

SCHEDULE 2

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

Substitution of regulation 6(5)

40. For regulation 6(5) substitute—

“(5) In regulation 39 (exemptions from regulations 34, 36 and 38)—

- (a) in paragraph (1)(b) omit “Directive 98/79 or”;
- (b) in paragraph (2) for “CE marking” substitute “UK marking”;
- (c) after paragraph (2) insert—

“(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.””.