STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

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

[F1 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**

[F2 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) [F3]... in these Regulations[F4]...—

[F5]...

"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]...

[[F7]"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]...

[[F11]"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;**]**

[[F12]"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);**]**

[[F13]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;

[[F14]"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 **[**[F15]as it had effect immediately before IP completion day**];]**

[[F16]"Directive 93/42" means Council Directive 93/42/EEC of 14 June 1993 concerning medical devices **[**[F17]as it had effect immediately before IP completion day**];]**

[[F18]"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 **[**[F19]as it had effect immediately before IP completion day**];]**

[F20]...

[F21‘‘“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…

[F23‘‘“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;**]**

[F24‘‘“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;**]**

F25…

‘‘F26... CAB” shall be construed in accordance with regulation 48(1);

F27…

F28…

F29…

[F30‘‘“hazard” means a potential source of injury or damage to health;**]**

[F31‘‘“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);**]**

[F32‘‘“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 **[**F33Great 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;

[F34‘‘machinery” has the meaning given to it by **[**F35regulation 4 of the Supply of Machinery (Safety) Regulations 2008**]**;**]**

“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;

“medical device” means **[**F36any 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, **[**F37both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012**]** and Directive 98/79;

F38…

“medicinal product” has the meaning given in **[**F39regulation 2(1) of the Human Medicines Regulations 2012**]**;

[F40‘‘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 **[**F41that country**]** will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies;**]**

F42 …

F43 …

F44 …

"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 **[**F45Great Britain**]** market **[**F46and related expressions must be construed accordingly**]**;

"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 **[**F47Great Britain**]** to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

[F48"Regulation (EU) No 207/2012" means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices;**[**F49(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; **[**F50(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)**]]**

[F51"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;**]**

[F51"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;**]**

"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 **[**F52regulation 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;

[F53"*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

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

[F54"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;**]**

F55...

[F56"UK marking" has the meaning given in Article 2(22) of Regulation (EC) No 765/2008;**]** and

F57...

[F58"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.**]**

[F59(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 **[**F60as they applied immediately before IP completion day and as modified by Schedule 2A.**]]**

[F61(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)

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)

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**

F52 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)

F53 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**

F54 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)

F55 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)**

F56 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)**

F57 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)**

F58 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)

F59 Reg. 2(1A) inserted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(b)**

F60 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)

F61 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[F98]...—

[F5]...

"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;

[F99]...

"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;

[F100"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 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 **[**F101European Union**]**;

(b) in the context of any requirement relating to any other medical device, the European Economic Area;

[F102"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;**]**

[F12"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;

[F103"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;**]**

[F104"Directive 93/42" means Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;**]**

[F105"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 **F106[F107**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**]**;

[F108"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;**]**

F109...

[F110"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;**]**

[F111"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;**]**

"F112... CAB" shall be construed in accordance with regulation 48(1);

F113...

[F114"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 F115, 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 **[**F101European Union**]**;

[F116"hazard" means a potential source of injury or damage to health;**]**

[F117"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);**]**

[F118"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 **[**F119relevant 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;

[F120"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;

[F121"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, **[**F122both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012**]** and Directive 98/79;

F123...

"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 **[**F124a relevant state**]** which transposes, and corresponds to, a harmonised standard;

F125...

"notified body" means a body authorised in accordance with **[**F126Part 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

intended for clinical investigation, with a view to distribution, use, or both, on **[**F127a 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 **[**F128a 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;

[F129"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;**]**

[F130"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;**]**

"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;

[F131"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—

(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;

F132 ...

[F131"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

[F131"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.**]**

[F133(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.**]**

[F134(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

E3 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**

F98 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)**

F99 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)**

F100 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)**

F101 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))

F102 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)**

F103 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)**

F104 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)**

F105 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)**

F106 OJ No. L 311, 28.11.2001, p.67.

F107 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**

F108 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)**

F109 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)**

F110 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)**

F111 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)**

F112 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)**

F113 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)**

F114 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)**

F115 OJ No. L 204, 21.7.1998, p.37; amended by Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).

F116 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)**

F117 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)**

F118 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)**

F119 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)**

F120 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)**

F121 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)**

F122 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)**

F123 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)**

F124 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)**

F125 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)**

F126 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)**

F127 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)**

F128 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)**

F129 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)**

F130 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)**

F131 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)**

F132 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)**

F133 Reg. 2(1A) inserted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(b)**

F134 Reg. 2(1B) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(6)**

[F62Medical devices which are qualifying Northern Ireland goods

2A.—(1) 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—

(a) which meets the requirements of these Regulations as they apply in Northern Ireland **[**F63or of Regulation (EU) 2017/745**]**; 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.

(2) In this regulation,

[F64(a)**]** "qualifying Northern Ireland good" has the meaning given in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

[F65(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.**]]**

Textual Amendments

F62 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)**

F63 Words in reg. 2A(1)(a) inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **31(a)**

F64 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)**

F65 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 **[**F66the Human Medicines Regulations 2012**]** (including medicinal products derived from human blood or human plasma F67...);

(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 **[**F68—

(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 **[**F69, except for F70..., *in vitro* diagnostic medical devices and accessories to such devices**][**F71save where medicinal products are incorporated as ancillary to the device**]**;

[F72(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 F73... an *in vitro* diagnostic medical device, or an accessory to such a device;**]**

(f) cosmetic products governed by **[**F74Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products;**]** or

F75(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

Textual Amendments

F66 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)

F67 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)

F68 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)**

F69 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)**

F70 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)**

F71 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)**

F72 Reg. 3(e) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), **3(c)**

F73 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)**

F74 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)

F75 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 **[**F135—

(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 **[**F136, except for F137..., *in vitro* diagnostic medical devices and accessories to such devices**][**F138save where medicinal products are incorporated as ancillary to the device**]**;

[F139(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 F140... an *in vitro* diagnostic medical device, or an accessory to such a device;**]**

(f) cosmetic products governed by Council Directive 76/768/EECF141, as amended F142; or

F143(g) . . . . . .

Extent Information

E4 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

F135 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)**

F136 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)**

F137 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)**

F138 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)**

F139 Reg. 3(e) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), **3(c)**

F140 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)**

F141 OJ No. L 262, 27.9.1976, p.169.

F142 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).

F143 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)**

[F76Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745

3ZA.—(1) Subject to paragraph (2)—

(a) Parts 2 and 3 only apply in Northern Ireland for the purposes of regulating qualifying devices.

(b) Parts 5 to 7 only apply in Northern Ireland for the purposes of regulating qualifying devices and devices within the scope of Part 4.

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph whether or not the device to which they apply is referred to in paragraph (1)—

(a) for the purposes of registration of medical 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), and

(iii) regulation 53 (fees in connection with the registration of devices and changes to registration details),

apply until the date which is 6 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745.

(b) Parts 5 to 7 apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) For the purposes of paragraph (1), a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of Directive 93/42 or Directive 90/385, rather than Regulation (EU) 2017/745; 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, 3 and 5 to 7.**]**

Textual Amendments

F76 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**

[F77Designated 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 **[F78**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—

(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).

[
F79(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 **[**F80such**]** technical specifications adopted by the other recognised standardisation bodies **[**F81or 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

F77 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)**

F78 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)

F79 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)

F80 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)

F81 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

[F82 3B. . . . . . .**]**

Textual Amendments

F77 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)**

F82 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 [M1].

(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) an*in 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) an*in 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.

[[F83](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

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

[F84(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

F83 Reg. 4(5) inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **3(a)**

F84 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

M1 S.I. 1993/2360.

[F85Transitional 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

(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

F85 Reg. 4A inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **4**

[F86Revocations, 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).

(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

F86 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 [F87]... is revoked on 26th May 2025.

[F88](2) . . . . . .

Textual Amendments

F86 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)

F87 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)**

F88 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

F86 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)

[F89Revocation 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

F89 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**

[F90Revocation of Regulation (EU) No 722/2012 on 26th May 2025

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

Textual Amendments

F90 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 **[**F91approved**]** 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.

F92(4) . . . . . .

F93(5) . . . . . .

Textual Amendments

F86 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)

F91 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)**

F92 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)**

F93 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

F86 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

F94**4N.** . . . . . .

Textual Amendments

F94 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

F86 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

F86 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.—(1) In section 1(12)(a) of the Human Tissue Act 2004 (authorisation of activities for scheduled purposes), the references to Directive 98/79 are to be construed, to the extent necessary for the practical application of that section, as references also or instead to Part IV.

(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

F95(b) . . . . . .

F96[(c) the reference to the expression "Directive 93/42/EEC" is to be construed, to the extent 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

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 **F97**...;

(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

F86 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)

F95 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)**

F96 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)**

F97 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)**

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medical Devices Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 8 inserted by S.I. 2019/791 reg. 10 (This amendment not applied to legislation.gov.uk. Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)
- Pt. 9 inserted by S.I. 2019/791 reg. 11 (This amendment not applied to legislation.gov.uk. Reg. 11 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 55)
- Sch. 3 inserted by 2021 c. 3 Sch. 3 para. 2
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(2)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(2)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) heading words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by S.I. 2019/1385 Sch. 2 para. 11(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 2A(1A) inserted by S.I. 2024/221 reg. 11(b)
- reg. 3ZA(2)(a)(aa) substituted for reg. 3ZA(2)(a) by S.I. 2024/221 reg. 12(c)(ii)
- reg. 4D(10)(b) substituted by S.I. 2019/791, reg. 3(7) (as amended) by S.I. 2019/1385 Sch. 2 para. 2(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 4E(7) words substituted by S.I. 2019/791, reg. 3(7) (as amended) by S.I. 2019/1385 Sch. 2 para. 2(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 6(d) inserted by S.I. 2019/791 reg. 4(2) (This amendment not applied to legislation.gov.uk. Reg. 4(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 10)
- reg. 33(1)(c) inserted by S.I. 2019/791 reg. 6(2)(a) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 33(2)(c) inserted by S.I. 2019/791 reg. 6(2)(b) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 34D inserted by S.I. 2024/221 reg. 17
- reg. 60A excluded by 2021 c. 3 Sch. 2 para. 4
- reg. 60A excluded by 2021 c. 3 Sch. 2 para. 5(2)
- reg. 60A-60C inserted by 2021 c. 3 Sch. 3 para. 1

- reg. 75(3) words inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(2)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 75(7) inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(2)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 93(4) inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(3) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 119(6) words inserted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(4) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 124(5) words substituted by S.I. 2019/791, reg. 10 (as amended) by S.I. 2019/1385 Sch. 2 para. 9(5) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 149(5)(e) words substituted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(2) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(1) substituted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(3) inserted by S.I. 2019/791, reg. 11 (as amended) by S.I. 2019/1385 Sch. 2 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))