SCHEDULE 2

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

Amendment of regulation 3(3)

4. In regulation 3(3)—

(a) after sub-paragraph (a) insert—

"(aa) after the definition of "active implantable medical device" insert—

""approved body" is to be construed in accordance with regulation A45;";";

(b) for sub-paragraph (c) substitute—

"(c) omit the definition of "authorised representative";";

(c) after sub-paragraph (d) insert—

"(da) omit the definition of "the Community";";

(d) in sub-paragraph (e) for "exit day" substitute "IP completion day";

(e) in sub-paragraph (f) for "exit day" substitute "IP completion day";

(f) in sub-paragraph (g) for "exit day" substitute "IP completion day";

(g) after paragraph (j) insert—

(h) "(ja) omit the definition of "European Economic Area";";

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

(j) for sub-paragraph (q) substitute—

"(q) omit the definition of "notified body";";

(k) in sub-paragraph (r)(i) for "United Kingdom" substitute "Great Britain";

(l) in sub-paragraph (s) for "for "Community" substitute "United Kingdom"" substitute "for "the Community" substitute "Great Britain"";

(m) after sub-paragraph (u) insert—

"(ua) after the definition of "third country conformity assessment body" insert—

""UK marking" has the meaning given in Article 2(22) of Regulation (EC) No 765/2008(**1**);";";

(n) for sub-paragraph (v) substitute—

"(v) omit the definition of "UK notified body";";

(o) in sub-paragraph (w) in the definition of "UK responsible person" inserted by sub-paragraph (w), after "established in" insert "any part of".

(**1**) Article 2(22) was inserted into Regulation (EC) No 765/2008 by paragraph 3 of Schedule 33 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696). This Regulation was incorporated into domestic law by section 3 of the European Union Withdrawal Act 2018 c. 16.