

## SCHEDULE 2

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

#### Insertion of regulation 4(10)

**23.** After regulation 4(9) insert—

“(10) In regulation 19 (registration of persons placing general medical devices on the market)—

- (a) in paragraphs (1), (3), (4) and (5) for “Subject to paragraph (6), for” substitute “For”;
- (b) in paragraph (2)(a) for “CE marked” substitute “UK marked”;
- (c) in paragraphs (2)(a) and (b) for “the United Kingdom” in each place substitute “Great Britain”;
- (d) in paragraph (3)—
  - (i) in the opening words for—
    - (aa) “the United Kingdom” in both places substitute “Great Britain”;
    - (bb) “the Community or in a State which is a Party to an Association Agreement” substitute “the United Kingdom”;
  - (ii) omit sub-paragraph (c) and “;and” which precedes it;
- (e) in paragraph (4), in the opening words for—
  - (i) “the United Kingdom” in both places substitute “Great Britain”;
  - (ii) “CE marked” substitute “UK marked”;
- (f) in paragraph (5)—
  - (i) for “the United Kingdom” in each place substitute “Great Britain”;
  - (ii) omit “(including the authorised representative of a manufacturer of a Class IIa, IIb or III device who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement)”;
- (g) omit paragraph (6).”.