This draft Statutory Instrument supersedes the draft of the same title which was laid before Parliament and published on 15 October 2020 (ISBN 978-0-348-21380-5). It is being issued free of charge to all known recipients of that draft Statutory Instrument.

Draft Regulations laid before Parliament under paragraphs 1(1) and 8F(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2020 No.

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C of, paragraphs 1(1)(ab) and 7(2) of Schedule 4, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**) and section 41(1) of the European Union (Withdrawal Agreement) Act 2020(**b**).

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 1(1) and 8F(1)(**c**) of Schedule 7 to the European Union (Withdrawal) Act 2018.

The Treasury has consented to the making of these Regulations as required by paragraphs 3(1) and 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020.

(2) This regulation and regulation 4 come into force on the day after the day on which these Regulations are made.

(3) Regulations 2 and 3 come into force immediately before IP completion day.

(**a**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C was inserted by section 21 of the 2020 Act, and paragraph 1(1)(ab) of Schedule 4 by section 28 of that Act. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**b**) 2020 c. 1.

(**c**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.

(4) Regulation 2 applies in relation to Northern Ireland only.

Amendment of the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**a**) are amended in accordance with Schedule 1.

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

3. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019(**b**) are amended in accordance with Schedule 2.

Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

4.—(1) The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019(**c**) are amended as follows.

(2) In Schedule 2 (amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019)—

(a) in paragraph 2—

(i) in sub-paragraph (2)(a), in paragraph (1) as substituted by that provision, for "Parts II, III, IV, VIII and IX" substitute "Parts II, III and IV";

(ii) omit sub-paragraph (3);

(b) omit paragraph 6;

(c) omit paragraphs 9 to 11.

Name
Parliamentary Under Secretary of State
Department for Health and Social Care

Date

Name
Name
Two Lords Commissioners of Her Majesty's Treasury

Date

SCHEDULE 1

Regulation 2

Amendment of the Medical Devices Regulations 2002

1. The Medical Devices Regulations 2002 are amended in accordance with this Schedule.

Amendment of regulation 2

2. In regulation 2 (interpretation)—

(a) for the definition of "authorised representative" substitute—

""authorised representative" means a person established within a relevant state, explicitly designated by the manufacturer who is not a person established in a relevant state, who acts for the manufacturer and may be addressed by authorities and bodies in a relevant state instead of the manufacturer with regard to the latter's obligation under Directive 90/385, Directive 93/42 and Directive 98/79;";

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

(**a**) S.I. 2002/618, as amended by S.I. 2003/1400, 2003/1697, 2005/2759, 2909, 2007/400, 803, 2008/2936, 2009/383, 2010/557, 2012/1426, 2013/525, 2327, and 2017/207.
(**b**) S.I. 2019/791, as amended by S.I. 2019/1385.
(**c**) S.I. 2019/1385.

(c) in the definition of "intended for clinical investigation", in paragraph (b) for "Member State" substitute "relevant state";

(d) in the definition of "national standard" for "a Member State of the Community" substitute "a relevant state";

(e) in the definition of "placing on the market", for "the Community market" substitute "a relevant market";

(f) in paragraph (b) of the definition of "putting into service" for "the Community" substitute "a relevant state";

(g) in the appropriate places insert—

""relevant market" means a market of a relevant state;";

""relevant state" means—

(a) in relation to any requirement relating to an *in vitro* diagnostic medical device, Northern Ireland or a Member State of the European Union;

(b) in relation to any requirement relating to any other medical device, Northern Ireland or a state in the European Economic Area;

(c) a State other than a Member State of the European Union which is a Party to an Association Agreement (where applicable under that Association Agreement);";

""UK mutual recognition agreement" means an agreement between the United Kingdom and another country that covers matters including the conditions under which the United Kingdom and that country will accept or recognise the results of the conformity assessment procedures undertaken by each other's designated bodies;";

""UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020;";

""UK responsible person" is to be construed in accordance with regulation 19B(2) for the purposes of Part II, regulation 21C(2) for the purposes of Part III and regulation 44A(2) for the purposes of part IV.".

Insertion of regulation 10A

3. After regulation 10 (CE marking of general medical devices) insert—

"**UK(NI) indication: general medical devices**

10A.—(1) Where the CE marking referred to in regulation 10 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever such marking is affixed in accordance with regulation 13.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.".

Amendment of regulation 16

4. In regulation 16(1) (procedures for general medical devices for clinical investigations), for "the United Kingdom" substitute "Northern Ireland".

Amendment of regulation 17

5. In regulation 17 (manufacturers etc and conformity assessment procedures for general medical devices) omit paragraph (3).

Substitution of regulation 19

6. For regulation 19 (registration of persons placing general medical devices on the market) substitute—

"Registration of persons placing general medical devices on the market

19.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are neither Class I devices nor custom-made devices, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any general medical device of any class, other than a system or procedure pack which is not CE marked;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to Class I devices and custom-made devices, to—

(i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland;

(c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of their address and registered place of business;

(b) supply the Secretary of State with a description of each category of device concerned;

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has so appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;

(b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;

(c) in the case of a device that is a Class IIa or Class IIb non-implantable device, on 1st September 2021.

(5) A UK responsible 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) 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 notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 93/42.".

Insertion of regulation 19B

7. After regulation 19 insert—

"**Requirement to appoint a UK responsible person for general medical devices**

19B.—(1) Paragraph (2) applies in relation to a manufacturer who—

(a) does not have a registered place of business in the United Kingdom;

(b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and

(c) places a relevant device, other than a Class I or custom-made device, on the market in Northern Ireland.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 19(2) and (5).".

Insertion of regulation 21B

8. After regulation 21 (scope of Part III) insert—

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

21B.—(1) Paragraph (2) applies—

(a) in relation to relevant devices other than custom-made devices, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any relevant device;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to relevant devices that are custom-made devices, to—

(i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of the address of their registered place of business; and

(b) supply the Secretary of State with a description of each category of device concerned;

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of the date specified in paragraph (4).

(4) The obligations in paragraph (2) begin to apply on 1st May 2021.

(5) A UK responsible 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) 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 notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 90/385.

Requirement to appoint a UK responsible person for active implantable medical devices

21C.—(1) Paragraph (2) applies in relation to a manufacturer who—

(a) does not have a registered place of business in the United Kingdom; and

(b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and

(c) places a relevant device, other than a custom-made device, on the market in Northern Ireland.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 21B(2) and (5).".

Insertion of regulation 24A

9. After regulation 24 (CE marking of active implantable medical devices) insert—

"**UK(NI) indication: active implantable medical devices**

24A.—(1) Where the CE marking referred to in regulation 24 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 27.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service";".

Amendment of regulation 29

10. In regulation 29(1) (procedures for active implantable medical devices for clinical investigations) for "the United Kingdom" substitute "Northern Ireland".

Amendment of regulation 30

11. In regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable devices)—

(a) in paragraph (4) for "a Member State" in both places substitute "a relevant state";

(b) in paragraph (5) for "the Member State" substitute "the relevant state".

Amendment of regulation 35

12. In regulation 35(2) (determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements) for "the United Kingdom" substitute "Northern Ireland".

Insertion of regulation 36A

13. After regulation 36 (CE marking of *in vitro* diagnostic medical devices) insert—

"**UK(NI) indication: *in vitro* diagnostic medical devices**

36A.—(1) Where the CE marking referred to in regulation 36 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 36.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service".".

Amendment of regulation 41

14. In regulation 41 (manufacturers etc and conformity assessment procedures for in vitro diagnostic medical devices), in paragraph (5), for "in the United Kingdom" substitute "in Northern Ireland".

Substitution of regulation 44

15. For regulation 44 (registration of manufacturers etc. of *in vitro* diagnostic medical devices and devices for performance evaluation) substitute—

"Registration of persons placing *in vitro* diagnostic medical devices on the market or for performance evaluation

44.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are Annex II devices or devices for self-testing, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland, or makes available for performance evaluation, any relevant device;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to relevant devices other than Annex II devices or devices for self-testing, to—

(i) a manufacturer who places a device on the Northern Ireland market, or makes such a device available for performance evaluation, and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of the address of their registered place of business; and

(b) supply the Secretary of State with—

(i) a description of each category of device concerned;

(ii) the relevant information in paragraph (7);

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market, or making them available for performance evaluation, is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market, or making them available for performance evaluation;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) where a device is being placed on the market by a manufacturer with a registered place of business in Northern Ireland or by a person who has designated an authorised representative with a registered place of business in Northern Ireland, on 1st January 2021;

(b) in circumstances other than those described in sub-paragraph (a)—

(i) in the case of a relevant device that is a List A device, on 1st May 2021;

(ii) in the case of a relevant device that is a device for self-testing, on 1st September 2021; and

(iii) in the case of a relevant device that is a List B device, on 1st September 2021.

(5) A UK responsible 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) 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 notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 98/79.

(7) 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.

(8) 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.

(9) In paragraphs (7) and (8) a device is a "new relevant device" if—

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

Requirement to appoint a UK responsible person for placing *in vitro* diagnostic medical devices on the market or for performance evaluation

44A.—(1) Paragraph (2) applies in relation to a manufacturer who—

(a) does not have a registered place of business in the United Kingdom;

(b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and

(c) places a relevant device a device that is an Annex II device or a device for self-testing, on the market in Northern Ireland; or

(d) makes available such a device for performance evaluation.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 44(2) and (5).".

Amendment of regulation 45

16. In regulation 45(1) (designation etc. of UK notified bodies), after "any of the tasks of a notified body" insert "with respect to devices to be placed on the market in Northern Ireland".

Insertion of regulation 47A

17. After regulation 47 (general matters relating to UK notified bodies) insert—

"Register of UK notified bodies

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

(a) each notified body established in the United Kingdom is assigned an identification number; and

(b) there is a register of—

(i) notified bodies established in the United Kingdom;

(ii) their notified body identification number;

(iii) the tasks for which they have been notified;

(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).".

Amendment of regulation 48

18. 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 UK 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 UK mutual recognition agreement";

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

(e) in paragraph (5)—

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

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

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

(g) in paragraph (7)—

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

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

Amendment of regulation 49

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

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

(b) in the opening words of paragraph (1) for "EC CAB" substitute "CAB";

(c) in paragraph (1)(a) for "the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure set out in the Medical Devices Directives" substitute "the Medical Devices Directives or a UK mutual recognition agreement in respect of a conformity assessment procedure set out in the Medical Devices Directives or these Regulations as they apply in Great Britain";

(d) in paragraph (1)(b)—

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

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

(e) in paragraph (3) for "EC CAB" substitute "CAB";

(f) in paragraph (4) for "EC CAB" substitute "CAB".

Amendment of regulation 53

20. In regulation 53 (fees in connection with the registration of devices and changes to registration details), after "regulation 19" insert ", 21B".

Amendment of regulation 55

21. 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 UK mutual recognition agreement".

Amendment of regulation 58

22. In regulation 58(2)(b)(ii) (waivers, reductions and refunds), for "an EC CAB" substitute "a CAB".

Amendment of regulation 60

23. In regulation 60 (designation etc of authorised representatives)—

(a) in paragraph (1)—

(i) omit ", other than an obligation referred to in regulation 17(3),";

(ii) for "in the Community or (where appropriate) in a State which is a Party to an Association Agreement" substitute "in a relevant state";

(b) in paragraph (2)—

(i) for "in the Community or (where appropriate) in a State which is a Party to an Association Agreement" substitute "in a relevant state";

(ii) in sub-paragraph (a) for "in the Community" substitute "in a relevant state";

(c) in paragraph (3)—

(i) for "the Community" substitute "a relevant state";

(ii) in sub-paragraph (b)—

(aa) for "the United Kingdom" substitute "Northern Ireland";

(bb) for "the Community or in a State which is a Party to an Association Agreement" substitute "a relevant state".

Amendment of regulation 61

24. In regulation 61 (enforcement etc.)—

(a) after paragraph (1) insert—

"(1A) Paragraph (1) applies in relation to regulations 10A, 24A and 36A (UK(NI) indication) as it does in relation to any other provision of these Regulations to which it applies.".

(b) in paragraph (2) omit "each weights and measures authority in Great Britain and";

(c) in paragraph (3) omit "each weights and measures authority in Great Britain and";

(d) in paragraph (5) omit "authority and";

(e) in paragraph (6) omit sub-paragraphs (a) and (c).

Amendment of regulation 63

25. In regulation 63 (restriction notices)—

(a) in paragraph (4) omit "or a sheriff";

(b) in paragraph (5)—

(i) in the words before sub-paragraph (a) omit "or a sheriff";

(ii) in sub-paragraph (a) omit "or the sheriff";

(iii) in sub-paragraph (b) omit "or the sheriff";

(iv) in the words after sub-paragraph (b) omit "or the sheriff".

Amendment of regulation 65

26. In regulation 65 (centralised system of records etc.) for "the United Kingdom" substitute "Northern Ireland".

SCHEDULE 2

Regulation 3

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

1. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 are amended as follows.

Amendment of regulation 1

2. In regulation 1—

(a) for the heading substitute "Citation, commencement and application";

(b) in regulation (1), for "paragraphs (2) to (4)" substitute "paragraph (2)";

(c) in paragraph (2), in the opening words, for "exit day" substitute "IP completion day";

(d) after paragraph (2) insert—

"(2A) These regulations apply in relation to England and Wales and Scotland.".

(e) omit paragraphs (3) and (4).

Substitution of regulation 3(2)

3. For regulation 3(2) substitute—

"(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.".".

Amendment of regulation 3(3)

4. In regulation 3(3)—

(a) after sub-paragraph (a) insert—

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

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

(b) for sub-paragraph (c) substitute—

"(c) omit the definition of "authorised representative";";

(c) after sub-paragraph (d) insert—

"(da) omit the definition of "the Community";";

(d) in sub-paragraph (e) for "exit day" substitute "IP completion day";

(e) in sub-paragraph (f) for "exit day" substitute "IP completion day";

(f) in sub-paragraph (g) for "exit day" substitute "IP completion day";

(g) after paragraph (j) insert—

(h) "(ja) omit the definition of "European Economic Area";";

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

(j) for sub-paragraph (q) substitute—

"(q) omit the definition of "notified body";";

(k) in sub-paragraph (r)(i) for "United Kingdom" substitute "Great Britain";

(l) in sub-paragraph (s) for "for "Community" substitute "United Kingdom"" substitute "for "the Community" substitute "Great Britain"";

(m) after sub-paragraph (u) insert—

"(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(**a**);";";

(n) for sub-paragraph (v) substitute—

"(v) omit the definition of "UK notified body";";

(o) in sub-paragraph (w) in the definition of "UK responsible person" inserted by sub-paragraph (w), after "established in" insert "any part of".

Amendment of regulation 3(4)

5. In regulation 3(4) for "exit day" substitute "IP completion day".

Insertion of regulation 3(4A)

6. After regulation 3(4) insert—

"(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.".".

Amendment of regulation 3(5)

7. In regulation 3(5) omit sub-paragraphs (a) and (b).

Amendment of regulation 3(6)

8. In—

(a) regulation 3A as inserted by regulation 3(6), in paragraph (1) for "IV, VIII and IX" substitute "and IV";

(b) regulation 3B as inserted by regulation 3(6), for "notified bodies (including UK notified bodies)" substitute "approved bodies".

Amendment of regulation 3(7)

9. In regulation 3(7)—

(a) omit regulation 4B and 4C as inserted by regulation 3(7);

(b) in regulation 4D as inserted by regulation 3(7)—

(i) in each place "exit day" occurs substitute "IP completion day";

(**a**) Article 2(22) was inserted into Regulation (EC) No 765/2008 by paragraph 3 of Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696). This Regulation was incorporated into domestic law by section 3 of the European Union Withdrawal Act 2018 c. 16.

(ii) in paragraph (1), for "the day on which" substitute "when";

(iii) for paragraph (2)(a) substitute—

"(a) that is a relevant device for the purposes of Part II; and";

(iv) in paragraph (2)(b) omit "(whether or not Part II applies in respect of the device)";

(v) for paragraph (3)(a) substitute—

"(a) that is a relevant device for the purposes of Part II; and";

(vi) in paragraph (3)(b) omit "(whether or not Part II applies in respect of the device)";

(vii) in paragraph (4) omit ", with the modifications in paragraph (5)—";

(viii) omit paragraph (5);

(ix) in paragraph (6) for "the day on which" substitute "when";

(x) omit paragraph (7);

(xi) in paragraph (8) for "the day on which" substitute "when";

(xii) for paragraph (9)(a) substitute—

"(a) that is a relevant device for the purposes of Part IV, or";

(xiii) for paragraph (10) substitute—

"(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).";

(xiv) in paragraph (11) omit the words from ", with the following modifications" to the end;

(xv) omit paragraph (12);

(c) omit regulation 4E as inserted by regulation 3(7);

(d) omit regulation 4F as inserted by regulation 3(7);

(e) omit regulation 4G as inserted by regulation 3(7);

(f) in regulation 4H(2) as inserted by regulation 3(7) for "exit day" substitute "IP completion day";

(g) in regulation 4J as inserted by regulation 3(7) omit paragraphs (2) and (3);

(h) in regulation 4K as inserted by regulation 3(7) omit paragraphs (2), (3) and (4);

(i) in regulation 4L as inserted by regulation 3(7)—

(i) omit paragraphs (2) and (3);

(ii) in paragraph (4) for "UK notified bodies" substitute "approved bodies";

(j) in regulation 4M as inserted by regulation 3(7) omit paragraph (2);

(k) in regulation 4N as inserted by regulation 3(7), for the opening words substitute—

"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—;";

(l) in regulation 4O as inserted by regulation 3(7), omit paragraph (2);

(m) in regulation 4P as inserted by regulation 3(7), omit paragraph (2);

(n) omit regulation 4Q as inserted by regulation 3(7);

(o) omit regulation 4R as inserted by regulation 3(7);

(p) omit regulation 4S as inserted by regulation 3(7);

(q) in regulation 4T as inserted by regulation 3(7)—

(i) in paragraph (1), for "Parts IV and IX" substitute "Part IV";

(ii) in paragraph (2)(a) omit "or 69";

(iii) in paragraph (3) omit "or VIII";

(iv) in paragraph (4)—

(aa) in sub-paragraph (b) omit "or 69";

(bb) in sub-paragraph (c) omit "or to "accessory for a medical device" in regulation 69";

(cc) in sub-paragraph (d) for the words from "the practical application of that definition" to "regulation 137.", substitute "the practical application of that definition, as having the meaning given to it in regulation 2;";

(dd) in sub-paragraph (e) omit "or to "accessory for an *in vitro* diagnostic medical device" in regulation 137".

Omission of regulation 4(2)

10. Omit regulation 4(2).

Amendment of regulation 4(3)

11. For regulation 4(3) substitute—

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

Amendment of regulation 4(4)

12. In regulation 7A as inserted by regulation 4(4)—

(a) in paragraph (1)—

(i) in the opening words omit "(or Part VIII insofar as it applies to relevant devices)";

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

(b) for paragraph (2) substitute—

"(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.";

(c) in paragraph (3)—

(i) for the opening words substitute—

"The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—";

(ii) for sub-paragraphs (d) to (g) substitute—

"(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.";

(d) for paragraph (4) substitute—

"(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.".

Amendment of regulation 4(6)

13. In regulation 4(6), after sub-paragraph (a) insert—

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

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

Insertion of regulation 4(6A)

14. After regulation 4(6) insert—

"(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 (**a**)" ;

(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)—

(**a**) Annex 2 was inserted by paragraph 39 of Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 S.I. 2019/696.

(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".".

Insertion of regulation 4(6B)

15. After regulation 4(6A) insert—

"(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.".".

Substitution of regulation 4(7)

16. For regulation 4(7) substitute—

"(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.".".

Insertion of regulation 4(7A)

17. After regulation 4(7) insert—

"(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".".

Insertion of regulation 4(7B)

18. After regulation 4(7A) insert—

"(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".".

Insertion of regulation 4(7C)

19. After regulation 4(7B) insert—

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

Insertion of regulation 4(7D)

20. After regulation 4(7C) insert—

"(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".".

Substitution of regulation 4(8)

21. For regulation 4(8) substitute—

"(8) In regulation 17(**a**) (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).".

(**a**) There are amendments to regulation 17 which are not relevant to these Regulations.

Substitution of regulation 4(9)

22. For regulation 4(9) substitute—

"(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).".

Insertion of regulation 4(10)

23. After regulation 4(9) insert—

"(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).".

Insertion of regulation 4(11)

24. After regulation 4(10) insert—

"(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(**a**) 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(**b**);

(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

(**a**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
(**b**) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.12, p. 3).

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(**a**), 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.

(**a**) 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 (OJ L 117 5.5.2017, p. 1).

(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".".

Amendment of regulation 5(3)

25. In regulation 21A as inserted by regulation 5(3)—

(a) in paragraph (1)—

(i) in the opening words, omit "or Part VIII insofar as it applies to relevant devices";

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

(b) for paragraph (2) substitute—

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

(a) where—

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

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

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

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

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

(c) in paragraph (3)—

(i) for the opening words substitute—

"The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—";

(ii) for sub-paragraphs (d) to (g) substitute—

"(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.";

(d) for paragraph (4) substitute—

"(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.".

Insertion of regulation 5(4A)

26. After regulation 5(4) insert—

"(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".".

Insertion of regulation 5(4B)

27. After regulation 5(4A) insert—

"(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.".".

Substitution of regulation 5(5)

28. For regulation 5(5) substitute—

"(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.".".

Insertion of regulation 5(5A)

29. After regulation 5(5) insert—

"(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".".

Insertion of regulation 5(5B)

30. After regulation 5(5A) insert—

"(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.".

Insertion of regulation 5(5C)

31. After regulation 5(5B) insert—

"(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".".

Substitution of regulation 5(6)

32. For regulation 5(6) substitute—

"(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).".

Substitution of regulation 5(7)

33. For regulation 5(7) substitute—

"(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".".

Insertion of regulation 5(8)

34. In regulation 5 at the end insert—

"(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(**a**) 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(**a**) as it has effect in EU Law;

(**a**) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

(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

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(**a**) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.12, p. 3).

(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".".

Omission of regulation 6(2)

35. Omit regulation 6(2).

Amendment of regulation 6(3)

36. In regulation 33A as inserted by regulation 6(3)—

(a) in paragraph (1)—

(i) in the opening words, omit ", or Part IX insofar as it applies to relevant devices,";

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

(b) for paragraph (2) substitute—

"(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.";

(c) in paragraph (3)—

(i) for the opening words substitute—

"The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—";

(ii) for sub-paragraphs (d) to (g) substitute—

"(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.";

(d) in paragraph (6) for "or other market" in both places substitute "or EEA market";

(e) for paragraph (7) substitute—

"(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.".

Substitution of regulation 6(4)

37. For regulation 6(4) substitute—

"(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".".

Insertion of regulation 6(4A)

38. After regulation 6(4) insert—

"(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".".

Insertion of regulation 6(4B)

39. After regulation 6(4A) insert—

"(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.".".

Substitution of regulation 6(5)

40. For regulation 6(5) substitute—

"(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.".".

Insertion of regulation 6(5A)

41. After regulation 6(5) insert—

"(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".".

Substitution of regulation 6(6)

42. For regulation 6(6) substitute—

"(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".".

Substitution of regulation 6(7)

43. For regulation 6(7) substitute—

"(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".".

Insertion of regulation 6(8)

44. After regulation 6(7) insert—

"(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".".

Insertion of regulation 6(9)

45. After regulation 6(8) insert—

"(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).".

Insertion of regulation 6(10)

46. After regulation 6(9) insert—

"(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(**a**) as amended from time to time;

(b) "Regulation 722/2012"(**b**) 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

(**a**) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

(**b**) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.12, p. 3).

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(**a**) 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;

(**a**) 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 (OJ L 117 5.5.2017, p. 176).

(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".".

Substitution of regulation 7

47. For regulation 7 substitute—

"**Amendment of Part V of the 2002 Regulations**

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

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

(3) Before regulation 45 insert—

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

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

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

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

(2) In this regulation—

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

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

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

(b) in paragraph (1)—

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

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

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

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

(d) in paragraph (2)(a)—

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

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

(e) in paragraph (2)(b)—

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

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

(f) in paragraph (2)(c)—

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

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

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

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

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

(j) in paragraph (6)—

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

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

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

(l) in paragraph (8)—

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

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

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

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

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

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

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

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

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

(b) in paragraph (1)—

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

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

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

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

(c) in paragraph (2)—

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

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

(d) in paragraph (3)—

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

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

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

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

(e) in paragraph (4)—

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

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

(f) in paragraph (5)—

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

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

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

(g) in paragraph (6)—

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

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

(h) in paragraph (8)—

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

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

(7) After regulation 47 insert—

"**Register of approved bodies**

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

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

(b) there is a register of—

(i) approved bodies;

(ii) their approved body identification number;

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

(iv) any restrictions on those tasks.

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

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

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

(a) in the heading omit "EC";

(b) in paragraph (1)—

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

(ii) omit "European Community";

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

(c) in paragraph (2)—

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

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

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

(e) in paragraph (5)(b)—

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

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

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

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

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

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

(h) in paragraph (8)—

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

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

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

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

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

(c) for paragraph (1)(a) substitute—

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

(d) in paragraph (1)(b)—

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

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

(e) in paragraph (3)—

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

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

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

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

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

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

(c) in paragraph (2)—

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

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

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

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

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

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

Substitution of regulation 8(2) and (3)

48. For regulation 8(2) and (3) substitute—

“(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”.”.

Insertion of regulation 8(4A)

49. After regulation 8(4) insert—

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

Amendment of regulation 8(5)

50. For regulation 8(5) substitute—

"(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".".

Substitution of regulation 9(4)

51. For regulation 9(4) substitute—

"(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".".

Amendment of regulation 9(5)

52. In regulation 9(5) after sub-paragraph (ii) insert—

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

Insertion of regulation 9(6A)

53. After regulation 9(6) insert—

"(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".".

Omission of regulation 10

54. Omit regulation 10.

Omission of regulation 11

55. Omit regulation 11.

Substitution of Schedule 2A as inserted by regulation 12

56. For Schedule 2A as inserted by regulation 12 substitute—

"SCHEDULE 2A

Regulation 1A

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

PART 1

Modification of Annexes to Directive 90/385

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

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

2. In Annex 1—

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

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

(b) for Section 10 substitute—

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

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

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

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

(**a**) S.I. 2012/1916.
(**b**) Schedule 8B was inserted by S.I. 2019/775.

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

(c) in Section 14.2 —

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

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

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

3. In Annex 2—

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

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

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

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

(e) in Section 2—

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

(ii) omit "established within the Community";

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

(f) in Section 3.1—

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

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

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

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

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

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

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

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

(k) for Section 4.3 substitute—

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

In the case of devices referred to in Annex 1, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State

shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

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

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

(m) in Section 6.1—

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

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

(n) for Section 6.2 substitute—

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

(o) for Section 7 substitute—

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

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

4. In Annex 3—

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

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

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

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

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

(f) in Section 2—

(i) for the first sentence substitute—

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

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

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

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

(h) for Sections 4 and 5, substitute—

(**a**) 2020 c. 7.

"**4.** The approved body shall—

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

4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements where the standards referred to in regulation 3A of the Regulations have not been applied.

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

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

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

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

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

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

(j) for Section 7 substitute—

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

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

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

5. For Annex 4 substitute—

"*ANNEX 4*

VERIFICATION

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

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

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

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

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

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

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

6. Statistical verification

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

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

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

6.4. Where batches are accepted, the approved body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of

conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity. Where a batch is rejected, the approved body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the approved body may suspend the statistical verification.

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

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

7. Application to the devices incorporating human blood derivative:

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

6. For Annex 5, substitute—

"*ANNEX 5*

DECLARATION OF CONFORMITY TO TYPE

(Assurance of production quality)

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

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

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

3. Quality system

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

The application shall include:

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

— the quality-system documentation,

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

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

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

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

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

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

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

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

(a) the manufacturer's quality objectives;

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Surveillance

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

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

— the quality-system documentation,

— the technical documentation,

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

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

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

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

6. Application to the devices incorporating human blood derivative:

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

7. In Annex 6—

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

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

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

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

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

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

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

9. In Annex 8—

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

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

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

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

10. Omit Annex 9.

PART 2

Modification of Annexes to Directive 93/42

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

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

12. In Annex I—

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

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

(c) for Section 7.4, substitute—

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

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

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

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body must be informed of the changes and must consult the Secretary of State in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State

must take account of the data related to the usefulness of incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

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

(d) in Section 7.5—

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

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

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

(f) in Section 13.3—

(i) in point (a) —

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

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

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

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

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

13. In Annex II—

(a) in the title omit "EC";

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

(c) in Section 1 omit "Community";

(d) in Section 2—

(i) omit "EC";

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

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

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

(e) in Section 3.2—

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

(ii) in point (c)—

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

(**a**) S.I. 1986/1082 amended by S.I. 1994/2867, 1995/1804 2001/55 and 2019/1211.

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

(f) for Section 3.3 substitute—

"**3.3.** The approved body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.".

(g) for Section 3.4 substitute—

"**3.4.** The manufacturer must inform the approved body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The approved body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.";

(h) in Section 4.2, for "this Directive" substitute "the Regulations";

(i) for Section 4.3 substitute—

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

In the case of devices referred to in Annex 1, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(j) in Section 4.4, omit each reference to "EC";

(k) in Section 6.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(l) in Section 7.1 for "Article 11(2) and (3)" substitute "regulation 13(2) and (3) of the Regulations";

(m) in Section 7.2 omit "for compliance with the provisions of this Directive";

(n) in Section 7.3 omit "for compliance with the provisions of this Directive";

(o) in Section 7.4 —

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

(ii) for "the competent authority" substitute "the Secretary of State";

(p) for Section 8, substitute—

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

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

14. In Annex III—

(a) for each reference to "EC type-examination" (including in the title), substitute "type-examination";

(b) in Section 1—

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

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

(c) in Section 2—

(i) in the first indent,—

(aa) for "authorized representative" substitute "UK responsible person" ;

(bb) for "the representative" substitute "the UK responsible person";

(ii) in the second indent, for the second and third sentences substitute—

"The applicant must provide samples at the request of the approved body.";

(iii) in the third indent, for "notified" substitute "approved";

(d) in Section 3—

(i) for each reference to "Article 5" substitute "regulation 3A of these Regulations";

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

(e) for Sections 4 and 5 substitute—

"**4.** The approved body must—

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

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of the Regulations where the standards referred to in regulation 3A of the Regulations have not been applied; if the device is to be connected to another device or other devices in order to operate as intended, proof must be provided that it

conforms to the essential requirements when connected to any such device having the characteristics specified by the manufacturer;

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

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

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

In the case of devices referred to in Annex I, Section 7.4, second paragraph, the approved body must, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body must give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State must be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.

In the case of devices manufactured utilizing tissues of animal origin referred to in Commission Regulation 722/2012, the approved body must follow the procedures referred to in that Regulation.";

(f) in Section 6—

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

(ii) omit each reference to "EC";

(g) for Section 7.2 substitute—

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

(h) in Section 7.3 —

(i) for "authorised representative" substitute "UK responsible person";

(ii) omit "EC".

15. In Annex IV—

(a) omit "EC" (including in the title) each time it occurs;

(b) for both references to "this Directive" substitute "the Regulations";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 1 for "authorized representative" substitute "UK responsible person";

(e) in Section 2—

(i) for “CE marking” substitute “UK marking”;

(ii) for “Article 17” substitute “regulation 10 of the Regulations”;

(f) in Section 3 for “competent authorities” substitute “Secretary of State”;

(g) for Sections 4 to 6 substitute—

“**4.** The approved body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Regulations either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every product must be examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them.

5.2. The approved body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample must be taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them in order to determine whether to accept or reject the batch.

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

6.4. If the batch is accepted, the approved body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the approved body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the approved body may suspend the statistical verification.

The manufacturer may, on the responsibility of the approved body, affix the approved body’s identification number during the manufacturing process.”;

(h) in Section 7—

(i) for “authorised representative” substitute “UK responsible person”;

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

(i) in Section 8, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 9—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012".

16. In Annex V—

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

(b) omit "EC" each time it occurs, including in the title;

(c) in Section 1, omit "Community";

(d) in Section 2—

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

(ii) for "CE marking in accordance with Article 17" substitute "UK marking";

(e) in the eighth indent of Section 3.1, for "competent authorities" substitute "Secretary of State";

(f) in Section 3.3, for the first sentence substitute—

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

(g) in Section 3.4, for the last two paragraphs substitute—

"The proposed changes must be evaluated by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(i) in Section 6 for each reference to "this Directive" substitute "the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State";

(k) in Section 7—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

17. In Annex VI—

(a) omit "EC" each time it occurs including in the title;

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

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

(d) in Section 2—

(i) for "CE marking in accordance with Article 17" substitute "UK marking";

(ii) for "CE marking must" substitute "UK marking must";

(e) in Section 3.1, for—

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

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

(f) in Section 3.3, for the first sentence substitute—

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

(g) in Section 3.4, for the second paragraph substitute—

"The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(i) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State".

18. In Annex VII—

(a) in the title and in Section 1, omit "EC";

(b) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

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

(c) in Section 2 for—

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

(ii) "national authorities" substitute "Secretary of State";

(d) in Section 3—

(i) in the opening paragraph for "the Directive" substitute "the Regulations";

(ii) in the fourth indent—

(aa) for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(bb) for "of the Directive" substitute "in Annex I";

(e) in Section 4, for "competent authorities" substitute "Secretary of State";

(f) in Section 5, for "the intervention by the notified body" substitute "the intervention by the approved body";

(g) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations".

19. In Annex VIII—

(a) in Section 1, for "authorized representative" substitute "UK responsible person";

(b) in Section 2.2 in the seventh indent for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(c) in Section 3, for "competent national authorities" substitute "Secretary of State";

(d) in Sections 3.1 and 3.2, for "this Directive" each time it occurs substitute "the Regulations";

(e) in Section 3.2—

(i) in the fourth indent, for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(ii) in the sixth indent, for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(f) in Section 5, for "competent authorities" substitute "Secretary of State".

20. In Annex IX for "this Directive" each time it occurs substitute "the Regulations".

21. In Annex X—

(a) in Section 1.1 for "harmonised standards" substitute "designated standards";

(b) in Section 2.3.5 for the words from "all competent authorities of the Member States" to the end substitute "the Secretary of State".

22. In Annex X1—

(a) in the title, for "notified bodies" substitute "approved bodies";

(b) for the words "notified body" each time they occur substitute "approved body";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 2, for "national authorities" substitute "the Secretary of State";

(e) in Section 3, for "this Directive" substitute "the Regulations";

(f) in Section 6, omit the words from ", unless liability" to the end of that Section;

(g) in Section 7, omit the words from "(except *vis a vis* the competent administrative authorities" to the end.

23. Omit Annex XII.

PART 3

Modification of Annexes to Directive 98/79

24.—(1) The Annexes to Directive 98/79 are modified so that they read as if amended by paragraphs 25 to 33.

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

25. In Annex 1—

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

(b) in Section 4.2 in part B, for "Council Directive 80/181/EEC of 20th December 1979" substitute "the Units of Measurement Regulations 1986";

(c) in Section 8.1 in part B, omit the words from "The decision whether" to the end;

(d) in Section 8.2 in part B, for "harmonised standards" substitute "designated standards";

(e) in Section 8.3 in part B —

(i) in the first sentence omit "of Directive 67/548/EEC and Directive 88/379/EEC";

(ii) in the second sentence omit "by those Directives";

(iii) omit the words from "The provisions of" to the end;

(f) in Section 8.4 in point (a), for the sentence beginning "For devices imported", substitute—

> "Where the manufacturer does not have a registered place of business in the United Kingdom the label, the outer packaging or instructions for use shall contain in addition the name and address of the UK responsible person.".

26. In Annex III—

(a) in the title and in Section 1, omit "EC";

(b) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

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

(iii) for "CE marking in accordance with Article 16" substitute "UK marking in accordance with regulation 36 of the Regulations";

(c) in Section 3, for "the Directive" in both places substitute "the Regulations";

(d) in Section 3, in the sixth indent, for "Article 5" in both places substitute "regulation 3A of the Regulations";

(e) in Section 5, for "competent authorities" substitute "Secretary of State";

(f) in Section 6, for "a notified body" substitute "an approved body";

(g) in Section 6.2—

(i) for "notified body", both times those words occur, substitute "approved body";

(ii) in the first sentence, for "this Directive" substitute "the Regulations";

(iii) in the second sentence omit "of the Directive";

(iv) for "an EC" substitute "a" ;

(h) in Section 6.3—

(i) for "notified body" in both places substitute "approved body";

(ii) omit each reference to "EC";

(iii) for "the Directive" substitute "the Regulations".

27. In Annex IV—

(a) in the title, omit "EC";

(b) for each reference to "this Directive" and "the Directive" substitute "the Regulations";

(c) in Section 2, for "CE marking" substitute "UK marking";

(d) in Section 3.1—

(i) for "of his quality system with a notified body" substitute "of its quality system with an approved body";

(ii) in the third indent for "notified body" substitute "approved body";

(e) in Section 3.3 for the first paragraph substitute—

"The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to the requirements.";

(f) in Section 3.4, in both paragraphs, for "notified body" substitute "approved body";

(g) in Section 4.1 for "notified body" substitute "approved body";

(h) in Section 4.3—

(i) for "notified body" both times those words occur substitute "approved body";

(ii) for "an EC" substitute "a";

(i) in Section 4.4—

(i) for "notified body" both times those words occur substitute "approved body";

(ii) omit each reference to "EC";

(j) in Section 4.5, for "notified body" both times those words occur substitute "approved body";

(k) in Sections 5 and 6 for "notified body" each time those words occur substitute "approved body".

28. In Annex V—

(a) in the title, omit "EC" ;

(b) in Section 1—

(i) for "EC type-examination" substitute "Type-examination";

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

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

(c) in Section 2—

(i) in the first paragraph—

(aa) omit "EC";

(bb) for "his authorised representative" substitute "its UK responsible person";

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

(ii) in the first indent—

(aa) for "authorised representative" substitute "UK responsible person";

(bb) for "the representative" substitute "the UK responsible person";

(iii) in the second indent for "this Directive" substitute "the Regulations";

(iv) in the second and third indents for "notified body" each time those words occur substitute "approved body";

(d) in Section 4—

(i) for "notified body shall" substitute "approved body must";

(ii) for both references to "Article 5" substitute "regulation 3A of the Regulations";

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

(e) in Section 5—

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

(ii) for "notified body" in both places substitute "approved body";

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

(f) in Section 6—

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

(ii) omit "EC" each time it occurs;

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

(g) for Section 7, substitute—

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

29. In Annex VI—

(a) in the title omit "EC";

(b) in Section 1—

(i) for "EC verification" substitute "Verification";

(ii) for “authorised representative” substitute “UK responsible person”;

(iii) for “EC type-examination” substitute “type-examination”;

(iv) for “this Directive” substitute “the Regulations”;

(c) in Section 2.1—

(i) for “EC type-examination” in both places substitute “type-examination”;

(ii) for “the Directive” substitute “the Regulations”;

(iii) for “this Directive” substitute “the Regulations”;

(d) in Section 2.2 for “notified body” substitute “approved body”;

(e) in Section 4—

(i) for “notified body” in both places substitute “approved body”;

(ii) for “the Directive” substitute “the Regulations”;

(f) in Section 5.1—

(i) for “Article 5” substitute “regulation 3A of the Regulations”;

(ii) omit “EC”;

(iii) for “the Directive” substitute “the Regulations”;

(g) in Section 5.2 for “notified body” substitute “approved body”;

(h) in Section 6.2—

(i) for “Article 5” substitute “regulation 3A of the Regulations”;

(ii) omit “EC”;

(iii) for “the Directive” substitute “the Regulations”;

(i) in Section 6.3 for “the harmonised standards referred to in Article 5” substitute “the designated standards referred to in regulation 3A of the Regulations”;

(j) in Section 6.4—

(i) for the first two paragraphs, substitute—

“Where the approved body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.”;

(ii) in the third paragraph, for “notified body”, in both places, substitute “approved body”.

30. In Annex VII—

(a) in the title and in Section 2, omit “EC”;

(b) in Section 2—

(i) for “this Directive” substitute “the Regulations”;

(ii) for “CE marking in accordance with Article 16” substitute “UK marking in accordance with regulation 36 of the Regulations”;

(c) in Section 3.1—

(i) for “a notified body” substitute “an approved body”;

(ii) for “EC type-examination” substitute “type-examination”;

(d) in Section 3.2, for “EC type-examination” substitute “type-examination”;

(e) in Section 3.3 for the first two sentences substitute—

“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2. The approved body must presume that quality systems which implement the relevant designated standards conform to the requirements.”;

(f) in Section 3.4—

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

(ii) for the first sentence of the second paragraph substitute "The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would meet the requirements referred to in Section 3.2.";

(g) in Sections 5.1 and 5.2, for each reference to "notified body" substitute "approved body".

31. In Annex VIII—

(a) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

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

(b) in Section 2, for "the Directive" substitute "the Regulations";

(c) in Section 3—

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

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

32. In Annex IX—

(a) in the title, for "notified bodies" substitute "approved bodies";

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

(c) in Section 1, for "authorised representative" substitute "UK responsible person";

(d) in Section 2—

(i) for "the Directive" substitute "the Regulations";

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

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

(e) in Section 3—

(i) for "has been notified" substitute "has been designated";

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

(f) in Section 6, omit the words from "unless liability" to the end;

(g) in Section 7, omit the words from "(except *vis à vis* the competent administrative authorities" to the end.

33. Omit Annex X.".

Omission of Schedules 3 to 28 as inserted by regulation 12

57. Omit Schedules 3 to 28 as inserted by regulation 12.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 8C of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a)) arising from the withdrawal of the United Kingdom from the European Union, and in order to give effect to the Protocol on Ireland/Northern Ireland in the withdrawal agreement, respectively.

Schedule 1 to these Regulations amends the Medical Devices Regulations 2002 (S.I. 2002/618) in relation to Northern Ireland. The provisions in that Schedule ensure that S.I. 2002/618 continues to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day

Schedule 2 to these Regulations amends the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791) and makes provision in respect of the regulatory regime applying to medical devices in Great Britain following IP completion day.

An explanatory memorandum is published alongside this instrument on www.legislation.gov.uk.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sector is foreseen.

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