SCHEDULE 2

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

Amendment of regulation 12 (new Schedules to the 2002 Regulations)

11.—(1) Regulation 12 is amended as follows.

(2) In inserted Schedule 19 to the 2002 Regulations (technical documentation on post-market surveillance for in vitro diagnostic medical devices), in paragraph 5—

(a) for "Article 81" substitute "regulation 189";

(b) for "Article 80" substitute "regulation 188".

(3) In inserted Schedule 24 to the 2002 Regulations (conformity assessment based on quality management system and on assessment of technical documentation - in vitro diagnostic medical devices), in paragraph 1(7)—

(a) in the heading, omit "applicable to Class C and Class D devices";

(b) omit "of Class C and D devices".