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PUBLIC HEALTH, ENGLAND

HEALTH AND SAFETY, ENGLAND

CONSUMER PROTECTION, ENGLAND

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

Made - - - - - *8th December 2020*

Laid before Parliament *9th December 2020*

Coming into force in accordance with regulation 1(1)

The Secretary of State makes 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(a).

The Secretary of State considers 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 England.

The Secretary of State declares, in accordance with section 45Q(3) of the Public Health (Control of Disease) Act 1984, that he is 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) (England) Regulations 2020 and come into force on IP completion day.

(2) These Regulations apply in relation to England only.

(3) In these Regulations—

(a) 1984 c. 22; sections 45C to 45T were inserted by section 129 of the Health and Social Care Act 2008 (c. 14); there are other amendments to the Act, but none is relevant. The Secretary of State is the appropriate Minister who may make regulations as respects England under section 45T(6) of the Act.

- (a) “the PPE Regulation” 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(a);
 - (b) expressions in these Regulations which appear in the PPE Regulation have the same meaning as in the PPE Regulation;
 - (c) “the 2018 Regulations” means the Personal Protective Equipment (Enforcement) Regulations 2018(b).
- (4) In these Regulations—
- “Covid PPE” means PPE that is—
- (i) 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” has the meaning given to it in Article 3(18) of Regulation 2016/425 (pre-exit);
- “coronavirus” means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);
- “coronavirus disease” means COVID-19 (the official designation of the disease which can be caused by coronavirus);
- “EHSR” means the essential health and safety requirements applicable to the Covid PPE as set out in Annex 2 to the PPE Regulation;
- “the HSE” means the Health and Safety Executive(c);
- “notified body” means a conformity assessment body that is not an approved body, that has been assigned an identification number under Article 29 of Regulation 2016/425 (pre-exit).

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—

(a) 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) 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.

(c) 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—

- (i) the applicable conformity assessment procedure having been carried out; and
- (ii) 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 the Secretary of State 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” means an individual working as part of the health service continued under section 1(1) of the National Health Service Act 2006(a);

“NHS body” has the meaning given in section 275 of the National Health Service Act 2006(b);

“other frontline services” means the provision of social care and community or residential drug and alcohol services;

“other frontline workers” means any individual working in other frontline services;

“social care” 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.

(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

(a) 2006 c. 41. Section 1(1) was substituted by the Health and Social Care Act 2012 (c. 7).

(b) Section 275 was inserted by section 55(1) of and paragraph 138(1) and (2)(c) of Schedule 4 to the Health and Social Care Act 2012 (c. 7).

(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 IP 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^(a), these Regulations do not affect the validity of that HSE assessment.

Paul Scully

Parliamentary Under Secretary of State

8th December 2020

Department for Business, Energy and Industrial Strategy

EXPLANATORY NOTE

(This note is not part of the Regulations)

The Regulations are made under section 45C of the Public Health (Control of Disease) Act 1984 implementing temporary arrangements to facilitate the production and supply of PPE necessary for use 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 England, may only be relied on if the HSE has authorised it 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 before any conformity marking has been affixed. Regulation 3 permits PPE to be procured without undergoing conformity assessment procedures and without any conformity marking being affixed but this PPE must only be made available to healthcare workers and other frontline workers. In both cases, the PPE must have been assessed by the HSE and found to be compliant with the relevant elements of the essential health and safety requirements in Annex 2 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.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

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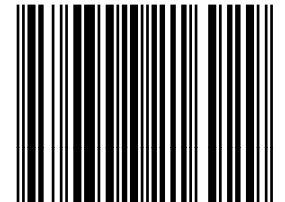
(a) OJ L 79I, 16.3.2020, p. 1–5.

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