Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2021 No.

MEDICAL DEVICES

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

Made - - - -	***
Coming into force - -	***

The Secretary of State has carried out a public consultation, and makes these Regulations in exercise of the powers conferred by sections 15(1), 16(1)(a), (b), (c) and (h), 17(1)(a), 18 and 43 of the Medicines and Medical Devices Act 2021(**a**) and after having considered the matters set out in section 15(2) to (4) of that Act.

In accordance with section 47(3) and (6)(a) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021, and come into force on the day after the day on which they are made.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**b**) are amended in accordance with regulations 3 to 9.

3. In regulation 2(**c**) 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);".

4. In regulation 33(1) after "*in vitro* diagnostic medical devices", insert "(including coronavirus test devices)".

5. After regulation 34, insert—

(**a**) 2021 c. 3.
(**b**) S.I. 2002/618. The Regulations have been amended on a number of occasions, most recently by S.I. 2020/1478.
(**c**) 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.

"Approval requirement for coronavirus test devices

34A.—(1) Subject to regulations 34B, 34C, 39(1) and 39A, no person other than the Secretary of State may place on the market or put into service a coronavirus test device, unless—

(a) the Secretary of State has approved it in accordance with regulation 38A(5); and

(b) the approval remains valid in accordance with regulation 38A(6).

(2) Subject to regulations 34B, 34C, 39(1) and 39A, no person other than the Secretary of State may supply a coronavirus test device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless the Secretary of State has approved it in accordance with regulation 38A(5) and the approval remains valid in accordance with regulation 38A(6).

(3) The requirements in paragraphs (1) and (2) are without prejudice to the other requirements of this Part.

Public sector use of coronavirus test devices

34B.—(1) Regulation 34A(1) does not apply in relation to a coronavirus test device that is placed on the market or put into service only for use by—

(a) the Secretary of State;

(b) a devolved public health body; or

(c) a health service body supplied pursuant to an existing contract.

(2) Regulation 34A(2) does not apply in relation to a coronavirus test device that is supplied to—

(a) the Secretary of State;

(b) a devolved public health body; or

(c) a health service body pursuant to an existing contract.

(3) In this regulation—

"a devolved public health body" is—

(a) in Wales, Welsh Ministers or Public Health Wales National Health Service Trust(**a**);

(b) in Scotland, Scottish Ministers;

(c) in Northern Ireland, the Department of Health in Northern Ireland;

"an existing contract" is a contract entered into before the coming into force of regulation 34A;

"a health service body" is—

(a) an NHS body as defined in section 275 of the National Health Service Act 2006(**b**) or in section 206 of the National Health Service (Wales) Act 2006(**c**);

(b) a body listed in section 17A(2)(a) to (c) or (e) of the National Health Service (Scotland) Act 1978(**d**); or

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(**a**) Public Health Wales National Health Service Trust is an NHS Trust (see section 18 of the National Health Service (Wales) Act 2006 (c. 42)) established under the Public Health Wales National Health Service Trust (Establishment) Order 2009/2058 (W.177).

(**b**) 2006 c. 41. The definition was inserted by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 138.

(**c**) 2006 c. 42. The definition was inserted by the Health and Social Care Act 2012, Schedule 21, paragraph 38.

(**d**) 1978 c. 29. Section 17A was inserted by the National Health Service and Community Care Act 1990 (c. 19), section 30, and amended by: the Health Act 1999 (c. 8), Schedule 4, paragraph 46 and Schedule 5, paragraph 1; the Health and Social Care

(c) a health and social care body as defined in section 1(5)(a) to (e) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(**a**).

Transitional provisions for coronavirus test devices

34C.—(1) The requirements in regulation 34A do not apply in respect of any period before 1st September 2021.

(2) A person may place on the market, put into service or supply a coronavirus test device from 1st September 2021 until the end of 31st October 2021 if—

(a) that person has made an application to the Secretary of State in respect of that device, in accordance with regulation 38A; or

(b) that person is not—

(i) the manufacturer of the device,

(ii) a person acting as the manufacturer's UK responsible person appointed for the purposes of regulation 33A or under regulation 44A, or

(iii) a person acting as the manufacturer's authorised representative in Northern Ireland in accordance with regulation 44.".

6. After regulation 38, insert—

"Applications for approval of coronavirus test devices

38A.—(1) A person may make an application to the Secretary of State under this regulation for approval of a coronavirus test device.

(2) An application must include such information as the Secretary of State may require for the purposes of exercising their functions under—

(a) paragraph (5); and

(b) regulation 38C.

(3) An application must be made through the gov.uk website.

(4) The Secretary of State may treat an application made before the coming into force of this regulation as an application made under this regulation, if it meets the requirements of paragraph (2).

(5) The Secretary of State must approve a coronavirus test device if the Secretary of State is satisfied on the basis of the information contained in the application that the coronavirus test device meets the requirements of regulation 38B.

(6) An approval granted under paragraph (5) is valid for a period of 5 years, beginning with the day on which it is granted.

(7) Nothing in this regulation shall be taken to prevent—

(a) the Secretary of State;

(b) a weights and measures authority in Great Britain; or

(c) a district council in Northern Ireland,

from exercising a duty under regulation 61 to enforce these Regulations.

Performance requirements for coronavirus test devices

38B.—(1) The requirements that a coronavirus test device must meet for the purposes of regulation 38A(5) are set out in paragraphs (2) to (6).

(Community Health and Standards) Act 2003 (c. 43), Schedule 14, paragraph 1; the Public Services Reform (Scotland) Act 2010 (asp 8), Schedule 17, paragraph 8; and the 2012 Act, Schedule 21, paragraph 2.

(**a**) 2009 c. 1 (N.I.).

(2) A coronavirus test device must be able to be put into service in accordance with this Part.

(3) A coronavirus test device that is an antigen test must have—

(a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 60%;

(b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 93%.

(4) A coronavirus test device that is a direct molecular test must have—

(a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 70%;

(b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 93%.

(5) A coronavirus test device that is an extracted molecular test must have—

(a) a level of sensitivity, using a 95% two-sided confidence interval, that is entirely above 93%;

(b) a level of specificity, using a 95% two-sided confidence interval, that is entirely above 97%.

(6) Where a coronavirus test device is also intended to detect the presence of anything other than a viral antigen or viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the requirements in paragraphs (2) to (5) apply only in relation to its performance in detecting the presence of that viral antigen or viral ribonucleic acid (RNA).

(7) In this regulation and in regulation 38C—

"antigen test" means an *in vitro* diagnostic medical device for the detection of the presence of a viral antigen specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

"direct molecular test" means an *in vitro* diagnostic medical device which—

(a) is for the detection of the presence of viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and

(b) does not use a preliminary step of purification and concentration;

"extracted molecular test" means an *in vitro* diagnostic medical device which—

(a) is for the detection of the presence of viral ribonucleic acid (RNA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and

(b) uses a preliminary step of purification and concentration;

"sensitivity", in relation to a coronavirus test device, means the proportion of true positives that are correctly identified by the test, calculated using the equation—

$$Sensitivity = \frac{True\ Positives}{(True\ Positives + False\ Negatives)}$$

;

"specificity", in relation to a coronavirus test device, means the proportion of true negatives that are correctly identified by the test, calculated using the equation—

$$Specificity = \frac{True\ Negatives}{(True\ Negatives + False\ Positives)}$$

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Register of approved coronavirus test devices

38C.—(1) The Secretary of State must establish a register of coronavirus test devices which the Secretary of State has approved in accordance with regulation 38A.

(2) The Secretary of State must publish the register on the gov.uk website.

(3) The register must contain the following information in respect of each coronavirus test device—

(a) the name and address of the registered place of business of the person who made the application under regulation 38A;

(b) if the person who made the application was not the manufacturer, the name and address of the registered place of business of the manufacturer;

(c) the country in which the manufacturer is established;

(d) the name and address of the registered place of business of the UK responsible person or the manufacturer's authorised representative having a registered place of business in Northern Ireland, if there is one in respect of the device;

(e) the name and description of the coronavirus test device;

(f) the date and version number of the instructions for use included in the application;

(g) whether the coronavirus test device is an antigen test, a direct molecular test, or an extracted molecular test;

(h) the date on which the coronavirus test device was approved in accordance with regulation 38A and the date on which that approval ceases to be valid.

(4) The register may contain such other information relating to the coronavirus test device and its intended use as the Secretary of State considers appropriate.".

7. In regulation 39 in the heading, for "regulations 34, 36 and 38" substitute "this Part".

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).".

9. After regulation 56 (fees payable in relation to clinical investigation bodies) insert—

"Fees in connection with approval of coronavirus test devices

56A.—(1) A person who makes an application to the Secretary of State under regulation 38A(1) must pay to the Secretary of State a fee of—

(a) £14,000; or

(b) if the person is a small or medium-sized enterprise, £6,200.

(2) Where the Secretary of State, in accordance with regulation 38A(4), treats an application made before the coming into force of regulation 38A as an application made under that regulation, a payment made in respect of that application before the coming into force of this regulation must be treated as—

(a) a payment meeting the requirements of paragraph (1), if that payment would have met those requirements after their coming into force; or

(b) a payment contributing in part to the payment required by paragraph (1), if that payment would not have met those requirements after their coming into force.

(3) In this regulation—

(a) a person is a small or medium-sized enterprise if it and persons associated with it employ no more than 250 individuals in total; and

(b) "persons associated with it" has the same meaning as in section 882 of the Corporation Tax Act 2010(**a**).".

Review

10.—(1) The Secretary of State must carry out a review of the provision made by these Regulations and publish a report setting out the conclusions of the review.

(2) The report must be published on or before 31st December 2022.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the provision made by these Regulations;

(b) assess the extent to which those objectives are achieved;

(c) assess whether those objectives remain appropriate; and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous provision.

Name
Address — Parliamentary Under Secretary of State
Date — Department of Health and Social Care

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 this impact assessment is annexed to the Explanatory Memorandum which is available alongside this instrument on the legislation.gov.uk website. Copies may also be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.

(**a**) 2010 c. 4.

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