

SCHEDULE 2

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

Substitution of regulation 6(4)

37. For regulation 6(4) substitute—

“(4) In regulation 35 (determining compliance of in vitro diagnostic medical devices with relevant essential requirements)—

- (a) in paragraph (2), omit the words from “if the device may reach a final user” to the end; and
- (b) in paragraph (3) for “national standard” substitute “designated standard”.