EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618), to require that coronavirus test devices must be approved by the Secretary of State, before they are placed on market or put into service. They specify the application procedure for approval, and the performance requirements that such devices must meet for the purposes of approval. They also provide for exemptions from that procedure for public service use and provide that the Secretary of State must establish a register of approved coronavirus test devices. There are transitional provisions in respect of devices placed on the market before 31st October 2021. Regulation 10 requires the Regulations to be reviewed, and a report published on or before 31st December 2022.

An assessment of the impact of this instrument has been made. A copy of an iteration of the Impact Assessment is published and available at www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation. Copies may also be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.