SCHEDULE 2

Amendments to EU tertiary legislation

PART 3

Amendments to Commission Regulation (EU) No 722/2012

9. In Article 2 (which relates to interpretation), in the stem of the paragraph, for "Directive 90/385/EEC and Directive 93/42/EEC" substitute "the Medical Devices Regulations 2002".

10. In Article 3 (which relates to risk analysis and risk management), for paragraph 1, substitute—

"**1.** Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.".

11. In Article 4 (which relates to verification of the fitness of notified bodies, which are now approved bodies)—

(a) for paragraph 1 substitute—

"The Secretary of State must verify on a regular basis that approved bodies designated under Part 5 of the Medical Devices Regulations 2002 have up-to-date knowledge and expertise of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of those Regulations and with the particular requirements of Annex I to this Regulation.";

(b) omit paragraph 2.

12. In Article 5 (which relates to conformity assessment procedures)—

(a) in paragraph 1, for "Directive 90/385/EEC or Directive 93/42/EEC" substitute "Part 3 or Part 2 of the Medical Devices Regulations 2002";

(b) in paragraph 2, for "Notified bodies" substitute "Approved bodies";

(c) in paragraph 3—

(i) in the first sub-paragraph, for "Notified bodies" substitute "Approved bodies";

(ii) in the second sub-paragraph, for "notified bodies" substitute "approved bodies";

(d) for paragraphs 4 to 6 substitute—

"**4.** Before issuing a design-examination certificate or a type-examination certificate the approved body must inform the Secretary of State of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5. The Secretary of State may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

(a) in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4;

(b) in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4.

6. The approved bodies must—

(a) give due consideration to any comments received in accordance with paragraph 5;

(b) provide an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, along with their final decisions to the Secretary of State.";

(e) in paragraph 7—

(i) for "notified body" substitute "approved body",

(ii) for "paragraphs 1-6" substitute "paragraphs 1 to 3".

13. Omit Articles 6 (which relates to the obligation on Member States to ensure compliance with the requirements of the Regulation), 7 (which relates to certificates issued before 29th August 2013) and 8 (which relates to the repeal of an earlier piece of EU legislation).

14. In Article 9 (which relates to entry into force and application) omit "This Regulation is binding in its entirety and directly applicable in all Member States".

15. In Annex I (which relates to risk assessment, management and evaluation of notified bodies which have now become approved bodies)—

(a) in section 1.2, in the fifth paragraph, for "European or" to the end of that paragraph, substitute "international scientific committees or bodies.";

(b) in section 1.2.5.2, in the second paragraph, omit "European or";

(c) in section 2—

(i) for the heading substitute "EVALUATION BY APPROVED BODIES",

(ii) for "notified bodies referred to in Article 4" substitute "approved bodies referred to in Article 4";

(d) in section 2.1—

(i) for the heading substitute "Information of the Approved Body regarding changes and new information",

(ii) for "notified body", in both places it occurs, substitute "approved body";

(e) in section 2.2—

(i) for "an EC", in both places it occurs, substitute "a",

(ii) for "Article 9(8) of Directive 90/385/EEC or Article 11(11) of Directive 93/42/EEC" substitute "regulation 18(3) or regulation 31(3) of the Medical Devices Regulations 2002",

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

(f) in section 2.3—

(i) for "a notified body" substitute "an approved body",

(ii) for "this notified body" substitute "this approved body".

16. In Annex II (which relates to summary evaluation reports)—

(a) in the table headed "Details relating to the submitting notified body"—

(i) for the heading substitute "Details relating to the submitting approved body",

(ii) in entry 1 for "notified body" substitute "approved body",

(iii) in entry 2 for "Notified body" substitute "Approved body",

(iv) in entry 10, for the stem substitute—

"Confirmation that the submitting approved body has been designated by the Secretary of State for the conformity assessment of";

(b) in the box headed "Notified Body Statement"—

(i) for the heading substitute "Approved Body Statement",

(ii) for "Council Directive 90/385/EEC" substitute "Part 3 of the Medical Devices Regulations 2002",

(iii) for "Council Directive 93/42/EEC" substitute "Part 2 of the Medical Devices Regulations 2002".