SCHEDULE 2

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

Insertion of regulation 6(10)

46. After regulation 6(9) insert—

"(10) Before the heading to Part V (notified bodies, conformity assessment bodies and marking of products) insert—

"**Obligations in Part IV which are met by complying with obligations in Directive 98/79**

44ZA.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79(**1**) as amended from time to time;

(b) "Regulation 722/2012"(**2**) means Commission Regulation (EU) 722/2012 as it applies in the European Union;

(c) "CE marking" means the CE marking required by Article 16 and shown in Annex X;

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

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device 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 (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device 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 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 III, IV, V, VI or VII;

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

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

(**1**) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, 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).

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

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

(a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;

(b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;

(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 Section 3 of Annex VIII.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) 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; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".

Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

44ZB.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Regulation (EU) 2017/746(**3**) as it has effect in EU law;

(b) "CE marking" means the CE marking required by Article 18 and presented in Annex V;

(c) "harmonised standard" has the meaning given in Article 2(73);

(d) "sponsor" has the meaning given in Article 2(57).

(2) Where paragraph (3) applies, regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device 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 (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 48;

(**3**) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176).

(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 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 procedures set out in Annexes IX, X and XI;

(f) draws up an EU declaration of conformity in accordance with Article 17; and

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

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where, before a person supplies or makes available a device falling within Part IV for the purposes of performance evaluation, the sponsor of the performance evaluation—

(a) has been able to provide the Secretary of State with the required notice in the form of the application required by Chapter I of Annex XIV in English;

(b) has been able to provide the Secretary of State with an undertaking to keep available information contained in the application in accordance with Chapter II of Annex XIV.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) 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; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation, in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".".".