

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”.