SCHEDULE 2

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

Substitution of regulation 5(7)

33. For regulation 5(7) substitute—

"(7) In regulation 31 (UK notified bodies and the conformity assessment procedures for active implantable medical devices)—

(a) in the heading, for "UK notified bodies" substitute "Approved bodies"

(b) in paragraph (1)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "Directive 90/385" substitute "this Part";

(iii) 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 the words from "Where" to "representative" substitute "Where an approved body and a manufacturer or the manufacturer's UK responsible person";

(ii) for "his authorised representative" substitute "the manufacturer's UK responsible person".".