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 Authorisations) (Amendment) Regulations 2021

Made	- - - -	*****
Coming into force	- -	*in accordance with regulation 1*

The Secretary of State, 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, extent and application

1.—(1) These Regulations may be cited as the Medical Devices (Coronavirus Test Device Authorisations) (Amendment) Regulations 2021.

(2) These Regulations, apart from regulation 8—

(a) come into force on the day after the day on which they are made, and

(b) extend to England and Wales, Scotland and Northern Ireland.

(3) Regulation 8—

(a) comes into force on 1st January 2022;

(b) extends to England and Wales; and

(c) applies in relation to England;

Amendment of the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**b**) are amended as follows.

3. In regulation 2(**c**) after the definition of "clinical data", insert—

(**a**) 2021 c.3.

(**b**) S.I.2002/618. The Regulations have been amended on a number of occasions, most recently by the Medical Devices (Amendment etc.) (EU Exit) Regulation 2020 (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.

""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. After regulation 34, insert—

"Authorisation requirement for coronavirus test devices

34A.—(1) Subject to regulations 34B, 34C and 39A, no person other than the Secretary of State may place on the market or put into service a coronavirus test device, unless the Secretary of State has authorised it in accordance with regulation 38B(5), and the authorisation remains valid in accordance with regulation 38B(6).

(2) Subject to regulations 34B, 34C 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 authorised it in accordance with regulation 38B(5) and the authorisation remains valid in accordance with regulation 38B(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 relevant hospital 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) to a relevant hospital 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 entry into force of these Regulations;

"a relevant hospital" is—

(a) in England, a health service hospital as defined by section 275 of the National Health Service Act 2006(**b**);

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

(**b**) 2006 c.41. The definition of "health service hospital" in section 275 was amended by paragraph 138(2)(b) of Schedule 4 to the Health and Social Care Act 2012 (c. 7) and by S.I. 2013/160.

(b) in Wales, a health service hospital as defined by section 206 of the National Health Service (Wales) Act 2006(**a**);

(c) in Scotland, a health service hospital as defined by section 108 of the National Health Service (Scotland) Act 1978(**b**);

(d) in Northern Ireland, a hospital as defined by Article 2(2) of the Health and Personal Social Services (Northern Ireland) Order 1972(**c**).

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 30th September 2021 if—

(a) that person has made an application to the Secretary of State in respect of that device before 1st October 2021, in accordance with regulation 38A; or

(b) that person is not the manufacturer of the device.

(3) A person may place on the market, put into service or supply a coronavirus test device from 1st October 2021 until the end of 31st December 2021 if the Secretary of State has approved it in accordance with regulation 38A(5).".

5. After regulation 38, insert—

"Applications for preliminary 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 for the purpose of regulation 34C(2) or 38B(1) (or both).

(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 38D.

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

(4) The Secretary of State may treat an application made before the entry in 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 38C.

Applications for authorisation of coronavirus test devices

38B.—(1) A person may make an application to the Secretary of State for authorisation of a coronavirus test device, if the Secretary of State has approved that device in accordance with regulation 38A(5).

(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 38D.

(**a**) 2006 c.42.
(**b**) 1978 c.29.
(**c**) 1971 No.1265 (N.I. 14).

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

(4) A person making an application must deliver to the address specified by the Secretary of State—

(a) such assays of the coronavirus test device, and

(b) such equipment and ancillary materials as it requires to perform its function,

as the Secretary of State may require for the purpose of exercising the functions under paragraph (5).

(5) The Secretary of State must authorise a coronavirus test device if the Secretary of State is still satisfied on the basis of—

(a) the information contained in the application, and

(b) such assessments of the assays as the Secretary of State considered necessary,

that the coronavirus test device meets the requirements of regulation 38C.

(6) An authorisation 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 or regulation 38A 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

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

(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 38D—

"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 how often the device correctly generates a positive result;

"specificity", in relation to a coronavirus test device, means how often the device correctly generates a negative result.

Register of authorised coronavirus test devices

38D.—(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 or authorised in accordance with regulation 38B.

(2) The Secretary of State may publish some or all parts of 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 or 38B, as the case may be;

(b) if that person 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 device is an antigen test, a direct molecular test, or an extracted molecular test;

(h) whether the device has been—

(i) approved in accordance with regulation 38A, or

(ii) approved in accordance with regulation 38A and authorised in accordance with regulation 38B;

(i) the date on which any such approval or authorisation was granted and, in the case of an authorisation, the date on which it ceases to be valid;

(j) the levels of sensitivity and specificity determined by any assessments of the assays conducted by the Secretary of State for the purpose of regulation 38B(5).

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

6. 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 authorised under regulation 38B(5); and

(b) has not withdrawn that permission.

(2) The Secretary of State may make their permission under paragraph (1) subject to conditions, if those conditions 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 that the Secretary of State has published.".

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

"Fees in connection with authorisation 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 entry into force of regulation 38A as an application made under that regulation, a payment made in respect of that application before the entry into force of this regulation must be treated as a payment made for the purpose of paragraph (1).

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

(a) £75,000; or

(b) if the person is a small or medium-sized enterprise, £28,800.

(4) In this regulation—

(a) a person is a small or medium-sized enterprise if it and persons associated with it employ no more than 50 individuals in total; and

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

Amendment of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020

8. In regulation 4 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020(**b**)—

(a) for paragraph (1), substitute—

"(1) Any device used for the purposes of an applicable test must be able to be put into service in accordance with Part 4 of the Medical Devices Regulations 2002, other than by virtue of an authorisation or permission under regulation 39(2) or 39A(1) of those Regulations.";

(**a**) 2010 c.4.
(**b**) S.I.. 2020/1549.

(b) omit paragraph (2);

(c) in paragraph (3), omit the definitions of "specificity" and "sensitivity".

Review

9.—(1) The Secretary of State must carry out a review of the provisions 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

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 authorised by the Secretary of State, before they are placed on market or put into service. They specify application procedures for authorisation and preliminary approval, and the performance requirements that such devices must meet for the purposes of those procedures. They also provide for exemptions from that procedure for public service use and provide that the Secretary of State must establish a register of authorised coronavirus test devices. There are transitional provisions in respect of devices placed on the market before 31st December 2021. Consequential amendments are made to the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020. Regulation 9 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.