

## SCHEDULE 2

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

#### **Substitution of regulation 6(7)**

**43.** For regulation 6(7) substitute—

“(7) In regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic 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 98/79”;
  - (iii) in sub-paragraph (b) omit the words from “including in particular” to the end of that sub-paragraph (but not the “and” following it);
  - (iv) in sub-paragraph (c) for “his authorised representative” substitute “their UK responsible person”;
- (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 it occurs substitute “their UK responsible person”.