STATUTORY INSTRUMENTS

2019 No. 791

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

PART 1

Amendment of the 2002 Regulations

Amendment of Part 1 of the 2002 Regulations

3.—(1) Part 1 of the 2002 Regulations is amended as follows.

[F1(2) After regulation 1 (citation and commencement) insert—

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

1ZA. Regulations 19B, 19C, 30A, 44ZA and 44ZB cease to have effect at 23:59 on 30th June 2023.

Schedules

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

(3) M1In regulation 2 (interpretation)—

(a) at the start, before "In these Regulations" insert " Subject to Parts VIII and IX, ";

[F2(aa) after the definition of "active implantable medical device" insert—

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

(b) omit the definition of "Association Agreement";

[F3(c) omit the definition of "authorised representative";**]**

(d) after the definition of "clinical data" insert—

""designated standard" has the meaning given in regulation 3A;";

[F4(da) omit the definition of "the Community";**]**

(e) at the end of the definition of "Directive 90/385" insert " as it had effect immediately before **[**F5IP completion day**]**";

(f) at the end of the definition of "Directive 93/42" insert " as it had effect immediately before **[**F6IP completion day**]**";

(g) at the end of the definition of "Directive 98/79" insert " as it had effect immediately before **[**F7IP completion day**]**";

(h) omit the definition of "Directive 2001/83";

(i) omit the definition of "Directive 2006/42";

(j) in the definition of "EC CAB" omit "EC";

[F8(ja) omit the definition of "European Economic Area";**]**

(k) omit the definition of "harmonised standard";

(l) in the definition of "intended for clinical investigation", in paragraph (b), for "a Member State" substitute "**[**F9Great Britain**]**";

(m) in the definition of "machinery" for "Article 2(a) of Directive 2006/42" substitute " regulation 4 of the Supply of Machinery (Safety) Regulations 2008 M2; ";

(n) in the definition of "medicinal product" for "article 1.2 of Directive 2001/83" substitute " regulation 2(1) of the Human Medicines Regulations 2012 M3 ";

(o) for the definition of "Mutual Recognition Agreements" substitute—

""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 the that country will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies;";

(p) omit the definition of "national standard";

[F10(q) omit the definition of "notified body";**]**

(r) in the definition of "placing on the market"—

(i) for "Community" substitute " **[**F11Great Britain**]**";

(ii) at the end insert, " and related expressions must be construed accordingly ";

(s) in the definition of "putting into service" in paragraph (b) **[**F12for "the Community" substitute "Great Britain"**]**;

(t) in the definition of "stable derivatives device", in sub-paragraph (a), for "article 1.10 of Directive 2001/83" substitute " regulation 2(2) of the Human Medicines Regulations 2012 ";

(u) for the definition of "third country conformity assessment body" substitute—

""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;"

[F13(ua) after the definition of "third country conformity assessment body" insert—

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

[F14(v) omit the definition of "UK notified body";**]**

(w) after the definition of "UK notified body" insert—

""UK responsible person" means a person established in **[**F15any 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."

(4) In paragraph (1A), for the words "as amended from time to time" substitute " as they applied immediately before **[**F16IP completion day**]** and as modified by Schedule 2A. ".

[F17(4A) After regulation 2 (interpretation) insert—

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

(5) In regulation 3 [M4] (scope of these Regulations)—

[F18](a) . . . . . .

[F19](b) . . . . . .

(c) in paragraph (a)—

(i) for "Directive 2001/83" in the first place it occurs, substitute " the Human Medicines Regulations 2012 ";

(ii) omit "governed by Title X of Directive 2001/83";

(d) in paragraph (f), for "Council Directive 76/768, as amended" substitute " Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products; ".

(6) After regulation 3 insert—

"**Designated standard**

3A.—[[F20](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, 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 **[**F21(CENELEC)**]**;

(c) the British Standards Institute (BSI).

(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 technical specifications adopted by the other recognised standardisation bodies.

(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.

[F22(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.**]**

Confidentiality

3B.—(1) Subject to paragraph (2), and unless otherwise provided for in these Regulations, all parties involved in the application of these Regulations must respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following—

(a) personal data in accordance with the Data Protection Act 2018 M5;

(b) commercially confidential information, trade secrets of a person, including intellectual property rights (unless disclosure is in the public interest);

(c) the effective operation of these Regulations, in particular for the purposes of inspections, investigations or audits.

(2) Paragraph (1) does not affect—

(a) the rights and obligations of the Secretary of State, manufacturers, persons placing products on the market, UK responsible persons, importers, distributors and **[**F23approved bodies**]** with regard to the exchange of information and the dissemination of warnings;

(b) obligations to disclose information under the criminal law.".

(7) After regulation 4A M6 (transitional provisions for hip, knee and shoulder replacement) insert—

[F24]"**4B.** . . . . . .

[F24]**4C.** . . . . . .

Revocations, transitional and saving provisions in respect of the new national registration requirements

4D.—(1) Regulation 19 is revoked on the day that is 4 months after **[**[F25]IP completion day**]** (which is **[**[F26]when**]** regulation 7A comes into force).

(2) Regulation 7A does not apply until the day that is 8 months after **[**[F25]IP completion day**]** in respect of a device or accessory—

[[F27](a) that is a relevant device for the purposes of Part II; and**]**

(b) that is classified [F28]... 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 **[**[F25]IP completion day**]** in respect of a device or accessory—

[[F29](a) that is a relevant device for the purposes of Part II; and**]**

(b) that is classified [F30]... 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[F31]...

[F32](5) . . . . . .

(6) Regulation 30(3) is revoked on the day that is 4 months after **[**[F25]IP completion day**]** (which is **[**[F33]when**]** regulation 21A comes into force).

[F34](7) . . . . . .

(8) Regulation 44 is revoked on the day that is 4 months after **[**[F25]IP completion day**]** (which is **[**[F35]when**]** regulation 33A comes into force).

(9) Regulation 33A does not apply until the day that is 8 months after **[**[F25]IP completion day**]** in respect of a device or accessory—

[[F36](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)).

[[F37](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[F38]....

[F39](12) . . . . . .

F40 **4E.** . . . . . .

F41 **4F.** . . . . . .

F42 **4G.** . . . . . .

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 M7 ("the Decision") (insofar as it is retained EU law) is revoked on 26th May 2025.

(2) Pending its revocation, the Decision has effect as it had effect immediately before **[**F43IP completion day**]**.

Revocation of Commission Decision 2010/227

4I. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) M8 is revoked.

Revocation of Regulation (EU) No 207/2012 on 26th May 2025 and its effect before that date

4J.—(1) Except as provided for in this regulation, pending its revocation by the European Commission M9, Regulation (EU) No 207/2012 has effect as it had effect immediately before exit day.

F44(2) . . . . . .

F44(3) . . . . . .

Revocation of Regulation (EU) No 722/2012 on 26th May 2025 and its effect before that date

4K.—(1) Except as provided for in this regulation, pending its revocation by the European Commission M10, Regulation (EU) No 722/2012 has effect as it had effect immediately before exit day.

F45(2) . . . . . .

F45(3) . . . . . .

F45(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 notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices M11 ("Regulation (EU) No 920/2013") (insofar as it is retained EU law) is revoked on 26th May 2025.

F46(2) . . . . . .

F46(3) . . . . . .

(4) Before 26th May 2025, Regulation (EU) No 920/2013 only applies as regards the functions of the Secretary of State as a designating authority for the purpose of that Regulation, to the extent necessary for the fulfilment by the Secretary of State of the Secretary of State's obligations as regards the supervision of **[**F47approved bodies**]**.

(5) Paragraph (4) only applies in respect of the functions of the Secretary of State—

(a) which allow for or require the exchange of information with designating authorities in the European Union or with the European Commission; and

(b) insofar as there are in place reciprocal arrangements with the EU, an EU entity, a member State or a public authority in a member State that allow for or require that exchange.

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 M12 ("Regulation (EU) No 2017/2185") is revoked.

F48(2) . . . . . .

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

4N. [F49Where regulation 7 applies for the purposes of regulation 4D(2)(b) or (3)(b), Directives 2003/12 and 2005/50 apply with the following modifications—**]**

(a) in the case of Directive 2013/12, as if Articles 2 to 4 were omitted; and

(b) in the case of Directive 2005/50, as if Articles 3 to 6 were omitted.

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.

F50(2) . . . . . .

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.

F51(2) . . . . . .

F52**4Q.** . . . . . .

F53 4R. . . . . . .

F54 4S. . . . . . .

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 **M13** (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 **[**F55Part IV**]**.

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016 **M14** (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 **F56**...; and

(b) the reference to paragraph 5 of Annex III to 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 Schedule 11.

(3) In Schedule 1 to the Pressure Equipment (Safety) Regulations 2016 **M15** (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 **F57**....

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013 **M16** (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 or in accordance with Schedule 9;

(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 **F58**...;

(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 **F59**...;

(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 **[**F60the 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 **F61**....

(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 [M17] (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 [M18] (provision of personal protective equipment).".

F1 Reg. 3(2) substituted (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. 2 para. 3**

F2 Reg. 3(3)(aa) inserted (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. 2 para. 4(a)**

F3 Reg. 3(3)(c) substituted (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. 2 para. 4(b)**

F4 Reg. 3(3)(da) inserted (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. 2 para. 4(c)**

F5 Words in reg. 3(3)(e) substituted (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. 2 para. 4(d)**

F6 Words in reg. 3(3)(f) substituted (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. 2 para. 4(e)**

F7 Words in reg. 3(3)(g) substituted (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. 2 para. 4(f)**

F8 Reg. 3(3)(ja) inserted (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. 2 para. 4(g)(h)

F9 Words in reg. 3(3)(l) substituted (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. 2 para. 4(i)**

F10 Reg. 3(3)(q) substituted (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. 2 para. 4(j)**

F11 Words in reg. 3(3)(r)(i) substituted (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. 2 para. 4(k)**

F12 Words in reg. 3(3)(s) substituted (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. 2 para. 4(l)**

F13 Reg. 3(3)(ua) inserted (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. 2 para. 4(m)**

F14 Reg. 3(3)(v) substituted (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. 2 para. 4(n)**

F15 Words in reg. 3(3)(w) inserted (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. 2 para. 4(o)**

F16 Words in reg. 3(4) substituted (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. 2 para. 5**

F17 Reg. 3(4A) inserted (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. 2 para. 6**

F18 Reg. 3(5)(a) omitted (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. 2 para. 7**

F19 Reg. 3(5)(b) omitted (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. 2 para. 7**

F20 Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 2(2)(a)** (as amended by S.I. 2020/1478, regs. 1(2), **4(2)(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F21 Word in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 2(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 2(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in reg. 3(6) substituted (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. 2 para. 8(b)**

F24 Words in reg. 3(7) omitted (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. 2 para. 9(a)**

F25 Words in reg. 3(7) substituted (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. 2 para. 9(b)(i)**

F26 Word in reg. 3(7) substituted (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. 2 para. 9(b)(ii)**

F27 Words in reg. 3(7) substituted (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. 2 para. 9(b)(iii)**

F28 Words in reg. 3(7) omitted (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. 2 para. 9(b)(iv)**

F29 Words in reg. 3(7) substituted (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. 2 para. 9(b)(v)**

F30 Words in reg. 3(7) omitted (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. 2 para. 9(b)(vi)**

F31 Words in reg. 3(7) omitted (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. 2 para. 9(b)(vii)**

F32 Words in reg. 3(7) omitted (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. 2 para. 9(b)(viii)**

F33 Word in reg. 3(7) substituted (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. 2 para. 9(b)(ix)**

F34 Words in reg. 3(7) omitted (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. 2 para. 9(b)(x)**

F35 Word in reg. 3(7) substituted (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. 2 para. 9(b)(xi)**

F36 Words in reg. 3(7) substituted (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. 2 para. 9(b)(xii)**

F37 Words in reg. 3(7) substituted (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. 2 para. 9(b)(xiii)**

F38 Words in reg. 3(7) omitted (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. 2 para. 9(b)(xiv)**

F39 Words in reg. 3(7) omitted (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. 2 para. 9(b)(xv)**

F40 Words in reg. 3(7) omitted (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. 2 para. 9(c)**

F41 Words in reg. 3(7) omitted (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. 2 para. 9(d)**

F42 Words in reg. 3(7) omitted (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. 2 para. 9(e)**

F43 Words in reg. 3(7) substituted (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. 2 para. 9(f)**

F44 Words in reg. 3(7) omitted (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. 2 para. 9(g)**

F45 Words in reg. 3(7) omitted (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. 2 para. 9(h)**

F46 Words in reg. 3(7) omitted (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. 2 para. 9(i)(i)**

F47 Words in reg. 3(7) substituted (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. 2 para. 9(i)**(ii)**

F48 Words in reg. 3(7) omitted (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. 2 para. 9(j)**

F49 Words in reg. 3(7) substituted (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. 2 para. 9(k)**

F50 Words in reg. 3(7) omitted (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. 2 para. 9(l)**

F51 Words in reg. 3(7) omitted (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. 2 para. 9(m)**

F52 Words in reg. 3(7) omitted (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. 2 para. 9(n)**

F53 Words in reg. 3(7) omitted (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. 2 para. 9(o)**

F54 Words in reg. 3(7) omitted (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. 2 para. 9(p)**

F55 Words in reg. 3(7) substituted (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. 2 para. 9(q)(i)**

F56 Words in reg. 3(7) omitted (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. 2 para. 9(q)(ii)**

F57 Words in reg. 3(7) omitted (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. 2 para. 9(q)(iii)**

F58 Words in reg. 3(7) omitted (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. 2 para. 9(q)(iv)(aa)**

F59 Words in reg. 3(7) omitted (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. 2 para. 9(q)(iv)(bb)**

F60 Words in reg. 3(7) substituted (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. 2 para. 9(q)(iv)(cc)**

F61 Words in reg. 3(7) omitted (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. 2 para. 9(q)(iv)(dd)**

Commencement Information

I1 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(1)

Marginal Citations

M1 Regulation 2 was amended by S.I. 2003/1697, 2005/2759, 2007/400, 2008/2936, 2011/1043,.2012/1426 and 2013/2327.

M2 S.I. 2008/1597; no relevant amendments.

M3 S.I. 2012/1916; relevant amendments are S.I. 2013/1855, 2013/2593, 2014/324, 2014/1878, 2015/354, 2015/1503, 2016/407, 2016/186, 2017/241, 2017/715, 2018/64, 2018/199.

M4 Regulation 3 was amended by S.I. 2007/400 and S.I. 2008/2936.

M5 2018 c. 12.

M6 Regulation 4A was inserted by S.I. 2007/400.

M7 OJ No. L 131, 16.5.2002, p. 17.

M8 OJ No. L 102, 23.4.2010, p. 45.

M9 see Article 122 of Regulation (EU) 2017/745for reference to when the Regulation is to be revoked.

M10 see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.

M11 OJ No. L 253, 25.9.2013, p. 8.

M12 OJ No. L 309, 24.11.2017, p. 7.

M13 2004 c. 30. There have been no amendments to subsection (12) of section 1.

M14 S.I. 2016/190.

M15 S.I. 2016/1105.

M16 S.I. 2013/3113; amended by S.I. 2015/1968, 2016/738 and 1154, and 2018/102 and 942.

M17 S.R. 1993 No. 20; amended by S.I. 2015/223, **S.I**. 2012/179, 2017/229.

M18 S.I. 1992/2966; amended by S.I. 1999/860, 2002/2174, 2015/1637 and 2018/390.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 3.