SCHEDULE 2

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

Insertion of regulation 6(9)

45. After regulation 6(8) insert—

"(9) In regulation 44 (registration of manufacturers etc. of in vitro diagnostic medical devices and devices for performance evaluation)—

(a) in paragraph (1)—

(i) in the opening words, for "Subject to paragraph (3), for" substitute "For";

(ii) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(iii) in sub-paragraph (b) for—

(aa) "an authorised representative" substitute "a UK responsible person";

(bb) "that he is the authorised representative of the manufacturer" substitute "that they are the manufacturer's UK responsible person";

(iv) in sub-paragraph (c) for "Community market" in both places substitute "the United Kingdom or EEA market";

(v) in sub-paragraph (g)(ii) for "the United Kingdom" substitute "Great Britain";

(b) in paragraph (2)—

(i) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(ii) in sub-paragraph (b)—

(aa) for "the United Kingdom" in both places substitute "Great Britain";

(bb) for "the Community or in a State which is a Party to an Association Agreement" substitute "the United Kingdom";

(cc) for "his authorised representative" substitute "their UK responsible person";

(c) omit paragraph (3).".