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WELSH STATUTORY INSTRUMENTS

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**2020 No. 1489 (W. 318)**

**PUBLIC HEALTH, WALES**

**The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020**

*Made - - - - 9 December 2020*

*Laid before Senedd Cymru 10 December 2020*

*Coming into force in accordance with regulation 1(1)*

The Welsh Ministers make the following regulations in exercise of the powers conferred by section 45C, 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984<sup>(1)</sup>.

The Welsh Ministers consider that the restrictions and requirements imposed by these Regulations are proportionate to what they seek to achieve, which is a public health response to the threat to public health posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wales.

The Welsh Ministers declare, in accordance with section 45Q(3), that they are of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of that Act which imposes or enables the imposition of a special restriction or requirement, or any other restriction or requirement which has or would have a significant effect on a person's rights.

**Citation, commencement, application and interpretation**

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020 and come into force on implementation period completion day.

(2) These Regulations apply in relation to Wales.

(3) In these Regulations—

(a) “the PPE Regulation” (“*y Rheoliad PPE*”) means Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council [Directive 89/686/EEC](#)(2);

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(1) [1984 c. 22](#) Section 45C was inserted by section 129 of the Health and Social Care Act [2008 \(c. 14\)](#). The function under this section is conferred on “the appropriate Minister”. Under section 45T(6) of the 1984 Act the appropriate Minister, in respect of Wales, is the Welsh Ministers.

(2) The PPE Regulation is incorporated into domestic law by section 3(1) of the European Union (Withdrawal) Act [2018 \(c. 16\)](#) and is prospectively amended with effect from IP completion day by regulation 38 of, and Schedule 35 to, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 ([S.I. 2019/696](#)).

- (b) expressions in these Regulations which appear in the PPE Regulation have the same meaning as in the PPE Regulation;
  - (c) “the 2018 Regulations” (“*Rheoliadau 2018*”) means the Personal Protective Equipment (Enforcement) Regulations 2018(3).
- (4) In these Regulations—
- “Covid PPE” (“*PPE Covid*”) means PPE that—
    - (i) is necessary for protection against the coronavirus disease; and
    - (ii) requires conformity assessment by an approved body, in accordance with Article 19 of the PPE Regulation;
  - “CE marking” (“*nod CE*”) has the meaning given to it in Article 3(18) of Regulation (EU) 2016/425 (as it has effect in EU law);
  - “coronavirus” (“*coronafeirws*”) means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);
  - “coronavirus disease” (“*clefyd y coronafeirws*”) means COVID-19 (the official designation of the disease which can be caused by coronavirus);
  - “EHSR” (“*GIDH*”) means the essential health and safety requirements applicable to the Covid PPE as set out in Annex 2 to the PPE Regulation;
  - “the HSE” (“*yr Awdurdod Gweithredol Iechyd a Diogelwch*”) means the Health and Safety Executive(4);
  - “notified body” (“*corff a hysbyswyd*”) means a conformity assessment body that is not an approved body, that has been assigned an identification number under Article 29 of Regulation (EU) 2016/425 (as it has effect in EU law).

### **Temporary arrangements for the making available of Covid PPE**

- 2.—(1) This regulation applies to Covid PPE only.
- (2) Notwithstanding the requirements of Articles 8(2), 10(2) and 11(2) of the PPE Regulation, where the conditions set out in paragraph (3) are met, Covid PPE may be made available on the market by a relevant economic operator before—
- (a) the applicable conformity assessment procedure has been carried out; and
  - (b) the UK marking has been affixed.
- (3) The conditions referred to in paragraph (2) are that before an economic operator makes the Covid PPE available—
- (a) the Covid PPE has been submitted for conformity assessment to an approved body; and
  - (b) after the Covid PPE has been submitted to an approved body, the HSE—
    - (i) has assessed the Covid PPE as compliant with the EHSR relevant to the assessment process; and
    - (ii) has notified an economic operator at any time before 1st April 2021 of the assessment that the Covid PPE is compliant with the EHSR against which it has been assessed.
- (4) Where an economic operator relies on regulation 2A of the 2018 Regulations and submits Covid PPE to a notified body, a reference in this regulation to—

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(3) [S.I. 2018/390](#); the instrument was made in part under section 2(2) of the European Communities Act 1972 (c. 68) and is accordingly saved by virtue of section 2(2)(a) of the European Union (Withdrawal) Act 2018 (c. 16); amendments extending to Great Britain are made prospectively with effect from IP completion day, by [S.I. 2019/696](#); there are other amendments, but none are relevant to these Regulations.

(4) Established under section 10 of the Health and Safety at Work etc. Act 1974 (c. 37).

- (a) the UK marking is to be read as a reference to the CE marking;
- (b) an approved body is to be read as a reference to a notified body.

### **Temporary arrangements for the making available of Covid PPE for healthcare and other frontline workers**

3.—(1) This regulation applies to Covid PPE only.

(2) Notwithstanding the requirements of Articles 8(2), 10(2) and 11(2) of the PPE Regulation, where the conditions set out in paragraph (3) are met, Covid PPE may be made available by a relevant economic operator for the use of healthcare and other frontline workers, without—

- (a) the applicable conformity assessment procedure having been carried out; and
- (b) the UK marking having been affixed.

(3) The conditions referred to in paragraph (2) are that before an economic operator makes the Covid PPE available—

- (a) the Covid PPE has been purchased by or on behalf of the Welsh Ministers or an NHS body for use in the health service or other frontline services; and
- (b) the HSE—
  - (i) has assessed the Covid PPE as compliant with the EHSR relevant to the assessment process; and
  - (ii) has notified an economic operator at any time before 1st July 2021 of the assessment that the Covid PPE is compliant with the EHSR against which it has been assessed.

(4) In this regulation—

“healthcare worker” (“*gweithiwr gofal iechyd*”) means an individual working as part of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006<sup>(5)</sup>;

“NHS body” (“*corff y GIG*”) has the meaning given in section 206 of the National Health Service (Wales) Act 2006<sup>(6)</sup>;

“other frontline services” (“*gwasanaethau rheng flaen eraill*”) means the provision of social care and community or residential drug and alcohol services;

“other frontline workers” (“*gweithwyr rheng flaen eraill*”) means any individual working in other frontline services;

“social care” (“*gofal cymdeithasol*”) includes all forms of personal care and other practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstances, are in need of such care or other assistance.

### **Enforcement**

4.—(1) Where an economic operator has made Covid PPE available in reliance on regulations 2 or 3, the economic operator will not be treated as having contravened the requirements and obligations set out in Articles 8(2), 10(2) or 11(2) of the PPE Regulation for the purposes of regulation 7(1) of the 2018 Regulations if—

- (a) the applicable conformity assessment procedure has not been completed in relation to the Covid PPE; or
- (b) the UK marking has not been affixed to the Covid PPE.

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<sup>(5)</sup> 2006 c. 42.

<sup>(6)</sup> Section 206 was inserted by section 297 of and paragraph 12 and 38(1)(b) of Schedule 21 to the Health and Social Care Act 2012 (c.7).

(2) Paragraph (3) applies where an economic operator has made Covid PPE available in reliance on regulation 3 and—

- (a) the applicable conformity assessment procedure has not been completed in relation to the Covid PPE; or
- (b) the Covid PPE does not bear the UK marking.

(3) Where this paragraph applies, a failure by an economic operator to take the action required under Article 41(1)(b), (c) and (d) of the PPE Regulation will not be treated as non-compliance with the PPE Regulation and the economic operator will not be guilty of an offence for the purposes of regulation 7(3) of the 2018 Regulations.

(4) Where PPE has been assessed by HSE before implementation period completion day, pursuant to the European Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat<sup>(7)</sup>, these Regulations do not affect the validity of that HSE assessment.

9 December 2020

*Vaughan Gething*  
Minister for Health and Social Services, one of  
the Welsh Ministers

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(7) OJ L 79I, 16.3.2020, p. 1–5

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made under section 45C, 45F(2) and 45(P) of the Public Health (Control of Disease) Act 1984 implementing temporary arrangements to facilitate the production and supply of PPE during the Covid-19 crisis. These arrangements are similar to the proposals in the European Commission's Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat ((OJ L 79I, 16.3.20 p. 1-5), but the arrangements in these Regulations are specific to Wales and may only be relied on if the HSE has authorised them by a specified date and come into force on IP completion day.

Regulation 2 permits PPE to be placed on the market while it is undergoing conformity assessment procedures but before these have been completed and any conformity marking has been affixed. Regulation 3 permits PPE to be procured without undergoing conformity assessment procedures and conformity marking being affixed but this must only be made available to healthcare and frontline workers. In both cases, the PPE must have been assessed by the HSE and found to be compliant with the essential health and safety requirements in Annex II of Regulation 2016/425/EU of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (as amended and retained in UK law). Where the conditions are met, the obligations in Regulation 2016/425 will be treated as satisfied for the purposes of the Personal Protective Equipment (Enforcement) Regulations 2018 (S.I. 2018/390) and in respect of PPE for healthcare workers and other frontline workers, the market surveillance authority will not require the non-compliance to be brought to an end. This is solely in cases where the conformity assessment procedure has not been completed and the conformity mark has not been affixed due to reliance on regulation 2 or 3 of these Regulations.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has not been prepared as to the likely cost and benefit of complying with these Regulations.