

## SCHEDULE 2

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

#### **Substitution of regulation 4(9)**

**22.** For regulation 4(9) substitute—

“(9) In regulation 18 (UK notified bodies and the conformity assessment procedures for general medical devices)—

- (a) in the heading, for “UK notified bodies” substitute “Approved bodies”;
- (b) in paragraph (1)—
  - (i) in the opening words, for “A UK notified body” substitute “An approved body”;
  - (ii) in sub-paragraph (a) omit “in accordance with Directive 93/42”;
  - (iii) in sub-paragraph (b) omit the words from “including in particular” to “EEA State”;
- (c) in paragraph (2) for “a UK notified body” substitute “an approved body”;
- (d) in paragraph (3)—
  - (i) for “a UK notified body” substitute “an approved body”;
  - (ii) for “his authorised representative”, in both places, substitute “the manufacturer’s UK responsible person”;
- (e) omit paragraph (4).”.