SCHEDULE 2

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Insertion of regulation 4(11)

24. After regulation 4(10) insert—

"(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(**1**) 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(**2**);

(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

(**1**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
(**2**) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.12, p. 3).

(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(**3**), 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—

(**3**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 5.5.2017, p. 1).

(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”.”.”.