

SCHEDULE 2

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

Insertion of regulation 3(4A)

6. After regulation 3(4) insert—

“(4A) After regulation 2 (interpretation) insert—

“Medical devices which are qualifying Northern Ireland goods

2A.—(1) Notwithstanding the effect of regulations 19B, 19C, 30A, 44ZA and 44ZB and the expiry of the period during which those regulations apply by virtue of regulation 1ZA, any medical device—

(a) which meets the requirements of these Regulations as they apply in Northern Ireland; and

(b) which is a qualifying Northern Ireland good,

may be placed on the Great Britain market as if it meets the requirements of these Regulations as they apply in Great Britain.

(2) In this regulation, “qualifying Northern Ireland good” has the meaning given in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.””.