

SCHEDULE 1

Amendments to Medical Devices Regulations 2002

17. In regulation 36(1) (UK marking of in vitro diagnostic medical devices), after paragraph (5), insert—

“(6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of [Regulation \(EU\) No 765/2008](#), the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

- (a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and
- (b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).”.