
STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part 1 of the 2002 Regulations

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

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

“Expiry of certain provisions in these Regulations

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

Schedules

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

(3) ^{M1}In regulation 2 (interpretation)—

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

[^{F2}(aa) after the definition of “active implantable medical device” insert—

““approved body” is to be construed in accordance with regulation A45;”];

(b) omit the definition of “Association Agreement”;

[^{F3}(c) omit the definition of “authorised representative”];

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

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

[^{F4}(da) omit the definition of “the Community”];

(e) at the end of the definition of “Directive 90/385” insert “ as it had effect immediately before [^{F5}IP completion day]”;

(f) at the end of the definition of “Directive 93/42” insert “ as it had effect immediately before [^{F6}IP completion day]”;

(g) at the end of the definition of “Directive 98/79” insert “ as it had effect immediately before [^{F7}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”;

- [^{F8}(ja) omit the definition of “European Economic Area”];
- (k) omit the definition of “harmonised standard”;
- (l) in the definition of “intended for clinical investigation”, in paragraph (b), for “a Member State” substitute “[^{F9}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 ^{M2}.”;
- (n) in the definition of “medicinal product” for “article 1.2 of Directive 2001/83” substitute “regulation 2(1) of the Human Medicines Regulations 2012 ^{M3}”;
- (o) for the definition of “Mutual Recognition Agreements” substitute—
 ““mutual recognition agreement” means an agreement that—
 (a) is between the United Kingdom and a country listed in Schedule 2, and
 (b) covers matters including the conditions under which the United Kingdom and the that country will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies;”
- (p) omit the definition of “national standard”;
- [^{F10}(q) omit the definition of “notified body”];
- (r) in the definition of “placing on the market”—
 (i) for “Community” substitute “[^{F11}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) [^{F12}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;”
- [^{F13}(ua) after the definition of “third country conformity assessment body” insert—
 ““UK marking” has the meaning given in Article 2(22) of Regulation (EC) No 765/2008;”];
- [^{F14}(v) omit the definition of “UK notified body”];
- (w) after the definition of “UK notified body” insert—
 ““UK responsible person” means a person established in [^{F15}any part of] the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations.”
- (4) In paragraph (1A), for the words “as amended from time to time” substitute “ as they applied immediately before [^{F16}IP completion day] and as modified by Schedule 2A. ”.
- [^{F17}(4A) After regulation 2 (interpretation) insert—

“Medical devices which are qualifying Northern Ireland goods

2A.—(1) Notwithstanding the effect of regulations 19B, 19C, 30A, 44ZA and 44ZB and the expiry of the period during which those regulations apply by virtue of regulation 1ZA, any medical device—

- (a) which meets the requirements of these Regulations as they apply in Northern Ireland; and
- (b) which is a qualifying Northern Ireland good,

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

(2) In this regulation, “qualifying Northern Ireland good” has the meaning given in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.”.]

(5) In regulation 3^{M4} (scope of these Regulations)—

^{F18}(a)

^{F19}(b)

(c) in paragraph (a)—

- (i) for “Directive 2001/83” in the first place it occurs, substitute “ the Human Medicines Regulations 2012 ”;
- (ii) omit “governed by Title X of Directive 2001/83”;

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

(6) After regulation 3 insert—

“Designated standard

3A.—^{F20}(1) In Parts II, III and IV of these Regulations, a “designated standard” means—

- (a) a technical specification which is—
 - (i) adopted by a recognised standardisation body, for repeated or continuous application with which compliance is not compulsory; and
 - (ii) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate; or
- (b) a monograph of the European Pharmacopoeia (in particular on surgical sutures and on the interaction between medicinal products and materials used in devices containing medicinal products) which has been published in the Official Journal of the European Union.]

(2) For the purposes of paragraph (1), a “technical specification” means a document which prescribes technical requirements to be fulfilled by a device, process, service or system (“the product”) and which lays down—

- (a) the characteristics required of a product, including levels of quality, performance, interoperability, environmental protection, health and safety and dimensions;
- (b) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and

(c) the production methods and processes relating to the product, where these have an effect on its characteristics.

(3) For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—

- (a) the European Committee for Standardisation (CEN);
- (b) the European Committee for Electrotechnical Standardisation [^{F21}(CENELEC)];
- (c) the British Standards Institute (BSI).

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a standard in relation to a technical specification which has been adopted by BSI, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

[^{F22}(8) In this regulation—

- (a) a reference to a “device” is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply;
- (b) a reference to “the European Pharmacopoeia” is a reference to the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.]

Confidentiality

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

- (a) personal data in accordance with the Data Protection Act 2018 ^{M5};
- (b) commercially confidential information, trade secrets of a person, including intellectual property rights (unless disclosure is in the public interest);
- (c) the effective operation of these Regulations, in particular for the purposes of inspections, investigations or audits.

(2) Paragraph (1) does not affect—

- (a) the rights and obligations of the Secretary of State, manufacturers, persons placing products on the market, UK responsible persons, importers, distributors and [^{F23}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 ^{M6} (transitional provisions for hip, knee and shoulder replacement) insert—

^{F24c}**4B.**

^{F24}**4C.**

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

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

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

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

(b) that is classified ^{F28}... as belonging to—

(i) Class IIa, as referred to in regulation 7, or

(ii) Class IIb, as referred to in regulation 7, and is also a Group A device (within the meaning given in regulation 52(1)).

(3) Regulation 7A does not apply until the day that is 12 months after [^{F25}IP completion day] in respect of a device or accessory—

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

(b) that is classified ^{F30}... as belonging to Class I, as referred to in regulation 7.

(4) Where regulation 7A does not apply in respect of a device or accessory by virtue of paragraph (2) or (3), regulation 19 continues to have effect after its revocation in respect of that device or accessory^{F31}...

^{F32}(5)

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

^{F34}(7)

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

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

[^{F36}(a) that is a relevant device for the purposes of Part IV, or]

(b) that is—

(i) referred to in List B, mentioned in regulation 40(4), or

(ii) a device for self-testing (as defined in relation 32(1)).

[^{F37}(10) Regulation 33A does not apply until the day that is 12 months after IP completion day in respect of a device or accessory that is a relevant device for the purposes of Part IV which follows the procedure in regulation 40(1).]

(11) Where regulation 33A does not apply in respect of a device or accessory by virtue of paragraph (9), regulation 44 continues to have effect after its revocation in respect of that device or accessory^{F38}....

^{F39}(12)

^{F40} **4E.**

^{F41} **4F.**

^{F42} **4G.**

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

4H.—(1) Commission Decision [2002/364/EC](#) of 7 May 2002 on the common specifications for in vitro diagnostic medical devices ^{M7} (“the Decision”) (insofar as it is retained EU law) is revoked on 26th May 2025.

(2) Pending its revocation, the Decision has effect as it had effect immediately before [^{F43}IP completion day].

Revocation of Commission Decision 2010/227

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

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

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

^{F44}(2)

^{F44}(3)

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

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

^{F45}(2)

^{F45}(3)

^{F45}(4)

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

4L.—(1) Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive [90/385/EEC](#) on active implantable medical devices and Council Directive [93/42/EEC](#) on medical devices ^{M11} (“Regulation (EU) No 920/2013”) (insofar as it is retained EU law) is revoked on 26th May 2025.

^{F46}(2)

^{F46}(3)

(4) Before 26th May 2025, Regulation (EU) No 920/2013 only applies as regards the functions of the Secretary of State as a designating authority for the purpose of that Regulation, to the extent necessary for the fulfilment by the Secretary of State of the Secretary of State's obligations as regards the supervision of [^{F47}approved bodies].

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

- (a) which allow for or require the exchange of information with designating authorities in the European Union or with the European Commission; and
- (b) insofar as there are in place reciprocal arrangements with the EU, an EU entity, a member State or a public authority in a member State that allow for or require that exchange.

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

4M.—(1) Insofar as it is retained EU law, Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council ^{M12} (“Regulation (EU) No 2017/2185”) is revoked.

^{F48}(2)

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

4N. [^{F49}Where 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 2003/12, as if Articles 2 to 4 were omitted; and
- (b) in the case of Directive 2005/50, as if Articles 3 to 6 were omitted.

Revocation of Regulation (EU) 2017/745

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

^{F50}(2)

Revocation of Regulation (EU) 2017/746

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

^{F51}(2)

^{F52}**4Q.**

^{F53}4R.

^{F54}4S.

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

4T.—(1) In section 1(12)(a) of the Human Tissue Act 2004 ^{M13} (authorisation of activities for scheduled purposes), the references to Directive 98/79 are to be construed, to the extent necessary for the practical application of that section, as references also or instead to [^{F55}Part IV].

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016 ^{M14} (fee for advice for other purposes)—

- (a) the reference to the expression “medical device” having the meaning given in Article 1(2)(a) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to having the meaning given in regulation 2 ^{F56} ...; and
- (b) the reference to paragraph 5 of Annex III to Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to Schedule 11.

(3) In Schedule 1 to the Pressure Equipment (Safety) Regulations 2016 ^{M15} (excluded pressure equipment and assemblies), the reference in paragraph 1(f)(iv) to not being covered by Directive 93/42 is to be construed, to the extent necessary for the practical application of that provision, as a reference also or instead to not being covered by Part II ^{F57}....

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013 ^{M16} (interpretation)—

- (a) the reference to the expression “active implantable medical device” having the meaning given in Article 1(2)(c) of Directive 90/385 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to it having the meaning given in regulation 2 or in accordance with Schedule 9;
- (b) the reference to the expression “medical device” having the meaning given in Article 1(2)(a) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference to it also or instead having the meaning given to it in regulation 2 ^{F58} ...;
- (c) the reference to the expression “accessory” having the meaning given in Article 1(2)(b) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as also or instead having the meaning given to “accessory” in regulation 5 ^{F59} ...;
- (d) the reference to the expression “in vitro diagnostic medical device” having the meaning given in Article 1(2)(b) of Directive 98/79 is to be construed, to the extent necessary for [^{F60}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 ^{F61}....

(5) These Regulations are an enactment implementing a relevant Community Directive for the purposes of regulation 4 of the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993^{M17} (provision of personal protective equipment).

(6) These Regulations are also an enactment implementing a relevant Community Directive for the purposes of regulation 4(5)(a) of the Personal Protective Equipment at Work Regulations 1992^{M18} (provision of personal protective equipment).”.

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| F1 | Reg. 3(2) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 3 |
| F2 | Reg. 3(3)(aa) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(a) |
| F3 | Reg. 3(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(b) |
| F4 | Reg. 3(3)(da) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(c) |
| F5 | Words in reg. 3(3)(e) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(d) |
| F6 | Words in reg. 3(3)(f) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(e) |
| F7 | Words in reg. 3(3)(g) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(f) |
| F8 | Reg. 3(3)(ja) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(g)(h) |
| F9 | Words in reg. 3(3)(l) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(i) |
| F10 | Reg. 3(3)(q) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(j) |
| F11 | Words in reg. 3(3)(r)(i) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(k) |
| F12 | Words in reg. 3(3)(s) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(l) |
| F13 | Reg. 3(3)(ua) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(m) |
| F14 | Reg. 3(3)(v) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(n) |
| F15 | Words in reg. 3(3)(w) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 4(o) |
| F16 | Words in reg. 3(4) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 5 |
| F17 | Reg. 3(4A) inserted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 6 |
| F18 | Reg. 3(5)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 7 |
| F19 | Reg. 3(5)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478) , reg. 1(3), Sch. 2 para. 7 |
| F20 | Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385) , reg. 1, Sch. 2 para. 2(2)(a) (as amended by S.I. 2020/1478 , regs. 1(2), 4(2)(a)(i)); 2020 c. 1, Sch. 5 para. 1(1) |

- F21** Word in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 2(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 2(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 8(b)**
- F24** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(a)**
- F25** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(i)**
- F26** Word in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(ii)**
- F27** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(iii)**
- F28** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(iv)**
- F29** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(v)**
- F30** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(vi)**
- F31** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(vii)**
- F32** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(viii)**
- F33** Word in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(ix)**
- F34** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(x)**
- F35** Word in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(xi)**
- F36** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(xii)**
- F37** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(xiii)**
- F38** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(xiv)**

- F39** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(b)(xv)**
- F40** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(c)**
- F41** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(d)**
- F42** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(e)**
- F43** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(f)**
- F44** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(g)**
- F45** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(h)**
- F46** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(i)(i)**
- F47** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(i)(ii)**
- F48** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(j)**
- F49** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(k)**
- F50** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(l)**
- F51** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(m)**
- F52** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(n)**
- F53** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(o)**
- F54** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(p)**
- F55** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(q)(i)**
- F56** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 9(q)(ii)**

- F57** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 2 para. 9(q)(iii)**
- F58** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 2 para. 9(q)(iv)(aa)**
- F59** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 2 para. 9(q)(iv)(bb)**
- F60** Words in reg. 3(7) substituted (31.12.2020 immediately before IP completion day) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 2 para. 9(q)(iv)(cc)**
- F61** Words in reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1478\)](#), reg. 1(3), **Sch. 2 para. 9(q)(iv)(dd)**

Commencement Information

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

Marginal Citations

- M1** Regulation 2 was amended by [S.I. 2003/1697](#), [2005/2759](#), [2007/400](#), [2008/2936](#), [2011/1043](#), [2012/1426](#) and [2013/2327](#).
- M2** [S.I. 2008/1597](#); no relevant amendments.
- M3** [S.I. 2012/1916](#); relevant amendments are [S.I. 2013/1855](#), [2013/2593](#), [2014/324](#), [2014/1878](#), [2015/354](#), [2015/1503](#), [2016/407](#), [2016/186](#), [2017/241](#), [2017/715](#), [2018/64](#), [2018/199](#).
- M4** Regulation 3 was amended by [S.I. 2007/400](#) and [S.I. 2008/2936](#).
- M5** [2018 c. 12](#).
- M6** Regulation 4A was inserted by [S.I. 2007/400](#).
- M7** OJ No. L 131, 16.5.2002, p. 17.
- M8** OJ No. L 102, 23.4.2010, p. 45.
- M9** see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.
- M10** see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.
- M11** OJ No. L 253, 25.9.2013, p. 8.
- M12** OJ No. L 309, 24.11.2017, p. 7.
- M13** [2004 c. 30](#). There have been no amendments to subsection (12) of section 1.
- M14** [S.I. 2016/190](#).
- M15** [S.I. 2016/1105](#).
- M16** [S.I. 2013/3113](#); amended by [S.I. 2015/1968](#), [2016/738](#) and [1154](#), and [2018/102](#) and [942](#).
- M17** [S.R. 1993 No. 20](#); amended by [S.I. 2015/223](#), [S.I. 2012/179](#), [2017/229](#).
- M18** [S.I. 1992/2966](#); amended by [S.I. 1999/860](#), [2002/2174](#), [2015/1637](#) and [2018/390](#).

Amendment of Part II of the 2002 Regulations

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

^{F62}(2)

[^{F63}(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 ^{F64}... unless that person—

- (a) is established in [^{F65}Great Britain]; and
- (b) has complied with paragraph (2).

[^{F66}(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.]

[^{F67}(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) [^{F68}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;
- [^{F69}(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.]
- [^{F70}(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);
- [^{F71}(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 ”.
- [^{F72}(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”.]

[^{F73}(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.”.]

[^{F74}(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.”.]

[^{F75}(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”.]

[^{F76}(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”.]

[^{F77}(7C) In regulation 15 (procedures for custom-made general medical devices) for “his authorised representative” substitute “their UK responsible person.”]

[^{F78}(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”.]

[^{F79}(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).]

[^{F80}(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).]

[^{F81}(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).]
- [^{F82}(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”.”.]

- F62** 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**
- F63** 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**
- F64** 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)**
- F65** 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)**
- F66** 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)**
- F67** 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)
- F68** 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)**
- F69** 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)**
- 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(d)**
- F71** 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**
- F72** 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**

- F73** 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**
- F74** 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**
- F75** 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**
- F76** 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**
- F77** 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**
- F78** 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**
- F79** 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**
- F80** 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**
- F81** 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**
- F82** 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

- I2** 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)**
- I3** 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^{M19} (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^{F83} ... unless that person—

- (a) is established in [^{F84}Great Britain]; and
- (b) has complied with paragraph (2).

[^{F85}(2) A person who places a relevant device^{F85} 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.]

[^{F86}(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) [^{F87}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;
- [^{F88}(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.]

[^{F89}(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).

[^{F90}(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”.]

[^{F91}(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.”.]

[^{F92}(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.”.]

[^{F93}(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”.]

[^{F94}(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.”]

[^{F95}(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”.]

[^{F96}(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).]

[^{F97}(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”.]

[^{F98}(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”.”.]

- F83** 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)**
- F84** 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)**
- F85** 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)**
- F86** 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)
- F87** 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)**
- F88** 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)**
- 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(d)**
- F90** 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**
- F91** 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**
- F92** 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**
- F93** 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**
- F94** 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**
- F95** 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**
- F96** 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**
- F97** 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**
- F98** 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

- I4** 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)**
- I5** 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

- M19** 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.

^{F99}(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 ^{F100}... unless that person—

- (a) is established in [^{F101}Great Britain]; and
- (b) has complied with paragraph (2).

[^{F102}(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.]

[^{F103}(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) [^{F104}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;
 - [^{F105}(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 I;
 - (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 [^{F106}or EEA market] during the previous three years for the relevant analyte or other parameter; or
- (b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom [^{F106}or EEA market] during the previous three years.

[^{F107}(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.”].

[^{F108}(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”.]

[^{F109}(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”.]

[^{F110}(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.”.]

[^{F111}(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.”.]

[^{F112}(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”.]

[^{F113}(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”.]

[^{F114}(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”.]

[^{F115}(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”.]

[^{F116}(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).]

[^{F117}(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”.”.]

- F99** 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**
- F100** 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)**
- F101** 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)**
- F102** 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)**
- F103** 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)
- F104** 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)**
- F105** 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)**
- 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(d)**

- 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(e)**
- F108** 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**
- F109** 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**
- F110** 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**
- F111** 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**
- F112** 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**
- F113** 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**
- F114** 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**
- F115** 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**
- F116** 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**
- F117** 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

- I6** 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)**
- I7** 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

- [^{F1187}—(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”.]

F118 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

I8 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.

[^{F119}(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”.]

[^{F120}(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 ”.]

[^{F121}(4A) In regulation 56 (fees payable in relation to clinical investigation notices), in paragraph (2), for “his authorised representative” substitute “their UK responsible person”.]

[^{F122}(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”.]

F119 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**

F120 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)

F121 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**

F122 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

I9 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\(1\)](#)

I10 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^{M20}(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)^{M21}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.”.

[^{F123}(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 ”.]
- [^{F124}(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 ”;
- [^{F125}(iii) in sub-paragraph (c) omit “and, where applicable any relevant provision of the Medical Devices Directives”.]
- (6) In regulation 63 ^{M22} (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 ”.
- [^{F126}(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 ^{M23} (review), for “2019” substitute “ 2025 ”.
- (9) Omit Schedule 1 ^{M24} (association agreements).
- (10) For Schedule 2 ^{M25} (mutual recognition agreements) substitute—

“SCHEDULE 2

Regulation 1A

Mutual Recognition Agreement countries

- Australia
- New Zealand
- Canada
- The United States of America
- The Swiss Confederation”.

- F123** 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)
- F124** 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**
- F125** 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**
- F126** 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

- I11** 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\(1\)](#)
- I12** 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

- M20** Regulation 59 was amended by [S.I. 2003/1697](#).
- M21** Regulation 60 was amended by [S.I. 2008/2936](#).
- M22** Regulation 63 was amended by [S.I. 2008/2936](#).
- M23** Regulation 67 was inserted by [S.I. 2013/2327](#).
- M24** Schedule 1 was amended by [2013/2327](#).
- M25** Schedule 2 was amended by [S.I. 2013/2327](#).

Changes to legislation:

There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, PART 1.