
STATUTORY INSTRUMENTS

2021 No. 910

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

Amendment of the Medical Devices Regulations 2002

8. After regulation 39, insert—

“Exemptions for coronavirus test devices

39A.—(1) Regulation 34A does not apply where, in circumstances which give rise to a need to protect the public from a risk of serious harm to health, the Secretary of State—

(a) has decided to permit, where appropriate for a specified period, the placing on the market or putting into service of a particular coronavirus test device or coronavirus test devices of a particular class or description that has not been approved under regulation 38A(5); and

(b) has not withdrawn that permission.

(2) The Secretary of State may give permission under paragraph (1) subject to such conditions as are set out in a protocol published by the Secretary of State.

(3) If the Secretary of State publishes a protocol for the purpose of paragraph (2), the protocol must specify the period of time for which it has effect.

(4) The Secretary of State may withdraw or amend a protocol published under paragraph (2).”