SCHEDULE 2

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

Insertion of regulation 5(8)

34. In regulation 5 at the end insert—

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

(**1**) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

(**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).

(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”.”.”.