(3\)](#), [Sch. 1 para. 21\(c\)\(ii\)](#)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F694** Reg. 55(3)(a)-(d) substituted for reg. 55(3)(a)-(c) (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(3)(c)(ii)**
- F695** Sum in reg. 55(3)(a) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(4)(a)**
- F696** Sum in reg. 55(3)(b) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(4)(b)**
- F697** Sum in reg. 55(3)(c) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(c)(iii)**
- F698** Sum in reg. 55(3)(d) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(4)(b)**
- F699** Reg. 55(3A)-(3D) inserted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(3)(d)**
- F700** Sum in reg. 55(3A) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(5)**
- F701** Sums in reg. 55(3A) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(d)**
- F702** Sum in reg. 55(3B) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(6)**
- F703** Sums in reg. 55(3B) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(e)**
- F704** Sum in reg. 55(3C) substituted (1.4.2010) by The Medical Devices (Fees Amendment) Regulations 2010 (S.I. 2010/557), regs. 1, **3(3)(f)**
- F705** Sum in reg. 55(3D)(a)(i) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(7)(a)**
- F706** Sum in reg. 55(3D)(a)(ii) substituted (N.I.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **12(7)(b)**

### Fees payable in relation to clinical investigation notices **E+W+S**

**56.**—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

- (a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—
- (i) a fee, if the device is a Group A device, of [<sup>F492</sup>£5,711], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F493</sup>£11,069]; or
- (b) in all other cases—
- (i) a fee, if the device is a Group A device, of [<sup>F494</sup>£7,472], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F495</sup>£15,627].

(2) Except where paragraph (3) [<sup>F496</sup>or (3A)] applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or [<sup>F497</sup>their UK responsible person] has previously given such notice in relation to that device.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

- (a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;
- (b) a change to the number of patients or devices forming the basis of the proposed trial;
- (c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;
- (d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or
- (e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

[<sup>F498</sup>(3A) Any person who submits an amendment to a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall pay to the Secretary of State—

- (a) a fee, if the device is a Group A device, of £207; or
- (b) a fee, if the device is a Group B device, of £331.]

[<sup>F499</sup>(3B) A person who requests a meeting with the Secretary of State in respect of an intended clinical investigation under regulation 16(1A) or 29(1A) must pay the following fees in advance of the meeting—

- (a) £906 for a regulatory advice meeting under regulation 16(1A)(a) or 29(1A)(a); and
- (b) £782 for a statistical review meeting under regulation 16(1A)(b) or 29(1A)(b).]

(4) A fee under this regulation—

- (a) shall be payable when the notice to which it relates is given to the Secretary of State; and
- (b) shall accompany that notice when it is given.

#### Extent Information

**E44** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F492** Sum in reg. 56(1)(a)(i) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **13(1)(a)**

**F493** Sum in reg. 56(1)(a)(ii) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **13(1)(b)**

**F494** Sum in reg. 56(1)(b)(i) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **13(1)(c)**

**F495** Sum in reg. 56(1)(b)(ii) substituted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **13(1)(d)**

**F496** Words in reg. 56(2) inserted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **5(2)**

**F497** Words in reg. 56(2) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **8(4A)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **49**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F498** Reg. 56(3A) inserted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **5(3)**

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**F499** Reg. 56(3B) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), 13(2)

### Fees payable in relation to clinical investigation notices **N.I.**

**56.**—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

- (a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—
  - (i) a fee, if the device is a Group A device, of [<sup>F707</sup>£2,920], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F707</sup>£3,570]; or
- (b) in all other cases—
  - (i) a fee, if the device is a Group A device, of [<sup>F708</sup>£3,820], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F708</sup>£5,040].

(2) Except where paragraph (3) [<sup>F709</sup> or (3A)] applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or his authorised representative has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

- (a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;
- (b) a change to the number of patients or devices forming the basis of the proposed trial;
- (c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;
- (d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or
- (e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

[<sup>F710</sup>(3A) Any person who submits an amendment to a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall pay to the Secretary of State—

- (a) a fee, if the device is a Group A device, of £207; or
- (b) a fee, if the device is a Group B device, of £331.]
- (4) A fee under this regulation—
  - (a) shall be payable when the notice to which it relates is given to the Secretary of State; and
  - (b) shall accompany that notice when it is given.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

#### Extent Information

- E92** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F707** Sums in reg. 56(1)(a) substituted (1.4.2013) by [The Medical Devices \(Fees Amendment\) Regulations 2013 \(S.I. 2013/525\)](#), regs. 1, **2(2)(a)**
- F708** Sums in reg. 56(1)(b) substituted (1.4.2013) by [The Medical Devices \(Fees Amendment\) Regulations 2013 \(S.I. 2013/525\)](#), regs. 1, **2(2)(b)**
- F709** Words in reg. 56(2) inserted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **5(2)**
- F710** Reg. 56(3A) inserted (1.4.2017) by [The Medical Devices \(Fees Amendment\) Regulations 2017 \(S.I. 2017/207\)](#), regs. 1(1), **5(3)**

#### [<sup>F500</sup> Fees in connection with approval of coronavirus test devices

**56A.**—(1) A person who makes an application to the Secretary of State under regulation 38A(1) must pay to the Secretary of State a fee of—

- (a) £14,000; or
- (b) if the person is a small or medium-sized enterprise, £6,200.

(2) Where the Secretary of State, in accordance with regulation 38A(4), treats an application made before the coming into force of regulation 38A as an application made under that regulation, a payment made in respect of that application before the coming into force of this regulation must be treated as—

- (a) a payment meeting the requirements of paragraph (1), if that payment would have met those requirements after their coming into force; or
  - (b) a payment contributing in part to the payment required by paragraph (1), if that payment would not have met those requirements after their coming into force.
- (3) In this regulation—
- (a) a person is a small or medium-sized enterprise if it and persons associated with it employ no more than 250 individuals in total; and
  - (b) “persons associated with it” has the same meaning as in section 882 of the Corporation Tax Act 2010.]

#### Textual Amendments

- F500** Reg. 56A inserted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), **9**

#### [<sup>F501</sup> Circumstances in which a fee is payable in relation to a consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device

**56B.**—(1) Subject to paragraph (2), the fee payable by an approved body in respect of a consultation or further consultation with the Secretary of State in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device is the fee specified in regulation 56C.



(2) No fee is payable if it is the first time the Secretary of State has been consulted by any approved body in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device if the medicinal substance is an authorised medicinal product.]

**Textual Amendments**

**F501** Reg. 56B inserted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **14**

**[<sup>F502</sup>Fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device**

**56C.**—(1) Subject to regulation 56B(2) and paragraph (3), the fee in respect of a consultation in relation to a device which incorporates one or more medicinal substances is—

- (a) £4,550 if each medicinal substance is manufactured by an approved manufacturer of that substance;
- (b) £10,604 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(2) Subject to paragraph (3), the fee in respect of a further consultation in relation to a device which incorporates one or more medicinal substances is—

- (a) £900 if each medicinal substance is manufactured by an approved manufacturer of that substance;
- (b) £2,451 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(3) In relation to a device which incorporates a new medicinal substance, the fee is—

- (a) £46,526 for a consultation; and
- (b) £11,551 for a further consultation.

(4) Where an approved body consults the Secretary of State in relation to more than one device at the same time and those devices—

- (a) are of similar construction and are designed to perform similar functions;
- (b) incorporate medicinal substances of the same specification which are manufactured by the same manufacturer or manufacturers; and
- (c) do not incorporate any other medicinal substance;

the fee payable for that consultation is the fee which would be payable under this regulation for a consultation in relation to one of those devices.

(5) Any fee payable under this regulation must be paid to the Secretary of State not later than the day on which an approved body consults the Secretary of State.]

**Textual Amendments**

**F502** Reg. 56C inserted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **15**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### [<sup>F503</sup> Fees payable in connection with pre-consultation meetings

**56D.**—(1) The fee payable by a person other than an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that person making an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that body consulting the Secretary of State in relation to an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(3) The fee payable is—

- (a) £824, if the advice provided at that meeting consists of advice in connection with—
  - (i) quality development only, or
  - (ii) safety development only;
- (b) £1,044, if the advice provided at that meeting consists of advice in connection with—
  - (i) quality and safety development only, or
  - (ii) clinical development only;
- (c) £1,429, if the advice provided at that meeting consists of advice in connection with—
  - (i) quality and clinical development only, or
  - (ii) safety and clinical development only;
- (d) £1,813, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

(4) Any fee payable under this regulation must be paid within 14 days following written notice from the Secretary of State requiring payment of that fee ]

#### Textual Amendments

**F503** Reg. 56D inserted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), 16

### Unpaid fees

**57.** All unpaid sums due by way of, or on account of, any fees payable under this Part are recoverable as debts due to the Crown.

### Waivers, reductions and refunds **E+W+S**

**58.**—(1) The Secretary of State may—

- (a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;
  - (b) refund the whole or part of any fee paid pursuant to this Part.
- (2) Without prejudice to the generality of paragraph (1), where—
- (a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or
  - (b) an application for designation as—

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(i) [<sup>F504</sup>an approved body] under regulation 45(1), or

(ii) [<sup>F505</sup>a CAB] under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

#### Textual Amendments

**F504** Words in reg. 58(2)(b)(i) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **8(5)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **50**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F505** Words in reg. 58(2)(b)(ii) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **8(5)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **50**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### Waivers, reductions and refunds **N.I.**

**58.**—(1) The Secretary of State may—

- (a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;
- (b) refund the whole or part of any fee paid pursuant to this Part.

(2) Without prejudice to the generality of paragraph (1), where—

- (a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or
- (b) an application for designation as—
  - (i) a notified body under regulation 45(1), or
  - (ii) [<sup>F711</sup>a CAB] under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

#### Textual Amendments

**F711** Words in [reg. 58\(2\)\(b\)\(ii\)](#) substituted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 22**

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

## PART VII

### *General, Enforcement and Miscellaneous*

#### Interpretation of Part VII

59. In this Part <sup>F506</sup>...—

[<sup>F507</sup>“registrable device” means a device in respect of which, in accordance with the Medical Devices Directives, registration is required with the competent authorities of a Member State or (where appropriate) a State which is a Party to an Association Agreement;]

“relevant device” means a device that is a “relevant device” for the purposes of Part II, III or IV <sup>F508</sup>....

#### Textual Amendments

**F506** Words in reg. 59 omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **17**

**F507** Words in reg. 59 omitted (E.W.S.) (30.4.2021) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(2)(e), **9(2)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

**F508** Words in reg. 59 omitted (11.8.2021) by virtue of [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 20**

#### [<sup>F509</sup>Status of UK responsible person] **E+W+S**

60.—<sup>F510</sup>(1) .....

<sup>F510</sup>(2) .....

[<sup>F511</sup>(3) A UK responsible person—

- (a) may be proceeded against as a person placing the device on the market for the purposes of these regulations;
- (b) in relation to the supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market.]

(4) If a person claims or purports to act as [<sup>F512</sup>a UK responsible person], the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient [<sup>F513</sup>evidence that he is [<sup>F514</sup>a UK responsible person]].

#### Extent Information

**E45** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

**F509** Reg. 60 heading substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **9(3)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- F510** Reg. 60(1)(2) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(3)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F511** Reg. 60(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(3)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
- F512** Words in reg. 60(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(3)(d)(i)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 8** and S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F513** Words in reg. 60(4) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(b)**
- F514** Words in reg. 60(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(3)(d)(ii)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 8** and S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

### Designation etc. of authorised representatives **N.I.**

**60.**—(1) Where these Regulations place any obligation<sup>F712</sup>... on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business<sup>F713</sup> in a relevant state], no person shall—

- (a) place that device on the market; or
- (b) supply that device in circumstances where it has been placed on the market,

unless the manufacturer of the device has designated [<sup>F714</sup>a single authorised representative] to perform that obligation, but once the manufacturer has designated [<sup>F714</sup>a single authorised representative] to perform that obligation, that obligation shall be performed by the authorised representative (although in all other cases it shall be performed by the manufacturer).

(2) If the manufacturer of a registrable device does not have a registered place of business<sup>F715</sup> in a relevant state], no person shall place that device on the market or supply that device in circumstances where it has been placed on the market unless its manufacturer has designated [<sup>F714</sup>a single authorised representative] as—

- (a) the person responsible for marketing the device [<sup>F716</sup>in a relevant state]; and
- (b) the person responsible for registering in respect of that device with—
  - (i) the Secretary of State in accordance with regulation 19 or, as the case may be, 44, or
  - (ii) the competent authorities of another Member State or (where appropriate) a State which is a Party to an Association Agreement.

(3) Where a manufacturer of a registrable device, or of a relevant device that is not registrable, has designated [<sup>F714</sup>a single authorised representative] as the person responsible for marketing the device within [<sup>F717</sup>a relevant state], that authorised representative—

- (a) may be proceeded against as a person placing the device on the market for the purposes of these Regulations;
- (b) in relation to any supply of the device to a person within [<sup>F718</sup>Northern Ireland] after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market, unless that supply is due to an act of another person established in [<sup>F719</sup>a relevant state].

(4) If a person claims or purports to act as an authorised representative of a manufacturer of a device, the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his

**Status:** Point in time view as at 21/03/2024.

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functions under these Regulations, require that person to furnish the Secretary of State with sufficient [<sup>F720</sup>evidence that he is the single authorised representative of the manufacturer].

#### Extent Information

**E93** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F712** Words in reg. 60(1) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(a)(i)**
- F713** Words in reg. 60(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(a)(ii)**
- F714** Words in reg. 60(1)(2)(3) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(a)**
- F715** Words in reg. 60(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(b)(i)**
- F716** Words in reg. 60(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(b)(ii)**
- F717** Words in reg. 60(3) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(c)(i)**
- F718** Words in reg. 60(3)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(c)(ii)(aa)**
- F719** Words in reg. 60(3)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 23(c)(ii)(bb)**
- F720** Words in reg. 60(4) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(b)**

#### Enforcement etc. **E+W+S**

[<sup>F515</sup>61.—(1A) It is the duty of the Secretary of State to enforce these regulations in relation to relevant devices and devices for performance evaluation.

(1B) It is the duty of each weights and measures authority in Great Britain and each district council in Northern Ireland to enforce these regulations within its area (concurrently with the Secretary of State) in relation to relevant devices that are ordinarily intended for private use or consumption.

(1C) Nothing in this regulation authorises a weights and measures authority to bring proceedings in Scotland for an offence.]

#### Textual Amendments

**F515** Reg. 61(1A)-(1C) substituted for reg. 61(1)-(8) (26.5.2021) by Medicines and Medical Devices Act 2021 (c. 3), ss. 41(6), 50(3) (with s. 41(8)); S.I. 2021/610, reg. 2(c) (with reg. 3)

**Enforcement etc. N.I.**

61.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings, notices or otherwise) <sup>F721</sup>... as safety regulations as defined in that Act <sup>F722</sup>, and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act <sup>M19</sup>.

[<sup>F723</sup>(1A) Paragraph (1) applies in relation to regulations 10A, 24A and 36A (UK(NI) indication) as it does in relation to any other provision of these Regulations to which it applies.]

(2) Except as provided by paragraph (3), <sup>F724</sup>... each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) does not relieve an authority or council of its duty in relation to devices which are consumer goods <sup>F725</sup>..., and accordingly but subject to paragraph (4), <sup>F726</sup>... each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

(4) The powers of an enforcement authority to serve restriction notices under regulation 63 are only exercisable by the Secretary of State.

(5) Each <sup>F727</sup>... council referred to in paragraph (3) on whom a duty is imposed by section 27(1) of the 1987 Act to enforce the provisions of these Regulations shall give immediate notice to the Secretary of State of—

- (a) any suspension notice served by it under section 14 of the 1987 Act in respect of a device to which paragraph (3) applies;
- (b) any application made by it under section 16 of the 1987 Act for an order for forfeiture of any such device; and
- (c) any other thing done by it in respect of such a device for the purposes of, or in connection with the operation of, sections 14 to 17 of the 1987 Act.

[<sup>F728</sup>(6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

- <sup>F729</sup>(a) .....
- (b) a magistrates' court in Northern Ireland may hear and determine any complaint made—
  - (i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or
  - (ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier; and

<sup>F730</sup>(c) .....]

(7) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non—conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to goods considered unsafe by the Secretary of State), and in relation to non-conforming devices, Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to relevant devices being or not being non-conforming devices.

[<sup>F731</sup>(7A) In paragraph (3), “consumer goods” means any goods which are ordinarily intended for private use or consumption.]

(8) In paragraph (7), “non-conforming devices” means—

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (a) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a CE marking which he considers to be devices—
  - (i) which do not conform as respects a relevant essential requirement [<sup>F732</sup>or a requirement of Regulation (EU) No 722/2012 (if applicable)]; or
  - (ii) to which a CE marking has or should have been applied following a conformity assessment procedure set out in the Medical Devices Directives, and—
- (aa) the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or
- (bb) they do not conform to the design or type described in any certificate granted as a result of that procedure; or
- (b) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with these Regulations.

#### Extent Information

**E94** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

- F721** Words in reg. 61(1) revoked (20.6.2003) by [The Enterprise Act 2002 \(Part 9 Restrictions on Disclosure of Information\) \(Amendment and Specification\) Order 2003 \(S.I. 2003/1400\)](#), art. 1, **Sch. 5**
- F722** See section s 11(1) and 45(1) of that Act.
- F723** [Reg. 61\(1A\)](#) inserted (N.I.) (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(a)**
- F724** Words in [reg. 61\(2\)](#) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(b)**
- F725** Words in [reg. 61\(3\)](#) omitted (22.11.2005) by virtue of [The Medical Devices \(Amendment\) Regulations 2005 \(S.I. 2005/2909\)](#), regs. 1, **2(a)**
- F726** Words in [reg. 61\(3\)](#) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(c)**
- F727** Words in [reg. 61\(5\)](#) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(d)**
- F728** [Reg. 61\(6\)](#) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **6**
- F729** [Reg. 61\(6\)\(a\)](#) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(e)**
- F730** [Reg. 61\(6\)\(c\)](#) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 1 para. 24(e)**
- F731** [Reg. 61\(7A\)](#) inserted (22.11.2005) by [The Medical Devices \(Amendment\) Regulations 2005 \(S.I. 2005/2909\)](#), regs. 1, **2(b)**
- F732** Words in [reg. 61\(8\)\(a\)\(i\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **17**



**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

### Marginal Citations

**M19** See section 45(1) of that Act.

### Compliance notices

<sup>F516</sup>**62.** . . . . .

#### Textual Amendments

**F516** Reg. 62 omitted (26.5.2021) by virtue of Medicines and Medical Devices Act 2021 (c. 3), ss. 41(7)(a), 50(3) (with s. 41(8)); S.I. 2021/610, reg. 2(c) (with reg. 3)

### Restriction notices

<sup>F517</sup>**63.** . . . . .

#### Textual Amendments

**F517** Reg. 63 omitted (26.5.2021) by virtue of Medicines and Medical Devices Act 2021 (c. 3), ss. 41(7)(b), 50(3) (with s. 41(8)); S.I. 2021/610, reg. 2(c) (with reg. 3)

### Notification of decisions etc.

<sup>F518</sup>**64.** . . . . .

#### Textual Amendments

**F518** Reg. 64 omitted (26.5.2021) by virtue of Medicines and Medical Devices Act 2021 (c. 3), ss. 41(7)(c), 50(3) (with s. 41(8)); S.I. 2021/610, reg. 2(c) (with reg. 3)

### [<sup>F519</sup> Centralised systems of records etc.

**65.** The Secretary of State shall perform, as respects [<sup>F520</sup>Northern Ireland], the functions of the Member State under article 8 of Directive 90/385, article 10 of Directive 93/42 and article 11(1) to (3) of Directive 98/79.]

#### Textual Amendments

**F519** Reg. 65 omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), 9(7) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)  
**F520** Words in reg. 65 substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), Sch. 1 para. 26

### Revocations

**66.** The following provisions are hereby revoked—

- (a) the Active Implantable Medical Devices Regulations 1992 <sup>M7</sup>;

**Status:** Point in time view as at 21/03/2024.

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- (b) the Medical Devices Regulations 1994 <sup>M8</sup>;
- (c) the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 <sup>M9</sup>;
- (d) the Medical Devices Fees Regulations 1995 <sup>M10</sup>;
- (e) the Medical Devices Fees (Amendment) Regulations 1997 <sup>M11</sup>;
- (f) the *In Vitro* Diagnostic Medical Devices Regulations 2000 <sup>M12</sup>; and
- (g) regulations 6 and 13 of the Medicines (Codification Amendments Etc.) Regulations 2002 <sup>M13</sup>.

#### Marginal Citations

- M7** S.I. 1992/3146.  
**M8** S.I. 1994/3017.  
**M9** S.I. 1995/1671.  
**M10** S.I. 1995/2487.  
**M11** S.I. 1997/694.  
**M12** S.I. 2000/1315.  
**M13** S.I. 2002/236.

#### [<sup>F521</sup> Review **E+W+S**

67. Before the end of 31st December [<sup>F522</sup>2025], the Secretary of State must—
- (a) carry out a review of these Regulations;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.]

#### Extent Information

- E46** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F521** Reg. 67 inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), **18**
- F522** Word in reg. 67 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **9(8)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

#### [<sup>F733</sup> Review **N.I.**

67. Before the end of 31st December 2019, the Secretary of State must—
- (a) carry out a review of these Regulations;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.]

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**Extent Information**

**E95** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Textual Amendments**

**F733** [Reg. 67](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **18**

Signed by authority of the Secretary of State for Health

*Hunt*  
Parliamentary Under Secretary of State,  
Department of Health

We consent,

*Tony McNulty*  
*Nick Ainger*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

## [<sup>F523</sup>SCHEDULE 1

Regulation 2(1)

### ASSOCIATION AGREEMENTS

#### Textual Amendments

**F523** Sch. 1 omitted (E.W.S.) (31.12.2020) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **9(9)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F524</sup>1. The Agreement establishing an Association between the European Economic Community and Turkey signed at Ankara on 12th September 1963.]]

#### Textual Amendments

**F524** Sch. 1 para. 1 substituted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **19**

## SCHEDULE 2

Regulation 2(1)

### MUTUAL RECOGNITION AGREEMENTS

#### Extent Information

**E47** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only for the substitution of Sch. 2 in relation to E.W.S. (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **9(10)** (as amended by [S.I. 2020/1478](#), regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, Sch. 5 para. 1(1)

1. The agreement on mutual recognition in relation to conformity assessment certificates and markings between the European Community and Australia, initialled on 19th July 1996 <sup>M14</sup>.

#### Marginal Citations

**M14** OJ No. L 229, 17.8.1998, p.3.

2. The agreement on mutual recognition in relation to conformity assessment between the European Union and New Zealand, initialled on 19th July 1996 <sup>M15</sup>.

#### Marginal Citations

**M15** OJ No. L 229, 17.8.1998, p.62.

3. The agreement on mutual recognition between the European Community and Canada, signed in London on 14th May 1998 <sup>M16</sup>.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

**Marginal Citations**

**M16** OJ No. L 280, 16.10.1998, p.3.

4. The agreement on mutual recognition between the European Community and the United States of America, signed in London on 18th May 1998 <sup>M17</sup>.

**Marginal Citations**

**M17** OJ No. L 31, 4.2.1999, p.3.

<sup>F525</sup>5. The agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment signed in Luxembourg on 21st June 1999.]

**Textual Amendments**

**F525** Sch. 2 para. 5 added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **20**

<sup>F526</sup>SCHEDULE 2

Regulation 1A

Mutual Recognition Agreement countries

**Extent Information**

**E48** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Textual Amendments**

**F526** Sch. 2 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **9(10)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, Sch. 5 para. 1(1)

- Australia
- New Zealand
- Canada
- The United States of America
- The Swiss Confederation]

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

## [<sup>F527</sup>SCHEDULE 2A

Regulation 1A

### Modification of Annexes to Directives 90/385, 93/42, 98/79

#### Textual Amendments

**F527** Sch. 2A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **12** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, 56, **57**); 2020 c. 1, **Sch. 5 para. 1(1)**

## PART 1

### Modification of Annexes to Directive 90/385

1.—(1) The Annexes to Directive 90/385 are modified so that they read as if amended by paragraphs 2 to 10.

(2) In this Part any reference to “the Regulations” is a reference to the Medical Devices Regulations 2002.

2. In Annex 1—

[ in Section 2, for “the functions referred to in Article 1(2)(a)” substitute “the purposes <sup>F528</sup>(za) referred to in the definition of a medical device in regulation 2(1) of the Regulations]

(a) in Section 8 for the fifth indent substitute —

“—risks connected with ionising radiation from radioactive substances included in the device,”;

(b) for Section 10 substitute—

“**10.** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with an action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to [Directive 2001/83/EC](#) as modified by Schedule 8B to the Human Medicines Regulations 2012.

For the substances referred to in the first paragraph, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body shall be informed of the changes and shall consult the Secretary of State, in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the Secretary of State has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, the Secretary of State shall provide the approved body with advice on whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The approved body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.”;

- (c) in Section 14.2 —
  - (i) for “the name and address of the authorised representative” substitute “, where such a person is appointed under regulation 21A of the Regulations, the name and address of the UK responsible person,”;
  - (ii) for “the Community” substitute “the United Kingdom”;
  - [ for “a device within the meaning of Article 1(4a)” substitute “a stable derivatives <sup>F529</sup>(iii) device]
- (d) in Section 15 in the first indent for “CE mark” substitute “UK mark”.

#### Textual Amendments

**F528** Sch. 2A para. 2(za) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(a)**

**F529** Sch. 2A para. 2(c)(iii) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(b)**

- 3. In Annex 2—
  - (a) for the heading substitute “Declaration of conformity”;
  - (b) for “the notified body” each time it occurs substitute “the approved body”;
  - (c) for “this Directive” each time it occurs substitute “the Regulations”;
  - (d) in Section 1, for “EC Surveillance” substitute “Surveillance”;
  - (e) in Section 2—
    - (i) for “his authorized representative” substitute “their UK responsible person”;
    - (ii) omit “established within the Community”;
    - (iii) for “CE marking” [<sup>F530</sup>, in both places it occurs,] substitute “UK marking”;
    - [ for “Article 12” substitute “regulation 24”];
  - (f) in Section 3.1—
    - (i) in the opening words, for “a notified body” substitute “an approved body”;
    - (ii) in the fifth indent, for “competent authorities” substitute “Secretary of State”;
  - [<sup>F532</sup>(g) in Section 3.2—

**Status:** Point in time view as at 21/03/2024.

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- (i) in the first paragraph, omit “of this Directive”;
- (ii) in point (c), for “Article 5” substitute “regulation 3A of the Regulations”;
- [<sup>F533</sup>(h) in Section 3.3—
  - (i) for the first sentence substitute—
 

“The quality system shall be audited by an approved body to determine whether it meets the requirements referred to in Section 3.2.”
  - (ii) in the second sentence for “harmonized” substitute “designated”;
- (i) in Section 3.4, in the second paragraph, for the first sentence substitute—
 

“The proposed modifications shall be evaluated by the approved body so as to verify whether the quality system so modified would still meet the requirements referred to in Section 3.2.”;
- (j) in Section 4.2 in the second indent for “Article 5” substitute “regulation 3A of the Regulations”;
- (k) for Section 4.3 substitute—
 

“**4.3.** The approved body must examine the application and, where the product complies with the relevant provisions of the Regulations, shall issue the applicant with a design certificate. The approved body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Regulations may be evaluated. The certificate shall contain conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State’s decision is unfavorable. It must convey its final decision to the Secretary of State.”;
- (l) in Section 4.4, for each reference to “EC design” substitute “design”;
- (m) in Section 6.1—
  - (i) for “national authorities” substitute “Secretary of State”;
  - (ii) for “his authorised representative” substitute “their UK responsible person”;
- (n) for Section 6.2 substitute—
 

“**6.2.** On request, an approved body must make available to other approved bodies and to the Secretary of State all relevant information on approvals of quality systems, issued, refused or withdrawn.”;
- (o) for Section 7 substitute—
 

“**7.** Application to the devices incorporating a human blood derivative:



**Status:** Point in time view as at 21/03/2024.

**Changes to legislation:** The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Upon completing the manufacture of each batch of devices incorporating a human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

#### Textual Amendments

- F530** Words in Sch. 2A para. 3(e)(iii) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(c)(i)**
- F531** Sch. 2A para. 3(e)(iv) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(c)(ii)**
- F532** Sch. 2A para. 3(g) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(c)(iii)**
- F533** Sch. 2A para. 3(h) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(c)(iv)**

#### 4. In Annex 3—

- (a) in the title for “EC TYPE-EXAMINATION” substitute “TYPE-EXAMINATION”;
- (b) for “EC type-examination” in each other place substitute “type-examination”;
- (c) for “a notified body” in each place substitute “an approved body”;
- (d) for “the notified body” in each place substitute “the approved body”;
- (e) in Section 1, for “this Directive” substitute “the Regulations”;
- (f) in Section 2—
  - (i) for the first sentence substitute—

“The application for type-examination shall be made by the manufacturer to the approved body.”;
  - (ii) for “the authorized representative” substitute “the UK responsible person”;
  - (iii) for “this Directive” substitute “the Regulations”;
- (g) in Section 3, for each reference to “Article 5” substitute “regulation 3A of the Regulations”;
- (h) for Sections 4 and 5, substitute—

“4. The approved body shall—

  - 4.1. examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 3A of the Regulations, as well as the items for which the design is not based on the relevant provisions of the said standards.
  - 4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements where the standards referred to in regulation 3A of the Regulations have not been applied.
  - 4.3. carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

**Status:** Point in time view as at 21/03/2024.

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**4.4.** agree with the applicant on the place where the necessary inspections and tests will be carried out.

**5.** Where the type meets the provisions of the Regulations, the approved body shall issue a type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the approved body.

In the case of devices referred to in Annex I, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.”;

- (i) in Section 6 omit “EC” each time it occurs;
- (j) for Section 7 substitute—

“**7.1.** On request, an approved body shall make available to other conformity assessment bodies (including other approved bodies) and to the Secretary of State all relevant information on type-examination certificates and addenda to those certificates issued, refused and withdrawn.

**7.2.** The approved body must cooperate with other approved bodies with regard to making available copies of the type examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.

**7.3.** The manufacturer or their UK responsible person shall keep with the technical documentation a copy of the UK type-examination certificates and the supplements to them for a period of at least 15 years from the manufacture of the last product.”.

- 5.** For Annex 4 substitute—

#### “ANNEX 4

#### **VERIFICATION**

**1.** Verification is the procedure whereby the manufacturer ensures and declares that the products subject to the provisions of Section 3 are in conformity with the type as described in the type-examination certification and satisfy the requirements of the Regulations that apply to them.

**2.** The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the type-examination

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certification and to the requirements of the Regulations that apply to them. The manufacturer shall affix the UK marking to each product and draw up a written declaration of conformity.

**3.** The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the type examination certificate as well as with the relevant requirements of the Regulations.

**4.** The manufacturer must undertake to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7. This undertaking must include the obligation on the part of the manufacturer to notify the Secretary of State of the following events immediately on learning of them—

- (i) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in the patient's state of health;
- (ii) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.

**5.** The approved body must carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of the Regulations by examination and testing of products on a statistical basis, as specified in Section 6. The manufacturer must authorize the approved body to evaluate the efficiency of the measures taken pursuant to Section 3, by audit where appropriate.

#### **6. Statistical verification**

**6.1.** Manufacturers must present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

**6.2.** A random sample must be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standards referred to in regulation 3A of the Regulations, or equivalent tests must be carried out to verify their conformity to the type as described in the type-examination certificate and thereby determine whether a batch is to be accepted or rejected.

**6.3.** Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the designated standards referred to in regulation 3A of the Regulations, taking account of the specific nature of the product categories in question.

**6.4.** Where batches are accepted, the approved body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity. Where a batch is rejected, the approved body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the approved body may suspend the statistical verification.

The manufacturer may, with the agreement of the approved body, affix the approved body's identification number during the manufacturing process.

**6.5.** The manufacturer or their UK responsible person must ensure that they are able to supply the approved body's certificates of conformity on request.

#### **7. Application to the devices incorporating human blood derivative:**

**Status:** Point in time view as at 21/03/2024.

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Upon completing the manufacture of each batch of devices incorporating human blood derivative the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

6. For Annex 5, substitute—

“ANNEX 5

**DECLARATION OF CONFORMITY TO TYPE**

*(Assurance of production quality)*

1. The manufacturer shall apply the quality system approved for the manufacture and must conduct the final inspection of the products concerned as specified in Section 3; the manufacturer shall be subject to the surveillance referred to in Section 4.

2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of Section 1 guarantees and declares that the products concerned conform to the type described in the type-examination certificate and meet the provisions of the Regulations which apply to them.

The manufacturer must affix the UK marking in accordance with regulation 24 of the Regulations and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The UK marking shall be accompanied by the identification number of the approved body responsible.

3. Quality system

3.1. The manufacturer shall make an application for evaluation of their quality system to an approved body.

The application shall include:

- all appropriate information concerning the products which it is intended to manufacture,
- the quality-system documentation,
- an undertaking to fulfil the obligations arising from the quality system as approved,
- an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,
- where appropriate, the technical documentation relating to the approved type and a copy of the type-examination certificate,
- an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Annex 7. The undertaking shall include an obligation for the manufacturer to notify the Secretary of State of the following incidents immediately on learning of them:
  - (i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in the patient’s state of health;
  - (ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

**Status:** Point in time view as at 21/03/2024.

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**3.2.** Application of the quality system must ensure that the products conform to the type described in the type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for their quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular an adequate description of—

- (a) the manufacturer's quality objectives;
- (b) the organization of the business and in particular—
  - the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,
  - methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform,
  - where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;
- (c) the techniques of control and of quality assurance at the manufacturing stage and in particular—
  - the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
  - product identification procedures drawn up and kept up-to-date from drawings, specifications or other relevant documents at every stage of manufacture;
- (d) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

**3.3.** Without prejudice to regulation 50 of the Regulations, the approved body shall effect an audit of the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

**3.4.** The manufacturer shall inform the approved body which has approved the quality system of any plan to alter that system.

The approved body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in Section 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

#### 4. Surveillance

**Status:** Point in time view as at 21/03/2024.

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**4.1.** The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

**4.2.** The manufacturer shall authorize the approved body to carry out all necessary inspections and shall supply it with all appropriate information, in particular—

- the quality-system documentation,
- the technical documentation,
- the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/ calibrations and the qualifications of the staff concerned, etc.

**4.3.** The approved body must periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

**4.4.** In addition, the approved body may make unannounced visits to the manufacturer, and must supply the manufacturer with an inspection report.

**5.** The approved body shall communicate to the other approved bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

**6.** Application to the devices incorporating human blood derivative:

Upon completing the manufacture of each batch of devices, incorporating human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

**7.** In Annex 6—

- (a) in Section 1, for “authorised representative established within the Community” substitute “UK responsible person”;
- (b) in Section 3 for “the competent national authorities” substitute “the Secretary of State”;
- (c) in Section 3.1 for “this Directive” substitute “the Regulations”;
- (d) in Section 3.2 for the fourth indent substitute—

“—the results of the risk analysis and a list of the designated standards provided for in regulation 3A of the Regulations, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards in regulation 3A of the Regulations have not been applied,”;

- (e) in Section 5, in the opening paragraph, for “competent authorities” substitute “Secretary of State”.

[<sup>F534</sup>**8.** In Annex 7—

- (a) in Section 1.1 for “harmonised” substitute “designated”;
- (b) in Section 2.3.5 for “all competent authorities of the Member States in which the clinical investigation is being performed” substitute “the Secretary of State”];

#### Textual Amendments

**F534** Sch. 2A para. 8 substituted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 21\(d\)](#)

**Status:** Point in time view as at 21/03/2024.

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**9.** In Annex 8—

(a) in the title for “when designating inspection bodies to be notified” substitute “when designating approved bodies”;

[ in Section 1 for “authorized representative” substitute “UK responsible person”];  
F535(aa)

(b) in Section 3 omit the words “and for which it has been notified”;

(c) in Section 6 omit from “unless liability” to the end;

(d) in Section 7 omit from “(except *vis-à-vis*” to the end.

**Textual Amendments**

**F535** Sch. 2A para. 9(aa) inserted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 21\(e\)](#)

**10.** Omit Annex 9.

## PART 2

### Modification of Annexes to Directive 93/42

**11.—**(1) The Annexes to Directive 93/42 are modified so that they read as if amended by paragraphs 12 to 23.

(2) In this Part any reference to “the Regulations” is a reference to the Medical Devices Regulations 2002.

**12.** In Annex I—

(a) in Section 3, for “Article 1(2)(a)” substitute “regulation 2(1) of the Regulations”;

(b) in Section 7, for “notified body” each time it occurs substitute “approved body”;

(c) for Section 7.4, substitute—

“**7.4.** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to [Directive 2001/83/EC](#) as modified by the Human Medicines Regulations 2012.

For the substances referred to in the first paragraph, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical

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benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body must be informed of the changes and must consult the Secretary of State in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State must take account of the data related to the usefulness of incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the Secretary of State has obtained information on an ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, the Secretary of State must provide the approved body with advice on whether this information has any impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The approved body must take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.”;

- (d) in Section 7.5—
  - (i) for the reference to “Annex 1 to Council [Directive 67/548/EEC](#) of 27 June 1967”, substitute “Regulation [\(EC\) No. 1272/2008](#)”;
  - (ii) for the reference to “Annex 1 to Council [Directive 67/548/EEC](#)”, substitute “the UK mandatory classification and labelling list established and maintained in accordance with Article 38A of Regulation 1272/2008”;
- (e) in Section 10.3 for “the provisions of Council [Directive 80/181/EEC](#)” substitute “the Units of Measurement Regulations 1986”;
- (f) in Section 13.3—
  - (i) in point (a) —
    - (aa) for the first two references to “the Community” substitute “Great Britain”;
    - (bb) for the third reference to “the Community” substitute “the United Kingdom”;
    - (cc) for “the authorised representative” substitute “the UK responsible person (where appointed in accordance with regulation 7A of the Regulations)”;
  - (ii) in point (f) omit the second sentence;
  - (iii) in point (n) omit “in the case of a device within the meaning of Article 1(4a)”.

### 13. In Annex II—

- (a) in the title omit “EC”;
- (b) for each reference to “the notified body” substitute “the approved body”;
- (c) in Section 1 omit “Community”;
- (d) in Section 2—
  - (i) omit “EC”;
  - (ii) for “this Directive” substitute “the Regulations”;
  - (iii) for “CE marking” substitute “UK marking”;
  - (iv) omit the words “in accordance with Article 17”;

- [ in Section 3.1—



**Status:** Point in time view as at 21/03/2024.

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- <sup>F536</sup>(da) (i) in the first sentence, for “a notified body” substitute “an approved body”;  
(ii) for “other notified body” substitute “other approved body”;  
(iii) for “the competent authorities” substitute “the Secretary of State”];
- (e) in Section 3.2—  
(i) in the first paragraph for “this Directive” substitute “the Regulations”  
(ii) in point (c)—  
(aa) for “Article 5” substitute “regulation 3A of the Regulations”;  
(bb) for “Commission Directive 2003/32/EC” substitute “Commission Regulation 722/2012”;
- (f) for Section 3.3 substitute—

**“3.3.** The approved body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product concerned, an inspection on the manufacturer’s premises and, in duly substantiated cases, on the premises of the manufacturer’s suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.”.

- (g) for Section 3.4 substitute—  
**“3.4.** The manufacturer must inform the approved body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The approved body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.”;
- (h) in Section 4.2, for “this Directive” substitute “the Regulations”;
- (i) for Section 4.3 substitute—

**“4.3.** The approved body must examine the application and, where the product complies with the relevant provisions of the Regulations, must issue the applicant with a design certificate. The approved body may require the application to be supplemented by further tests or proof so that compliance with the requirement of the Regulations may be evaluated. The certificate must contain conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

**Status:** Point in time view as at 21/03/2024.

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In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State’s decision is unfavorable. It must convey its final decision to the Secretary of State.”;

- (j) in Section 4.4, omit each reference to “EC”;
- (k) in Section 6.1—
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) for “national authorities” substitute “Secretary of State”;
- (l) in Section 7.1 for “Article 11(2) and (3)” substitute “regulation 13(2) and (3) of the Regulations”;
- (m) in Section 7.2 omit “for compliance with the provisions of this Directive”;
- (n) in Section 7.3 omit “for compliance with the provisions of this Directive”;
- (o) in Section 7.4 —
  - (i) for “this Directive” substitute “the Regulations”;
  - (ii) for “the competent authority” substitute “the Secretary of State”;
- (p) for Section 8, substitute—

**“8. Application to the devices incorporating a human blood derivative**

Upon completing the manufacture of each batch of devices incorporating a human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

**Textual Amendments**

**F536** Sch. 2A para. 13(da) inserted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 21\(f\)\(i\)](#)

**14. In Annex III—**

- (a) for each reference to “EC type-examination” (including in the title), substitute “type-examination”;
- (b) in Section 1—
  - (i) for “a notified body” substitute “an approved body”;
  - (ii) for “this Directive” substitute “the Regulations”;
- (c) in Section 2—
  - (i) in the first indent,—
    - (aa) for “authorized representative” substitute “UK responsible person” ;
    - (bb) for “the representative” substitute “the UK responsible person”;
  - (ii) in the second indent, for the second and third sentences substitute—
 

“The applicant must provide samples at the request of the approved body.”;

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- (iii) in the third indent, for “notified” substitute “approved”;
  - (d) in Section 3—
    - (i) for each reference to “Article 5” substitute “regulation 3A of these Regulations”;
    - (ii) for “[Directive 2003/32/EC](#)” substitute “Commission Regulation 722/2012”;
  - (e) for Sections 4 and 5 substitute—
    - “4. The approved body must—
      - 4.1. examine and assess the documentation, verify that the type has been manufactured in accordance with that documentation; it must also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 3A of the Regulations, as well as the items for which the design is not based on the relevant provisions of the said standards;
      - 4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of the Regulations where the standards referred to in regulation 3A of the Regulations have not been applied; if the device is to be connected to another device or other devices in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device having the characteristics specified by the manufacturer;
      - 4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
      - 4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.
    - 5. Where the type meets the provisions of the Regulations, the approved body must issue a type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the approved body.
- In the case of devices referred to in Annex I, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body must give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.
- In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State’s decision is unfavorable. It must convey its final decision to the Secretary of State.
- In the case of devices manufactured utilizing tissues of animal origin referred to in Commission Regulation 722/2012, the approved body must follow the procedures referred to in that Regulation.”;

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- (f) in Section 6—
  - (i) for each reference to “notified body” substitute “approved body”;
  - (ii) omit each reference to “EC”;
- (g) for Section 7.2 substitute—
 

“7.2. An approved body must cooperate with other approved bodies with regard to making available copies of the type-examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.”.
- (h) in Section 7.3 —
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) omit “EC”.

**15. In Annex IV—**

- (a) omit “EC” (including in the title) each time it occurs;
- (b) for both references to “this Directive” substitute “the Regulations”;
- (c) for each reference to “the Directive” substitute “the Regulations”;
- (d) in Section 1 for “authorized representative” substitute “UK responsible person”;
- (e) in Section 2—
  - (i) for “CE marking” substitute “UK marking”;
  - (ii) for “Article 17” substitute “regulation 10 of the Regulations”;
- (f) in Section 3 for “competent authorities” substitute “Secretary of State”;
- (g) for Sections 4 to 6 substitute—

“4. The approved body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Regulations either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

**5. Verification by examination and testing of every product**

**5.1.** Every product must be examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them.

**5.2.** The approved body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

**6. Statistical verification**

**6.1.** The manufacturer must present the manufactured products in the form of homogeneous batches.

**6.2.** A random sample must be taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in

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the type-examination certificate and with the requirements of the Regulations which apply to them in order to determine whether to accept or reject the batch.

**6.3.** Statistical control of products will be based on attributes and/or variables entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the designated standards referred to in regulation 3A of the Regulations, taking account of the specific nature of the product categories in question.

**6.4.** If the batch is accepted, the approved body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the approved body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the approved body may suspend the statistical verification.

The manufacturer may, on the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.”;

(h) in Section 7—

(i) for “authorised representative” substitute “UK responsible person”;

(ii) for “national authorities” substitute “Secretary of State”;

(i) in Section 8, in the opening paragraph, for “Article 11(2)” substitute “regulation 13(2) of the Regulations”;

[ in Section 8.2 for “notified body” substitute “approved body”];

<sup>F537</sup>(zj)

(j) in Section 9—

(i) for the words “referred to in Article 1(4a)” substitute “which incorporate a substance derived from human blood or human plasma”;

[ for “notified body” substitute “approved body”];

<sup>F538</sup>(ia)

(ii) for the words from “a State laboratory” to the end of that Section, substitute “a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012”.

#### Textual Amendments

**F537** Sch. 2A para. 15(zj) inserted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 21(g)(i)**

**F538** Sch. 2A para. 15(j)(ia) inserted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), **Sch. 1 para. 21(g)(ii)**

**16.** In Annex V—

(a) for “notified body” each time it occurs substitute “approved body”;

(b) omit “EC” each time it occurs, including in the title;

(c) in Section 1, omit “Community”;

(d) in Section 2—

(i) for “this Directive” substitute “the Regulations”;

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- (ii) for “CE marking in accordance with Article 17” substitute “UK marking”;
- (e) in the eighth indent of Section 3.1, for “competent authorities” substitute “Secretary of State”;
- (f) in Section 3.3, for the first sentence substitute—
 

“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2.”;
- (g) in Section 3.4, for the last two paragraphs substitute—
 

“The proposed changes must be evaluated by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”;
- (h) in Section 5.1—
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) for “national authorities” substitute “Secretary of State”;
- (i) in Section 6 for each reference to “this Directive” substitute “the Regulations”;
- (j) in Section 6.3, for “competent authority” substitute “Secretary of State”;
- (k) in Section 7—
  - (i) for the words “referred to in Article 1(4a)” substitute “which incorporate a substance derived from human blood or human plasma”;
  - (ii) for the words from “a State laboratory” to the end of that Section, substitute “a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

**17. In Annex VI—**

- (a) omit “EC” each time it occurs including in the title;
- (b) for “the notified body” each time it occurs substitute “the approved body”;
- (c) for “this Directive” each time it occurs substitute “the Regulations”;
- (d) in Section 2—
  - (i) for “CE marking in accordance with Article 17” substitute “UK marking”;
  - (ii) for “CE marking must” substitute “UK marking must”;
- (e) in Section 3.1, for—
  - (i) “a notified body” substitute “an approved body”;
  - (ii) “other notified body” substitute “other approved body”;
  - [ for “competent authorities” substitute “Secretary of State”];
- <sup>F539</sup>(iii)
- (f) in Section 3.3, for the first sentence substitute—
 

“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2.”;
- (g) in Section 3.4, for the second paragraph substitute—
 

“The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”;
- [ in Section 4.4 for “Article 5” substitute “regulation 3A of the Regulations”];

<sup>F540</sup>(ga)

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- (h) in Section 5.1—
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) for “national authorities” substitute “Secretary of State”;
- (i) in Section 6, in the opening paragraph, for “Article 11(2)” substitute “regulation 13(2) of the Regulations”;
- (j) in Section 6.3, for “competent authority” substitute “Secretary of State”.  
[ in Section 6.4 for “notified body” substitute “approved body”.]
- <sup>F541</sup>(k)

#### Textual Amendments

- F539** Sch. 2A para. 17(e)(iii) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(h)(i)**
- F540** Sch. 2A para. 17(ga) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(h)(ii)**
- F541** Sch. 2A para. 17(k) inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 21(h)(iii)**

#### 18. In Annex VII—

- (a) in the title and in Section 1, omit “EC”;
- (b) in Section 1—
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) for “this Directive” substitute “the Regulations”;
- (c) in Section 2 for—
  - (i) “his authorised representative” substitute “the manufacturer’s UK responsible person”;
  - (ii) “national authorities” substitute “Secretary of State”;
- (d) in Section 3—
  - (i) in the opening paragraph for “the Directive” substitute “the Regulations”;
  - (ii) in the fourth indent—
    - (aa) for “Article 5” in both places it occurs substitute “regulation 3A of the Regulations”;
    - (bb) for “of the Directive” substitute “in Annex I”;
- (e) in Section 4, for “competent authorities” substitute “Secretary of State”;
- (f) in Section 5, for “the intervention by the notified body” substitute “the intervention by the approved body”;
- (g) in Section 6, in the opening paragraph, for “Article 11(2)” substitute “regulation 13(2) of the Regulations”.

#### 19. In Annex VIII—

- (a) in Section 1, for “authorized representative” substitute “UK responsible person”;
- (b) in Section 2.2 in the seventh indent for “[Directive 2003/32/EC](#)” substitute “Regulation 722/2012”;
- (c) in Section 3, for “competent national authorities” substitute “Secretary of State”;

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- (d) in Sections 3.1 and 3.2, for “this Directive” each time it occurs substitute “the Regulations”;
  - (e) in Section 3.2—
    - (i) in the fourth indent, for “Article 5” in both places it occurs substitute “regulation 3A of the Regulations”;
    - (ii) in the sixth indent, for “[Directive 2003/32/EC](#)” substitute “Regulation 722/2012”;
  - (f) in Section 5, for “competent authorities” substitute “Secretary of State”.
- 20.** In Annex IX for “this Directive” each time it occurs substitute “the Regulations”.
- 21.** In Annex X—
- (a) in Section 1.1 for “harmonised standards” substitute “designated standards”;
  - (b) in Section 2.3.5 for the words from “all competent authorities of the Member States” to the end substitute “the Secretary of State”.
- 22.** In Annex XI—
- (a) in the title, for “notified bodies” substitute “approved bodies”;
  - (b) for the words “notified body” each time they occur substitute “approved body”;
  - (c) for each reference to “the Directive” substitute “the Regulations”;
  - (d) in Section 2, for “national authorities” substitute [<sup>F542</sup>“Secretary of State”];
  - (e) in Section 3, for “this Directive” substitute “the Regulations”;
  - (f) in Section 6, omit the words from “, unless liability” to the end of that Section;
  - (g) in Section 7, omit the words from “(except *vis a vis* the competent administrative authorities” to the end.

#### Textual Amendments

**F542** Words in [Sch. 2A para. 22\(d\)](#) substituted (11.8.2021) by [The Medical Devices \(Amendment\) \(EU Exit\) Regulations 2021 \(S.I. 2021/873\)](#), reg. 1(1), [Sch. 1 para. 21\(i\)](#)

- 23.** Omit Annex XII.

## PART 3

### Modification of Annexes to Directive 98/79

**24.**—(1) The Annexes to Directive 98/79 are modified so that they read as if amended by paragraphs 25 to 33.

(2) In this Part any reference to “the Regulations” is a reference to the Medical Devices Regulations 2002.

- 25.** In Annex 1—
- (a) in Section 3 in part A, for “Article 1(2)(b)” substitute “regulation 2(1) of the Regulations”;
  - (b) in Section 4.2 in part B, for “Council [Directive 80/181/EEC](#) of 20th December 1979” substitute “the Units of Measurement Regulations 1986”;
  - (c) in Section 8.1 in part B, omit the words from “The decision whether” to the end;
  - (d) in Section 8.2 in part B, for “harmonised standards” substitute “designated standards”;



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- (e) in Section 8.3 in part B —
    - (i) in the first sentence omit “of [Directive 67/548/EEC](#) and [Directive 88/379/EEC](#)”;
    - (ii) in the second sentence omit “by those Directives”;
    - (iii) omit the words from “The provisions of” to the end;
  - (f) in Section 8.4 in point (a), for the sentence beginning “For devices imported”, substitute—  
“Where the manufacturer does not have a registered place of business in the United Kingdom the label, the outer packaging or instructions for use shall contain in addition the name and address of the UK responsible person.”.
- 26.** In Annex III—
- (a) in the title and in Section 1, omit “EC”;
  - (b) in Section 1—
    - (i) for “authorised representative” substitute “UK responsible person”;
    - (ii) for “this Directive” substitute “the Regulations”;
    - (iii) for “CE marking in accordance with Article 16” substitute “UK marking in accordance with regulation 36 of the Regulations”;
  - (c) in Section 3, for “the Directive” in both places substitute “the Regulations”;
  - (d) in Section 3, in the sixth indent, for “Article 5” in both places substitute “regulation 3A of the Regulations”;
  - (e) in Section 5, for “competent authorities” substitute “Secretary of State”;
  - (f) in Section 6, for “a notified body” substitute “an approved body”;
  - (g) in Section 6.2—
    - (i) for “notified body”, both times those words occur, substitute “approved body”;
    - (ii) in the first sentence, for “this Directive” substitute “the Regulations”;
    - (iii) in the second sentence omit “of the Directive”;
    - (iv) for “an EC” substitute “a” ;
  - (h) in Section 6.3—
    - (i) for “notified body” in both places substitute “approved body”;
    - (ii) omit each reference to “EC”;
    - (iii) for “the Directive” substitute “the Regulations”.
- 27.** In Annex IV—
- (a) in the title, omit “EC”;
  - (b) for each reference to “this Directive” and “the Directive” substitute “the Regulations”;
  - (c) in Section 2, for “CE marking” substitute “UK marking”;
  - (d) in Section 3.1—
    - (i) for “of his quality system with a notified body” substitute “of its quality system with an approved body”;
    - (ii) in the third indent for “notified body” substitute “approved body”;
  - (e) in Section 3.3 for the first paragraph substitute—  
“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to the requirements.”;

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- (f) in Section 3.4, in both paragraphs, for “notified body” substitute “approved body”;
  - (g) in Section 4.1 for “notified body” substitute “approved body”;
  - (h) in Section 4.3—
    - (i) for “notified body” both times those words occur substitute “approved body”;
    - (ii) for “an EC” substitute “a”;
  - (i) in Section 4.4—
    - (i) for “notified body” both times those words occur substitute “approved body”;
    - (ii) omit each reference to “EC”;
  - (j) in Section 4.5, for “notified body” both times those words occur substitute “approved body”;
  - (k) in Sections 5 and 6 for “notified body” each time those words occur substitute “approved body”.
- 28.** In Annex V—
- (a) in the title, omit “EC” ;
  - (b) in Section 1—
    - (i) for “EC type-examination” substitute “Type-examination”;
    - (ii) for “a notified body” substitute “an approved body”;
    - (iii) for “this Directive” substitute “the Regulations”;
  - (c) in Section 2—
    - (i) in the first paragraph—
      - (aa ) omit “EC”;
      - (bb) for “his authorised representative” substitute “its UK responsible person”;
      - (cc) for “a notified body” substitute “an approved body”;
    - (ii) in the first indent—
      - (aa) for “authorised representative” substitute “UK responsible person”;
      - (bb) for “the representative” substitute “the UK responsible person”;
    - (iii) in the second indent for “this Directive” substitute “the Regulations”;
    - (iv) in the second and third indents for “notified body” each time those words occur substitute “approved body”;
  - (d) in Section 4—
    - (i) for “notified body shall” substitute “approved body must”;
    - (ii) for both references to “Article 5” substitute “regulation 3A of the Regulations”;
    - (iii) for “this Directive” substitute “the Regulations”;
  - (e) in Section 5—
    - (i) for “this Directive” substitute “the Regulations”;
    - (ii) for “notified body” in both places substitute “approved body”;
    - (iii) for “an EC” substitute “a”;
  - (f) in Section 6—
    - (i) for “notified body” each time it occurs substitute “approved body”;
    - (ii) omit “EC” each time it occurs;

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- (iii) for “the Directive” substitute “the Regulations”;
- (g) for Section 7, substitute—
  - “7. An approved body must cooperate with other approved bodies with regard to making available copies of the type-examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.”.
- 29.** In Annex VI—
  - (a) in the title omit “EC”;
  - (b) in Section 1—
    - (i) for “EC verification” substitute “Verification”;
    - (ii) for “authorised representative” substitute “UK responsible person”;
    - (iii) for “EC type-examination” substitute “type-examination”;
    - (iv) for “this Directive” substitute “the Regulations”;
  - (c) in Section 2.1—
    - (i) for “EC type-examination” in both places substitute “type-examination”;
    - (ii) for “the Directive” substitute “the Regulations”;
    - (iii) for “this Directive” substitute “the Regulations”;
  - (d) in Section 2.2 for “notified body” substitute “approved body”;
  - (e) in Section 4—
    - (i) for “notified body” in both places substitute “approved body”;
    - (ii) for “the Directive” substitute “the Regulations”;
  - (f) in Section 5.1—
    - (i) for “Article 5” substitute “regulation 3A of the Regulations”;
    - (ii) omit “EC”;
    - (iii) for “the Directive” substitute “the Regulations”;
  - (g) in Section 5.2 for “notified body” substitute “approved body”;
  - (h) in Section 6.2—
    - (i) for “Article 5” substitute “regulation 3A of the Regulations”;
    - (ii) omit “EC”;
    - (iii) for “the Directive” substitute “the Regulations”;
  - (i) in Section 6.3 for “the harmonised standards referred to in Article 5” substitute “the designated standards referred to in regulation 3A of the Regulations”;
  - (j) in Section 6.4—
    - (i) for the first two paragraphs, substitute—
      - “Where the approved body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.”;
    - (ii) in the third paragraph, for “notified body”, in both places, substitute “approved body”.
- 30.** In Annex VII—
  - (a) in the title and in Section 2, omit “EC”;

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- (b) in Section 2—
    - (i) for “this Directive” substitute “the Regulations”;
    - (ii) for “CE marking in accordance with Article 16” substitute “UK marking in accordance with regulation 36 of the Regulations”;
  - (c) in Section 3.1—
    - (i) for “a notified body” substitute “an approved body”;
    - (ii) for “EC type-examination” substitute “type-examination”;
  - (d) in Section 3.2, for “EC type-examination” substitute “type-examination”;
  - (e) in Section 3.3 for the first two sentences substitute—
 

“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. The approved body must presume that quality systems which implement the relevant designated standards conform to the requirements.”;
  - (f) in Section 3.4—
    - (i) for “notified body” substitute “approved body”;
    - (ii) for the first sentence of the second paragraph substitute “The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would meet the requirements referred to in Section 3.2.”;
  - (g) in Sections 5.1 and 5.2, for each reference to “notified body” substitute “approved body”.
- 31. In Annex VIII—**
- (a) in Section 1—
    - (i) for “authorised representative” substitute “UK responsible person”;
    - (ii) for “this Directive” substitute “the Regulations”;
  - (b) in Section 2, for “the Directive” substitute “the Regulations”;
  - (c) in Section 3—
    - (i) for “competent national authorities” substitute “Secretary of State”;
    - (ii) for “this Directive” substitute “the Regulations”.
- 32. In Annex IX—**
- (a) in the title, for “notified bodies” substitute “approved bodies”;
  - (b) for each reference to “notified body” substitute “approved body”;
  - (c) in Section 1, for “authorised representative” substitute “UK responsible person”;
  - (d) in Section 2—
    - (i) for “the Directive” substitute “the Regulations”;
    - (ii) for “national authorities” substitute “Secretary of State”;
    - (iii) for “this Directive” substitute “the Regulations”;
  - (e) in Section 3—
    - (i) for “has been notified” substitute “has been designated”;
    - (ii) for “this Directive” substitute “the Regulations”;
  - (f) in Section 6, omit the words from “unless liability” to the end;
  - (g) in Section 7, omit the words from “(except *vis à vis* the competent administrative authorities” to the end.

### 33. Omit Annex X.]

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations contain the legislative measures necessary for the implementation of three European Community Directives: Council Directive [90/385/EEC](#) on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; Council Directive [93/42/EEC](#) concerning medical devices, as amended; and Directive [98/79/EC](#) of the European Parliament and of the Council *on in vitro* diagnostic medical devices (“the Medical Devices Directives”). They also contain the legislative measures necessary for the implementation, in relation to medical devices, of the agreements on mutual recognition between the European Community and Australia, New Zealand, Canada and the United States of America—and of the Association Agreement between the European Communities, and their Member States, and Hungary.

Part I contains introductory provisions. These include an interpretation provision (regulation 2), and provisions both limiting the scope of the application of the Regulations so that they only apply to products covered by the Medical Devices Directives (regulation 3) and delaying the application of provisions of the Regulations in relation to specific categories of medical devices, to take account of the transitional arrangements in the Medical Devices Directives (regulation 4).

Part II deals with the marketing of medical devices generally, but not with active implantable medical devices or *in vitro* diagnostic medical devices. Medical devices covered by this Part must generally meet the essential requirements set out in Annex I to Directive [93/42/EEC](#) (regulations 8 and 9), and must be CE-marked according to the conformity assessment procedures set out in that Directive (regulations 10 and 13). There are exemptions for certain products (regulation 12), and special arrangements for products covered by more than one European Community Directive (regulation 11). There are also specific arrangements for systems and procedure packs, custom-made devices and devices intended for clinical investigations (regulations 14 to 16). Arising out of the conformity assessment procedures, there are specific obligations placed on manufacturers of devices or their authorised representatives (regulation 17), and on the notified bodies involved in carrying out assessments in respect of devices (regulation 18). Manufacturers of certain medical devices, or their authorised representatives, must register with the Secretary of State (regulation 19).

Part III deals with active implantable medical devices. Again, these can only be marketed if they meet specified essential requirements, set out in Directive [90/385/EEC](#) (regulations 22 and 23), and are assessed under conformity assessment procedures (regulations 24 and 27). There are special arrangements for devices that come under more than one European Community Directive (regulation 25), and some exemptions from the scheme (regulation 26). Again, there are different procedures for custom-made devices and devices for clinical investigation (regulations 28 and 29). Specific obligations are imposed on manufacturers or their authorised representatives (regulation 30), and on notified bodies carrying out assessments in respect of the devices (regulation 31).

Part IV deals with *in vitro* diagnostic medical devices. These also must conform to the essential requirements set out in Directive [98/79/EC](#) (regulations 33 and 34), and must be CE-marked according to one of the conformity assessment procedures set out in the Directive (regulations 36 and 40). There are again exemptions (regulation 39), and special arrangements for products caught by more than one European Community Directive (regulation 37). There are also special

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arrangements for devices for performance evaluation (regulation 43). Manufacturers or their authorised representatives have specific obligations relating to the conformity assessment procedures (regulation 41), and generally have to register (regulation 44). Notified bodies also have specific obligations relating to the conformity assessment procedures (regulation 42). Part V contains general provisions relating to the designation of notified bodies within the United Kingdom (regulation 45). Companies may apply to any European Community notified body or third country conformity assessment body (the equivalent body under a Mutual Recognition Agreement) to carry out tasks under a conformity assessment procedure, if the task is within the framework of tasks that the body is designated to carry out (regulation 46). There are also provisions for designating conformity assessment bodies to carry out conformity assessment work for other Parties to Mutual Recognition Agreements (regulation 48). This Part also contains prohibitions on marking products with CE marks or with notified body or conformity assessment body numbers if they are not entitled to bear those markings (regulations 50 and 51). Part VI sets out the fees charged by the Secretary of State in relation to work done pursuant to the Regulations. These include charges in connection with the registration of devices and changes to registration details (regulation 53), charges to UK notified bodies and EC Conformity Assessment Bodies (regulations 54 and 55), and fees payable in connection with clinical investigation notices (regulation 56). There are also arrangements for unpaid fees, waivers, reductions and refunds (regulations 57 and 58). Part VII includes general matters, including the provisions relating to designation of authorised representatives and enforcement (regulations 60 to 64), and requirements to keep a centralised system of records (regulation 65). This Part also contains revocations of provisions that are superseded as a result of the coming into force of these Regulations (regulation 66). A Regulatory Impact Appraisal and a Transposition Note in relation to the implementation of Directives [2000/70/EC](#) and [2001/104/EC](#) (the two most recent Directives amending Council Directive [93/42/EEC](#)), have been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.

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