STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Interpretation of Part II

5.—(1) In this Part [F1]...—

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;

"custom-made device" means a relevant device that is—

(a) manufactured specifically in accordance with a written prescription of a **[**[F2]registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification,**]** which gives, under his responsibility, specific characteristics as to its design; and

(b) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

"relevant device" shall be construed in accordance with regulation 6;

"single-use combination product" means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and

"system or procedure pack" has the same meaning as in article 12 of Directive 93/42.

(2) In this Part [F1]..., a reference to a numbered article or Annex is to the article or Annex of Directive 93/42 bearing that number.

Textual Amendments

F1 Words in reg. 5(1)(2) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **4**

F2 Words in reg. 5(1) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **4**

Scope of Part II

6. The requirements of this Part in respect of relevant devices apply in respect of medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than—

(a) active implantable medical devices and accessories to such devices; **[**F3and**]**

(b) *in vitro* diagnostic medical devices and accessories to such devices; **[**F4and**]**

(c) **[**F5devices that come within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.**]**

Textual Amendments

F3 Word in reg. 6(a) inserted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 8(a)**

F4 Word in reg. 6(b) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 8(b)**

F5 Reg. 6(c) omitted (E.W.S) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 8(c)**

Classification of general medical devices E+W+S

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42 **[**F6, read with Directive 2003/12**][**F7and Directive 2005/50**]**.

(2) In the event of a dispute between a manufacturer and **[**F8an approved body**]** over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42 **[**F6, read with Directive 2003/12**][**F7and Directive 2005/50**]**.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F6 Words in reg. 7 inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **5**

F7 Words in reg. 7 inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **5**

F8 Words in reg. 7(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(3)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **11**); 2020 c. 1, **Sch. 5 para. 1(1)**

Classification of general medical devices N.I.

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42 **[**F105, read with Directive 2003/12**][**F106and Directive 2005/50**]**.

(2) In the event of a dispute between a manufacturer and a notified body over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42 **[**F105, read with Directive 2003/12**][**F106and Directive 2005/50**]**.

Extent Information

E14 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F105 Words in reg. 7 inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **5**

F106 Words in reg. 7 inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **5**

[F9Registration of persons placing general medical devices on the market

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

(a) is established in Great Britain; and

(b) has complied with paragraph (2).

(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.

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

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

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

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

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

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

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

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

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

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

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

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

(4) In this regulation—

(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.**]**

Textual Amendments

F9 Reg. 7A inserted (E.W.S.) (30.4.2021) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(2)(a), **4(4)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 3** and S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **12**); 2020 c. 1, Sch. 5 para. 1(1)

Essential requirements for general medical devices E+W+S

8.—(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it **[**[F10]and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

(2) Subject to regulation 12, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it **[**[F11]and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

[[F12](3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in **[**[F13]Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008**]** to the extent to which those essential health and safety requirements are more specific than the essential requirements to Directive 93/42.**]**

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F10 Words in reg. 8(1) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **3**

F11 Words in reg. 8(2) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **3**

F12 Reg. 8(3) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **5**

F13 Words in reg. 8(3) substituted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(5)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

Essential requirements for general medical devices N.I.

8.—(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it **[**[F107]and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

(2) Subject to regulation 12, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it **[**[F108]and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

[[F109](3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to Directive 2006/42 to the extent to which those essential health and safety requirements are more specific than the essential requirements to Directive 93/42.**]**

Extent Information

E15 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F107 Words in reg. 8(1) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **3**

F108 Words in reg. 8(2) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **3**

F109 Reg. 8(3) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **5**

Determining compliance of general medical devices with relevant essential requirements E+W+S

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

(i) such instructions are in English [F14]...

[F15](ii) . . . . . .

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant **[**[F16]designated standard**]**, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[[F17](5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.**]**

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or **[**[F18]their UK responsible person**]**, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I [F19]... that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[[F20](9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in **[**[F21]Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC**]** and Directive 93/42, the relevant basic health and safety requirements of **[**[F22]Regulation (EU) 2016/425**]** shall also be fulfilled.**]**

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F14 Words in reg. 9(3)(b)(i) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(a)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F15 Reg. 9(3)(b)(ii) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(a)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 9(4) substituted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 9**

F17 Reg. 9(5A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(a)**

F18 Words in reg. 9(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **13**); 2020 c. 1, **Sch. 5 para. 1(1)**

F19 Words in reg. 9(8) omitted (E.W.S.) (31.12.2020) by virtue of y The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(ab)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **13**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Reg. 9(9) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(b)**

F21 Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(b)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

Determining compliance of general medical devices with relevant essential requirements **N.I.**

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

(i) such instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[[F110](5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.**]**

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or his authorised representative, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I of Directive 93/42 that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[F111(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in Council Directive 89/686/EEC on the approximation or the laws of the Member States relating to personal protective equipment and Directive 93/42, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.**]**

Extent Information

E16 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F110 Reg. 9(5A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(a)**

F111 Reg. 9(9) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(b)**

[F23**UK marking] of general medical devices** E+W+S

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a **[**F24UK marking**]** which—

(a) meets the requirements set out in **[**F25Annex 2 of Regulation (EC) No 765/2008**]**;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant **[**F26approved body**]** or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a **[**F27UK marking**]** which—

(a) meets the requirements set out in **[**F28Annex 2 of Regulation (EC) No 765/2008**]**;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant **[**F29approved body**]** or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless **[**F30a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008**]**, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that **[**[F31]UK marking**]** is accompanied by any relevant **[**[F32]approved body**]** or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless **[**[F33]a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008**]**, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that **[**[F34]UK marking**]** is accompanied by any relevant **[**[F35]approved body**]** or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the **[**[F36]UK marking**]** or which reduces the visibility or the legibility of the **[**[F36]UK marking**]**.

[[F37](6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F23 Words in reg. 10 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in reg. 10(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F25 Words in reg. 10(1)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Words in reg. 10(1)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 Words in reg. 10(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F28 Words in reg. 10(2)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F29 Words in reg. 10(2)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(c)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F31 Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(d)(ii)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F32 Words in reg. 10(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(d)(ii)(bb)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F33 Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F34 Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(e)(Ii)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F35 Words in reg. 10(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(e)(ii)(bb)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F36 Words in reg. 10(5) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6A)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F37 Reg. 10(6) inserted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 10**

CE marking of general medical devices **N.I.**

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

Extent Information

E17 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F38UK(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.

[

F39(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.**]**

(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.**]**

Textual Amendments

F38 Reg. 10A inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 3**

F39 Reg. 10A(3A) inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **33**

[F40 UK marking of general medical devices that come within the scope of this Part and other legislation E+W+S

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.**]**

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F40 Reg. 11 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6B)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **15**); 2020 c. 1, **Sch. 5 para. 1(1)**

CE marking of general medical devices that come within the scope of more than one Directive N.I.

11. Where a relevant device comes within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 93/42;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 93/42, as published in the Official Journal of the **[**F112European Union**]**, are given in the documents, notices or instructions accompanying the device.

Extent Information

E18 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F112 Words in Regulations substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **4** (with art. 3(3))

Exemptions from regulations 8 and 10 E+W+S

12.—(1) A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of [F41]... these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

(a) the system or procedure pack incorporates a medical device which does not bear a **[**[F42]UK marking**]**; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a **[**[F43]UK marking**]**, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[[F44](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.**]**

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F41 Words in reg. 12(1) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F42 Words in reg. 12(3)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F43 Words in reg. 12(5) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F44 Reg. 12(6)(7) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

Exemptions from regulations 8 and 10 N.I.

12.—(1) A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 93/42 or these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

(a) the system or procedure pack incorporates a medical device which does not bear a CE marking; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Extent Information

E19 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Procedures for affixing a [F45UK marking] to general medical devices E+W+S

13.—(1) A relevant device falling within Class I may bear a **[**F46UK marking**]** only if its manufacturer or **[**F47their UK responsible person**]**—

(a) fulfils the applicable obligations imposed by Annex VII;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of **[**F48this Part**]** which apply to it; and

(c) ensures that the device meets the provisions of **[**F48this Part**]** which apply to it.

(2) A relevant device falling within Class IIa may bear a **[**F46UK marking**]** only if its manufacturer or **[**F47their UK responsible person**]**—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex VII, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of **[**F48this Part**]** which apply to it; and

(c) ensures that the device meets the provisions of **[**F48this Part**]** which apply to it.

(3) A relevant device falling within Class IIb may bear a **[**F46UK marking**]** only if its manufacturer or **[**F47their UK responsible person**]**—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex III, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of **[**F48this Part**]** which apply to it; and

(c) ensures that the device meets the provisions of **[**F48this Part**]** which apply to it.

(4) A relevant device falling within Class III may bear a **[**F46UK marking**]** only if its manufacturer or **[**F47their UK responsible person**]**—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, or

(ii) Annex III, together with Annex IV or V;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of **[**F48this Part**]** which apply to it; F49...

(c) ensures that the device meets the provisions of **[**F48this Part**]** which apply to it; **[**F50and**]**

[F51(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).**]**

F52(5) . . . . . .

F52(6) . . . . . .

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F45 Words in reg. 13 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7A)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F46 Words in reg. 13 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7A)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F47 Words in reg. 13 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7A)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F48 Words in reg. 13 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7A)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F49 Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(a)**

F50 Word in reg. 13(4)(c) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(b)**

F51 Reg. 13(4)(d) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(c)**

F52 Reg. 13(5)(6) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(3)**

Procedures for affixing a CE marking to general medical devices N.I.

13.—(1) A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Annex VII;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(2) A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex VII, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex III, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, or

(ii) Annex III, together with Annex IV or V;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; F113...

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it; **[**F114and**]**

[F115(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).**]**

F116(5) . . . . . .

F116(6) . . . . . .

Extent Information

E20 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F113 Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(a)**

F114 Word in reg. 13(4)(c) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(b)**

F115 Reg. 13(4)(d) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(2)(c)**

F116 Reg. 13(5)(6) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **4(3)**

Procedures for systems and procedure packs, and for devices to be sterilised before use E+W+S

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(b) the person who places or has placed it on the market has drawn up a declaration that—

(i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,

(ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

[F53(a) follow the procedures referred to in either Annex II or IV that relate to obtaining sterility; and**]**

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

[F54(4A) The application of Annex II or IV and the intervention of the **[**F55approved body**]** are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.**]**

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

(a) no person shall affix a **[**F56UK marking**]** to that device as a result of that procedure; and

(b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F53 Reg. 14(4)(a) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **7(a)**

F54 Reg. 14(4A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **7(b)**

F55 Words in reg. 14(4A) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7B)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

F56 Words in reg. 14(5)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7B)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

Procedures for systems and procedure packs, and for devices to be sterilised before use N.I.

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(b) the person who places or has placed it on the market has drawn up a declaration that—

(i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,

(ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

[F117(a) follow the procedures referred to in either Annex II or IV that relate to obtaining sterility; and**]**

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

[F118(4A) The application of Annex II or IV and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.**]**

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

(a) no person shall affix a CE marking to that device as a result of that procedure; and

(b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

Extent Information

E21 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F117 Reg. 14(4)(a) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **7(a)**

F118 Reg. 14(4A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **7(b)**

Procedures for custom-made general medical devices E+W+S

15. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or **[**F57their UK responsible person**]**—

(a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII **[**F58, read with Regulation (EU) No 722/2012**]**;

(b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and

(c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII; [F59]...

(d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b) **[**[F60]; and

(e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.**]**

Extent Information

E9 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F57 Words in reg. 15 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7C)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F58 Words in reg. 15(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **5**

F59 Word in reg. 15(c) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **8(1)**

F60 Reg. 15(e) and word inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **8(2)**

Procedures for custom-made general medical devices N.I.

15. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII **[**[F119], read with Regulation (EU) No 722/2012**]**;

(b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and

(c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII; [F120]...

(d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b) **[**[F121]; and

(e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.**]**

Extent Information

E22 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F119 Words in reg. 15(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **5**

F120 Word in reg. 15(c) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **8(1)**

F121 Reg. 15(e) and word inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **8(2)**

Procedures for general medical devices for clinical investigations E+W+S

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in **[**F61Great Britain**]** unless, before he does so, the manufacturer of the device or **[**F62their UK responsible person**]** has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (3), the statement required by **[**F63Sections 1 and 2.2**]** of Annex VIII **[**F64, read with Regulation (EU) No 722/2012**]**; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

[F65(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

(a) obtain advice on regulatory requirements relating to an intended clinical investigation; or

(b) obtain a statistical review in relation to an intended clinical investigation.**]**

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a **[**F66UK marking**]** otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was **[**F67UK marked**]** in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or **[**F62their UK responsible person**]** as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer **[**F68or UK responsible person**]** (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or **[**F62their UK responsible person**]** pursuant to paragraph (1), give written notice to the manufacturer or **[**F62their UK responsible person**]**—

(a) that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or **[**F62their UK responsible person**]**, shall—

(a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;

(b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and

(c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

(a) the manufacturer or **[**F62their UK responsible person**]** does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or

(b) the manufacturer or **[**F62their UK responsible person**]** does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

(10) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex X; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or **[**F62their UK responsible person**]** shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

[F69(11) The manufacturer, or their **[**F70single UK responsible person**]**, shall—

(a) notify the Secretary of State of the end of the clinical investigation; and

(b) provide justification where premature termination has resulted.**]**

Extent Information

E10 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F61 Words in reg. 16(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F62 Words in reg. 16 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F63 Words in reg. 16(1)(a) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(a)**

F64 Words in reg. 16(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **6**

F65 Reg. 16(1A) inserted (E.W.S.) (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **5**

F66 Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F67 Words in reg. 16(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F68 Words in reg. 16(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F69 Reg. 16(11) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(b)**

F70 Words in reg. 16(11) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(7D)(e)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

Procedures for general medical devices for clinical investigations N.I.

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in **[**F122Northern Ireland**]** unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (3), the statement required by **[**F123Sections 1 and 2.2**]** of Annex VIII **[**F124, read with Regulation (EU) No 722/2012**]**; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a CE marking otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was CE marked in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended

investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

(a) that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

(a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;

(b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and

(c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

(a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or

(b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

(10) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex X; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

[F125(11) The manufacturer, or their single authorised representative, shall—

(a) notify the Secretary of State of the end of the clinical investigation; and

(b) provide justification where premature termination has resulted.**]**

Extent Information

E23 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F122 Words in reg. 16(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 4**

F123 Words in reg. 16(1)(a) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(a)**

F124 Words in reg. 16(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **6**

F125 Reg. 16(11) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(b)**

Manufacturers etc. and conformity assessment procedures for general medical devices E+W+S

17.—(1) A manufacturer of a relevant device or, where applicable, **[**F71their UK responsible person**]** who is required to follow, or follows or has followed a conformity assessment procedure set out in **[**F72this Part**]** shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, **[**F71their UK responsible person**]** shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with **[**F72this Part**]** at an intermediate stage of manufacture of the device.

F73(3) . . . . . .

F74(4) . . . . . .

F74(5) . . . . . .

Extent Information

E11 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F71 Words in reg. 17 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(8)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **21**); 2020 c. 1, **Sch. 5 para. 1(1)**

F72 Words in reg. 17 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(8)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **21**); 2020 c. 1, **Sch. 5 para. 1(1)**

F73 Reg. 17(3) omitted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(8)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **21**); 2020 c. 1, **Sch. 5 para. 1(1)**

F74 Reg. 17(4)(5) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **7**

Manufacturers etc. and conformity assessment procedures for general medical devices N.I.

17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device.

F126(3) . . . . . .

F127(4) . . . . . .

F127(5) . . . . . .

Extent Information

E24 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F126 Reg. 17(3) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 5**

F127 Reg. 17(4)(5) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **7**

[F75Approved bodies] and the conformity assessment procedures for general medical devices E+W+S

18.—(1) **[**F76An approved body**]** which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out F77... at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, F78...; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where **[**F79an approved body**]** takes a decision in accordance with **[**F80Annex II, III, V or VI,**]** they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where **[**F81an approved body**]** and a manufacturer or **[**F82the manufacturer's UK responsible person**]** have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or **[**F82the manufacturer's UK responsible person**]**, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

F83(4) . . . . . .

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F75 Words in reg. 18 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F76 Words in reg. 18(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F77 Words in reg. 18(1)(a) omitted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F78 Words in reg. 18(1)(b) omitted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F79 Words in reg. 18(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F80 Words in reg. 18(2) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **10**

F81 Words in reg. 18(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F82 Words in reg. 18(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

F83 Reg. 18(4) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(9)(e)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

UK notified bodies and the conformity assessment procedures for general medical devices N.I.

18.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any **[**F128EEA State**]**; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where a UK notified body takes a decision in accordance with **[**F129Annex II, III, V or VI,**]** they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

[F130(4) Decisions taken by UK notified bodies before 1st September 2003 in accordance with Annex II in respect of breast implants may not be extended.**]**

Extent Information

E25 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F128 Words in reg. 18(1)(b) substituted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **8**

F129 Words in reg. 18(2) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **10**

F130 Reg. 18(4) added (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **8**

[F84**[**F85**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;

F86(ii) . . . . . .

(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 **[**[F87]that are not 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;

[F88](c) . . . . . .

(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.

[F89](5) . . . . . .

[F90](6) . . . . . .**]]**

Textual Amendments

F84 Reg. 19 revoked (E.W.S) (30.4.2021) by S.I. 2002/618, **reg. 4D(1)** (as inserted by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)

F85 Reg. 19 substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 6**

F86 Reg. 19(1)(a)(ii) omitted (N.I.) (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **34(a)**

F87 Words in reg. 19(1)(b) substituted (N.I.) (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **34(b)**

F88 Reg. 19(2)(c) omitted (N.I.) (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **34(c)**

F89 Reg. 19(5) omitted (N.I) (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **34(d)**

F90 Reg. 19(6) omitted (N.I.) (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **34(e)**

Additional requirements relating to use of animal tissues

F91 19A. . . . . . .

Textual Amendments

F91 Reg. 19A omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **9**

[F92 Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42 E+W+S

19B.—(1) In this regulation—

(a) "the Directive" means Directive 93/42 **[**F93as it had effect on 25 May 2021**]** and any reference to an Article or Annex is a reference to that Article or Annex in the Directive F94...;

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

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

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

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

(3) **[**F95Subject to paragraph (3A),**]** 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;

[F96(ba) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;**]**

(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) **[**F97has drawn up before 26 May 2021**]** 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.

[

F98(3A) Paragraph (3) only applies to a class I device under the Directive if—

(a) the conformity assessment procedure under Article 11 required the involvement of a notified body; or

(b) the conformity assessment procedure for that device under Article 52 of Regulation (EU) 2017/745 would require the involvement of a notified body (if it were to be assessed under that regulation).**]**

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

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

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

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

(c) undertakes to the Secretary of State—

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

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

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

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

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

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

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

[

F99(ba) ensures that any certificate in relation to the system or procedure pack or a device within it that was issued by a notified body under the Directive is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;

(bb) ensures that the declarations required by Article 12 were drawn up before 26 May 2021;**]**

(c) undertakes to keep the declarations required by Article 12 for the period specified in Article 12(4); F100...

(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 **[**F101English; and**]**

[

F102(e) ensures that the system or procedure pack does not contain a class I device under the Directive for which—

(i) the conformity assessment procedure under Article 11 did not require the involvement of a notified body; and

(ii) the conformity assessment procedure under Article 52 of Regulation (EU) 2017/745 would not require the involvement of a notifed body (if it were to be assessed under that regulation).**]**

(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".

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F92 Regs. 19B, 19C inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F93 Words in reg. 19B(1)(a) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(2)(a)**

F94 Words in reg. 19B(1)(a) omitted (E.W.S.) (1.7.2023) by virtue of The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(2)(b)**

F95 Words in reg. 19B(3) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(a)**

F96 Reg. 19B(3)(ba) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(b)**

F97 Words in reg. 19B(3)(f) substituted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(c)**

F98 Reg. 19B(3A) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(4)**

F99 Reg. 19B(7)(ba)(bb) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(a)**

F100 Word in reg. 19B(7)(c) omitted (E.W.S.) (1.7.2023) by virtue of The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(b)**

F101 Words in reg. 19B(7)(d) substituted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(c)**

F102 Reg. 19B(7)(e) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(d)**

[F131Requirement to appoint a UK responsible person for general medical devices N.I.

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).**]**

Extent Information

E26 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F131 Reg. 19B inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 7**

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

19C.—(1) In this regulation—

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

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

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

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

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

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

(a) ensures—

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

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

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

[F103(ba) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn;**]**

(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.

[F104(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—

(a) has complied with the relevant requirements of Article 22 including where that Article requires a conformity assessment in accordance with Annex IX or XI; and

(b) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn.**]**

(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".**]**

Textual Amendments

F92 Regs. 19B, 19C inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F103 Reg. 19C(3)(ba) inserted (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **7(2)**

F104 Reg. 19C(7) substituted (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **7(3)**

Status:
Point in time view as at 01/07/2023.

Changes to legislation:
The Medical Devices Regulations 2002, PART II is up to date with all changes known to be in force on or before 06 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.