SCHEDULE 2

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

Substitution of regulation 6(6)

42. For regulation 6(6) substitute—

"(6) In regulation 41 (manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices)—

(a) for each reference to "his authorised representative" substitute "their UK responsible person";

(b) for both references to "Directive 98/79" substitute "this Part";

(c) in paragraph (1) for "that apply to him" substitute "that apply to the manufacturer or, as the case may be, their UK responsible person";

(d) in paragraph (3)(c) for "notified bodies" substitute "approved bodies";

(e) in paragraph (5)—

(i) omit from the beginning to "established";

(ii) omit "in the United Kingdom".".