SCHEDULE 1

Regulation 2

Amendments to Medical Devices Regulations 2002

1. In regulation 2(1)(**1**) (interpretation)—

(a) at the beginning omit "Subject to Parts VIII and IX,";

(b) in the definition of "mutual recognition agreement", for "the that country" substitute "that country";

(c) in the definition of "Regulation (EU) No 207/2012", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)";

(d) in the definition of "Regulation (EU) No 722/2012", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018 and modified under section 8 of that Act)".

2. In regulation 4H(**2**) (revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date)—

(a) in paragraph (1), omit "("the Decision") (insofar as it is retained EU law)";

(b) omit paragraph (2).

3. For regulation 4J(**3**) (revocation of Regulation (EU) No 207/12 on 26th May 2020 and its effect before that date), substitute—

"**Revocation of Commission Regulation (EU) No 207/2012 on 26th May 2025**

4J. Commission Regulation (EU) No 207/2012 is revoked on 25th May 2025.".

4. For regulation 4K(**4**) (revocation of Regulation (EU) No 722/2012 on 26th May 2025 and its effect before that date), substitute—

"**Revocation of Regulation (EU) No 722/2012 on 26th May 2025**

4K. Regulation (EU) No 722/2012 is revoked on 26th May 2025.".

5. In regulation 4L(**5**) (Revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date)—

(a) in paragraph (1), for "notified" substitute "approved";

(b) omit paragraphs (4) and (5).

6. Omit regulation 4N(**6**) (the classification criteria in Directives 2003/12 and 2005/50).

7. In regulation 4T(**7**) (references in other legislation to Directives 90/385, 93/42 and 98/79)—

(a) in paragraph (2)—

(i) omit sub-paragraph (b),

(ii) at the end of the paragraph insert—

(**1**) Relevant amendments have been made by S.I. 2013/2327 and 2019/791.
(**2**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**3**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**4**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**5**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).
(**6**) Inserted by S.I 2019/971 (as amended by S.I. 2020/1478).
(**7**) Inserted by S.I. 2019/971 (as amended by S.I. 2020/1478).

"(c) the reference to the expression "Directive 93/42/EEC" is to be construed, to the extent necessary for the practical application of that expression, as a reference also or instead to Part II of the Medical Devices Regulations 2002;

(d) the references to "paragraph 4.3 of Annex II to Directive 93/42/EEC" and "paragraph 5 of Annex III to Directive 93/42/EEC" are to be construed, to the extent necessary for the practical application of those provisions, as references also or instead to those paragraphs and those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A.";

(b) in paragraph (4)(a), omit "or in accordance with Schedule 9".

8. In regulation 6 (scope of Part II)—

(a) at the end of paragraph (a), insert "and";

(b) at the end of paragraph (b), omit "and";

(c) omit paragraph (c).

9. In regulation 9(**8**) (determining compliance of general medical devices with relevant essential requirements) in paragraph (4), for "national standard" substitute "designated standard".

10. In regulation 10(**9**) (UK marking of general medical devices), after paragraph (5), insert—

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

11. In regulation 21(**10**) (scope of Part III)—

(a) in paragraph (1), omit from "except for devices" to the end;

(b) for paragraph (3), substitute—

"(3) Where an active implantable device is intended to administer a medicinal product, that device must be governed by this Part without prejudice to the provisions of the Human Medicines Regulations 2012.";

(c) omit paragraph (4).

12. In regulation 23(**11**) (determining compliance of active implantable medical devices with relevant essential requirements), in paragraph (4) for "national standard" substitute "designated standard".

13. In regulation 24(**12**) (UK marking of active implantable medical devices), after paragraph (5), insert—

(**8**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**9**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**10**) Amended by S.I. 2008/2936 and 2019/791.
(**11**) Amended by S.I. 2019791.
(**12**) Amended by S.I. 2019/971 (as amended by S.I. 2020/1478).

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

14. In regulation 30(**13**) (manufacture etc. and conformity assessment procedures for active implantable medical devices)—

(a) in paragraph (1), for "set out in Directive 90/385" substitute "in the Annexes referred to in regulation 27(a)";

(b) in paragraph (2)—

(i) after "conformity assessment procedure" insert "in the Annexes referred to in regulation 27(a)",

(ii) omit "in accordance with Directive 90/385".

15. In regulation 32(**14**) (interpretation of Part IV), for the definition of "common technical specification" substitute—

""common technical specification" means a technical specification set out in the Annex to Commission Decision 2002/364/EC (as retained under section 3 of the European Union Withdrawal Act 2018(**15**) and modified under section 8 of that Act) for a relevant device referred to in a list in Annex II;".

16. In regulation 33 (Scope of Part IV)—

(a) in paragraph (1)—

(i) at the end of sub-paragraph (a) omit "and",

(ii) omit sub-paragraph (b);

(b) in paragraph (2)—

(i) at the end of sub-paragraph (a) omit "and",

(ii) omit sub-paragraph (b).

17. In regulation 36(**16**) (UK marking of in vitro diagnostic medical devices), after paragraph (5), insert—

"(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).".

(**13**) Amended by S.I. 2008/2936, 2019/791 (as amended by S.I. 2020/1478) and S.I. 2020/1478.
(**14**) Amended by S.I. 2003/1697 and 2011/1043.
(**15**) 2018 c.16.
(**16**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).

18. In regulation 41(**17**) (manufacture etc. and conformity assessment procedures for in vitro diagnostic medical devices), omit paragraph (5).

19. In regulation 54(**18**) (fees payable in connection with the designation of approved bodies), in paragraph (5), in the definition of "Regulation (EU) No 920/2013", at the end insert "(as retained under section 3 of the European Union Withdrawal Act 2018(**19**) and modified under section 8 of that Act)".

20. In regulation 59(**20**) (interpretation of Part VII) omit "or a device for the purposes of Part VIII or IX".

21. In Schedule 2A(**21**) (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—

(**17**) Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).
(**18**) The relevant amending instrument is S.I. 2017/207.
(**19**) 2018 c.16.
(**20**) Amended by S.I. 2003/1697 and 2019/791.
(**21**) Inserted by S.I. 2019/791 (as amended by S.I. 2020/1478).

"(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";

(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".