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DRAFT STATUTORY INSTRUMENTS

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**2021 No.**

**MEDICAL DEVICES**

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

*Made* - - - - - \*\*\*

*Coming into force* \*\*\*

THE MEDICAL DEVICES (CORONAVIRUS TEST DEVICE APPROVALS) (AMENDMENT) REGULATIONS 2021

1. Citation, commencement and extent
2. Amendment of the Medical Devices Regulations 2002
3. In regulation 2 after the definition of “clinical data”, insert—...
4. In regulation 33(1) after “in vitro diagnostic medical devices”, insert...
5. After regulation 34, insert— Approval requirement for coronavirus test devices...
6. After regulation 38, insert— Applications for approval of coronavirus test...
7. In regulation 39 in the heading, for “regulations 34, 36...
8. After regulation 39, insert— Exemptions for coronavirus test devices (1) Regulation 34A does not apply where, in circumstances which...
9. After regulation 56 (fees payable in relation to clinical investigation...
10. Review  
Signature  
Explanatory Note