STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART I

Introductory Provisions Relating to all Medical Devices

Interpretation E+W+S

2.—(1) [F1]... in these Regulations[F2]...—

[F3]...

"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;

[F4]...

[[F5]"approved body" is to be construed in accordance with regulation A45;**]**

[F6]...

[F7]...

"CE marking" means a conformity marking consisting of the initials "CE";

[F8]...

[[F9]"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(c) published or unpublished reports on other clinical experiences of either the device in question or a similar device for which equivalence to the device in question can be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;**]**

[[F10]"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);**]**

[[F11]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;

[F12"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 **[**F13as it had effect immediately before IP completion day**];]**

[F14"Directive 93/42" means Council Directive 93/42/EEC of 14 June 1993 concerning medical devices **[**F15as it had effect immediately before IP completion day**];]**

[F16"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 **[**F17as it had effect immediately before IP completion day**];]**

F18…

[F19"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;**]**

F20…

[F21"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;**]**

[F22"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;**]**

F23…

"F24... CAB" shall be construed in accordance with regulation 48(1);

F25…

F26…

F27…

[F28"hazard" means a potential source of injury or damage to health;**]**

[F29"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);**]**

[F30"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 **[**F31Great 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;

[[F32]"machinery" has the meaning given to it by **[**[F33]regulation 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 **[**[F34]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, **[**F35both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012**]** and Directive 98/79;

F36...

"medicinal product" has the meaning given in **[**F37regulation 2(1) of the Human Medicines Regulations 2012**]**;

[F38"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 **[**F39that country**]** will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies;**]**

F40...

F41...

F42...

"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 **[**F43Great Britain**]** market **[**F44and 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 **[**F45Great Britain**]** to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

[F46"Regulation (EU) No 207/2012" means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices;**[**F47(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; **[**F48(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)**]]**

[F49"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;**]**

[F49"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 **[**F50regulation 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;

[F51"*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;

[F52"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;**]**

F53...

[F54"UK marking" has the meaning given in Article 2(22) of Regulation (EC) No 765/2008;**]** and

F55...

[F56"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.**]**

[F57(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 **[**F58as they applied immediately before IP completion day and as modified by Schedule 2A.**]]**

[F59(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

F1 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)**

F2 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)**

F3 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)

F4 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)**

F5 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)**

F6 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)

F7 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)**

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)(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)**

F9 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)**

F10 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**

F11 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)

F12 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)**

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)(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)

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)(ii)**

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)(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)

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)(iii)**

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)(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)

F18 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)

F19 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)**

F20 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)**

F21 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)**

F22 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)**

F23 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)

F24 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)

F25 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)**

F26 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)**

F27 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)

F28 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)**

F29 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)**

F30 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)**

F31 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)

F32 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)**

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)(m)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F34 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)**

F35 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)**

F36 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)**

F37 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)

F38 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)

F39 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)**

F40 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)

F41 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)**

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)(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)**

F43 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)

F44 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)

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)(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)

F46 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)**

F47 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)**

F48 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)**

F49 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**

F50 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)

F51 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**

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)(u)** (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) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(2)(e)**

F54 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)**

F55 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)**

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)(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)

F57 Reg. 2(1A) inserted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(b)**

F58 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)

F59 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[F60]...—

F3 …

"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;

F61 …

"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;

[F62"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 **[**F63European Union**]**;

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

[F64"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;**]**

[F10"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;

[F65"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;**]**

[F66"Directive 93/42" means Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;**]**

[F67“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 F68**[**F69as 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**]**;

[F70“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;**]**

F71…

[F72“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;**]**

[F73“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;**]**

“F74... CAB” shall be construed in accordance with regulation 48(1);

F75…

[F76“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 F77, 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 **[**F63European Union**]**;

[F78“hazard” means a potential source of injury or damage to health;**]**

[[F79]"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);**]**

[[F80]"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 **[**[F81]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;

[[F82]"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;

[[F83]"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, **[**F84both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012**]** and Directive 98/79;

F85...

"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 **[**F86a relevant state**]** which transposes, and corresponds to, a harmonised standard;

F87...

"notified body" means a body authorised in accordance with **[**F88Part 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 **[**F89a 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 **[**F90a 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;

[F91"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;**]**

[F92"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;

[F93"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;

F94…

[F93"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

[F93"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.**]**

[F95(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.**]**

[F96(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

E2 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

F3 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)

F10 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**

F60 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)**

F61 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)**

F62 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)**

F63 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))

F64 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)**

F65 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)**

F66 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)**

F67 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)**

F68 OJ No. L 311, 28.11.2001, p.67.

F69 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**

F70 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)**

F71 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)**

F72 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)**

F73 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)**

F74 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)**

F75 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)**

F76 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)**

F77 OJ No. L 204, 21.7.1998, p.37; amended by Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).

F78 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)**

F79 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)**

F80 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)**

F81 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)**

F82 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)**

F83 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)**

F84 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)**

F85 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)**

F86 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)**

F87 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)**

F88 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)**

F89 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)**

F90 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)**

F91 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)**

F92 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)**

F93 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)**

F94 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)**

F95 Reg. 2(1A) inserted (1.7.2012) by The Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426), regs. 1(1), **2(b)**

F96 Reg. 2(1B) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **2(6)**

Status:
There are multiple versions of this provision on screen. These apply to different geographical extents.
Skip to:

- E+W+S - England, Wales and Scotland extent
- N.I. - Northern Ireland extent

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 :

- reg. 2 words inserted by S.I. 2019/791 reg. 3(3)(q)(iii) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(q) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(j))
- reg. 2 words omitted by S.I. 2019/791 reg. 3(3)(q)(i) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(q) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(j))
- reg. 2 words substituted by S.I. 2019/791 reg. 3(3)(c)(i) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(c) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(b))
- reg. 2 words substituted by S.I. 2019/791 reg. 3(3)(c)(ii) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(c) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(b))
- reg. 2 words substituted by S.I. 2019/791 reg. 3(3)(q)(ii) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(q) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(j))
- reg. 2 words substituted by S.I. 2019/791 reg. 3(3)(v) (This amendment not applied to legislation.gov.uk. Reg. 3(3)(v) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 4(n))
- reg. 2(1) words inserted by S.I. 2024/221 reg. 9
- reg. 2(1) words inserted by S.I. 2024/221 reg. 10

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))