

SCHEDULE 2

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

Insertion of regulation 4(6A)

14. After regulation 4(6) insert—

- “(6A) In regulation 10 (CE marking of general medical devices)—
- (a) in the heading for “CE Marking” substitute “UK marking”;
 - (b) in paragraph (1)—
 - (i) in the opening words for “CE marking” substitute “UK marking”;
 - (ii) in sub-paragraph (a) for “Annex XII” substitute “Annex 2 of Regulation (EC) No 765/2008(1)”;
 - (iii) in sub-paragraph (c) for “notified body” substitute “approved body”;
 - (c) in paragraph (2)—
 - (i) in the opening words for “CE marking” substitute “UK marking”;
 - (ii) in sub-paragraph (a) for “Annex XII” substitute “Annex 2 of Regulation (EC) No 765/2008”;
 - (iii) in sub-paragraph (c) for “notified body” substitute “approved body”;
 - (d) in paragraph (3)—
 - (i) in the words before sub-paragraph (a), for “a CE marking, meeting the requirements set out in Annex XII” substitute “a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008”;
 - (ii) in the words following sub-paragraph (b)—
 - (aa) for “CE marking” substitute “UK marking”;
 - (bb) for “notified body” substitute “approved body”;
 - (e) in paragraph (4)—
 - (i) in the words before sub-paragraph (a), for “a CE marking, meeting the requirements set out in Annex XII” substitute “a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008”;
 - (ii) in the words following sub-paragraph (b)—
 - (aa) for “CE marking” substitute “UK marking”;
 - (bb) for “notified body” substitute “approved body”;
 - (f) in paragraph (5) in the words after sub-paragraph (c), for both references to “CE marking” substitute “UK marking”.

(1) Annex 2 was inserted by paragraph 39 of Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 [S.I. 2019/696](#).