STATUTORY INSTRUMENTS

2019 No. 791

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

PART 1

Amendment of the 2002 Regulations

Amendment of Part III of the 2002 Regulations

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

(2) In regulation 21 [M1] (Scope of Part III)—

(a) in paragraph (2), for "Annex I to that Directive" substitute " Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 ";

(b) after paragraph (3) insert—

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

(3) After regulation 21 insert—

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

21A.—(1) No person may place a relevant device on the market in accordance with this Part [F1]... unless that person—

(a) is established in **[**[F2]Great Britain**]**; and

(b) has complied with paragraph (2).

[[F3](2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

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

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

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

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

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

[F4(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.**]**

(3) **[**F5The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

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

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

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

[F6(d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

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

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

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

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

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

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

[F7(4) In this regulation—

(a) the references to "technical documentation" are to be construed in accordance with Annex 2, 3 or 5;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes 2, 3 and 5."**]**.

(4) In regulation 23 (Determining compliance of active implantable medical devices with relevant essential requirements), in paragraph 3(b)—

(a) in sub-paragraph (i), omit "or another Community language, and";

(b) omit sub-paragraph (ii).

[F8(4A) In regulation 24 (CE marking of active implantable medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) for "CE marking" each time those words occur substitute "UK marking";

(c) for each reference to "Annex 9" substitute "Annex 2 of Regulation 765/2008";

(d) for "notified body" each time those words occur—

(i) in each of paragraphs (1)(c) and(2)(c);

(ii) in the words following paragraphs (3)(b) and (4)(b),

substitute "approved body".**]**

[[F9](4B) For regulation 25 (CE marking of active implantable medical devices that come within the scope of more than one Directive) substitute—

"**UK marking of active implantable medical devices that come within the scope of this Part and other legislation**

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

[[F10](5) In regulation 26 (exemptions from regulations 22 and 24)—

(a) in paragraph (1) omit "Directive 90/385 or";

(b) in paragraph (3) for "CE marking" substitute "UK marking";

(c) after paragraph (3) insert—

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

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

[[F11](5A) In regulation 27 (procedures for affixing a CE marking to active implantable medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) in the opening words for—

(i) "CE marking" substitute "UK marking";

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

(c) in sub-paragraphs (b) and (c) for "Directive 90/385" substitute "this Part".**]**

[[F12](5B) In regulation 28 (procedures for custom-made active implantable medical devices), in the opening words, for "his authorised representative" substitute "their UK responsible person.**]**

[[F13](5C) In regulation 29 (procedures for active implantable medical devices for clinical investigations)—

(a) for "his authorised representative" each time those words occur, substitute "their UK responsible person";

(b) in paragraph (1), in the opening words, for "the United Kingdom" substitute "Great Britain";

(c) in paragraph (3), for "or authorised representative" substitute "or UK responsible person";

(d) in paragraph (10) for "single authorised representative" substitute "single UK responsible person".**]**

[F14(6) In regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable medical devices)—

(a) in paragraphs (1) and (2) for the words "his authorised representative" both times they occur substitute "their UK responsible person";

(b) in paragraph (3) for the opening words substitute——

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

(c) omit paragraphs (4) and (5).**]**

[F15(7) In regulation 31 (UK notified bodies and the conformity assessment procedures for active implantable medical devices)—

(a) in the heading, for "UK notified bodies" substitute "Approved bodies"

(b) in paragraph (1)—

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

(ii) for "Directive 90/385" substitute "this Part";

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

(c) in paragraph (2) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

(i) for the words from "Where" to "representative" substitute "Where an approved body and a manufacturer or the manufacturer's UK responsible person";

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

[F16(8) After regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable medical devices), insert—

"**Obligations in Part III which are met by complying with obligations in Directive 90/385**

30A.—(1) In this regulation—

(a) "the Directive" means Directive 90/385 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".".**]**

F1 Words in reg. 5(3) omitted (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. 2 para. 25(a)(i)**

F2 Words in reg. 5(3) substituted (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. 2 para. 25(a)(ii)**

F3 Words in reg. 5(3) substituted (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. 2 para. 25(b)**

F4 Words in reg. 5(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 4**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in reg. 5(3) substituted (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. 2 para. 25(c)(i)**

F6 Words in reg. 5(3) substituted (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. 2 para. 25(c)(ii)**

F7 Words in reg. 5(3) substituted (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. 2 para. 25(d)**

F8 Reg. 5(4A) inserted (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. 2 para. 26**

F9 Reg. 5(4B) inserted (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. 2 para. 27**

F10 Reg. 5(5) substituted (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. 2 para. 28**

F11 Reg. 5(5A) inserted (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. 2 para. 29**

F12 Reg. 5(5B) inserted (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. 2 para. 30**

F13 Reg. 5(5C) inserted (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. 2 para. 31**

F14 Reg. 5(6) substituted (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. 2 para. 32**

F15 Reg. 5(7) substituted (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. 2 para. 33**

F16 Reg. 5(8) inserted (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. 2 para. 34**

Commencement Information

I1 Reg. 5(1)(2)(4)-(7) in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(1)

I2 Reg. 5(3) in force at 1.5.2021, see reg. 1(2)(b) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Marginal Citations

M1 Regulation 21 was amended by S.I. 2008/2936.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 5.