SCHEDULE 2

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

Substitution of regulation 5(6)

32. For regulation 5(6) substitute—

"(6) In regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable medical devices)—

(a) in paragraphs (1) and (2) for the words "his authorised representative" both times they occur substitute "their UK responsible person";

(b) in paragraph (3) for the opening words substitute——

"(3) The manufacturer of a relevant device, who places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, or, if not the manufacturer, the person placing custom-made devices on the market under that Article, must provide the Secretary of State with—";

(c) omit paragraphs (4) and (5).".