

## STATUTORY INSTRUMENTS

# 2002 No. 618

## The Medical Devices Regulations 2002

### PART II

#### *General Medical Devices*

#### **Interpretation of Part II**

5.—(1) In this Part <sup>F1</sup>...—

“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 [<sup>F2</sup>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 <sup>F1</sup>..., 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—

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- (a) active implantable medical devices and accessories to such devices;
- (b) *in vitro* diagnostic medical devices and accessories to such devices; and
- (c) devices 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.

### 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 [F3, read with Directive 2003/12][F4 and Directive 2005/50].

(2) In the event of a dispute between a manufacturer and [F5 an 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 [F3, read with Directive 2003/12][F4 and 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

- F3** Words in reg. 7 inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **5**
- F4** Words in reg. 7 inserted (1.9.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(b), **5**
- F5** 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 [F93, read with Directive 2003/12][F94 and 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 [F93, read with Directive 2003/12][F94 and Directive 2005/50].

#### 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

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### Textual Amendments

- F93** Words in reg. 7 inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **5**
- F94** Words in reg. 7 inserted (1.9.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(b), **5**

### 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 [<sup>F6</sup>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 [<sup>F7</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

[<sup>F8</sup>(3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in [<sup>F9</sup>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

- F6** Words in reg. 8(1) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **3**
- F7** Words in reg. 8(2) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **3**
- F8** Reg. 8(3) added (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **5**
- F9** 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 [<sup>F95</sup>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 [<sup>F96</sup>and the requirements set out in Regulation (EU) No 722/2012 (if applicable)].

**Status:** Point in time view as at 31/12/2020.

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[<sup>F97</sup>(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

**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

**F95** Words in reg. 8(1) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), 3

**F96** Words in reg. 8(2) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), 3

**F97** 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 <sup>F10</sup>...

<sup>F11</sup>(ii) .....

(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.

[<sup>F12</sup>(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—

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- (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 [<sup>F13</sup>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 <sup>F14</sup>... 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.
- [<sup>F15</sup>(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in [<sup>F16</sup>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 [<sup>F17</sup>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

- F10** 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)
- F11** 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)
- F12** Reg. 9(5A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008](#) (S.I. 2008/2936), regs. 1(1), [6\(a\)](#)
- F13** 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\(1\)](#)

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- F14** 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)**
- F15** Reg. 9(9) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **6(b)**
- F16** 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)
- F17** 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.

[<sup>F98</sup>(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.

[<sup>F99</sup>(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 of 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

**E17** 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

**F98** Reg. 9(5A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **6(a)**

**F99** Reg. 9(9) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **6(b)**

#### [<sup>F18</sup>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 [<sup>F19</sup>UK marking] which—

- (a) meets the requirements set out in [<sup>F20</sup>Annex 2 of Regulation (EC) No 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant [<sup>F21</sup>approved 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 [<sup>F22</sup>UK marking] which—

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- (a) meets the requirements set out in <sup>F23</sup>Annex 2 of Regulation (EC) No 765/2008];
- (b) is in a visible, legible and indelible form; and
- (c) is accompanied by any relevant <sup>F24</sup>approved 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 <sup>F25</sup>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 <sup>F26</sup>UK marking] is accompanied by any relevant <sup>F27</sup>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 <sup>F28</sup>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 <sup>F29</sup>UK marking] is accompanied by any relevant <sup>F30</sup>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 <sup>F31</sup>UK marking] or which reduces the visibility or the legibility of the <sup>F31</sup>UK marking].

#### 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

- F18** 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\(1\)](#)
- F19** 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\(1\)](#)
- F20** 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\(1\)](#)



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- F21** 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)**
- F22** 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)**
- F23** 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)**
- F24** 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)**
- F25** 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)**
- F26** 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)**
- F27** 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)**
- F28** 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)**
- F29** 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)**
- F30** 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)**
- F31** 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)**

## 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,

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

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**

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

#### **[<sup>F32</sup>UK(NI) indication: general medical devices**

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

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

- (a) visibly, legibly and indelibly; and
- (b) before a relevant device is placed on the market in Northern Ireland.

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

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

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

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

**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 28 May 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. (See end of Document for details)

### Textual Amendments

**F32** 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**

## [<sup>F33</sup> 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

**F33** 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 [<sup>F100</sup>European Union], are given in the documents, notices or instructions accompanying the device.

### 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

### Textual Amendments

**F100** 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))

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

## 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 <sup>F34</sup>... 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 [<sup>F35</sup>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 [<sup>F36</sup>UK marking], where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[<sup>F37</sup>(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

- F34** 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\(1\)](#)
- F35** 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\(1\)](#)
- F36** 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\(1\)](#)
- F37** 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

**E20** 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 [<sup>F38</sup>UK marking] to general medical devices **E+W+S**

13.—(1) A relevant device falling within Class I may bear a [<sup>F39</sup>UK marking] only if its manufacturer or [<sup>F40</sup>their 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 [<sup>F41</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [<sup>F41</sup>this Part] which apply to it.

(2) A relevant device falling within Class IIa may bear a [<sup>F39</sup>UK marking] only if its manufacturer or [<sup>F40</sup>their 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 [<sup>F41</sup>this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [<sup>F41</sup>this Part] which apply to it.

(3) A relevant device falling within Class IIb may bear a [<sup>F39</sup>UK marking] only if its manufacturer or [<sup>F40</sup>their UK responsible person]—

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- (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 <sup>F41</sup>[this Part] which apply to it; and
  - (c) ensures that the device meets the provisions of <sup>F41</sup>[this Part] which apply to it.
- (4) A relevant device falling within Class III may bear a <sup>F39</sup>[UK marking] only if its manufacturer or <sup>F40</sup>[their 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 <sup>F41</sup>[this Part] which apply to it; <sup>F42</sup>...
  - (c) ensures that the device meets the provisions of <sup>F41</sup>[this Part] which apply to it; <sup>F43</sup>and
  - <sup>F44</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]
  - <sup>F45</sup>(5) .....
  - <sup>F45</sup>(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**

- F38** 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)**
- F39** 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)**
- F40** 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)**
- F41** 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)**
- F42** 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)**
- F43** 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)**
- F44** 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)**
- F45** 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; <sup>F101</sup> ...
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it; <sup>F102</sup> and]

<sup>F103</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]

<sup>F104</sup>(5) .....

<sup>F104</sup>(6) .....

**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

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**Textual Amendments**

**F101** 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)

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- F102** 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)**
- F103** 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)**
- F104** 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—

- <sup>F46</sup>(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.

<sup>F47</sup>(4A) The application of Annex II or IV and the intervention of the <sup>F48</sup>approved 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 <sup>F49</sup>UK 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



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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

**F46** Reg. 14(4)(a) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(a)**

**F47** Reg. 14(4A) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(b)**

**F48** 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)**

**F49** 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).

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

(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—

[<sup>F105</sup>(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.

[<sup>F106</sup>(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

**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

**F105** Reg. 14(4)(a) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **7(a)**

**F106** 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 [<sup>F50</sup>their UK responsible person]—

(a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII [<sup>F51</sup>, 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; <sup>F52</sup>...

*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 28 May 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. (See end of Document for details)*

- (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) <sup>F53</sup>; 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

- F50** 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)**
- F51** Words in [reg. 15\(a\)](#) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), **5**
- F52** 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)**
- F53** [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 <sup>F107</sup>, 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; <sup>F108</sup> ...
- (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) <sup>F109</sup>; 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

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

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

### Textual Amendments

- F107** Words in reg. 15(a) inserted (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **5**
- F108** 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)**
- F109** 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 [<sup>F54</sup>Great Britain] unless, before he does so, the manufacturer of the device or [<sup>F55</sup>their 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 [<sup>F56</sup>Sections 1 and 2.2] of Annex VIII [<sup>F57</sup>, 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 [<sup>F58</sup>UK 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 [<sup>F59</sup>UK 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 [<sup>F55</sup>their 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 [<sup>F60</sup>or 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 [<sup>F55</sup>their UK responsible person] pursuant to paragraph (1), give written notice to the manufacturer or [<sup>F55</sup>their 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 [<sup>F55</sup>their 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 [<sup>F55</sup>their 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 [<sup>F55</sup>their 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 [<sup>F55</sup>their UK responsible person] shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.
- [<sup>F61</sup>(11) The manufacturer, or their [<sup>F62</sup>single 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

**F54** 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)**

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- F55** 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)**
- F56** 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)**
- F57** 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**
- F58** 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)**
- F59** 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)**
- F60** 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)**
- F61** Reg. 16(11) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **9(b)**
- F62** 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 [<sup>F110</sup>Northern 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 [<sup>F111</sup>Sections 1 and 2.2] of Annex VIII [<sup>F112</sup>, 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.

<sup>F113</sup>(11) The manufacturer, or their single authorised representative, shall—

**Status:** Point in time view as at 31/12/2020.

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- (a) notify the Secretary of State of the end of the clinical investigation; and
- (b) provide justification where premature termination has resulted.]

**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**

- F110** 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](#)
- F111** 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\(a\)](#)
- F112** 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](#)
- F113** [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, [<sup>F63</sup>their UK responsible person] who is required to follow, or follows or has followed a conformity assessment procedure set out in [<sup>F64</sup>this 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, [<sup>F63</sup>their 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 [<sup>F64</sup>this Part] at an intermediate stage of manufacture of the device.

- <sup>F65</sup>(3) .....
- <sup>F66</sup>(4) .....
- <sup>F66</sup>(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**

- F63** 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\(1\)](#)
- F64** 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\(1\)](#)
- F65** [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\(1\)](#)



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 28 May 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. (See end of Document for details)

**F66** 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.

- <sup>F114</sup>(3) .....
- <sup>F115</sup>(4) .....
- <sup>F115</sup>(5) .....

**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**

**F114** 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**

**F115** 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

**[<sup>F67</sup>Approved bodies] and the conformity assessment procedures for general medical devices** **E+W+S**

18.—(1) [<sup>F68</sup>An 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 <sup>F69</sup>... 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, <sup>F70</sup>...; 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 [<sup>F71</sup>an approved body] takes a decision in accordance with [<sup>F72</sup>Annex 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 [<sup>F73</sup>an approved body] and a manufacturer or [<sup>F74</sup>the 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

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

from and with the agreement of the manufacturer or <sup>F74</sup>the 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.

<sup>F75</sup>(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

- F67** 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)**
- F68** 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)**
- F69** 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)**
- F70** 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)**
- F71** 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)**
- F72** Words in reg. 18(2) substituted (21.3.2010) by *The Medical Devices (Amendment) Regulations 2008* (S.I. 2008/2936), regs. 1(1), **10**
- F73** 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)**
- F74** 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)**
- F75** 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 [<sup>F116</sup>EEA State]; and

**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 28 May 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. (See end of Document for details)

(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 [F117Annex 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.

[F118(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

**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

**F116** 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**

**F117** Words in reg. 18(2) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **10**

**F118** Reg. 18(4) added (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **8**

### Registration of persons placing general medical devices on the market **E+W+S**

**19.**—(1) [F76For] the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person to whom this paragraph applies shall—

- (a) inform the Secretary of State of the address of his registered place of business; and
- (b) supply the Secretary of State with a description of each category of device concerned.

(2) Paragraph (1) applies to—

- (a) a manufacturer with a registered place of business in [F77Great Britain] who, under his own name, places on the market in [F77Great Britain] a relevant device which is a Class 1 device or a custom-made device, other than a system or procedure pack which is not [F78UK marked]; and
- (b) a person with a registered place of business in [F79Great Britain] who sterilises before use relevant devices designed by their manufacturer to be sterilised before use.

(3) [F80For] the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in [F81Great Britain] who places a device mentioned in paragraph (2) on the market in [F81Great Britain] on behalf of a manufacturer who does not have a registered place of business in [F82the United Kingdom] shall inform the Secretary of State of—

- (a) the address of his registered place of business;

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

(b) the category of device; <sup>F83</sup> ...

<sup>F83</sup>(c) .....

(4) [<sup>F84</sup>For] the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in [<sup>F85</sup>Great Britain] who places a system or procedure pack which is not [<sup>F86</sup>UK marked] on the market in [<sup>F85</sup>Great Britain], or who sterilises systems or procedure packs before they are placed on the market, shall—

- (a) inform the Secretary of State of the address of that registered place of business; and
- (b) supply the Secretary of State with descriptions of the devices which are included in any such system or procedure pack in a manner sufficient to identify them.

(5) [<sup>F87</sup>For] the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in [<sup>F88</sup>Great Britain] who places a relevant device which is a Class IIb or III device on the market in [<sup>F88</sup>Great Britain]<sup>F89</sup> ... shall, if the Secretary of State so requests, supply the Secretary of State with all data allowing for the identification of the device together with the label and the instructions for use for when the device is put into service within [<sup>F88</sup>Great Britain].

<sup>F90</sup>(6) .....

**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**

- F76** Word in reg. 19(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(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F77** Words in reg. 19(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(10)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F78** Words in reg. 19(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(10)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F79** Words in reg. 19(2)(b) 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(10)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F80** Word in reg. 19(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(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F81** Words in reg. 19(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(10)(d)(i)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F82** Words in reg. 19(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(10)(d)(i)(bb)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**
- F83** Reg. 19(3)(c) and word 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(10)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 23); 2020 c. 1, **Sch. 5 para. 1(1)**

*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 28 May 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. (See end of Document for details)*

- F84** Word in reg. 19(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(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F85** Words in reg. 19(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(10)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F86** Words in reg. 19(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(10)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F87** Word in reg. 19(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(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F88** Words in reg. 19(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(10)(f)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F89** Words in reg. 19(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(10)(f)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F90** Reg. 19(6) 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(10)(g)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**

## <sup>F119</sup>Registration of persons placing general medical devices on the market **N.I.**

19.—(1) Paragraph (2) applies—

- (a) in relation to relevant devices that are neither Class I devices nor custom-made devices, to—
- (i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any general medical device of any class, other than a system or procedure pack which is not CE marked;
  - (ii) a UK responsible person;
  - (iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;
  - (iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;
- (b) in relation to Class I devices and custom-made devices, to—
- (i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;
  - (ii) an authorised representative with a registered place of business in Northern Ireland;
- (c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

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

- (a) inform the Secretary of State of their address and registered place of business;
- (b) supply the Secretary of State with a description of each category of device concerned;
- (c) in the case of a UK responsible person, supply the Secretary of State with—
  - (i) written evidence that they have been appointed as a UK responsible person;

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- (ii) details of the person who has so appointed them; and
  - (iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;
  - (d) in the case of an authorised representative, supply the Secretary of State with—
    - (i) written evidence that they have been designated as an authorised representative;
    - (ii) details of the person who has so designated them; and
    - (iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;
  - (e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.
- (3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.
- (4) The obligations in paragraph (2) begin to apply—
- (a) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;
  - (b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;
  - (c) in the case of a device that is a Class IIa or Class IIb non-implantable device, on 1st September 2021.
- (5) A UK responsible person must—
- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
  - (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
  - (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
  - (d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;
  - (e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;
  - (f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
  - (g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;
  - (h) if the manufacturer acts contrary to its obligations under these Regulations—
    - (i) terminate the legal relationship with the manufacturer; and

**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 28 May 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. (See end of Document for details)

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

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

**Extent Information**

**E27** 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** [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](#)

**Additional requirements relating to use of animal tissues**

<sup>F91</sup>**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](#)

**[<sup>F92</sup>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 and any reference to an Article or Annex is a reference to that Article or Annex in the Directive as amended from time to time;
- (b) “Regulation 722/2012” means Commission Regulation (EU) 722/2012 as it has effect in EU law;
- (c) “CE marking” means the CE marking required by Article 17 and shown in Annex XII;
- (d) “harmonised standard” is to be construed in accordance with Article 5.

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

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

- (a) ensures—
  - (i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation 722/2012, which apply to it; or
  - (ii) that paragraph (10) and (11) apply;
- (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 11;
- (c) ensures that the documentation required by the conformity assessment procedure is drawn up;

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

- (d) ensures that the technical and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;
  - (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes II, III, IV, V, VI or VII;
  - (f) draws up an EU declaration of conformity in accordance with Article 11; and
  - (g) ensures that the declaration of conformity is prepared in or translated into English.
- (4) Where paragraph (5) applies, regulations 8 and 15 are treated as being satisfied.
- (5) This paragraph applies where, before a custom-made device is placed on the market, the manufacturer—
- (a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex VIII, read with Regulation 722/2012;
  - (b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow an assessment of conformity of the device with the requirements of the Directive;
  - (c) undertakes to the Secretary of State—
    - (i) to comply with Section 3.1 of Annex VIII;
    - (ii) to keep all documentation required by Annex VIII available in accordance with Section 4 of Annex VIII; and
    - (iii) to pass the statement mentioned in subparagraph (a) on with the custom-made device so that it may be made available to the patient on request.
- (6) Where paragraph (7) applies, regulations 8 and 14 are treated as being satisfied.
- (7) This paragraph applies where before a system or procedure pack is placed on the market, the manufacturer—
- (a) has complied with Article 12(2);
  - (b) has complied with Article 12(3) and with the procedure in Annex II or V;
  - (c) undertakes to keep the declarations required by Article 12 for the period specified in Article 12(4); and
  - (d) ensures that the system or procedure pack is accompanied by the information referred to in point 13 of Annex I which must be in English.
- (8) Where paragraph (9) applies, regulations 8 and 16 are treated as being satisfied.
- (9) This paragraph applies where before a relevant device intended for clinical investigation is made available in Great Britain for the purpose of a clinical investigation, the manufacturer—
- (a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the Statement required by Sections 1 and 2.2 of Annex VIII;
  - (b) undertakes to keep available the documentation referred to in Section 3.2 of Annex VIII for the period specified in Section 4 of that Annex; and
  - (c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of paragraph 3.1 of Annex VIII.
- (10) Where paragraph (11) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).



**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 28 May 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. (See end of Document for details)

(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

**E14** 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)**

### <sup>F120</sup> Requirement 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

**E28** 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

**F120** [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.

**Status:** Point in time view as at 31/12/2020.

**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 28 May 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. (See end of Document for details)

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

- (a) ensures—
  - (i) that the device meets the general safety and performance requirements in Annex I which apply to it; or
  - (ii) that paragraphs (10) and (11) apply;
- (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 52;
- (c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;
- (d) ensures that the technical documentation required by Annexes II and III and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;
- (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes IX, X or XI;
- (f) draws up an EU declaration of conformity in accordance with Article 19;
- (g) ensures that the declaration of conformity is prepared in or translated into English.

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

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

- (a) has drawn up a statement in English containing the information specified in Section 1 of Annex XIII;
- (b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent national authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow assessment of the conformity of the device with the requirements of the Regulation; and
- (c) undertakes to comply with Sections 3 (manufacturing), 4 (retention of information) and 5 (review of experience) of Annex XIII.

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

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

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

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

- (a) has provided the Secretary of State with the required notice in the form of the application required by Article 70 in English; and
- (b) has provided the Secretary of State with an undertaking to keep available documentation contained in the application in accordance with Section 3 of Chapter III of Annex XV.

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

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

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

#### 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)**

**Status:**

Point in time view as at 31/12/2020.

**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 28 May 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.