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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).".

⁽¹⁾ Amended by S.I. 2019/791 (as amended by S.I. 2020/1478).