

## SCHEDULE 2

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

#### **Substitution of regulation 4(7)**

**16.** For regulation 4(7) substitute—

“(7) In regulation 12 (exemptions from regulations 8 and 10)—

- (a) in paragraph (1) omit “Directive 93/42 or”;
- (b) in paragraph (3)(a) for “CE marking” substitute “UK marking”;
- (c) in paragraph (5) for “CE marking” substitute “UK marking”;
- (d) after paragraph (5) insert—

“(6) Regulations 8 and 10 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 8 and 10, may be placed on the market.

(7) In paragraph (6), the Secretary of State, in determining whether another standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 8 and 10, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.””.