STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part II of the 2002 Regulations

4.—(1) Part II of the 2002 Regulations is amended as follows.

F1(2) . . . . . .

[F2(3) In regulation 7(2) (classification of general medical devices) for "a notified body" substitute "an approved body".**]**

(4) After regulation 7 insert—

"**Registration of persons placing general medical devices on the market**

7A.—(1) No person may place a relevant device on the market in accordance with this Part F3... unless that person—

(a) is established in **[**F4Great Britain**]**; and

(b) has complied with paragraph (2).

[F5(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

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

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

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

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

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

[F6(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) **[**F7The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

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

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

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

[F8(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.**]**

[F9(4) In this regulation—

(a) the references to "technical documentation" are to be construed in accordance with Annex II, III or VII;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes II, IV, V, VI and VII."**]**.

(5) In regulation 8 (essential requirements for general medical devices), in paragraph (3), for "Annex I to Directive 2006/42" insert " Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 ".

(6) In regulation 9 (determining compliance of general medical devices with relevant essential requirements)—

(a) in paragraph (3)(b)—

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

(ii) omit sub-paragraph (ii);

[F10(aa) in paragraph (6) for "his authorised representative" substitute "their UK responsible person";

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

(b) in paragraph (9)—

(i) for the words from "Council Directive 89/686/EEC to "protective equipment" substitute "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";

(ii) for "Directive 89/686" substitute " Regulation (EU) 2016/425 ".

[F11(6A) In regulation 10 (CE marking of general medical devices)—

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

(b) in paragraph (1)—

(i) in the opening words for "CE marking" substitute "UK marking";

(ii) in sub-paragraph (a) for "Annex XII" substitute "Annex 2 of Regulation (EC) No 765/2008" ;

(iii) in sub-paragraph (c) for "notified body" substitute "approved body";

(c) in paragraph (2)—

(i) in the opening words for "CE marking" substitute "UK marking";

(ii) in sub-paragraph (a) for "Annex XII" substitute "Annex 2 of Regulation (EC) No 765/2008";

(iii) in sub-paragraph (c) for "notified body" substitute "approved body";

(d) in paragraph (3)—

(i) in the words before sub-paragraph (a), for "a CE marking, meeting the requirements set out in Annex XII" substitute "a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008";

(ii) in the words following sub-paragraph (b)—

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

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

(e) in paragraph (4)—

(i) in the words before sub-paragraph (a), for "a CE marking, meeting the requirements set out in Annex XII" substitute "a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008";

(ii) in the words following sub-paragraph (b)—

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

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

(f) in paragraph (5) in the words after sub-paragraph (c), for both references to "CE marking" substitute "UK marking".**]**

[F12(6B) For regulation 11 (CE marking of general medical devices that come within the scope of more than one Directive) substitute—

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

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

[F13(7) In regulation 12 (exemptions from regulations 8 and 10)—

(a) in paragraph (1) omit "Directive 93/42 or";

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

(c) in paragraph (5) for "CE marking" substitute "UK marking";

(d) after paragraph (5) insert—

"(6) Regulations 8 and 10 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards, or which is marked other than with a UK marking, which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 8 and 10, may be placed on the market.

(7) In paragraph (6), the Secretary of State, in determining whether another standard or requirement or marking ("the other standard") is equivalent to a standard or requirement imposed by regulations 8 and 10, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.".**]**

[F14(7A) In regulation 13 (procedures for affixing a CE marking to general medical devices)—

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

(b) for each reference to "Directive 93/42" substitute "this Part";

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

(d) for "his authorised representative", each time those words occur, substitute "their UK responsible person".**]**

[F15(7B) In regulation 14 (procedures for systems and procedure packs, and for devices to be sterilised before use)—

(a) in paragraph (4A) for "notified body" substitute "approved body";

(b) in paragraph (5)(a) for "CE marking" substitute "UK marking".**]**

[F16(7C) In regulation 15 (procedures for custom-made general medical devices) for "his authorised representative" substitute "their UK responsible person.**]**

[F17(7D) In regulation 16 (procedures for general medical devices for clinical investigation)—

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

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

(c) in paragraph (2)—

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

(ii) for "CE marked" substitute "UK marked";

(d) in paragraph (4) for "or authorised representative" substitute "or UK responsible person";

(e) in paragraph (11) for "single authorised representative" substitute "single UK responsible person".**]**

[F18(8) In regulation 17 (manufacturers etc. and conformity assessment procedures for general medical devices)—

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

(b) for each reference to "Directive 93/42" substitute "this Part";

(c) omit paragraph (3).**]**

[F19(9) In regulation 18 (UK notified bodies and the conformity assessment procedures for general medical devices)—

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

(b) in paragraph (1)—

(i) in the opening words, for "A UK notified body" substitute "An approved body";

(ii) in sub-paragraph (a) omit "in accordance with Directive 93/42";

(iii) in sub-paragraph (b) omit the words from "including in particular" to "EEA State";

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

(d) in paragraph (3)—

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

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

(e) omit paragraph (4).**]**

[[F20](10) In regulation 19 (registration of persons placing general medical devices on the market)—

(a) in paragraphs (1), (3), (4) and (5) for "Subject to paragraph (6), for" substitute "For";

(b) in paragraph (2)(a) for "CE marked" substitute "UK marked";

(c) in paragraphs (2)(a) and (b) for "the United Kingdom" in each place substitute "Great Britain";

(d) in paragraph (3)—

(i) in the opening words for—

(aa) "the United Kingdom" in both places substitute "Great Britain";

(bb) "the Community or in a State which is a Party to an Association Agreement" substitute "the United Kingdom";

(ii) omit sub-paragraph (c) and ";and" which precedes it;

(e) in paragraph (4), in the opening words for—

(i) "the United Kingdom" in both places substitute "Great Britain";

(ii) "CE marked" substitute "UK marked";

(f) in paragraph (5)—

(i) for "the United Kingdom" in each place substitute "Great Britain";

(ii) omit "(including the authorised representative of a manufacturer of a Class IIa, IIb or III device who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement)";

(g) omit paragraph (6).**]**

[[F21](11) Before the heading to Part III (active implantable medical devices) insert—

"**Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42**

19B.—(1) In this regulation—

(a) "the Directive" means Directive 93/42 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;

(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).

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

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

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

19C.—(1) In this regulation—

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

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

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

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

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

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

(a) ensures—

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

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

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

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

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

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

(f) draws up an EU declaration of conformity in accordance with Article 19;

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

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

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

(a) has drawn up a statement in English containing the information specified in Section 1 of Annex XIII;

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

(c) undertakes to comply with Sections 3 (manufacturing), 4 (retention of information) and 5 (review of experience) of Annex XIII.

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

(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".".**]**

F1 Reg. 4(2) 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. 10**

F2 Reg. 4(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. 11**

F3 Words in reg. 4(4) 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. 12(a)(i)**

F4 Words in reg. 4(4) 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. 12(a)(ii)**

F5 Words in reg. 4(4) 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. 12(b)**

F6 Words in reg. 4(4) 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. 3**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 4(4) 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. 12(c)(i)**

F8 Words in reg. 4(4) 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. 12(c)(ii)**

F9 Words in reg. 4(4) 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. 12(d)**

F10 Reg. 4(6)(aa)(ab) 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. 13**

F11 Reg. 4(6A) 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. 14**

F12 Reg. 4(6B) 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. 15**

F13 Reg. 4(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. 16**

F14 Reg. 4(7A) 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. 17**

F15 Reg. 4(7B) 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. 18**

F16 Reg. 4(7C) 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. 19**

F17 Reg. 4(7D) 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. 20**

F18 Reg. 4(8) 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. 21**

F19 Reg. 4(9) 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. 22**

F20 Reg. 4(10) 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. 23**

F21 Reg. 4(11) 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. 24**

Commencement Information

I1 Reg. 4(1)-(3)(5)-(9) 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. 4(4) in force at 1.5.2021, see reg. 1(2)(a) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 4.