

SCHEDULE 1

Amendments to Medical Devices Regulations 2002

- 21.** In Schedule 2A(1) (modification of Annexes to Directives 90/385, 93/42 and 98/79)—
- (a) in paragraph 2, before sub-paragraph (a), insert—
 - “(za) in Section 2, for “the functions referred to in Article 1(2)(a)” substitute “the purposes referred to in the definition of a medical device in regulation 2(1) of the Regulations”;
 - (b) in paragraph 2(c), after paragraph (ii), insert—
 - “(iii) for “a device within the meaning of Article 1(4a)” substitute “a stable derivatives device”;
 - (c) in paragraph 3—
 - (i) in sub-paragraph (e)(iii), after ““CE marking”” insert “, in both places it occurs,”,
 - (ii) in sub-paragraph (e), after paragraph (iii), insert—
 - “(iv) for “Article 12” substitute “regulation 24”;
 - (iii) for sub-paragraph (g), substitute—
 - “(g) in Section 3.2—
 - (i) in the first paragraph, omit “of this Directive”;
 - (ii) in point (c), for “Article 5” substitute “regulation 3A of the Regulations”;
 - (iv) for sub-paragraph (h) substitute—
 - “(h) in Section 3.3—
 - (i) for the first sentence substitute—
 - “The quality system shall be audited by an approved body to determine whether it meets the requirements referred to in Section 3.2.”
 - (ii) in the second sentence for “harmonized” substitute “designated”;
 - (d) for paragraph 8, substitute—
 - “**8.** In Annex 7—
 - (a) in Section 1.1 for “harmonised” substitute “designated”;
 - (b) in Section 2.3.5 for “all competent authorities of the Member States in which the clinical investigation is being performed” substitute “the Secretary of State”;
 - (e) in paragraph 9, after sub-paragraph (a), insert—
 - “(aa) in Section 1 for “authorized representative” substitute “UK responsible person”;
 - (f) in paragraph 13—
 - (i) after sub-paragraph (d) insert—
 - “(da) in Section 3.1—
 - (i) in the first sentence, for “a notified body” substitute “an approved body”;
 - (ii) for “other notified body” substitute “other approved body”;

(1) Inserted by [S.I. 2019/791](#) (as amended by [S.I. 2020/1478](#)).

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- (iii) for “the competent authorities” substitute “the Secretary of State”;;
- (g) in paragraph 15—
 - (i) after sub-paragraph (i) insert—
 - “(zj) in Section 8.2 for “notified body” substitute “approved body”;;
 - (ii) in sub-paragraph (j), after paragraph (i), insert—
 - “(ia) for “notified body” substitute “approved body”;;
- (h) in paragraph 17—
 - (i) in sub-paragraph (e), after paragraph (ii), insert—
 - “(iii) for “competent authorities” substitute “Secretary of State”;;
 - (ii) after sub-paragraph (g), insert—
 - “(ga) in Section 4.4 for “Article 5” substitute “regulation 3A of the Regulations”;;
 - (iii) after sub-paragraph (j), insert—
 - “(k) in Section 6.4 for “notified body” substitute “approved body”.;
- (i) in paragraph 22, in sub-paragraph (d), for “the Secretary of State” substitute “Secretary of State”.