

SCHEDULE 2

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

Insertion of regulation 6(5A)

41. After regulation 6(5) insert—

“(5A) In regulation 40 (procedures for affixing a CE marking to *in vitro* diagnostic medical devices)—

- (a) in the heading and in each place in that regulation that “CE marking” occurs substitute “UK marking”;
- (b) for “his authorised representative”, each time those words occur, substitute “their UK responsible person”;
- (c) for each reference to “Directive 98/79” substitute “this Part”.