
STATUTORY INSTRUMENTS

2021 No. 910

The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

Amendment of the Medical Devices Regulations 2002

3. In regulation 2(1) after the definition of “clinical data”, insert—
- ““coronavirus test device” means an *in vitro* diagnostic medical device for the detection of the presence of a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);”.

(1) Regulation 2 has been amended on a number of occasions, most recently by [S.I. 2020/1478](#). The definition of “clinical data” was inserted by [S.I. 2008/2936](#).