

SCHEDULE 2

Amendments to EU tertiary legislation

PART 3

Amendments to [Commission Regulation \(EU\) No 722/2012](#)

- 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”.