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STATUTORY INSTRUMENTS

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**2021 No. 910**

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

**Amendment of the Medical Devices Regulations 2002**

5. After regulation 34, insert—

**“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<sup>(1)</sup>;
  - (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<sup>(2)</sup> or in section 206 of the National Health Service (Wales) Act 2006<sup>(3)</sup>;
  - (b) a body listed in section 17A(2)(a) to (c) or (e) of the National Health Service (Scotland) Act 1978<sup>(4)</sup>; or
  - (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<sup>(5)</sup>.

#### **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.”.

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(1) 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).

(2) 2006 c. 41. The definition was inserted by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 138.

(3) 2006 c. 42. The definition was inserted by the Health and Social Care Act 2012, Schedule 21, paragraph 38.

(4) 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 (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.

(5) 2009 c. 1 (N.I.).