STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III U.K.

Active Implantable Medical Devices

Interpretation of Part III U.K.

20.—(1) In this Part[F1]...—

"custom-made device" means an active implantable medical device that is—

(a) manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design; and

(b) intended to be used only for a particular patient; and

"relevant device" shall be construed in accordance with regulation 21.

(2) In this Part[F1]..., a reference to a numbered [F2]... Annex is to the [F2]... Annex of Directive 90/385 bearing that number.

Textual Amendments

F1 Words in reg. 20(1)(2) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **10(a)**

F2 Words in reg. 20(2) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **10(b)**

Scope of Part III E+W+S

21.—**[**[F3](1)**]** The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, except for devices that come within the scope of Directive 90/385 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(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; and

(b) the manufacturer chooses to follow the set of arrangements in the other Directive.

[[F4](2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in **[**[F5]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 set out in Annex I to Directive 90/385.

(3) Where an active implantable medical device is intended to administer a medicinal product, that device shall be governed by Directive 90/385 without prejudice to the provisions of Directive 2001/83/EC.**]**

[[F6](4) Except for the requirement to register in accordance with regulation 21A or 30(3) to (5), this Part does not apply to active implantable medical devices and accessories to such devices placed on the market in accordance with Part VIII.**]**

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 Reg. 21 renumbered as reg. 21(1) (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **12(a)**

F4 Reg. 21(2)(3) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **12(b)**

F5 Words in reg. 21(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), **5(2)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Reg. 21(4) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(2)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

Scope of Part III N.I.

21.—[[F53](1)**]** The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, except for devices that come within the scope of Directive 90/385 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(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; and

(b) the manufacturer chooses to follow the set of arrangements in the other Directive.

[[F54](2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to Directive 90/385.

(3) Where an active implantable medical device is intended to administer a medicinal product, that device shall be governed by Directive 90/385 without prejudice to the provisions of Directive 2001/83/EC.**]**

Extent Information

E10 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

F53 Reg. 21 renumbered as reg. 21(1) (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **12(a)**

F54 Reg. 21(2)(3) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **12(b)**

[F7Registration of persons placing active implantable medical devices on the market N.I.

21B.—(1) Paragraph (2) applies—

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

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

(ii) a UK responsible person;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) A UK responsible person must—

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

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

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

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

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

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

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

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

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

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

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

Textual Amendments

F7 Regs. 21B, 21C 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. 8**

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

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

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

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

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

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

Textual Amendments

F7 Regs. 21B, 21C 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. 8**

Essential requirements for active implantable medical devices U.K.

22.—(1) Subject to regulation 26, 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 1 which apply to it **[**F8and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

(2) Subject to regulation 26, 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 also been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex 1 which apply to it **[**F9and the requirements set out in Regulation (EU) No 722/2012 (if applicable)**]**.

Textual Amendments

F8 Words in reg. 22(1) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **10**

F9 Words in reg. 22(2) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **10**

Determining compliance of active implantable medical devices with relevant essential requirements U.K.

23.—(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) Any—

(a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and

(b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

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

(a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—

(i) the instructions are in English **[**F10or another Community language, and**]**

(ii) **[**F11if 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 the device does not comply with that requirement.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 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.

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

(a) the conditions specified in Annex 7 are satisfied;

(b) notice has been given under regulation 29(1); and

(c) either—

(i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 29(4),

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.

Textual Amendments

F10 Words in reg. 23(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), **5(4)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Reg. 23(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), **5(4)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

[F12UK marking] of active implantable medical devices E+W+S

24.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a [F13UK marking] which—

(a) meets the requirements set out in [F14Annex 2 of Regulation 765/2008];

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

(c) is accompanied by any relevant [F15approved body] or conformity assessment body identification number for that device.

(2) Subject to regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a [F13UK marking] which—

(a) meets the requirements set out in [F14Annex 2 of Regulation 765/2008];

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

(c) is accompanied by any relevant [F16approved 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 regulation 26, no person shall place on the market or put into service a relevant device unless a [F13UK marking], meeting the requirements set out in [F14Annex 2 of Regulation 765/2008], appears on—

(a) where appropriate, any sales packaging for that device; and

(b) the instructions for use for the device,

and that **[**F13UK marking**]** is accompanied by any relevant **[**F17approved body**]** or conformity assessment body identification number for that device.

(4) Subject to regulation 26, 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 **[**F13UK marking**]**, meeting the requirements set out in **[**F14Annex 2 of Regulation 765/2008**]**, appears on—

(a) where appropriate, any sales packaging for that device; and

(b) the instructions for use for the device,

and that **[**F13UK marking**]** is accompanied by any relevant **[**F18approved 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) where appropriate, 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 **[**F13UK marking**]** or which reduces the visibility or the legibility of the **[**F13UK marking**]**.

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

F12 Words in reg. 24 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), **5(4A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 24 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(4A)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 24 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(4A)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 24(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), **5(4A)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 24(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), **5(4A)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 Words in reg. 24(3)(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), **5(4A)(d)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F18 Words in reg. 24(4)(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), **5(4A)(d)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

CE marking of active implantable medical devices N.I.

24.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

(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 regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

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

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

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

(3) Subject to regulation 26, 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 9, appears on—

(a) where appropriate, 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 regulation 26, 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 9, appears on—

(a) where appropriate, 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) where appropriate, 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

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

[F19UK(NI) indication: active implantable medical devices N.I.

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

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

(a) visibly, legibly and indelibly; and

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

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

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

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

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

Textual Amendments

F19 Reg. 24A 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. 9**

[F20UK marking of active implantable medical devices that come within the scope of this Part and other legislation E+W+S

25. Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation ("the other legislation") a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.**]**

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

F20 Reg. 25 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(4B)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

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

25. Where a relevant device comes within the scope of Directive 90/385 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 90/385;

(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 90/385, as published in the Official Journal of the **[**F55European Union**]**, are given in the documents, notices or instructions accompanying the device, and in a manner in which those particulars are accessible without it being necessary to destroy the packaging which keeps the device sterile.

Extent Information

E12 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

F55 Words in Regulations substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **4** (with art. 3(3))

Exemptions from regulations 22 and 24 E+W+S

26.—(1) A relevant device 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 F21... these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 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 **[**F22UK marking**]**, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[F23(4) Regulations 22 and 24 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 22 and 24, may be placed on the market.

(5) In paragraph (4), the Secretary of State, in determining whether a standard or requirement or marking ("the other standard") is equivalent to a standard or requirement imposed by regulations 22 and 24, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.**]**

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

F21 Words in reg. 26(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), **5(5)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 26(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), **5(5)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Reg. 26(4)(5) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **28**); 2020 c. 1, **Sch. 5 para. 1(1)**

Exemptions from regulations 22 and 24 N.I.

26.—(1) A relevant device 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 90/385 or these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 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

E13 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 [F24UK marking] to active implantable medical devices E+W+S

27. A relevant device may bear a **[**F25UK marking**]** only if its manufacturer or **[**F26their UK responsible person**]**—

(a) fulfils the applicable obligations imposed by—

(i) Annex 2, or

(ii) Annex 3, together with Annex 4 or 5;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of **[**F27this Part**]** that apply to it; F28...

(c) ensures that the device meets the provisions of **[**F27this Part**]** which apply to it; **[**F29and**]**

[F30(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).**]**

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

F24 Words in reg. 27 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), **5(5A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**

F25 Words in reg. 27 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5A)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Words in reg. 27 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5A)(b)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 Words in reg. 27(b)(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), **5(5A)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **29**); 2020 c. 1, **Sch. 5 para. 1(1)**

F28 Word in reg. 27(b) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(a)**

F29 Word in reg. 27(c) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(b)**

F30 Reg. 27(d) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(c)**

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

27. A relevant device may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex 2, or

(ii) Annex 3, together with Annex 4 or 5;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 90/385 that apply to it; F56...

(c) ensures that the device meets the provisions of Directive 90/385 which apply to it; **[**F57and**]**

[F58(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).**]**

Extent Information

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

Textual Amendments

F56 Word in reg. 27(b) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(a)**

F57 Word in reg. 27(c) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(b)**

F58 Reg. 27(d) added (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **11(c)**

Procedures for custom-made active implantable medical devices E+W+S

28. 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 **[**F31their UK responsible person**]**—

(a) has drawn up the statement containing the information required by Section 2.1 of Annex 6**[**F32, read with Regulation (EU) No 722/2012**]**;

(b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;

(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 6; and

(d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

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

F31 Words in reg. 28 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5B)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **30**); 2020 c. 1, **Sch. 5 para. 1(1)**

F32 Words in reg. 28(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **12**

Procedures for custom-made active implantable medical devices N.I.

28. 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 the statement containing the information required by Section 2.1 of Annex 6**[**F59, read with Regulation (EU) No 722/2012**]**;

(b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;

(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 6; and

(d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

Extent Information

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

Textual Amendments

F59 Words in reg. 28(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **12**

Procedures for active implantable medical devices for clinical investigations E+W+S

29.—(1) 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 **[**F33Great Britain**]** unless, before he does so,

the manufacturer of the device or **[**F34their 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 (2), the statement required by Section 2.2 of Annex 6 **[**F35, 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 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 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 **[**F34their UK responsible person**]** as soon as it becomes available.

(3) 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 **[**F36or 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.

(4) The Secretary of State may, in respect of notice in writing given by a manufacturer or **[**F34their UK responsible person**]** pursuant to paragraph (1), give written notice to the manufacturer or **[**F34their UK responsible person**]**—

(a) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, 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 6 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.

(5) A written notice pursuant to paragraph (4) 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.

(6) Where a written notice pursuant to paragraph (4) 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.

(7) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or **[**F34their UK responsible person**]**, shall—

(a) take 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, and the first paragraph of Section 3.2, of Annex 6;

(b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and

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

(8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(b) are met, amongst other reasons, if—

(a) the manufacturer or **[**F34their 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 (7); or

(b) the manufacturer or **[**F34their 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).

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

(a) otherwise than in accordance with Annex 7; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or **[**F34their UK responsible person**]** shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex 7.

[F37(10) The manufacturer, or their **[**F38single 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

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

F33 Words in reg. 29(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), **5(5C)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**

F34 Words in reg. 29 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5C)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**

F35 Words in reg. 29(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **13**

F36 Words in reg. 29(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), **5(5C)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**

F37 Reg. 29(10) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **13**

F38 Words in reg. 29(10) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(5C)(d)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **31**); 2020 c. 1, **Sch. 5 para. 1(1)**

Procedures for active implantable medical devices for clinical investigations N.I.

29.—(1) 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 **[**F60Northern 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 (2), the statement required by Section 2.2 of Annex 6 **[**[F61], 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 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 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.

(3) 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.

(4) 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) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, 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 6 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.

(5) A written notice pursuant to paragraph (4) 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.

(6) Where a written notice pursuant to paragraph (4) 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.

(7) 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 ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1, and the first paragraph of Section 3.2, of Annex 6;

(b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and

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

(8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(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 (7); 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).

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

(a) otherwise than in accordance with Annex 7; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(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 7.

[F62(10) The manufacturer, or their single authorised representative, shall—

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

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

Extent Information

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

F60 Words in reg. 29(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. 10**

F61 Words in reg. 29(1)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **13**

F62 Reg. 29(10) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **13**

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

30.—(1) A manufacturer of a relevant device or, where applicable, **[**F39their UK responsible person**]** who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 90/385 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, **[**F40their 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 Directive 90/385 at an intermediate stage of manufacture of the device.

[F41(3) **[**F42The manufacturer of a relevant device, who places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, or, if not the manufacturer, the person placing custom-made devices on the market under that Article, must provide the Secretary of State with—**]**

(a) the address of their registered place of business;

(b) a description of the devices concerned; and

(c) details of the label and instructions for use that accompany each device.

F43(4) . . . . . .

F43(5) . . . . . .]

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

F39 Words in reg. 30(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), **5(6)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

F40 Words in reg. 30(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), **5(6)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

F41 Reg. 30(3)-(5) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **14**

F42 Words in reg. 30(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), **5(6)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

F43 Reg. 30(4)(5) 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), **5(6)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **32**); 2020 c. 1, **Sch. 5 para. 1(1)**

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

30.—(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 90/385 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 90/385 at an intermediate stage of manufacture of the device.

[F63(3) Except as provided in paragraphs (4) and (5), the manufacturer of a relevant device, who under their own name places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, shall provide the Secretary of State with—

(a) the address of their registered place of business;

(b) a description of the devices concerned; and

(c) details of the label and instructions for use that accompany each device.

(4) Where the manufacturer of a relevant device places a device on the market under their own name, but does not have a registered place of business in **[**F64a relevant state**]**, the manufacturer shall—

(a) designate a single authorised representative; and

(b) ensure that the authorised representative has a registered place of business in **[**F64a relevant state**]**.

(5) The authorised representative referred to in paragraph (4) shall provide the competent authority of **[**F65the relevant state**]** in which they have their registered place of business with the information referred to in paragraph (3) above.**]**

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

F63 Reg. 30(3)-(5) added (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **14**

F64 Words in reg. 30(4) 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. 11(a)**

F65 Words in reg. 30(5) 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. 11(b)**

[F44**Obligations in Part III which are met by complying with obligations in Directive 90/385** E+W+S

30A.—(1) In this regulation—

(a) "the Directive" means Directive 90/385 and any reference to an Article or Annex is a reference to that Article or Annex in the Directive as amended from time to time;

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

(c) "CE marking" means the CE marking required by Article 12 and shown in Annex 9;

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

(2) Where paragraph (3) applies regulations 22, 24(1) to (4), 25 and 27 are treated as being satisfied.

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

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or

(ii) that paragraphs (8) and (9) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device, where the device is a device other than those which are custom-made or intended for clinical investigations, has been carried out in accordance with Article 9;

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes 2, 3, 4 or 5;

(f) draws up an EU Declaration of Conformity in accordance with Article 9; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies, regulations 25 and 28 are treated as being satisfied.

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

(a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex 6, read with Regulation 722/2012;

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

(c) undertakes to the Secretary of State—

(i) to comply with Section 3.1 of Annex 6;

(ii) to keep all documentation required by Annex 6 for the period specified in Section 4 of Annex 6; and

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

(6) Where paragraph (7) applies, regulations, 22 and 29 are treated as being satisfied.

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

(a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the statement required by Section 2.2 of Annex 6;

(b) has provided an undertaking to keep available for five years the documentation referred to in Section 3.1 and 3.2 of Annex 6; and

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in Section 3.2 of Annex 6.

(8) Where paragraph (9) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).

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

(10) For the purpose of this regulation in regulations 24(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".**]**

Textual Amendments

F44 Reg. 30A inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **5(8)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **34**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F45Approved bodies] and the conformity assessment procedures for active implantable medical devices E+W+S

31.—(1) **[**F46An 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 in accordance with **[**F47this Part**]** at an intermediate stage of manufacture of the device; and

(b) lay down, by common accord with the manufacturer or **[**F48their UK responsible person**]**, the time limits for completion of the assessment and verification operations referred to in Annex 2 or 3.

(2) Where **[**F49an approved body**]** takes a decision in accordance with **[**F50Annex 2, 3 or 5**]**, they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) **[**F51Where an approved body and a manufacturer or 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 from and with the agreement of the manufacturer or **[**F52the 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.

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

F45 Words in reg. 31 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), **5(7)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F46 Words in reg. 31(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), **5(7)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F47 Words in reg. 31(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), **5(7)**(b(ii)) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F48 Words in reg. 31(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), **5(7)(b)(iii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F49 Words in reg. 31(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), **5(7)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F50 Words in reg. 31(2) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **15**

F51 Words in reg. 31(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), **5(7)(d)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

F52 Words in reg. 31(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), **5(7)(d)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **33**); 2020 c. 1, **Sch. 5 para. 1(1)**

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

31.—(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 90/385 at an intermediate stage of manufacture of the device; and

(b) 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 2 or 3.

(2) Where a UK notified body takes a decision in accordance with **[**[F66]Annex 2, 3 or 5**]**, 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.

Extent Information

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

Textual Amendments

F66 Words in reg. 31(2) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **15**

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

Changes to legislation:
The Medical Devices Regulations 2002, PART III is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.