STATUTORY INSTRUMENTS

2019 No. 791

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

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

Made - - - - 1st April 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, paragraph 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 [M1].

In accordance with paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

The Treasury has consented to the making of these Regulations as required by paragraph 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

Marginal Citations
M1 2018 c.16.

[F1Citation, commencement and application]

1.—(1) These Regulations may be cited as the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and, subject to [F2paragraph (2)], come into force on exit day.

(2) The following regulations come into force on the day that is 4 months after [F3IP completion day]—

(a) regulation 4(4);

(b) regulation 5(3);

(c) regulation 6(3);

(d) regulation 8(2);

(e) regulation 9(2).

[F4(2A) These regulations apply in relation to England and Wales and Scotland.]

F5(3) . . . . . .

F5(4) . . . . . .

F1 Words in reg. 1 heading 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. 2(a)**

F2 Words in reg. 1(1) 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. 2(b)**

F3 Words in reg. 1(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. 2(c)**

F4 Reg. 1(2A) 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. 2(d)**

F5 Reg. 1(3)(4) 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. 2(e)**

Commencement Information

I1 Reg. 1 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)

Interpretation

2. In these Regulations—

"the Act" means the European Union (Withdrawal) Act 2018;

"the 2002 Regulations" means the Medical Devices Regulations 2002 [M2].

Commencement Information

I2 Reg. 2 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

M2 S.I. 2002/618; these Regulations were made partly under section 2(2) of the European Communities Act 1972 c. 68 and were saved by virtue of s. 2(1) of the Act.

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.

[F6(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) [M3]In regulation 2 (interpretation)—

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

[[F7](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”;

[[F8](c) omit the definition of “authorised representative”;**]**

(d) after the definition of “clinical data” insert—

““designated standard” has the meaning given in regulation 3A;”;

[[F9](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 **[**[F10]IP completion day**]**”;

(f) at the end of the definition of “Directive 93/42” insert “ as it had effect immediately before **[**[F11]IP completion day**]**”;

(g) at the end of the definition of “Directive 98/79” insert “ as it had effect immediately before **[**[F12]IP 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”;

[[F13](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 “**[**[F14]Great 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 [M4]; ”;

(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 [M5] ”;

(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”;

[[F15](q) omit the definition of “notified body”;**]**

(r) in the definition of “placing on the market”—

(i) for “Community” substitute “ **[**[F16]Great Britain**]**”;

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

(s) in the definition of “putting into service” in paragraph (b) **[**[F17]for “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;"

[F18(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;";**]**

[F19(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 **[**F20any 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 **[**F21IP completion day**]** and as modified by Schedule 2A. ".

[F22(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 M6 (scope of these Regulations)—

F23(a) . . . . . .

F24(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.—**[**F25(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 **[**F26(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.

[F27(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 [M7];

(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 **[**[F28]approved 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 [M8] (transitional provisions for hip, knee and shoulder replacement) insert—

[F29]"**4B.** . . . . . .

[F29]**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 **[**[F30]IP completion day**]** (which is **[**[F31]when**]** regulation 7A comes into force).

(2) Regulation 7A does not apply until the day that is 8 months after **[**[F30]IP completion day**]** in respect of a device or accessory—

[[F32](a) that is a relevant device for the purposes of Part II; and**]**

(b) that is classified [F33]... 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 **[**[F30]IP completion day**]** in respect of a device or accessory—

[[F34](a) that is a relevant device for the purposes of Part II; and**]**

(b) that is classified [F35]... 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[F36]...

[F37](5) . . . . . .

(6) Regulation 30(3) is revoked on the day that is 4 months after **[**F30IP completion day**]** (which is **[**F38when**]** regulation 21A comes into force).

F39(7) . . . . . .

(8) Regulation 44 is revoked on the day that is 4 months after **[**F30IP completion day**]** (which is **[**F40when**]** regulation 33A comes into force).

(9) Regulation 33A does not apply until the day that is 8 months after **[**F30IP completion day**]** in respect of a device or accessory—

[F41(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)).

[F42(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 accessoryF43....

F44(12) . . . . . .

F45**4E.** . . . . . .

F46**4F.** . . . . . .

F47**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 M9 ("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 **[**F48IP 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) M10 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 M11, Regulation (EU) No 207/2012 has effect as it had effect immediately before exit day.

F49(2) . . . . . .

F49(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 M12, Regulation (EU) No 722/2012 has effect as it had effect immediately before exit day.

F50(2) . . . . . .

F50(3) . . . . . .

F50(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 M13 ("Regulation (EU) No 920/2013") (insofar as it is retained EU law) is revoked on 26th May 2025.

F51(2) . . . . . .

F51(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 **[**F52approved 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 M14 ("Regulation (EU) No 2017/2185") is revoked.

F53(2) . . . . . .

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

4N. [F54Where 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.

F55(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.

F56(2) . . . . . .

F57**4Q.** . . . . . .

F58**4R.** . . . . . .

F59**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 M15 (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 **[**F60Part IV**]**.

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016 M16 (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 F61...; 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 M17 (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 F62....

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013 M18 (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 [F63]...;

(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 [F64]...;

(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 **[**[F65]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 [F66]....

(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 [M19] (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 [M20] (provision of personal protective equipment).".

F6 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**

F7 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)**

F8 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)**

F9 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)**

F10 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)**

F11 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)**

F12 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)**

F13 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)

F14 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)**

F15 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)**

F16 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)**

F17 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)**

F18 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)**

F19 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)**

F20 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)**

F21 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**

F22 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**

F23 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**

F24 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**

F25 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)**

F26 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)

F27 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)

F28 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)**

F29 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)**

F30 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)**

F31 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)**

F32 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)**

F33 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)**

F34 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)**

F35 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)**

F36 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)**

F37 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)**

F38 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)**

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)(x)**

F40 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)**

F41 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)**

F42 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)**

F43 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)**

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(b)(xv)**

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(c)**

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(d)**

F47 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)**

F48 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)**

F49 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)**

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(h)**

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(i)(i)**

F52 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)**

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(j)**

F54 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)**

F55 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)**

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(m)**

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(n)**

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(o)**

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(p)**

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)(i)**

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)(ii)**

F62 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)**

F63 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)**

F64 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)**

F65 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)**

F66 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

I3 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

M3 Regulation 2 was amended by S.I. 2003/1697, 2005/2759, 2007/400, 2008/2936, 2011/1043,.2012/1426 and 2013/2327.

M4 S.I. 2008/1597; no relevant amendments.

M5 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.

M6 Regulation 3 was amended by S.I. 2007/400 and S.I. 2008/2936.

M7 2018 c. 12.

M8 Regulation 4A was inserted by S.I. 2007/400.

M9 OJ No. L 131, 16.5.2002, p. 17.

M10 OJ No. L 102, 23.4.2010, p. 45.

M11 see Article 122 of Regulation (EU) 2017/745for reference to when the Regulation is to be revoked.

M12 see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.
M13 OJ No. L 253, 25.9.2013, p. 8.
M14 OJ No. L 309, 24.11.2017, p. 7.
M15 2004 c. 30. There have been no amendments to subsection (12) of section 1.
M16 S.I. 2016/190.
M17 S.I. 2016/1105.
M18 S.I. 2013/3113; amended by S.I. 2015/1968, 2016/738 and 1154, and 2018/102 and 942.
M19 S.R. 1993 No. 20; amended by S.I. 2015/223, **S.I**. 2012/179, 2017/229.
M20 S.I. 1992/2966; amended by S.I. 1999/860, 2002/2174, 2015/1637 and 2018/390.

Amendment of Part II of the 2002 Regulations

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

F67(2) . . . . . .

[F68(3) In regulation 7(2) (classification of general medical devices) for "a notified body" substitute "an approved body".**]**

(4) After regulation 7 insert—

"**Registration of persons placing general medical devices on the market**

7A.—(1) No person may place a relevant device on the market in accordance with this Part F69... unless that person—

(a) is established in **[**F70Great Britain**]**; and

(b) has complied with paragraph (2).

[F71(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

(i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;

(ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;

(b) that person supplies the Secretary of State with a description of the relevant device; and

(c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.**]**

[F72(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.**]**

(3) **[**F73The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

[[F74](d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.**]**

[[F75](4) In this regulation—

(a) the references to "technical documentation" are to be construed in accordance with Annex II, III or VII;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes II, IV, V, VI and VII."**]**.

(5) In regulation 8 (essential requirements for general medical devices), in paragraph (3), for "Annex I to Directive 2006/42" insert " Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 ".

(6) In regulation 9 (determining compliance of general medical devices with relevant essential requirements)—

(a) in paragraph (3)(b)—

(i) in sub-paragraph (i) omit "or another Community language, and",

(ii) omit sub-paragraph (ii);

[[F76](aa) in paragraph (6) for "his authorised representative" substitute "their UK responsible person";

(ab) in paragraph (8) omit "of Directive 93/42";**]**

(b) in paragraph (9)—

(i) for the words from "Council Directive 89/686/EEC to "protective equipment" substitute "Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC";

(ii) for "Directive 89/686" substitute " Regulation (EU) 2016/425 ".

[F77(6A) In regulation 10 (CE marking of general medical devices)—

(a) in the heading for "CE Marking" substitute "UK marking";

(b) in paragraph (1)—

(i) in the opening words for "CE marking" substitute "UK marking";

(ii) in sub-paragraph (a) for "Annex XII" substitute "Annex 2 of Regulation (EC) No 765/2008" ;

(iii) in sub-paragraph (c) for "notified body" substitute "approved body";

(c) in paragraph (2)—

(i) in the opening words for "CE marking" substitute "UK marking";

(ii) in sub-paragraph (a) for "Annex XII" substitute "Annex 2 of Regulation (EC) No 765/2008";

(iii) in sub-paragraph (c) for "notified body" substitute "approved body";

(d) in paragraph (3)—

(i) in the words before sub-paragraph (a), for "a CE marking, meeting the requirements set out in Annex XII" substitute "a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008";

(ii) in the words following sub-paragraph (b)—

(aa) for "CE marking" substitute "UK marking";

(bb) for "notified body" substitute "approved body";

(e) in paragraph (4)—

(i) in the words before sub-paragraph (a), for "a CE marking, meeting the requirements set out in Annex XII" substitute "a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008";

(ii) in the words following sub-paragraph (b)—

(aa) for "CE marking" substitute "UK marking";

(bb) for "notified body" substitute "approved body";

(f) in paragraph (5) in the words after sub-paragraph (c), for both references to "CE marking" substitute "UK marking".**]**

[F78(6B) For regulation 11 (CE marking of general medical devices that come within the scope of more than one Directive) substitute—

"**UK marking of general medical devices that come within the scope of this Part and other legislation**

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

[F79(7) In regulation 12 (exemptions from regulations 8 and 10)—

(a) in paragraph (1) omit "Directive 93/42 or";

(b) in paragraph (3)(a) for "CE marking" substitute "UK marking";

(c) in paragraph (5) for "CE marking" substitute "UK marking";

(d) after paragraph (5) insert—

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

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

[[F80](7A) In regulation 13 (procedures for affixing a CE marking to general medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) for each reference to "Directive 93/42" substitute "this Part";

(c) for "CE marking", each time those words occur, substitute "UK marking";

(d) for "his authorised representative", each time those words occur, substitute "their UK responsible person".**]**

[[F81](7B) In regulation 14 (procedures for systems and procedure packs, and for devices to be sterilised before use)—

(a) in paragraph (4A) for "notified body" substitute "approved body";

(b) in paragraph (5)(a) for "CE marking" substitute "UK marking".**]**

[[F82](7C) In regulation 15 (procedures for custom-made general medical devices) for "his authorised representative" substitute "their UK responsible person.**]**

[[F83](7D) In regulation 16 (procedures for general medical devices for clinical investigation)—

(a) for "his authorised representative" each time those words occur, substitute "their UK responsible person";

(b) in paragraph (1), for "the United Kingdom" substitute "Great Britain";

(c) in paragraph (2)—

(i) for "CE marking" substitute "UK marking";

(ii) for "CE marked" substitute "UK marked";

(d) in paragraph (4) for "or authorised representative" substitute "or UK responsible person";

(e) in paragraph (11) for "single authorised representative" substitute "single UK responsible person".**]**

[[F84](8) In regulation 17 (manufacturers etc. and conformity assessment procedures for general medical devices)—

(a) for "his authorised representative" each time that those words occur substitute "their UK responsible person";

(b) for each reference to "Directive 93/42" substitute "this Part";

(c) omit paragraph (3).**]**

[[F85](9) In regulation 18 (UK notified bodies and the conformity assessment procedures for general medical devices)—

(a) in the heading, for "UK notified bodies" substitute "Approved bodies";

(b) in paragraph (1)—

(i) in the opening words, for "A UK notified body" substitute "An approved body";

(ii) in sub-paragraph (a) omit "in accordance with Directive 93/42";

(iii) in sub-paragraph (b) omit the words from "including in particular" to "EEA State";

(c) in paragraph (2) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "his authorised representative", in both places, substitute "the manufacturer's UK responsible person";

(e) omit paragraph (4).**]**

[F86(10) In regulation 19 (registration of persons placing general medical devices on the market)—

(a) in paragraphs (1), (3), (4) and (5) for "Subject to paragraph (6), for" substitute "For";

(b) in paragraph (2)(a) for "CE marked" substitute "UK marked";

(c) in paragraphs (2)(a) and (b) for "the United Kingdom" in each place substitute "Great Britain";

(d) in paragraph (3)—

(i) in the opening words for—

(aa) "the United Kingdom" in both places substitute "Great Britain";

(bb) "the Community or in a State which is a Party to an Association Agreement" substitute "the United Kingdom";

(ii) omit sub-paragraph (c) and ";and" which precedes it;

(e) in paragraph (4), in the opening words for—

(i) "the United Kingdom" in both places substitute "Great Britain";

(ii) "CE marked" substitute "UK marked";

(f) in paragraph (5)—

(i) for "the United Kingdom" in each place substitute "Great Britain";

(ii) omit "(including the authorised representative of a manufacturer of a Class IIa, IIb or III device who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement)";

(g) omit paragraph (6).**]**

[F87(11) Before the heading to Part III (active implantable medical devices) insert—

"**Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42**

19B.—(1) In this regulation—

(a) "the Directive" means Directive 93/42 and any reference to an Article or Annex is a reference to that Article or Annex in the Directive as amended from time to time;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it has effect in EU law;

(c) "CE marking" means the CE marking required by Article 17 and shown in Annex XII;

(d) "harmonised standard" is to be construed in accordance with Article 5.

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

(3) This paragraph applies where, before placing a relevant device other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation 722/2012, which apply to it; or

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

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 11;

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

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

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes II, III, IV, V, VI or VII;

(f) draws up an EU declaration of conformity in accordance with Article 11; and

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

(4) Where paragraph (5) applies, regulations 8 and 15 are treated as being satisfied.

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

(a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex VIII, read with Regulation 722/2012;

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

(c) undertakes to the Secretary of State—

(i) to comply with Section 3.1 of Annex VIII;

(ii) to keep all documentation required by Annex VIII available in accordance with Section 4 of Annex VIII; and

(iii) to pass the statement mentioned in subparagraph (a) on with the custom-made device so that it may be made available to the patient on request.

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

(7) This paragraph applies where before a system or procedure pack is placed on the market, the manufacturer—

(a) has complied with Article 12(2);

(b) has complied with Article 12(3) and with the procedure in Annex II or V;

(c) undertakes to keep the declarations required by Article 12 for the period specified in Article 12(4); and

(d) ensures that the system or procedure pack is accompanied by the information referred to in point 13 of Annex I which must be in English.

(8) Where paragraph (9) applies, regulations 8 and 16 are treated as being satisfied.

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

(a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the Statement required by Sections 1 and 2.2 of Annex VIII;

(b) undertakes to keep available the documentation referred to in Section 3.2 of Annex VIII for the period specified in Section 4 of that Annex; and

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of paragraph 3.1 of Annex VIII.

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

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

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

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

19C.—(1) In this regulation—

(a) "the Regulation" means Regulation (EU) 2017/745, as it has effect in EU law, and any reference to an Article or an Annex is a reference to an Article or Annex of the Regulation;

(b) "CE marking" means the CE marking required by Article 20 and presented in Annex V;

(c) "harmonised standard" has the meaning given in Article 2(70);

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

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

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

(a) ensures—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) This paragraph applies where, before a system or procedure pack is placed on the market, the person responsible for combining devices to produce that system or procedure pack has complied with the relevant requirements of Article 22 including where that Article requires a conformity assessment in accordance with Annex IX or XI.

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

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

(a) has provided the Secretary of State with the required notice in the form of the application required by Article 70 in English; and

(b) has provided the Secretary of State with an undertaking to keep available documentation contained in the application in accordance with Section 3 of Chapter III of Annex XV.

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

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

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

F67 Reg. 4(2) 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. 10**

F68 Reg. 4(3) 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. 11**

F69 Words in reg. 4(4) 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. 12(a)(i)**

F70 Words in reg. 4(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. 12(a)(ii)**

F71 Words in reg. 4(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. 12(b)**

F72 Words in reg. 4(4) inserted (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. 3**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Words in reg. 4(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. 12(c)(i)**

F74 Words in reg. 4(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. 12(c)(ii)**

F75 Words in reg. 4(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. 12(d)**

F76 Reg. 4(6)(aa)(ab) 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. 13**

F77 Reg. 4(6A) 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. 14**

F78 Reg. 4(6B) 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. 15**

F79 Reg. 4(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. 16**

F80 Reg. 4(7A) 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. 17**

F81 Reg. 4(7B) 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. 18**

F82 Reg. 4(7C) 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. 19**

F83 Reg. 4(7D) 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. 20**

F84 Reg. 4(8) 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. 21**

F85 Reg. 4(9) 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. 22**

F86 Reg. 4(10) 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. 23**

F87 Reg. 4(11) 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. 24**

Commencement Information

I4 Reg. 4(1)-(3)(5)-(9) 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)

I5 Reg. 4(4) in force at 1.5.2021, see reg. 1(2)(a) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Amendment of Part III of the 2002 Regulations

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

(2) In regulation 21 [M21] (Scope of Part III)—

(a) in paragraph (2), for "Annex I to that Directive" substitute " Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 ";

(b) after paragraph (3) insert—

"(4) Except for the requirement to register in accordance with regulation 21A or 30(3) to (5), this Part does not apply to active implantable medical devices and accessories to such devices placed on the market in accordance with Part VIII.".

(3) After regulation 21 insert—

"**Registration of persons placing active implantable medical devices on the market**

21A.—(1) No person may place a relevant device on the market in accordance with this Part [F88]... unless that person—

(a) is established in **[**[F89]Great Britain**]**; and

(b) has complied with paragraph (2).

[[F90](2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

(i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;

(ii) that person is the manufacturer of that device and is based outside the United Kingdom, and the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;

(b) that person supplies the Secretary of State with a description of the relevant device; and

(c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.**]**

[[F91](2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.**]**

(3) **[**[F92]The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available to the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

[F93(d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.**]**

[F94(4) In this regulation—

(a) the references to "technical documentation" are to be construed in accordance with Annex 2, 3 or 5;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes 2, 3 and 5."**]**.

(4) In regulation 23 (Determining compliance of active implantable medical devices with relevant essential requirements), in paragraph 3(b)—

(a) in sub-paragraph (i), omit "or another Community language, and";

(b) omit sub-paragraph (ii).

[F95(4A) In regulation 24 (CE marking of active implantable medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) for "CE marking" each time those words occur substitute "UK marking";

(c) for each reference to "Annex 9" substitute "Annex 2 of Regulation 765/2008";

(d) for "notified body" each time those words occur—

(i) in each of paragraphs (1)(c) and(2)(c);

(ii) in the words following paragraphs (3)(b) and (4)(b),

substitute "approved body".**]**

[F96(4B) For regulation 25 (CE marking of active implantable medical devices that come within the scope of more than one Directive) substitute—

"**UK marking of active implantable medical devices that come within the scope of this Part and other legislation**

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

[F97(5) In regulation 26 (exemptions from regulations 22 and 24)—

(a) in paragraph (1) omit "Directive 90/385 or";

(b) in paragraph (3) for "CE marking" substitute "UK marking";

(c) after paragraph (3) insert—

"(4) Regulations 22 and 24 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 22 and 24, may be placed on the market.

(5) In paragraph (4), the Secretary of State, in determining whether a standard or requirement or marking ("the other standard") is equivalent to a standard or requirement imposed by regulations 22 and 24, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.".**]**

[[F98](5A) In regulation 27 (procedures for affixing a CE marking to active implantable medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) in the opening words for—

(i) "CE marking" substitute "UK marking";

(ii) "his authorised representative" substitute "their UK responsible person";

(c) in sub-paragraphs (b) and (c) for "Directive 90/385" substitute "this Part".**]**

[[F99](5B) In regulation 28 (procedures for custom-made active implantable medical devices), in the opening words, for "his authorised representative" substitute "their UK responsible person.**]**

[[F100](5C) In regulation 29 (procedures for active implantable medical devices for clinical investigations)—

(a) for "his authorised representative" each time those words occur, substitute "their UK responsible person";

(b) in paragraph (1), in the opening words, for "the United Kingdom" substitute "Great Britain";

(c) in paragraph (3), for "or authorised representative" substitute "or UK responsible person";

(d) in paragraph (10) for "single authorised representative" substitute "single UK responsible person".**]**

[[F101](6) In regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable medical devices)—

(a) in paragraphs (1) and (2) for the words "his authorised representative" both times they occur substitute "their UK responsible person";

(b) in paragraph (3) for the opening words substitute——

"(3) The manufacturer of a relevant device, who places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, or, if not the manufacturer, the person placing custom-made devices on the market under that Article, must provide the Secretary of State with—";

(c) omit paragraphs (4) and (5).**]**

[[F102](7) In regulation 31 (UK notified bodies and the conformity assessment procedures for active implantable medical devices)—

(a) in the heading, for "UK notified bodies" substitute "Approved bodies"

(b) in paragraph (1)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "Directive 90/385" substitute "this Part";

(iii) for "his authorised representative" substitute "their UK responsible person";

(c) in paragraph (2) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

(i) for the words from "Where" to "representative" substitute "Where an approved body and a manufacturer or the manufacturer's UK responsible person";

(ii) for "his authorised representative" substitute "the manufacturer's UK responsible person".**]**

[F103(8) After regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable medical devices), insert—

"**Obligations in Part III which are met by complying with obligations in Directive 90/385**

30A.—(1) In this regulation—

(a) "the Directive" means Directive 90/385 and any reference to an Article or Annex is a reference to that Article or Annex in the Directive as amended from time to time;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it has effect in EU Law;

(c) "CE marking" means the CE marking required by Article 12 and shown in Annex 9;

(d) "harmonised standard" is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 22, 24(1) to (4), 25 and 27 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or

(ii) that paragraphs (8) and (9) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device, where the device is a device other than those which are custom-made or intended for clinical investigations, has been carried out in accordance with Article 9;

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

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

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes 2, 3, 4 or 5;

(f) draws up an EU Declaration of Conformity in accordance with Article 9; and

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

(4) Where paragraph (5) applies, regulations 25 and 28 are treated as being satisfied.

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

(a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex 6, read with Regulation 722/2012;

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

(c) undertakes to the Secretary of State—

(i) to comply with Section 3.1 of Annex 6;

(ii) to keep all documentation required by Annex 6 for the period specified in Section 4 of Annex 6; and

(iii) to pass on the statement mentioned in sub-paragraph (a) with the custom-made device so that it may be made available to the patient on request.

(6) Where paragraph (7) applies, regulations, 22 and 29 are treated as being satisfied.

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

(a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the statement required by Section 2.2 of Annex 6;

(b) has provided an undertaking to keep available for five years the documentation referred to in Section 3.1 and 3.2 of Annex 6; and

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in Section 3.2 of Annex 6.

(8) Where paragraph (9) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).

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

(10) For the purpose of this regulation in regulations 24(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".".**]**

F88 Words in reg. 5(3) 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. 25(a)(i)**

F89 Words in reg. 5(3) 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. 25(a)(ii)**

F90 Words in reg. 5(3) 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. 25(b)**

F91 Words in reg. 5(3) inserted (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. 4**; 2020 c. 1, Sch. 5 para. 1(1)

F92 Words in reg. 5(3) 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. 25(c)(i)**

F93 Words in reg. 5(3) 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. 25(c)(ii)**

F94 Words in reg. 5(3) 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. 25(d)**

F95 Reg. 5(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. 26**

F96 Reg. 5(4B) 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. 27**

F97 Reg. 5(5) 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. 28**

F98 Reg. 5(5A) 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. 29**

F99 Reg. 5(5B) 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. 30**

F100 Reg. 5(5C) 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. 31**

F101 Reg. 5(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. 32**

F102 Reg. 5(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. 33**

F103 Reg. 5(8) 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. 34**

Commencement Information

I6 Reg. 5(1)(2)(4)-(7) 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)

I7 Reg. 5(3) in force at 1.5.2021, see reg. 1(2)(b) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Marginal Citations

M21 Regulation 21 was amended by S.I. 2008/2936.

Amendment of Part IV of the 2002 Regulations

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

F104(2) . . . . . .

(3) After regulation 33 insert—

"**Registration etc. of persons placing in vitro diagnostic medical devices on the market**

33A.—(1) No person may place a relevant device on the market in accordance with this Part F105... unless that person—

(a) is established in **[**F106Great Britain**]**; and

(b) has complied with paragraph (2).

[F107(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

(i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;

(ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;

(b) that person supplies the Secretary of State with—

(i) a description of the relevant device; and

(ii) the relevant information in paragraph (4); and

(c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.**]**

[[F108](2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.**]**

(3) **[**[F109]The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

[[F110](d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.**]**

(4) In this regulation "relevant information" means—

(a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;

(b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;

(c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(d) in relation to devices in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

(ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;

(e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(5) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(6) In this regulation a device is a "new relevant device" if—

(a) there has been no such device continuously available on the United Kingdom **[**F111or EEA market**]** during the previous three years for the relevant analyte or other parameter; or

(b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom **[**F111or EEA market**]** during the previous three years.

[F112(7) In paragraph (3)—

(a) the references to "technical documentation" are to be construed in accordance with Annexes III to VIII;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes III, IV, V and VII."**]**.

[F113(4) In regulation 35 (determining compliance of in vitro diagnostic medical devices with relevant essential requirements)—

(a) in paragraph (2), omit the words from "if the device may reach a final user" to the end; and

(b) in paragraph (3) for "national standard" substitute "designated standard".**]**

[F114(4A) In regulation 36 (CE marking of *in vitro* diagnostic medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) for "CE marking" each time those words occur substitute "UK marking";

(c) for each reference to "Annex X" substitute "Annex 2 of Regulation 765/2008";

(d) for "notified body" each time those words occur substitute "approved body".**]**

[F115(4B) For regulation 37 (CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive) substitute—

"**UK marking of in vitro diagnostic devices that come within the scope of this Part and other legislation**

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

[[F116](5) In regulation 39 (exemptions from regulations 34, 36 and 38)—

(a) in paragraph (1)(b) omit "Directive 98/79 or";

(b) in paragraph (2) for "CE marking" substitute "UK marking";

(c) after paragraph (2) insert—

"(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking ("the other standard") is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.".**]**

[[F117](5A) In regulation 40 (procedures for affixing a CE marking to *in vitro* diagnostic medical devices)—

(a) in the heading and in each place in that regulation that "CE marking" occurs substitute "UK marking";

(b) for "his authorised representative", each time those words occur, substitute "their UK responsible person";

(c) for each reference to "Directive 98/79" substitute "this Part".**]**

[[F118](6) In regulation 41 (manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices)—

(a) for each reference to "his authorised representative" substitute "their UK responsible person";

(b) for both references to "Directive 98/79" substitute "this Part";

(c) in paragraph (1) for "that apply to him" substitute "that apply to the manufacturer or, as the case may be, their UK responsible person";

(d) in paragraph (3)(c) for "notified bodies" substitute "approved bodies";

(e) in paragraph (5)—

(i) omit from the beginning to "established";

(ii) omit "in the United Kingdom".**]**

[[F119](7) In regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic devices)—

(a) in the heading, for "UK notified bodies" substitute "Approved bodies";

(b) in paragraph (1)—

(i) in the opening words, for "A UK notified body" substitute "An approved body";

(ii) in sub-paragraph (a) omit "in accordance with Directive 98/79";

(iii) in sub-paragraph (b) omit the words from "including in particular" to the end of that sub-paragraph (but not the "and" following it);

(iv) in sub-paragraph (c) for "his authorised representative" substitute "their UK responsible person";

(c) in paragraph (2) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "his authorised representative" in both places it occurs substitute "their UK responsible person".**]**

[F120(8) In regulation 43 (devices for performance evaluation)—

(a) in the opening words, for "his authorised representative" substitute "their UK responsible person";

(b) in paragraph (b)(ii), for "the Directive" substitute "these Regulations".**]**

[F121(9) In regulation 44 (registration of manufacturers etc. of in vitro diagnostic medical devices and devices for performance evaluation)—

(a) in paragraph (1)—

(i) in the opening words, for "Subject to paragraph (3), for" substitute "For";

(ii) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(iii) in sub-paragraph (b) for—

(aa) "an authorised representative" substitute "a UK responsible person";

(bb) "that he is the authorised representative of the manufacturer" substitute "that they are the manufacturer's UK responsible person";

(iv) in sub-paragraph (c) for "Community market" in both places substitute "the United Kingdom or EEA market";

(v) in sub-paragraph (g)(ii) for "the United Kingdom" substitute "Great Britain";

(b) in paragraph (2)—

(i) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(ii) in sub-paragraph (b)—

(aa) for "the United Kingdom" in both places substitute "Great Britain";

(bb) for "the Community or in a State which is a Party to an Association Agreement" substitute "the United Kingdom";

(cc) for "his authorised representative" substitute "their UK responsible person";

(c) omit paragraph (3).**]**

[F122(10) Before the heading to Part V (notified bodies, conformity assessment bodies and marking of products) insert—

"**Obligations in Part IV which are met by complying with obligations in Directive 98/79**

44ZA.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79 as amended from time to time;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it applies in the European Union;

(c) "CE marking" means the CE marking required by Article 16 and shown in Annex X;

(d) "harmonised standard" is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 9;

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

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

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

(f) draws up an EU Declaration of Conformity in accordance with Article 9;

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

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

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

(a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;

(b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of Section 3 of Annex VIII.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".

Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

44ZB.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Regulation (EU) 2017/746 as it has effect in EU law;

(b) "CE marking" means the CE marking required by Article 18 and presented in Annex V;

(c) "harmonised standard" has the meaning given in Article 2(73);

(d) "sponsor" has the meaning given in Article 2(57).

(2) Where paragraph (3) applies, regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

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

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 48;

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

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

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

(f) draws up an EU declaration of conformity in accordance with Article 17; and

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

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where, before a person supplies or makes available a device falling within Part IV for the purposes of performance evaluation, the sponsor of the performance evaluation—

(a) has been able to provide the Secretary of State with the required notice in the form of the application required by Chapter I of Annex XIV in English;

(b) has been able to provide the Secretary of State with an undertaking to keep available information contained in the application in accordance with Chapter II of Annex XIV.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation, in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".".**]**

F104 Reg. 6(2) 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. 35**

F105 Words in reg. 6(3) 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. 36(a)(i)**

F106 Words in reg. 6(3) 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. 36(a)(ii)**

F107 Words in reg. 6(3) 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. 36(b)**

F108 Words in reg. 6(3) inserted (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. 5**; 2020 c. 1, Sch. 5 para. 1(1)

F109 Words in reg. 6(3) 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. 36(c)(i)**

F110 Words in reg. 6(3) 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. 36(c)(ii)**

F111 Words in reg. 6(3) 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. 36(d)**

F112 Words in reg. 6(3) 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. 36(e)**

F113 Reg. 6(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. 37**

F114 Reg. 6(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. 38**

F115 Reg. 6(4B) 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. 39**

F116 Reg. 6(5) 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. 40**

F117 Reg. 6(5A) 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. 41**

F118 Reg. 6(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. 42**

F119 Reg. 6(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. 43**

F120 Reg. 6(8) 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. 44**

F121 Reg. 6(9) 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. 45**

F122 Reg. 6(10) 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. 46**

Commencement Information

I8 Reg. 6(1)(2)(4)-(7) 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)

I9 Reg. 6(3) in force at 1.5.2021, see reg. 1(2)(c) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Amendment of Part V of the 2002 Regulations

[F123 7.—(1) Part V of the 2002 Regulations is amended as follows.

(2) In the Part V heading for "Notified Bodies" substitute "Approved Bodies".

(3) Before regulation 45 insert—

"**Meaning of approved body and UK notified body**

A45.—(1) An approved body is a conformity assessment body which—

(a) has been designated by the Secretary of State pursuant to the procedure set out in regulation 45 (designation etc. of approved bodies); or

(b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 45(5) to withdraw a designation.

(2) In this regulation—

"UK notified body" means a body which the Secretary of State had before IP completion day notified to the European Commission in accordance with Article 3(7) of Commission Implementing Regulation (EU) 920/2013 or under Article 15 of Directive 98/79.".".

(4) In regulation 45 (designation etc. of UK notified bodies)—

(a) in the heading for "UK notified bodies" substitute "approved bodies";

(b) in paragraph (1)—

(i) for "article 11 of Directive 90/385, article 16 of Directive 93/42 or article 15 of Directive 98/79" substitute "these Regulations";

(ii) for "a notified body" substitute "an approved body";

(iii) for "a "UK notified body"" substitute "an "approved body"";

(c) in the opening words of paragraph (2) for "a notified body" substitute "an approved body";

(d) in paragraph (2)(a)—

(i) for "Directive 90/385" substitute "Part III";

(ii) for "notified bodies set out in Annex 8 of that Directive" substitute "approved bodies set out in Annex 8 of Directive 90/385";

(e) in paragraph (2)(b)—

(i) for "Directive 93/42" substitute "Part II";

(ii) for "notified bodies set out in Annex XI of that Directive" substitute "approved bodies set out in Annex XI of Directive 93/42";

(f) in paragraph (2)(c)—

(i) for "Directive 98/79" substitute "Part IV";

(ii) for "notified bodies set out in Annex IX of that Directive" substitute "approved bodies set out in Annex IX of Directive 98/79";

(g) in paragraph (2)(d) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(h) in paragraph (4) for "a UK notified body" substitute "an approved body";

(i) in paragraph (5)(c) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(j) in paragraph (6)—

(i) for "the notified body's request" substitute "the approved body's request";

(ii) for "notified body" substitute "approved body";

(k) in paragraph (7), in the opening words, for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(l) in paragraph (8)—

(i) in the opening words for "a UK notified body" substitute "an approved body";

(ii) in sub-paragraph (b) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement".

(5) In regulation 46 (choice of notified bodies and conformity assessment bodies)—

(a) for the heading substitute "Choice of approved bodies and conformity assessment bodies";

(b) for "a notified body" substitute "an approved body"

(c) for "his authorised representative" substitute "the manufacturer's UK responsible person";

(d) for "any notified body" substitute "any approved body".

(6) In regulation 47 (general matters relating to UK notified bodies)—

(a) for the heading substitute "General matters relating to approved bodies";

(b) in paragraph (1)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "his authorised representative" substitute "the manufacturer's UK responsible person";

(iii) for "a notified body" substitute "an approved body";

(iv) for "the Medical Devices Directives" substitute "these Regulations";

(c) in paragraph (2)—

(i) for "his authorised representative" substitute "the manufacturer's UK responsible person";

(ii) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

(i) for "his authorised representative supplies to a notified body" substitute "the manufacturer's UK responsible person supplies to an approved body";

(ii) for "the Medical Devices Directives" substitute "these Regulations";

(iii) omit "if the notified body is within the United Kingdom";

(iv) omit "or some other Community language acceptable to the notified body concerned";

(e) in paragraph (4)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "other notified bodies" substitute "other approved bodies";

(f) in paragraph (5)—

(i) in the opening words for "a UK notified body" substitute "an approved body";

(ii) in sub-paragraph (a) for "the Medical Devices Directives" substitute "these Regulations";

(iii) in the words after sub-paragraph (b) for "notified body", both times those words occur, substitute "approved body";

(g) in paragraph (6)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "the Mutual Recognition Agreements" in both places substitute "a mutual recognition agreement";

(h) in paragraph (8)—

(i) for "A UK notified body" substitute "an approved body";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement".

(7) After regulation 47 insert—

"**Register of approved bodies**

47A.—(1) The Secretary of State must ensure that—

(a) each approved body is assigned an identification number; and

(b) there is a register of—

(i) approved bodies;

(ii) their approved body identification number;

(iii) the tasks for which they have been designated; and

(iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).".

(8) In regulation 48 (designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1)—

(i) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(ii) omit "European Community";

(iii) for "an "EC CAB"" substitute "a "CAB"";

(c) in paragraph (2)—

(i) for "an EC CAB" in both places substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(d) in paragraph (4) for "an EC CAB" substitute "a CAB";

(e) in paragraph (5)(b)—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(f) in paragraph (6) omit "EC" in both places;

(g) in paragraph (7), in the opening words—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(h) in paragraph (8)—

(i) for "an EC CAB" in both places substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement".

(9) In regulation 49 (fees charged by UK notified bodies and EC conformity assessment bodies)—

(a) for the heading substitute "Fees charged by approved bodies and conformity assessment bodies";

(b) in paragraph (1), in the opening words for "A UK notified body or EC CAB" substitute "An approved body or CAB";

(c) for paragraph (1)(a) substitute—

"(a) in the case of an approved body, performing the functions of an approved body or an importing Party under these Regulations or a mutual recognition agreement; and";

(d) in paragraph (1)(b)—

(i) for "an EC CAB" in both places it occurs substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(e) in paragraph (3)—

(i) in the opening words for "UK notified body or EC CAB" substitute "approved body or CAB";

(ii) in sub-paragraph (a) for "notified body" substitute "approved body";

(f) in paragraph (4) for "UK notified body or EC CAB" substitute "approved body or CAB".

(10) In regulation 50 (products incorrectly marked with a notified body or conformity assessment body number)—

(a) in the heading for "a notified body" substitute "an approved body";

(b) in paragraph (1) for "a notified body" in each place it occurs substitute "an approved body";

(c) in paragraph (2)—

(i) for "a notified body" each place it occurs substitute "an approved body";

(ii) in sub-paragraph (b) for "the notified body" substitute "the approved body";

(d) in paragraph (3)(a) for "a notified body" substitute "an approved body";

(e) in paragraph (3)(b) for "notified body" in both places substitute "approved body";

(f) in paragraph (4) for "a notified body" substitute "an approved body".

(11) In regulation 51 (products incorrectly marked with a CE marking) and in the heading, for "CE marking" in each place it occurs substitute "UK marking".**]**

F123 Reg. 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. 47**

Commencement Information

I10 Reg. 7 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)

Amendment of Part VI of the 2002 Regulations

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

[[F124](2) In regulation 53 (fees in connection with the registration of devices and changes in registration details) for "regulation 19 or 44" substitute "regulation 7A, 19, 21A, 33A or 44".

(3) In regulation 54 (fees payable in connection with the designation of UK notified bodies)—

(a) for the heading substitute "Fees payable in connection with the designation of approved bodies";

(b) in paragraph (1) for "a notified body" substitute "an approved body";

(c) in paragraph (3) for "the Mutual Recognition Agreements" in both places substitute "a mutual recognition agreement";

(d) in paragraph (3C) for "A UK notified body" substitute "An approved body";

(e) in paragraph (3D)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "the UK notified body" substitute "the approved body";

(f) in paragraph (3E) for "A UK notified body" substitute "An approved body".**]**

[[F125](4) In regulation 55 (fees payable in connection with the designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1), for "an EC CAB" substitute " a CAB ";

(c) in paragraph (3)—

(i) for "an EC CAB" substitute " a CAB ";

(ii) for "the Mutual Recognition Agreements" substitute " a mutual recognition agreement ".**]**

[[F126](4A) In regulation 56 (fees payable in relation to clinical investigation notices), in paragraph (2), for "his authorised representative" substitute "their UK responsible person".**]**

[[F127](5) In regulation 58 (waivers, reductions and refunds)—

(a) in paragraph (2)(b)(i) for "a notified body" substitute "an approved body";

(b) in paragraph (2)(b)(ii) for "an EC CAB" substitute "a CAB".**]**

F124 Reg. 8(2)(3) 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. 48**

F125 Reg. 8(4) 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. 7**; 2020 c. 1, Sch. 5 para. 1(1)

F126 Reg. 8(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. 49**

F127 Reg. 8(5) 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. 50**

Commencement Information

I11 Reg. 8(1)(3)-(5) 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)

I12 Reg. 8(2) in force at 1.5.2021, see reg. 1(2)(d) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Amendment of Part VII of the 2002 Regulations

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

(2) In regulation 59 [M22](interpretation of Part VII)—

(a) omit the definition of "registrable device";

(b) in the definition of "relevant device" after "IV" insert " or a device for the purposes of Part VIII or IX. ".

(3) [M23]In regulation 60 (designation etc. of authorised representatives)—

(a) for the heading substitute " Status of UK responsible person ";

(b) omit paragraphs (1) and (2);

(c) for paragraph (3), substitute—

"(3) A UK responsible person—

(a) may be proceeded against as a person placing the device on the market for the purposes of these regulations;

(b) in relation to the supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market.".

[[F128](d) in paragraph (4)—

(i) for "an authorised representative of a manufacturer of a device" substitute " a UK responsible person ";

(ii) for "the single authorised representative of the manufacturer" substitute " a UK responsible person ".**]**

[[F129](4) In regulation 61 (enforcement etc.)—

(a) for "CE marking" in both places substitute "UK marking";

(b) in paragraph (8)(a)(i), after "essential requirement" insert ", a general safety and performance requirement";

(c) in paragraph (8)(a)(ii), omit "set out in the Medical Devices Directives";

(d) in paragraph (8)(a)(ii)(aa), for "his authorised representative" substitute "their UK responsible person".**]**

(5) In regulation 62 (compliance notices) in paragraph (1)—

(i) after "performance evaluation" insert " or study ";

(ii) for "the manufacturer or his authorised representative" substitute " any person ";

[[F130](iii) in sub-paragraph (c) omit "and, where applicable any relevant provision of the Medical Devices Directives".**]**

(6) In regulation 63 [M24] (restriction notices) in paragraph (1)—

(i) in sub-paragraph (a), after "performance evaluation" insert " or study ";

(ii) in sub-paragraph (b), after "performance evaluation" insert " or study ".

[F131(6A) In regulation 64 (notification of decisions etc)—

(a) in paragraph (1)(c), for "him or his authorised representative" substitute "the applicant or the applicant's UK responsible person";

(b) in paragraph (2)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "his authorised representative" substitute "their UK responsible person".**]**

(7) Omit regulation 65(centralised system of records etc.).

(8) In regulation 67 M25 (review), for "2019" substitute " 2025 ".

(9) Omit Schedule 1 M26 (association agreements).

(10) For Schedule 2 M27 (mutual recognition agreements) substitute—

"SCHEDULE 2 Regulation 1A

Mutual Recognition Agreement countries

— Australia

— New Zealand

— Canada

— The United States of America

— The Swiss Confederation".

F128 Reg. 9(3)(d) 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. 8**; 2020 c. 1, Sch. 5 para. 1(1)

F129 Reg. 9(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. 51**

F130 Reg. 9(5)(iii) 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. 52**

F131 Reg. 9(6A) 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. 53**

Commencement Information

I13 Reg. 9(1)(3)-(10) 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)

I14 Reg. 9(2) in force at 1.5.2021, see reg. 1(2)(e) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Marginal Citations

M22 Regulation 59 was amended by S.I. 2003/1697.

M23 Regulation 60 was amended by S.I. 2008/2936.

M24 Regulation 63 was amended by S.I. 2008/2936.

M25 Regulation 67 was inserted by S.I. 2013/2327.

M26 Schedule 1 was amended by 2013/2327.

M27 Schedule 2 was amended by S.I. 2013/2327.

PART 2

New Part VIII of the Medical Devices Regulations

[F132]10. . . . . . .

F132 Reg. 10 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. 54**

PART 3

New part IX of the Medical Devices Regulations

PROSPECTIVE

[F133]11. . . . . . .

F133 Reg. 11 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. 55**

PART 4

New Schedules to the 2002 Regulations

12. After Schedule 2 to the 2002 Regulations insert—

[F134"SCHEDULE 2A Regulation 1A

Modification of Annexes to Directives 90/385, 93/42, 98/79

PART 1

Modification of Annexes to Directive 90/385

1.—(1) The Annexes to Directive 90/385 are modified so that they read as if amended by paragraphs 2 to 10.

(2) In this Part any reference to "the Regulations" is a reference to the Medical Devices Regulations 2002.

2. In Annex 1—

(a) in Section 8 for the fifth indent substitute —

"–risks connected with ionising radiation from radioactive substances included in the device,";

(b) for Section 10 substitute—

"**10.** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with an action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by Schedule 8B to the Human Medicines Regulations 2012.

For the substances referred to in the first paragraph, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body shall be informed of the changes and shall consult the Secretary of State, in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the Secretary of State has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, the Secretary of State shall provide the approved body with advice on whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The approved body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.";

(c) in Section 14.2 —

(i) for "the name and address of the authorised representative" substitute ", where such a person is appointed under regulation 21A of the Regulations, the name and address of the UK responsible person,";

(ii) for "the Community" substitute "the United Kingdom";

(d) in Section 15 in the first indent for "CE mark" substitute "UK mark".

3. In Annex 2—

(a) for the heading substitute "Declaration of conformity";

(b) for "the notified body" each time it occurs substitute "the approved body";

(c) for "this Directive" each time it occurs substitute "the Regulations";

(d) in Section 1, for "EC Surveillance" substitute "Surveillance";

(e) in Section 2—

(i) for "his authorized representative" substitute "their UK responsible person";

(ii) omit "established within the Community";

(iii) for "CE marking" substitute "UK marking";

(f) in Section 3.1—

(i) in the opening words, for "a notified body" substitute "an approved body";

(ii) in the fifth indent, for "competent authorities" substitute "Secretary of State";

(g) in Section 3.2(c), for "Article 5" substitute "regulation 3A of the Regulations";

(h) in Section 3.3 for the first sentence substitute—

"The quality system shall be audited by an approved body to determine whether it meets the requirements referred to in Section 3.2.";

(i) in Section 3.4, in the second paragraph, for the first sentence substitute—

"The proposed modifications shall be evaluated by the approved body so as to verify whether the quality system so modified would still meet the requirements referred to in Section 3.2.";

(j) in Section 4.2 in the second indent for "Article 5" substitute "regulation 3A of the Regulations";

(k) for Section 4.3 substitute—

"**4.3.** The approved body must examine the application and, where the product complies with the relevant provisions of the Regulations, shall issue the applicant with a design certificate. The approved body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Regulations may be evaluated. The certificate shall contain conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of

State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(l) in Section 4.4, for each reference to "EC design" substitute "design";

(m) in Section 6.1—

(i) for "national authorities" substitute "Secretary of State";

(ii) for "his authorised representative" substitute "their UK responsible person";

(n) for Section 6.2 substitute—

"**6.2.** On request, an approved body must make available to other approved bodies and to the Secretary of State all relevant information on approvals of quality systems, issued, refused or withdrawn.";

(o) for Section 7 substitute—

"**7.** Application to the devices incorporating a human blood derivative:

Upon completing the manufacture of each batch of devices incorporating a human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

4. In Annex 3—

(a) in the title for "EC TYPE-EXAMINATION" substitute "TYPE-EXAMINATION";

(b) for "EC type-examination" in each other place substitute "type-examination";

(c) for "a notified body" in each place substitute "an approved body";

(d) for "the notified body" in each place substitute "the approved body";

(e) in Section 1, for "this Directive" substitute "the Regulations";

(f) in Section 2—

(i) for the first sentence substitute—

"The application for type-examination shall be made by the manufacturer to the approved body.";

(ii) for "the authorized representative" substitute "the UK responsible person";

(iii) for "this Directive" substitute "the Regulations";

(g) in Section 3, for each reference to "Article 5" substitute "regulation 3A of the Regulations";

(h) for Sections 4 and 5, substitute—

"**4.** The approved body shall—

4.1. examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 3A of the Regulations, as well as the items for which the design is not based on the relevant provisions of the said standards.

4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the

essential requirements where the standards referred to in regulation 3A of the Regulations have not been applied.

4.3. carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. Where the type meets the provisions of the Regulations, the approved body shall issue a type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the approved body.

In the case of devices referred to in Annex I, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(i) in Section 6 omit "EC" each time it occurs;

(j) for Section 7 substitute—

"**7.1.** On request, an approved body shall make available to other conformity assessment bodies (including other approved bodies) and to the Secretary of State all relevant information on type-examination certificates and addenda to those certificates issued, refused and withdrawn.

7.2. The approved body must cooperate with other approved bodies with regard to making available copies of the type examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.

7.3. The manufacturer or their UK responsible person shall keep with the technical documentation a copy of the UK type-examination certificates and the supplements to them for a period of at least 15 years from the manufacture of the last product.".

5. For Annex 4 substitute—

"ANNEX 4

VERIFICATION

1. Verification is the procedure whereby the manufacturer ensures and declares that the products subject to the provisions of Section 3 are in conformity with the type as described in the type-examination certification and satisfy the requirements of the Regulations that apply to them.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the type-examination certification and to the requirements of the Regulations that apply to them. The manufacturer shall affix the UK marking to each product and draw up a written declaration of conformity.

3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the type examination certificate as well as with the relevant requirements of the Regulations.

4. The manufacturer must undertake to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7. This undertaking must include the obligation on the part of the manufacturer to notify the Secretary of State of the following events immediately on learning of them—

(i) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in the patient's state of health;

(ii) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.

5. The approved body must carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of the Regulations by examination and testing of products on a statistical basis, as specified in Section 6. The manufacturer must authorize the approved body to evaluate the efficiency of the measures taken pursuant to Section 3, by audit where appropriate.

6. Statistical verification

6.1. Manufacturers must present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

6.2. A random sample must be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standards referred to in regulation 3A of the Regulations, or equivalent tests must be carried out to verify their conformity to the type as described in the type-examination certificate and thereby determine whether a batch is to be accepted or rejected.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the designated standards referred to in regulation 3A of the Regulations, taking account of the specific nature of the product categories in question.

6.4. Where batches are accepted, the approved body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity. Where a batch is rejected, the approved body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the approved body may suspend the statistical verification.

The manufacturer may, with the agreement of the approved body, affix the approved body's identification number during the manufacturing process.

6.5. The manufacturer or their UK responsible person must ensure that they are able to supply the approved body's certificates of conformity on request.

7. Application to the devices incorporating human blood derivative:

Upon completing the manufacture of each batch of devices incorporating human blood derivative the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

6. For Annex 5, substitute—

"ANNEX 5

DECLARATION OF CONFORMITY TO TYPE

(Assurance of production quality)

1. The manufacturer shall apply the quality system approved for the manufacture and must conduct the final inspection of the products concerned as specified in Section 3; the manufacturer shall be subject to the surveillance referred to in Section 4.

2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of Section 1 guarantees and declares that the products concerned conform to the type described in the type-examination certificate and meet the provisions of the Regulations which apply to them.

The manufacturer must affix the UK marking in accordance with regulation 24 of the Regulations and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The UK marking shall be accompanied by the identification number of the approved body responsible.

3. Quality system

3.1. The manufacturer shall make an application for evaluation of their quality system to an approved body.

The application shall include:

— all appropriate information concerning the products which it is intended to manufacture,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

— where appropriate, the technical documentation relating to the approved type and a copy of the type-examination certificate,

— an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Annex 7. The undertaking shall include an obligation for the manufacturer to notify the Secretary of State of the following incidents immediately on learning of them:

(i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in the patient's state of health;

(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for their quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular an adequate description of—

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular—

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,

— methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform,

— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the techniques of control and of quality assurance at the manufacturing stage and in particular—

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— product identification procedures drawn up and kept up-to-date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. Without prejudice to regulation 50 of the Regulations, the approved body shall effect an audit of the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the approved body which has approved the quality system of any plan to alter that system.

The approved body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in Section 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4.2. The manufacturer shall authorize the approved body to carry out all necessary inspections and shall supply it with all appropriate information, in particular—

— the quality-system documentation,

— the technical documentation,

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/ calibrations and the qualifications of the staff concerned, etc.

4.3. The approved body must periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

4.4. In addition, the approved body may make unannounced visits to the manufacturer, and must supply the manufacturer with an inspection report.

5. The approved body shall communicate to the other approved bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

6. Application to the devices incorporating human blood derivative:

Upon completing the manufacture of each batch of devices, incorporating human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

7. In Annex 6—

(a) in Section 1, for "authorised representative established within the Community" substitute "UK responsible person";

(b) in Section 3 for "the competent national authorities" substitute "the Secretary of State";

(c) in Section 3.1 for "this Directive" substitute "the Regulations";

(d) in Section 3.2 for the fourth indent substitute—

"–the results of the risk analysis and a list of the designated standards provided for in regulation 3A of the Regulations, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards in regulation 3A of the Regulations have not been applied,";

(e) in Section 5, in the opening paragraph, for "competent authorities" substitute "Secretary of State".

8. In Annex 7, in Section 2.3.5, for "all competent authorities of the Member States in which the clinical investigation is being performed" substitute "the Secretary of State".

9. In Annex 8—

(a) in the title for "when designating inspection bodies to be notified" substitute "when designating approved bodies";

(b) in Section 3 omit the words "and for which it has been notified";

(c) in Section 6 omit from "unless liability" to the end;

(d) in Section 7 omit from "(except *vis-à-vis"* to the end.

10. Omit Annex 9.

PART 2

Modification of Annexes to Directive 93/42

11.—(1) The Annexes to Directive 93/42 are modified so that they read as if amended by paragraphs 12 to 23.

(2) In this Part any reference to "the Regulations" is a reference to the Medical Devices Regulations 2002.

12. In Annex I—

(a) in Section 3, for "Article 1(2)(a)" substitute "regulation 2(1) of the Regulations";

(b) in Section 7, for "notified body" each time it occurs substitute "approved body";

(c) for Section 7.4, substitute—

"**7.4.** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by the Human Medicines Regulations 2012.

For the substances referred to in the first paragraph, the approved body shall, having verified the usefulness of the substance as part of the medical device and

taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body must be informed of the changes and must consult the Secretary of State in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State must take account of the data related to the usefulness of incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the Secretary of State has obtained information on an ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, the Secretary of State must provide the approved body with advice on whether this information has any impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The approved body must take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.";

(d) in Section 7.5—

(i) for the reference to "Annex 1 to Council Directive 67/548/EEC of 27 June 1967", substitute "Regulation (EC) No. 1272/2008";

(ii) for the reference to "Annex 1 to Council Directive 67/548/EEC", substitute "the UK mandatory classification and labelling list established and maintained in accordance with Article 38A of Regulation 1272/2008";

(e) in Section 10.3 for "the provisions of Council Directive 80/181/EEC" substitute "the Units of Measurement Regulations 1986";

(f) in Section 13.3—

(i) in point (a) —

(aa) for the first two references to "the Community" substitute "Great Britain";

(bb) for the third reference to "the Community" substitute "the United Kingdom";

(cc) for "the authorised representative" substitute "the UK responsible person (where appointed in accordance with regulation 7A of the Regulations)";

(ii) in point (f) omit the second sentence;

(iii) in point (n) omit "in the case of a device within the meaning of Article 1(4a),".

13. In Annex II—

(a) in the title omit "EC";

(b) for each reference to "the notified body" substitute "the approved body";

(c) in Section 1 omit "Community";

(d) in Section 2—

(i) omit "EC";

(ii) for "this Directive" substitute "the Regulations";

(iii) for "CE marking" substitute "UK marking";

(iv) omit the words "in accordance with Article 17";

(e) in Section 3.2—

(i) in the first paragraph for "this Directive" substitute "the Regulations"

(ii) in point (c)—

(aa) for "Article 5" substitute "regulation 3A of the Regulations";

(bb) for "Commission Directive 2003/32/EC" substitute "Commission Regulation 722/2012";

(f) for Section 3.3 substitute—

"**3.3.** The approved body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.".

(g) for Section 3.4 substitute—

"**3.4.** The manufacturer must inform the approved body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The approved body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.";

(h) in Section 4.2, for "this Directive" substitute "the Regulations";

(i) for Section 4.3 substitute—

"**4.3.** The approved body must examine the application and, where the product complies with the relevant provisions of the Regulations, must issue the applicant

with a design certificate. The approved body may require the application to be supplemented by further tests or proof so that compliance with the requirement of the Regulations may be evaluated. The certificate must contain conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(j) in Section 4.4, omit each reference to "EC";

(k) in Section 6.1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "national authorities" substitute "Secretary of State";

(l) in Section 7.1 for "Article 11(2) and (3)" substitute "regulation 13(2) and (3) of the Regulations";

(m) in Section 7.2 omit "for compliance with the provisions of this Directive";

(n) in Section 7.3 omit "for compliance with the provisions of this Directive";

(o) in Section 7.4 —

(i) for "this Directive" substitute "the Regulations";

(ii) for "the competent authority" substitute "the Secretary of State";

(p) for Section 8, substitute—

"**8.** Application to the devices incorporating a human blood derivative

Upon completing the manufacture of each batch of devices incorporating a human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

14. In Annex III—

(a) for each reference to "EC type-examination" (including in the title), substitute "type-examination";

(b) in Section 1—

(i) for "a notified body" substitute "an approved body";

(ii) for "this Directive" substitute "the Regulations";

(c) in Section 2—

(i) in the first indent,—

(aa) for "authorized representative" substitute "UK responsible person" ;

(bb) for "the representative" substitute "the UK responsible person";

(ii) in the second indent, for the second and third sentences substitute—

"The applicant must provide samples at the request of the approved body.";

(iii) in the third indent, for "notified" substitute "approved";

(d) in Section 3—

(i) for each reference to "Article 5" substitute "regulation 3A of these Regulations";

(ii) for "Directive 2003/32/EC" substitute "Commission Regulation 722/2012";

(e) for Sections 4 and 5 substitute—

"**4.** The approved body must—

4.1. examine and assess the documentation, verify that the type has been manufactured in accordance with that documentation; it must also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 3A of the Regulations, as well as the items for which the design is not based on the relevant provisions of the said standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of the Regulations where the standards referred to in regulation 3A of the Regulations have not been applied; if the device is to be connected to another device or other devices in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device having the characteristics specified by the manufacturer;

4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. Where the type meets the provisions of the Regulations, the approved body must issue a type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the approved body.

In the case of devices referred to in Annex I, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body must give due consideration to the

views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.

In the case of devices manufactured utilizing tissues of animal origin referred to in Commission Regulation 722/2012, the approved body must follow the procedures referred to in that Regulation.";

(f) in Section 6—

(i) for each reference to "notified body" substitute "approved body";

(ii) omit each reference to "EC";

(g) for Section 7.2 substitute—

"**7.2.** An approved body must cooperate with other approved bodies with regard to making available copies of the type-examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.".

(h) in Section 7.3 —

(i) for "authorised representative" substitute "UK responsible person";

(ii) omit "EC".

15. In Annex IV—

(a) omit "EC" (including in the title) each time it occurs;

(b) for both references to "this Directive" substitute "the Regulations";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 1 for "authorized representative" substitute "UK responsible person";

(e) in Section 2—

(i) for "CE marking" substitute "UK marking";

(ii) for "Article 17" substitute "regulation 10 of the Regulations";

(f) in Section 3 for "competent authorities" substitute "Secretary of State";

(g) for Sections 4 to 6 substitute—

"**4.** The approved body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Regulations either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every product must be examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them.

5.2. The approved body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample must be taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes and/or variables entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the designated standards referred to in regulation 3A of the Regulations, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the approved body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the approved body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the approved body may suspend the statistical verification.

The manufacturer may, on the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.";

(h) in Section 7—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "national authorities" substitute "Secretary of State";

(i) in Section 8, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 9—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012".

16. In Annex V—

(a) for "notified body" each time it occurs substitute "approved body";

(b) omit "EC" each time it occurs, including in the title;

(c) in Section 1, omit "Community";

(d) in Section 2—

(i) for "this Directive" substitute "the Regulations";

(ii) for "CE marking in accordance with Article 17" substitute "UK marking";

(e) in the eighth indent of Section 3.1, for "competent authorities" substitute "Secretary of State";

(f) in Section 3.3, for the first sentence substitute—

"The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2.";

(g) in Section 3.4, for the last two paragraphs substitute—

"The proposed changes must be evaluated by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "national authorities" substitute "Secretary of State";

(i) in Section 6 for each reference to "this Directive" substitute "the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State";

(k) in Section 7—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

17. In Annex VI—

(a) omit "EC" each time it occurs including in the title;

(b) for "the notified body" each time it occurs substitute "the approved body";

(c) for "this Directive" each time it occurs substitute "the Regulations";

(d) in Section 2—

(i) for "CE marking in accordance with Article 17" substitute "UK marking";

(ii) for "CE marking must" substitute "UK marking must";

(e) in Section 3.1, for—

(i) "a notified body" substitute "an approved body";

(ii) "other notified body" substitute "other approved body";

(f) in Section 3.3, for the first sentence substitute—

"The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2.";

(g) in Section 3.4, for the second paragraph substitute—

"The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "national authorities" substitute "Secretary of State";

(i) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State".

18. In Annex VII—

(a) in the title and in Section 1, omit "EC";

(b) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "this Directive" substitute "the Regulations";

(c) in Section 2 for—

(i) "his authorised representative" substitute "the manufacturer's UK responsible person";

(ii) "national authorities" substitute "Secretary of State";

(d) in Section 3—

(i) in the opening paragraph for "the Directive" substitute "the Regulations";

(ii) in the fourth indent—

(aa) for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(bb) for "of the Directive" substitute "in Annex I";

(e) in Section 4, for "competent authorities" substitute "Secretary of State";

(f) in Section 5, for "the intervention by the notified body" substitute "the intervention by the approved body";

(g) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations".

19. In Annex VIII—

(a) in Section 1, for "authorized representative" substitute "UK responsible person";

(b) in Section 2.2 in the seventh indent for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(c) in Section 3, for "competent national authorities" substitute "Secretary of State";

(d) in Sections 3.1 and 3.2, for "this Directive" each time it occurs substitute "the Regulations";

(e) in Section 3.2—

(i) in the fourth indent, for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(ii) in the sixth indent, for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(f) in Section 5, for "competent authorities" substitute "Secretary of State".

20. In Annex IX for "this Directive" each time it occurs substitute "the Regulations".

21. In Annex X—

(a) in Section 1.1 for "harmonised standards" substitute "designated standards";

(b) in Section 2.3.5 for the words from "all competent authorities of the Member States" to the end substitute "the Secretary of State".

22. In Annex X1—

(a) in the title, for "notified bodies" substitute "approved bodies";

(b) for the words "notified body" each time they occur substitute "approved body";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 2, for "national authorities" substitute "the Secretary of State";

(e) in Section 3, for "this Directive" substitute "the Regulations";

(f) in Section 6, omit the words from ", unless liability" to the end of that Section;

(g) in Section 7, omit the words from "(except *vis a vis* the competent administrative authorities" to the end.

23. Omit Annex XII.

PART 3

Modification of Annexes to Directive 98/79

24.—(1) The Annexes to Directive 98/79 are modified so that they read as if amended by paragraphs 25 to 33.

(2) In this Part any reference to "the Regulations" is a reference to the Medical Devices Regulations 2002.

25. In Annex 1—

(a) in Section 3 in part A, for "Article 1(2)(b)" substitute "regulation 2(1) of the Regulations";

(b) in Section 4.2 in part B, for "Council Directive 80/181/EEC of 20th December 1979" substitute "the Units of Measurement Regulations 1986";

(c) in Section 8.1 in part B, omit the words from "The decision whether" to the end;

(d) in Section 8.2 in part B, for "harmonised standards" substitute "designated standards";

(e) in Section 8.3 in part B —

(i) in the first sentence omit "of Directive 67/548/EEC and Directive 88/379/EEC";

(ii) in the second sentence omit "by those Directives";

(iii) omit the words from "The provisions of" to the end;

(f) in Section 8.4 in point (a), for the sentence beginning "For devices imported", substitute—

"Where the manufacturer does not have a registered place of business in the United Kingdom the label, the outer packaging or instructions for use shall contain in addition the name and address of the UK responsible person.".

26. In Annex III—

(a) in the title and in Section 1, omit "EC";

(b) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "this Directive" substitute "the Regulations";

(iii) for "CE marking in accordance with Article 16" substitute "UK marking in accordance with regulation 36 of the Regulations";

(c) in Section 3, for "the Directive" in both places substitute "the Regulations";

(d) in Section 3, in the sixth indent, for "Article 5" in both places substitute "regulation 3A of the Regulations";

(e) in Section 5, for "competent authorities" substitute "Secretary of State";

(f) in Section 6, for "a notified body" substitute "an approved body";

(g) in Section 6.2—

(i) for "notified body", both times those words occur, substitute "approved body";

(ii) in the first sentence, for "this Directive" substitute "the Regulations";

(iii) in the second sentence omit "of the Directive";

(iv) for "an EC" substitute "a" ;

(h) in Section 6.3—

(i) for "notified body" in both places substitute "approved body";

(ii) omit each reference to "EC";

(iii) for "the Directive" substitute "the Regulations".

27. In Annex IV—

(a) in the title, omit "EC";

(b) for each reference to "this Directive" and "the Directive" substitute "the Regulations";

(c) in Section 2, for "CE marking" substitute "UK marking";

(d) in Section 3.1—

(i) for "of his quality system with a notified body" substitute "of its quality system with an approved body";

(ii) in the third indent for "notified body" substitute "approved body";

(e) in Section 3.3 for the first paragraph substitute—

"The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to the requirements.";

(f) in Section 3.4, in both paragraphs, for "notified body" substitute "approved body";

(g) in Section 4.1 for "notified body" substitute "approved body";

(h) in Section 4.3—

(i) for "notified body" both times those words occur substitute "approved body";

(ii) for "an EC" substitute "a";

(i) in Section 4.4—

(i) for "notified body" both times those words occur substitute "approved body";

(ii) omit each reference to "EC";

(j) in Section 4.5, for "notified body" both times those words occur substitute "approved body";

(k) in Sections 5 and 6 for "notified body" each time those words occur substitute "approved body".

28. In Annex V—

(a) in the title, omit "EC" ;

(b) in Section 1—

(i) for "EC type-examination" substitute "Type-examination";

(ii) for "a notified body" substitute "an approved body";

(iii) for "this Directive" substitute "the Regulations";

(c) in Section 2—

(i) in the first paragraph—

(aa) omit "EC";

(bb) for "his authorised representative" substitute "its UK responsible person";

(cc) for "a notified body" substitute "an approved body";

(ii) in the first indent—

(aa) for "authorised representative" substitute "UK responsible person";

(bb) for "the representative" substitute "the UK responsible person";

(iii) in the second indent for "this Directive" substitute "the Regulations";

(iv) in the second and third indents for "notified body" each time those words occur substitute "approved body";

(d) in Section 4—

(i) for "notified body shall" substitute "approved body must";

(ii) for both references to "Article 5" substitute "regulation 3A of the Regulations";

(iii) for "this Directive" substitute "the Regulations";

(e) in Section 5—

(i) for "this Directive" substitute "the Regulations";

(ii) for "notified body" in both places substitute "approved body";

(iii) for "an EC" substitute "a";

(f) in Section 6—

(i) for "notified body" each time it occurs substitute "approved body";

(ii) omit "EC" each time it occurs;

(iii) for "the Directive" substitute "the Regulations";

(g) for Section 7, substitute—

"**7.** An approved body must cooperate with other approved bodies with regard to making available copies of the type-examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.".

29. In Annex VI—

(a) in the title omit "EC";

(b) in Section 1—

(i) for "EC verification" substitute "Verification";

(ii) for "authorised representative" substitute "UK responsible person";

(iii) for "EC type-examination" substitute "type-examination";

(iv) for "this Directive" substitute "the Regulations";

(c) in Section 2.1—

(i) for "EC type-examination" in both places substitute "type-examination";

(ii) for "the Directive" substitute "the Regulations";

(iii) for "this Directive" substitute "the Regulations";

(d) in Section 2.2 for "notified body" substitute "approved body";

(e) in Section 4—

(i) for "notified body" in both places substitute "approved body";

(ii) for "the Directive" substitute "the Regulations";

(f) in Section 5.1—

(i) for "Article 5" substitute "regulation 3A of the Regulations";

(ii) omit "EC";

(iii) for "the Directive" substitute "the Regulations";

(g) in Section 5.2 for "notified body" substitute "approved body";

(h) in Section 6.2—

(i) for "Article 5" substitute "regulation 3A of the Regulations";

(ii) omit "EC";

(iii) for "the Directive" substitute "the Regulations";

(i) in Section 6.3 for "the harmonised standards referred to in Article 5" substitute "the designated standards referred to in regulation 3A of the Regulations";

(j) in Section 6.4—

(i) for the first two paragraphs, substitute—

"Where the approved body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.";

(ii) in the third paragraph, for "notified body", in both places, substitute "approved body".

30. In Annex VII—

(a) in the title and in Section 2, omit "EC";

(b) in Section 2—

(i) for "this Directive" substitute "the Regulations";

(ii) for "CE marking in accordance with Article 16" substitute "UK marking in accordance with regulation 36 of the Regulations";

(c) in Section 3.1—

(i) for "a notified body" substitute "an approved body";

(ii) for "EC type-examination" substitute "type-examination";

(d) in Section 3.2, for "EC type-examination" substitute "type-examination";

(e) in Section 3.3 for the first two sentences substitute—

"The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. The approved body must presume that quality systems which implement the relevant designated standards conform to the requirements.";

(f) in Section 3.4—

(i) for "notified body" substitute "approved body";

(ii) for the first sentence of the second paragraph substitute "The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would meet the requirements referred to in Section 3.2.";

(g) in Sections 5.1 and 5.2, for each reference to "notified body" substitute "approved body".

31. In Annex VIII—

(a) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

(ii) for "this Directive" substitute "the Regulations";

(b) in Section 2, for "the Directive" substitute "the Regulations";

(c) in Section 3—

(i) for "competent national authorities" substitute "Secretary of State";

(ii) for "this Directive" substitute "the Regulations".

32. In Annex IX—

(a) in the title, for "notified bodies" substitute "approved bodies";

(b) for each reference to "notified body" substitute "approved body";

(c) in Section 1, for "authorised representative" substitute "UK responsible person";

(d) in Section 2—

(i) for "the Directive" substitute "the Regulations";

(ii) for "national authorities" substitute "Secretary of State";

(iii) for "this Directive" substitute "the Regulations";

(e) in Section 3—

(i) for "has been notified" substitute "has been designated";

(ii) for "this Directive" substitute "the Regulations";

(f) in Section 6, omit the words from "unless liability" to the end;

(g) in Section 7, omit the words from "(except *vis à vis* the competent administrative authorities" to the end.

33. Omit Annex X.**]**

F135SCHEDULES 3-28

. . . . . ."

F134 Words in reg. 12 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. 56**

F135 Words in reg. 12 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. 57**

Commencement Information

I15 Reg. 12 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)

Signed by the authority of the Secretary of State for Health and Social Care

Jackie Doyle-Price
Mike Freer
Jeremy Quin
Parliamentary Under-Secretary of State, Two of the Lords Commissioners of Her Majesty's Treasury

Department of Health and Social Care
Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of , paragraph 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16) ("the Withdrawal Act") in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union

These Regulations make amendments to legislation in the field of medical devices.

Part 1 amends the existing Medical Devices Regulations 2002 ("the 2002 Regulations") which implemented three European Union Directives which aimed to ensure the safety and quality of general medical devices, active implantable medical devices and in vitro diagnostic medical devices ("the three Directives"). Part I also makes certain transitional and savings provisions which seek to mirror the transitional and savings provisions which exist as part of current EU law in the two EU Regulations (see below). Part 1 also amends EU tertiary legislation which relates to the regime implemented by the 2002 Regulations and revokes certain tertiary legislation along with the two EU Regulations insofar as they are retained EU law.

Parts 2 and 3 restate (by inserting restated new provisions into the 2002 Regulations) the provisions of two EU Regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices (the two EU Regulations). Rights, powers, liabilities, obligations restrictions, remedies and procedures contained in the two Regulations were retained by virtue Section 4 of the Withdrawal Act and limited provisions were retained by virtue of section 3 of that Act.

Part 4 inserts new Schedules into the 2002 Regulations which reproduce the procedures in the Annexes to the two EU Regulations.

An explanatory memorandum is published alongside this instrument on www.legislation.gov.uk.

An impact assessment of the effect that this instrument will have on the costs to business, the voluntary sector and the public sector is available from the Medicines and Healthcare Products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument www.legislation.gov.uk.

Status:
This version of this Instrument contains provisions that are prospective.

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