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.

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

"**Schedules**

1A. Schedules 2 to 28 have effect.";

(3) In regulation 2(**1**) (interpretation)—

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

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

(c) in the definition of "authorised representative" —

(i) for "established within the Community" substitute "established outside the United Kingdom but within the European Economic Area",

(ii) for "authorities and bodies in the Community" substitute "authorities and bodies in the European Economic Area";

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

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

(e) at the end of the definition of "Directive 90/385" insert "as it had effect immediately before exit day";

(f) at the end of the definition of "Directive 93/42" insert "as it had effect immediately before exit day";

(g) at the end of the definition of "Directive 98/79" insert "as it had effect immediately before exit 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";

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

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

(l) in the definition of "intended for clinical investigation", in paragraph (b), for "a Member State" substitute "the United Kingdom";

(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(**2**);";

(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(**3**)";

(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";

(q) in the definition of "notified body"

(i) omit "Part V or";

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

(iii) at the end insert "but, unless the context requires otherwise, does not include a UK notified body";

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

(i) for "Community" substitute "United Kingdom";

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

(s) in the definition of "putting into service" in paragraph (b) for "Community" substitute "United Kingdom";

(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;"

(v) in the definition of "UK notified body" for "regulation 45" substitute "regulations 4F(8) and 4G(8)";

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

> ""UK responsible person" means a person established in 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 exit day and as modified by Schedule 2A.".

(**2**) S.I. 2008/1597; no relevant amendments.
(**3**) 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.

(5) In regulation 3(**4**) (scope of these Regulations)—

(a) for the heading substitute, "Scope of Parts II to VII";

(b) in the opening words before paragraph (a), substitute "Parts II to VII of these Regulations do not apply to";

(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.—(1) In Parts II, III, IV, VIII and IX of these Regulations a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

(b) 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.

(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 (CENLAC);

(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.

(**4**) Regulation 3 was amended by S.I. 2007/400 and S.I. 2008/2936.

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

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

(8) In this regulation, a 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.

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(**5**);

(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 notified bodies (including UK notified 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(**6**) (transitional provisions for hip, knee and shoulder replacement) insert—

"**Application of Part VIII to medical devices and their accessories, other than in vitro diagnostic medical devices and their accessories, before 26th May 2020**

4B.—(1) Part VIII only applies before 26th May 2020 in respect of a device or accessory that is a relevant device for the purposes of Part II or III if the conformity assessment that the person placing it on the market or putting it into service relies on for doing so is the conformity assessment required by Part VIII (rather than by Part II or III).

(2) Accordingly, before 26th May 2020, unless paragraph (1) applies—

(a) Part II continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part; and

(b) Part III continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part.

(3) Where Part VIII applies —

(a) Part II ceases to apply, apart from regulations 7A and 19 (to the extent that those regulations otherwise apply, for which see regulations 4D(1) to (5) and 4E(4)); and

(b) Part III ceases to apply, apart from regulations 21A and 30(3) to (5) (to the extent that those regulations otherwise apply, for which see regulations 4D(6) and 4E(4)).

(**5**) 2018 c. 12.
(**6**) Regulation 4A was inserted by S.I. 2007/400.

Application of Part IX to in vitro diagnostic medical devices and their accessories before 26th May 2022

4C.—(1) Part IX only applies before 26th May 2022 in respect of a device or accessory that is a relevant device for the purposes of Part IV if the conformity assessment that the person placing it on the market or putting it into service relies on for doing so is the conformity assessment required by Part IX (rather than by Part IV).

(2) Accordingly, before 26th March 2022, unless paragraph (1) applies, Part IV continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part.

(3) Where Part IX applies, Part IV ceases to apply, apart from regulations 33A and 44 (to the extent that those regulations otherwise apply, for which see regulations 4D(8) to (11) and 4E(8)).

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 exit day (which is the day on which regulation 7A comes into force).

(2) Regulation 7A does not apply until the day that is 8 months after exit day in respect of a device or accessory—

(a) that—

(i) is a relevant device for the purposes of Part II, or

(ii) would be a relevant device for the purposes of Part II, but for the application of regulation 4B(1); and

(b) that is classified (whether or not Part II applies in respect of the device) 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 exit day in respect of a device or accessory—

(a) that—

(i) is a relevant device for the purposes of Part II, or

(ii) would be a relevant device for the purposes of Part II, but for the application of regulation 4B(1); and

(b) that is classified (whether or not Part II applies in respect of the device) 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, with the modifications in paragraph (5)—

(5) On and after exit day and until its revocation, regulation 19 continues to have effect with the following modifications—

(a) paragraph (3) applies as if for the words "the Community or in a State which is a Party to an Association Agreement" there were substituted "the United Kingdom"; and

(b) as if paragraph (6) were omitted.

(6) Regulation 30(3) is revoked on the day that is 4 months after exit day (which is the day on which regulation 21A comes into force).

(7) On or after exit day and until its revocation, regulation 30(3) continues to have effect with the following modifications—

(a) as if the words "Except as provided in paragraphs (4) and (5)" were omitted;

(b) as if the words "under their own name" were omitted;

(c) as if after Directive 90/385 the following words were inserted "or, if not the manufacturer, the person placing devices on the market under that Article,".

(8) Regulation 44 is revoked on the day that is 4 months after exit day (which is the day on which regulation 33A comes into force).

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

(a) that—

(i) is a relevant device for the purposes of Part IV, or

(ii) would be a relevant device for the purposes of Part IV, but for the application of regulation 4C(1); and

(b) that is—

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

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

(10) Regulation 33A does not apply until the day that is 12 months after exit day in respect of a device or accessory—

(a) that —

(i) is a relevant device for the purposes of Part IV, or

(ii) would be a relevant device for the purposes of Part IV, but for the application of regulation 4C(1); and

(b) that is classified (whether or not Part IX applies in respect of the device) as belonging to Class A, referred to in Schedule 23.

(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, with the following modifications—

(a) paragraph (2)(b) applies as if for the words "the Community or a State which is a Party to an Association Agreement" there were substituted "the United Kingdom"; and

(b) as if paragraph (3) were omitted.

(12) On and after exit day and until its revocation, regulation 44 continues to have effect with the following modifications—

(a) paragraph (2)(b) applies as if for the words "the Community or a State which is a Party to an Association Agreement" there were substituted "the United Kingdom"; and

(b) as if paragraph (3) were omitted.

Transitional provisions in respect of the European Commission's UDI database

4E.—(1) Subject to paragraph (3), regulations 91 to 95 do not apply until the date which is 6 months after the date on which the UDI database managed by the European Commission

becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union), unless that date ("the operational date") is before 26th May 2020.

(2) Accordingly, until the operational date—

(a) the following provisions do not apply—

(i) regulation 76(9)and (14)(c)(viii),

(ii) regulation 101(2),

(iii) paragraph 23(3)(h) of Schedule 3,

(iv) paragraph 1(c) of Schedule 6, and

(v) Schedule 8; and

(b) the following provisions only apply with the following modifications—

(i) regulation 100(2), as if the words from "Except for" to "94 to 96," were omitted; and

(ii) regulation 118(9)(a), as if the words "when the device is registered in accordance with regulation 94 and" were omitted.

(3) Regulation 91(4) only applies in respect of a device to which Part VIII applies, or in respect of an accessory to such a device—

(a) on and after 26th May 2021 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—

(i) an implantable device, or an accessory to such a device, or

(ii) a Class III device, or an accessory to such a device;

(b) on and after 26th May 2023 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—

(i) a Class IIa device, or an accessory to such a device, or

(ii) a Class IIb device, or an accessory to such a device;

(c) on and after 26th May 2025 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as a Class 1 device, or an accessory to such a device;

(d) on and after the date which is 2 years after the operational date, in the case of a device considered to be a reusable device, or an accessory to such a device, in circumstances where it is required to bear the UDI carrier on the device or accessory itself.

(4) If the operational date is before 26thMay 2020, regulations 7A and 21A cease to apply on the operational date in respect of a device or accessory to which Part VIII applies because regulation 4B(1) applies.

(5) Subject to paragraph (7), regulations 157 to 160 do not apply until the date which is 6 months after the operational date, unless the operational date is before 26th May 2022.

(6) Accordingly, before the operational date—

(a) the following provisions do not apply—

(i) regulation 145(8)and (13)(c)(viii), and

(ii) Schedule 22; and

(b) the following provisions only have effect with the following modifications—

(i) regulation 161(4)(a), as if the words "including the basic UDI-DI" were omitted; and

(ii) regulation 165(2), as if the words from "Except for" to "158 or 160," were omitted.

(7) Regulation 157(4) only applies in respect of a device to which Part VIII applies, or an accessory to such a device—

(a) on and after 26th May 2023 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as a Class D device, or an accessory to such a device;

(b) on and after 26th May 2025 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as—

(i) a Class C device, or an accessory to such a device, or

(ii) a Class B device, or an accessory to such a device; or

(c) on and after 26th May 2027 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as a Class A device, or an accessory to such a device.

(8) If the operational date is before 26thMay 2022, regulation 33A ceases to apply on the operational date in respect of a device or accessory to which Part IX applies because regulation 4C(1) applies.

Application of Parts II and III on and after 26th May 2020, the related transitional provisions and the revocation of Parts II and III on 26th May 2025

4F.—(1) Parts II and Part III are revoked on 26th May 2025.

(2) Pending their revocation, Parts II and III cease to apply on 26th May 2020, except as provided for in this regulation.

(3) Subject to paragraph (4), regulations 7A and 21A continue to apply on and after 26th May 2020 unless by virtue of regulation 4E(4) they ceased to apply before that date in respect of devices or accessories to which Part VIII applies (in which case regulations 7A and 21A cease to apply for all purposes on 26th May 2020).

(4) Unless, by virtue of paragraph (3), they ceased to apply for all purposes on 26th May 2020, regulations 7A and 21A cease to apply on the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union).

(5) Certificates issued in accordance with Directive 90/385 or Directive 93/42 before 26th May 2020 remain valid on and after 26th May 2020—

(a) if issued before 26th May 2017 otherwise than in accordance with Annex 4 of Directive 90/385 or Annex IV of Directive 93/42, until the end of the period indicated on the certificate or, if sooner, 26th May 2025;

(b) if issued before 26th May 2017 in accordance with Annex 4 of Directive 90/385 or Annex IV of Directive 93/42, until the end of the period indicated on the certificate or, if sooner, 26th May 2022;

(c) if issued on or after 26th May 2017 but before 26th May 2020, until whichever of the following is the soonest—

(i) the end of the period indicated on the certificate,

(ii) the end of the period of 5 years from the date on which the certificate was issued, or

(iii) 26th May 2024.

(6) Subject to paragraph (7), Part II or III continues to apply on and after 26th May 2020 in respect of a device or an accessory that is a relevant device for the purposes of Part II or III, in circumstances where—

(a) the conformity assessment that the person placing it on the market or it into service relies on for doing so is the conformity assessment required by Part II or III;

(b) as a consequence, there is in respect of that relevant device a certificate of conformity, the validity of which is preserved by paragraph (5);

(c) since the issuing of that certificate, there have been no significant changes to the design or intended purpose of the relevant device; and

(d) the notified body responsible for that certificate continues to fulfil its obligations in respect of the continued supervision of the relevant device.

(7) The requirements of Part VIII in respect of post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices apply in place of the corresponding requirements of Parts II and III (although regulations 7A and 21A may continue to apply, subject to paragraphs (3) and (4)).

(8) For the purposes of paragraph (6)(d)—

(a) a body does not cease, as a consequence of the withdrawal of the United Kingdom from the European Union, to be the notified body responsible for a certificate if—

(i) it was a notified body designated as a UK notified body in accordance with regulation 45 (designation of notified bodies) as it applied immediately before exit day, and

(ii) before exit day, that designation had not been withdrawn under regulation 45(5);

(b) a notified body fulfils its obligations if it carries out the activities required by the following provisions as they apply to the devices covered by the relevant certificate—

(i) for relevant devices to which Part II applies, the Annexes to Directive 93/42 and in particular sections 5 and 7.5 of Annex II, section 4 of Annex V and section 4 of Annex VI, and

(ii) for relevant devices to which Part III applies, the Annexes to Directive 90/385 and in particular section 5 of Annex 2 and section 4 of Annex 5 to Directive 90/385.

Application of Part IV on and after 26th May 2022, the related transitional provisions and the revocation of Part IV on 26th May 2025

4G.—(1) Part IV is revoked on 26th May 2025.

(2) Pending its revocation, Part IV ceases to apply on 26th May 2022, except as provided for in this regulation.

(3) Subject to paragraph (4), regulation 33A continues to apply on and after 26th May 2022 unless by virtue of regulation 4E(8) it ceased to apply before that date in respect of devices or accessories to which Part IX applies (in which case regulation 33A ceases to apply for all purposes on 26th May 2022).

(4) Unless, by virtue of paragraph (3), it ceased to apply for all purposes on 26th May 2022, regulation 33A ceases to apply on the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union).

(5) Certificates issued in accordance with Directive 98/79 before 26th May 2022 remain valid on and after 26th May 2022—

(a) if issued before 26th May 2017 otherwise than in accordance with Annex VI of Directive 98/79, until the end of the period indicated on the certificate or, if sooner, 26th May 2025;

(b) if issued before 26th May 2017 in accordance with Annex VI of Directive 98//79, until the end of the period indicated on the certificate or, if sooner, 26th May 2024;

(c) if issued on or after 26th May 2017 but before 26th May 2020, until the end of the period indicated on the certificate or, if sooner, 26th May 2024.

(6) Subject to paragraph (7), Part IV continues to apply on and after 26th May 2022 in respect of a device or an accessory that is a relevant device for the purposes of that Part, in circumstances where—

(a) the conformity assessment that the person placing it on the market or it into service relies on for doing so is the conformity assessment required by Part IV;

(b) as a consequence, there is in respect of that relevant device a certificate of conformity, the validity of which is preserved by paragraph (5);

(c) since the issuing of that certificate, there have been no significant changes to the design or intended purpose of the relevant device; and

(d) the notified body responsible for that certificate continues to fulfil its obligations in respect of the continued supervision of the relevant device.

(7) The requirements of Part IX in respect of post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices apply in place of the corresponding requirements of Part IV (although regulation 33A may continue to apply, subject to paragraphs (3) and (4)).

(8) For the purposes of paragraph (6)(d)—

(a) a body does not cease, as a consequence of the withdrawal of the United Kingdom from the European Union, to be the notified body responsible for a certificate if—

(i) it was a notified body designated as a UK notified body in accordance with regulation 45 (designation of notified bodies) as it applied immediately before exit day, and

(ii) before exit day, that designation had not been withdrawn under regulation 45(5); and

(b) a notified body fulfils its obligations if it carries out the activities required by the Annexes to Directive 98/79 and in particular by section 5 of Annex IV and section 4 of Annex VII to Directive 98/79, as they apply to the devices covered by the relevant certificate.

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(**7**) ("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 exit day.

(**7**) OJ No. L 131, 16.5.2002, p. 17.

Revocation of Commission Decision 2010/227

4I. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed)(**8**) 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(**9**), Regulation (EU) No 207/2012 has effect as it had effect immediately before exit day.

(2) Before 26th May 2020, Regulation (EU) No. 207/2012 only applies as regards—

(a) a device or accessory which is a relevant device for the purposes of Part II or III in respect of which Part II or III continue to apply by virtue of regulation 4B(2) or a device to which Part VIII applies by virtue of regulation 4B(1);

and

(b) as if—

(i) the reference to a notified body in Article 8 included reference to a UK notified body, where that UK notified body is responsible for the certificate of conformity that remains valid by virtue of regulation 4F(5), but

(ii) Article 8 were otherwise omitted.

(3) On and after 26th May 2020 but before 26th May 2025, Regulation (EU) No 207/2012 only applies as regards—

(a) a device or accessory that is a relevant device for the purposes of Part II or III in respect of which Part II or III continues to apply by virtue of regulation 4F(6) (subject to regulation 4F(7)) or a device to which Part VIII applies; and

(b) as if—

(i) the reference to a notified body in Article 8 included reference to a UK notified body, where that UK notified body is responsible for the certificate of conformity that remains valid by virtue of regulation 4F(5), but

(ii) Article 8 were otherwise omitted.

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

(2) Before 26th May 2020, Regulation (EU) No 722/2012 applies as regards—

(a) a device or accessory that is a relevant device for the purposes of Part II or III in respect of which Part II or III continues to apply by virtue of regulation 4B(2);

(b) a device to which Part VIII applies by virtue of regulation 4B(1);

(3) On and after 26th May 2020 but before 26th May 2025, Regulation (EU) No 722/2012 applies as regards a device or accessory that is a relevant device for the purposes of Part II or

(**8**) OJ No. L 102, 23.4.2010, p. 45.
(**9**) see Article 122 of Regulation (EU) 2017/745for reference to when the Regulation is to be revoked.
(**10**) see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.

III in respect of which Part II or III continues to apply by virtue of regulation 4F(6) (subject to regulation 4F(7)) or to devices to which Part VIII applies.

(4) Before 26th May 2025, Regulation (EU) No 722/2012 only applies as regards a UK notified body—

(a) where the UK notified body is responsible for a certificate of conformity issued for the relevant device in accordance with Directive 90/385 or Directive 93/42 that remains valid by virtue of regulation 4F(5); and

(b) to the extent this is necessary for the fulfilment by the UK notified body of its obligations as regards the relevant device for the purposes of Part II or III.

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

(2) Except as provided for in this regulation, pending its revocation, Regulation (EU) No 920/2013 has effect as it had effect immediately before exit day.

(3) Before 26th May 2025, Regulation (EU) No 920/2013 only applies as regards a UK notified body—

(a) where the UK notified body is responsible for a certificate of conformity issued for the device or accessory in accordance with Directive 90/385 or Directive 93/42 that remains valid by virtue of regulation 4F(5); and

(b) to the extent this is necessary for the fulfilment by the UK notified body of its obligations as regards the device or accessory for the purposes of Part II or III.

(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 UK notified 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(**12**) ("Regulation (EU) No 2017/2185") is revoked.

(**11**) OJ No. L 253, 25.9.2013, p. 8.
(**12**) OJ No. L 309, 24.11.2017, p. 7.

(2) Notwithstanding paragraph (1), where conformity assessment of medical devices under Part VIII or IX requires involvement of a notified body in the European Union and the use of one of the codes listed in Regulation (EU) No. 2017/2185, that that Regulation is saved to the extent necessary to give effect to that requirement.

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

4N. Where regulation 7 applies either in accordance with regulation 4B(2)(a), or for the purposes of regulation 4D(2)(b) or (3)(b), or by virtue of regulation 4F(6), Directives 2003/12 and 2005/50 apply with the following modifications—

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

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

Revocation of Regulation (EU) 2017/745

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

(2) Part VIII applies in respect of a device or accessory placed on the market or put into service before exit day in accordance with the conformity assessment required by the Medical Devices Regulation as it applies to a device or accessory placed on the market or put into service in accordance with Part VIII.

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.

(2) Part IX applies in respect of a device or accessory placed on the market or put into service before exit day in accordance with the conformity assessment required by the Medical Devices Regulation as it applies to a device or accessory placed on the market or put into service in accordance with Part IX.

Modifications to deal with serious shortages

4Q.—(1) The Secretary of State may by regulations modify the application of any of the provisions of these Regulations in circumstances where, in the Secretary of State's opinion, the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage, arising from the withdrawal of the United Kingdom from the European Union, of a device or accessory of a specified description that—

(a) is a relevant device for the purposes of Part II, III or IV; or

(b) would be a relevant device for the purposes of Part II, III or IV but for the application of regulation 4B(1) or 4C(1).

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that in the opinion of the Secretary of State is being or may be experienced.

(3) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where the

withdrawal of the United Kingdom from the European Union is one but not the only significant factor contributing to the shortage.

(4) No regulations under paragraph (1) may be made, or have effect after the end of the period of 2 years beginning with exit day.

(5) The power to make regulations under paragraph (1) is exercisable by statutory instrument.

(6) Regulations made under paragraph (1) are subject to annulment by resolution of either House of Parliament.

References in other legislation to expressions used in these Regulations

4R.—(1) In the following provisions, where reference is made, in whatever form, to the expression "medical device" having the meaning given in regulation 2, to the extent necessary for the practical application of that definition, the reference to regulation 2 is to be construed as a reference also or instead to regulation 69—

(a) the definitions of "electronic cigarette" and "electronic cigarette refill container" in section 368R of the Communications Act 2003(**13**) (interpretation of Part 4A);

(b) regulation 4(3)(b)(ii) of the National Health Service Commissioning Board (Additional Functions) Regulations 2017(**14**) (power to conclude and manage framework agreements);

(c) the definition of "medical device" in regulation 2(1) of the Tobacco and Related Products Regulations 2016(**15**) (interpretation);

(d) the definition of "medical device" in regulation 1(4) of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015(**16**) (citation, commencement and interpretation);

(e) the definition of "equipment" in regulation 2(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014(**17**) (interpretation);

(f) the definition of "medical device" in regulation 2(1) of the Restriction on the Use of Certain Hazardous Substances in Electrical and Electrical Equipment Regulations 2012(**18**) (interpretation); and

(g) the definition of "medical device" in article 3(1) of the Pharmacy Order 2010(**19**) (interpretation).

(2) In regulation 2(1) of the Restriction on the Use of Certain Hazardous Substances in Electrical and Electrical Equipment Regulations 2012, where reference is made to the expression "in vitro diagnostic medical device" having the meaning given in regulation 2, to the extent necessary for the practical application of that definition, "in vitro diagnostic medical device" is be construed as also or instead having the meaning given to "in vitro diagnostic medical device" in regulation 137.

(3) In sub-paragraph (c) of the definition of "manufacturer" in regulation 1(3) of the Blood Safety and Quality Regulations 2005(**20**) (citation, commencement and interpretation), the reference made to the definition of "manufacturer" in relation 2(1) is to be construed, to the

(**13**) 2003 c. 21. Section 368R was inserted by S.I. 2009/2979 and has been amended by S.I. 2010/831, 2012/1916 and 2016/507.
(**14**) S.I. 2017/212.
(**15**) S.I. 2016/507; amended by S.I. 2016/1127.
(**16**) S.I. 2015/895.
(**17**) S.I. 2014/2936; amended by S.I. 2015/64.
(**18**) S.I. 2012/3032; amended by S.I. 2018/942.
(**19**) S.I. 2010/231; amended by the Data Protection Act 2018 (c. 12), Schedule 19, paragraph 352, and by S.I. 2011/1043, 2015/806 and 968, and 2016/372 and 1030.
(**20**) S.I. 2005/50; amended by S.I. 2005/2898, 2006/2013, 2010/1881, 2011/2581, 2013/235 and 2018/231.

extent necessary for the practical application of that definition, as if it were defined also or instead by reference to regulation 69.

(4) In the following provisions, where reference is made to regulation 15, to the extent necessary for the practical application of the provision, that reference is to be construed as a reference also or instead to regulation 76(7)—

(a) paragraph 32(3)(e) of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(**21**) (other contractual terms – patient records);

(b) paragraph 33(3)(e) of Schedule 3 to the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(**22**) (other contractual terms – patient records);

(c) paragraph 33(3)(e) of Schedule 3 to the National Health Service (Personal Dental Services Agreements) Regulations 2005(**23**) (other contractual terms – patient records); and

(d) paragraph 32(3)(e) of Schedule 3 to the National Health Service (General Dental Services Contracts) Regulations 2005(**24**) (other contractual terms – patient records).

Use in other legislation of a definition of "medical device" based on the definition in Directive 93/42

4S. In the following provisions, the definition of "medical device" is to be construed, to the extent necessary for the practical application of that definition, as if it were defined also or instead by reference to regulation 69—

(a) regulation 1(3) of the National Health Service (Cross-Border Healthcare) Regulations 3013(**25**) (citation, commencement, extent and interpretation);

(b) regulation 2 of the National Health Service (Cross-Border Health Care) (Scotland) Regulations 2013(**26**) (interpretation); and

(c) regulation 2(1) of the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013(**27**) (interpretation).

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(**28**) (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 Parts IV and IX.

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016(**29**) (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 or 69; and

(**21**) S.I. 2006/490.
(**22**) S.I. 2006/489.
(**23**) S.I. 2005/3373.
(**24**) S.I. 2005/3361.
(**25**) S.I. 2013/2269.
(**26**) SSI 2013/292; amended by SSI 2015/91.
(**27**) S.R. 2013 No. 299.
(**28**) 2004 c. 30. There have been no amendments to subsection (12) of section 1.
(**29**) S.I. 2016/190.

(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(**30**) (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 or VIII.

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013(**31**) (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 or 69;

(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 or to "accessory for a medical device" in regulation 69;

(d) the reference to the expression "in vitro diagnostic medical device" having the meaning given in Article 1(2)(b) of Directive 98/79 is to be construed, to the extent necessary for the practical application of that definition, as—

(i) having the meaning given to it in regulation 2, or

(ii) also or instead having the meaning given to "in vitro medical device" in regulation 137.

(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 or to "accessory for an in vitro diagnostic medical device" in regulation 137.

(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(**32**) (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(**33**) (provision of personal protective equipment).".

Amendment of Part II of the 2002 Regulations

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

(2) In regulation 6 (Scope of Part II) after paragraph (c) insert—

(**30**) S.I. 2016/1105.
(**31**) S.I. 2013/3113; amended by S.I. 2015/1968, 2016/738 and 1154, and 2018/102 and 942.
(**32**) S.R. 1993 No. 20; amended by S.I. 2015/223, S.I. 2012/179, 2017/229.
(**33**) S.I. 1992/2966; amended by S.I. 1999/860, 2002/2174, 2015/1637 and 2018/390.

"(d) except for the requirement to register under regulation 7A or 19, medical devices or accessories to such devices placed on the market in accordance with Part VIII.".

(3) In regulation 7 (Classification of general medical devices), omit paragraph (2).

(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 (or Part VIII insofar as it applies to relevant devices) unless that person—

(a) is established in the United Kingdom; and

(b) has complied with paragraph (2).

(2) A person complies with this paragraph if, before placing the relevant device on the market, the person—

(a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered place of business, an address in the United Kingdom at which service of any document relating in any way to the person's placing of the relevant device on the market will be effective;

(b) if they are not the manufacturer of the relevant device, provides the Secretary of State with written evidence that they have the manufacturer's authority to place the relevant device on the market;

(c) supplies the Secretary of State with a description of the relevant device; and

(d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the written evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person 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;

(d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;

(e) 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;

(f) 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 designated;

(g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(4) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with the following—

(a) where this regulation applies and Part II applies —

(i) the reference to technical documentation is to be construed in accordance with Annex II, III or VII;

(ii) the reference to the declaration of conformity is to be construed in accordance with Annexes II, IV, V, VI and VII as applied by regulation 13;

(b) where this regulation applies and Part VIII applies—

(i) the reference to technical documentation is to be construed in accordance with Schedules 4 and 5;

(ii) the reference to the declaration of conformity is to be construed in accordance with regulation 84.".

(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);

(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".

(7) In regulation 12 (Exemptions from regulations 8 and 10) 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 CE 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 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.".

(8) In regulation 17(**34**) (Manufacturers etc. and conformity assessment procedures for general medical devices), omit paragraph (3).

(9) Omit regulation 18(**35**) (UK notified bodies and the conformity assessment procedures for general medical devices).

Amendment of Part III of the 2002 Regulations

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

(2) In regulation 21(**36**) (Scope of Part III)—

(**34**) There are amendments to regulation 17 which are not relevant to these Regulations.
(**35**) Regulation 18 was amended by S.I. 2003/1697, 2008/2936 and 2013/2327.
(**36**) Regulation 21 was amended by S.I. 2008/2936.

(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 or Part VIII insofar as it applies to relevant devices unless that person—

(a) is established in the United Kingdom; and

(b) has complied with paragraph (2).

(2) A person complies with this paragraph if, before placing the relevant device on the market, the person—

(a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered place of business, an address in the United Kingdom at which service of any document relating in any way to the person's placing of the relevant device on the market will be effective;

(b) if they are not the manufacturer of the relevant device, provides the Secretary of State with written evidence that they have the manufacturer's authority to place the relevant device on the market;

(c) supplies the Secretary of State with a description of each device concerned; and

(d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the written evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person 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;

(d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and verify that the Secretary of State receives the samples or is given access to the device;

(e) 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;

(f) 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 designated;

(g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(4) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with the following—

(a) where this regulation applies and Part III applies—

(i) the reference to technical documentation is to be construed in accordance with Annex 2, 3 or 5;

(ii) the reference to the declaration of conformity is to be construed in accordance with Annexes 2,3 and 5 as applied by regulation 27;

(b) where this regulation applies and Part VIII applies—

(i) the reference to technical documentation is to be construed in accordance with Schedules 4 and 5;

(ii) the reference to the declaration of conformity is to be construed in accordance with regulation 84.".

(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).

(5) In regulation 26 (Exemptions from regulations 22 and 24) 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 CE 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.".

(6) In regulation 30(**37**) omit paragraphs (4) and (5).

(7) Omit regulation 31(**38**) (UK notified bodies and the conformity assessment procedures for active implantable medical devices).

Amendment of Part IV of the 2002 Regulations

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

(2) In regulation 33 (Scope of Part IV)—

(a) after paragraph 1(b) insert—

"(c) in vitro diagnostic medical devices and accessories to such devices placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.";

(b) after paragraph 2(b) insert—

(**37**) Regulation 30 was amended by S.I. 2008/2396.
(**38**) Regulation 31 was amended by S.I. 2008/2936.

"(c) devices that are placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.".

(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, or Part IX insofar as it applies to relevant devices, unless that person—

(a) is established in the United Kingdom; and

(b) has complied with paragraph (2).

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

(a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered address, an address in the United Kingdom at which service of any document relating in any way to the person's placing of a relevant device on the market will be effective;

(b) if they are not the manufacturer of the relevant device, provides the Secretary of State with sufficient written evidence that they have the manufacturer's authority to place the relevant device on the market;

(c) supplies the Secretary of State with relevant information in relation to each device concerned; and

(d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person 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;

(d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;

(e) 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;

(f) 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 designated;

(g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

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

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

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

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

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

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

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

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

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

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

(a) there has been no such device continuously available on the United Kingdom or other 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 or other market during the previous three years.

(7) In paragraph (3) the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with the following—

(a) where this regulation applies and Part IV applies—

(i) the reference to technical documentation is to be construed in accordance with Annexes III to VIII;

(ii) the reference to the declaration of conformity is to be construed in accordance with Annexes III, IV, V and VII as applied by regulation 40;

(b) where this regulation applies and Part IX applies—

(i) the reference to technical documentation is to be construed in accordance with Schedules 18 and 19;

(ii) the reference to the declaration of conformity is to be construed in accordance with regulation 153.".

(4) In regulation 35 (Determining compliance of in vitro diagnostic medical devices with relevant essential requirements), in paragraph (2), omit the words from "if the device may reach a final user" to the end.

(5) In regulation 39 (Exemptions from regulations 34, 36 and 38), 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 CE 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.".

(6) In regulation 41 (Manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices) in paragraph (5)—

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

(b) omit "in the United Kingdom".

(7) Omit regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic medical devices).

Amendment of Part V of the 2002 Regulations

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

(2) In regulation 45(**39**) (Designation etc. of UK notified bodies)—

(a) in the heading, omit "Designation etc. of";

(b) for "the Mutual Recognition Agreements" in each place it occurs, substitute "a mutual recognition agreement";

(c) omit paragraphs (1) to (3);

(d) in paragraph (5)—

(i) in the introductory wording, omit "under paragraph (1)";

(ii) in sub-paragraph (c) omit "under paragraph (1)".

(3) In regulation 47(**40**)—

(a) in paragraph (1)—

(i) for "an application has been made" substitute ", before exit day, an application was made";

(ii) for "shall perform those functions", substitute "shall perform the functions set out in regulations 4F(8)(b) and 4G(8)(b)";

(b) in paragraph (3)—

(i) for the first mention of "notified body" substitute "UK notified body";

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

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

(c) in paragraph (5), for "notified body" in both places it occurs substitute "UK notified body";

(d) in paragraphs (6) and (8), for "the Mutual Recognition Agreements" in each place it occurs, substitute "a mutual recognition agreement".

(4) In regulation 48 (Designation etc. of EC conformity assessment bodies)—

(a) in the heading and in each other place it occurs omit "EC";

(b) for "the Mutual Recognition Agreements" in each place it occurs, substitute "a mutual recognition agreement";

(**39**) Regulation 45 was amended by S.I. 2003/1697 and S.I. 2013/2327.
(**40**) Regulation 47 was amended by S.I. 2008/2936 and S.I. 2013/2327.

(c) in paragraph (1) omit "European Community".

(5) In regulation 49 (Fees charged by UK notified bodies and EC conformity assessment bodies) —

(a) in the heading and in each other place it occurs omit "EC";

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

(c) in paragraph (1), for "under the Medical Devices Directives", substitute "under these Regulations".

Amendment of Part VI of the 2002 Regulations

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

(2) In regulation 53(**41**) (Fees in connection with the registration of devices and changes in registration details)—

(a) for "regulation 19 or 44" substitute "regulations 7A, 19, 21A, 33A, 44, 93, 95, 158 or 160";

(b) after "registration of that person" insert "or, in the case of registration of a device, the device".

(3) In regulation 54(**42**) (Fees payable in connection with the designation of UK notified bodies) —

(a) in the heading omit "with the designation etc. of";

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

(c) omit paragraph (1);

(d) omit paragraph (3C);

(e) in paragraph (4), omit sub-paragraph (a).

(4) In regulation 55(**43**) (Fees payable in connection with the designation etc. of EC conformity assessment bodies —

(a) in the heading and in every other place it occurs omit "EC";

(b) in paragraph (3), for "the Mutual Recognition Agreements", substitute "a mutual recognition agreement".

(5) In regulation 58 (Waivers, reductions and refunds) in paragraph (2)—

(a) at the end of sub-paragraph (a) omit "or";

(b) omit sub-paragraph (b);

(c) after sub-paragraph (b) in the full out words omit from "(other than" to "the Secretary of State".

Amendment of Part VII of the 2002 Regulations

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

(2) In regulation 59(**44**)(interpretation of Part VII)—

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

(**41**) Regulation 53 was amended by S.I. 2017/207.
(**42**) Regulation 54 was amended by S.I. 2003/1697, S.I. 2007/803, S.I. 2013/2327, S.I. 2017/207.
(**43**) Regulation 55 was amended by S.I. 2007/803, S.I. 2010/557 and S.I. 2017/207.
(**44**) Regulation 59 was amended by S.I. 2003/1697.

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

(3) In regulation 60(**45**) (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.".

(d) in paragraph (4), for "an authorised representative" substitute "a UK responsible person".

(4) In regulation 61(**46**) (enforcement etc.)—

(a) in paragraph (8) in sub-paragraph (a)—

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

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

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

(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".

(6) In regulation 63(**47**) (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".

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

(8) In regulation 67(**48**) (review), for "2019" substitute "2025".

(9) Omit Schedule 1(**49**) (association agreements).

(10) For Schedule 2(**50**) (mutual recognition agreements) substitute—

"SCHEDULE 2 Regulation 1A

Mutual Recognition Agreement countries

— Australia

— New Zealand

— Canada

— The United States of America

— The Swiss Confederation".

(**45**) Regulation 60 was amended by S.I. 2008/2936.
(**46**) Regulation 61 was amended by S.I. 2003/1400, S.I.2005/2009 and S.I. 2007/400.
(**47**) Regulation 63 was amended by S.I. 2008/2936.
(**48**) Regulation 67 was inserted by S.I. 2013/2327.
(**49**) Schedule 1 was amended by 2013/2327.
(**50**) Schedule 2 was amended by S.I. 2013/2327.