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STATUTORY INSTRUMENTS

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**2018 No. 390**

**The Personal Protective Equipment  
(Enforcement) Regulations 2018**

**PART 1**

Preliminary

**Citation, commencement and interpretation** **N.I.**

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Enforcement) Regulations 2018 and come into force on 21st April 2018.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974 <sup>M1</sup>;

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978 <sup>M2</sup>;

“the 1987 Act” means the Consumer Protection Act 1987 <sup>M3</sup>;

“the 2002 Regulations” means the Personal Protective Equipment Regulations 2002 <sup>M4</sup>;

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 <sup>M5</sup>;

“EU Regulation 2016/425” means Regulation (EU) No 2016/425 <sup>M6</sup> of the European Parliament and of the Council on personal protective equipment, repealing Council Directive 89/686/EEC<sup>M7</sup>, as amended from time to time;

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>M8</sup>, as amended from time to time;

“risk” means a risk which may result in harm to the health or safety of persons, domestic animals or property, if personal protective equipment (“PPE”) is used in a normal and predictable manner; and

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985 <sup>M9</sup>.

(3) In these Regulations a reference to—

(a) a numbered regulation, paragraph or Schedule is a reference to the regulation, paragraph or Schedule as numbered in these Regulations unless otherwise stated;

(b) an Article, paragraph of an Article or Annex is a reference to the Article, paragraph of an Article or Annex as numbered in EU Regulation 2016/425;

(c) a “relevant economic operator” in relation to PPE means an economic operator with obligations in respect of PPE under EU Regulation 2016/425; and

(d) an “enforcement authority” is to be construed in accordance with regulation 4.

(4) Expressions and words used in these Regulations which are used in EU Regulation 2016/425 have the same meaning as in EU Regulation 2016/425.

#### Extent Information

**E1** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Marginal Citations

**M1** 1974 c.37.

**M2** S.I. 1978/1039 (N.I. 9).

**M3** 1987 c.43.

**M4** S.I. 2002/1144 as amended by S.I. 2004/693, 2012/1848 and 2015/1630.

**M5** 1972 Chapter 9.

**M6** OJ No L81, 31.3.2016, p.51.

**M7** OJ No L399, 30.12.1989, p.18.

**M8** OJ No L 218, 13.8.2008, p.30.

**M9** 1985 c.72; section 69 was amended by the Local Government (Wales) Act 1994 (c.19), section 66 and Schedule 16, paragraph 75; the Local Government etc. (Scotland) Act 1994 (c.39), section 180 and Schedule 13, paragraph 144; and the Statute Law (Repeals) Act 1989 (c.43) Schedule 1, Part 1.

#### Citation, commencement and interpretation **E+W+S**

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Enforcement) Regulations 2018 and come into force on 21st April 2018.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974 <sup>F5</sup>;

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978 <sup>F6</sup>;

“the 1987 Act” means the Consumer Protection Act 1987 <sup>F7</sup>;

“the 2002 Regulations” means the Personal Protective Equipment Regulations 2002 <sup>F8</sup>;

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 <sup>F9</sup>;

“EU Regulation 2016/425” means Regulation (EU) No 2016/425 <sup>F10</sup> of the European Parliament and of the Council on personal protective equipment, repealing Council Directive 89/686/EEC<sup>F11</sup>, as amended from time to time;

[<sup>F12</sup>“Regulation 2016/425 (pre-exit)” means Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, as it had effect immediately before IP completion day;]

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>F13</sup>, as amended from time to time;

“risk” means a risk which may result in harm to the health or safety of persons, domestic animals or property, if personal protective equipment (“PPE”) is used in a normal and predictable manner; and

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985 <sup>F14</sup>.

(3) In these Regulations [<sup>F15</sup>(unless otherwise stated) ] a reference to—

- (a) a numbered regulation, paragraph or Schedule is a reference to the regulation, paragraph or Schedule as numbered in these Regulations <sup>F16</sup> ...;
  - (b) an Article, paragraph of an Article [<sup>F17</sup>, Chapter ] or Annex is a reference to the Article, paragraph of an Article [<sup>F17</sup>, Chapter ] or Annex as numbered in EU Regulation 2016/425;
  - (c) a “relevant economic operator” in relation to PPE means an economic operator with obligations in respect of PPE under EU Regulation 2016/425; and
  - (d) an “enforcement authority” is to be construed in accordance with regulation 4.
- (4) Expressions and words used in these Regulations which are used in EU Regulation 2016/425 have the same meaning as in EU Regulation 2016/425 [<sup>F18</sup>unless otherwise stated].

#### Extent Information

- E3** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F5** 1974 c.37.
- F6** S.I. 1978/1039 (N.I. 9).
- F7** 1987 c.43.
- F8** S.I. 2002/1144 as amended by S.I. 2004/693, 2012/1848 and 2015/1630.
- F9** 1972 Chapter 9.
- F10** OJ No L81, 31.3.2016, p.51.
- F11** OJ No L399, 30.12.1989, p.18.
- F12** Words in [reg. 1\(2\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(a\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F13** OJ No L 218, 13.8.2008, p.30.
- F14** [1985 c.72](#); [section 69](#) was amended by the [Local Government \(Wales\) Act 1994](#) (c.19), [section 66](#) and [Schedule 16](#), paragraph 75; the [Local Government etc. \(Scotland\) Act 1994](#) (c.39), [section 180](#) and [Schedule 13](#), paragraph 144; and the [Statute Law \(Repeals\) Act 1989](#) (c.43) [Schedule 1](#), Part 1.
- F15** Words in [reg. 1\(3\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(b\)\(i\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F16** Words in [reg. 1\(3\)\(a\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(b\)\(ii\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F17** Word in [reg. 1\(3\)\(b\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(b\)\(iii\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F18** Words in [reg. 1\(4\)](#) inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 35 para. 1\(2\)\(c\)](#) (as amended by S.I. 2020/676, [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Application, transitional provisions, savings and revocation **N.I.**

- 2.—(1) These Regulations apply to PPE placed on the market on or after 21st April 2018.
- (2) These Regulations do not apply to PPE—
- (a) designed for the uses specified in Article 2(2)(a) to (d); or
  - (b) that falls within Article 2(2)(e).

(3) Nothing in these Regulations prevents the showing of PPE at trade fairs, exhibitions, demonstrations or the like, which is not in compliance with the provisions of EU Regulation 2016/425, provided that a visible sign clearly indicates that such PPE does not comply with those provisions and that it is not for sale until it is made compliant.

(4) The 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market before 21st April 2019 <sup>M10</sup>, and in any such case the consequential amendments made by Schedule 5 do not apply.

(5) If, before 21st April 2019—

(a) an EC type-examination certificate is issued by an approved body under the 2002 Regulations, pursuant to the EC type-examination procedure set out in Schedule 7 to those Regulations, or

(b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring EC quality of production by means of monitoring) to the 2002 Regulations,

that certificate or decision remains valid until 21st April 2023 <sup>M11</sup>, or until its' expiry date if earlier, for the purpose of satisfying the requirements of an EU declaration of conformity set out in paragraphs 7 or 8 of Annex IX.

(6) The 2002 Regulations are revoked save to the extent required to give effect to paragraphs (4) and (5).

#### Extent Information

**E2** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Marginal Citations

**M10** [Article 47\(1\)](#) of EU Regulation 2016/425 provides for PPE which is in conformity with Council Directive 89/686/EEC to be placed on the market until 21 April 2019. The 2002 Regulations transposed Council Directive 89/686/EEC.

**M11** [Article 47\(2\)](#) of the EU Regulation 2016/425 provides for EC type-examination certificates and approval decisions issued under Council Directive 89/686/EEC to remain valid until 21 April 2023 unless they expire before that date.

### Application, transitional provisions, savings and revocation **E+W+S**

2.—(1) These Regulations apply to PPE placed on the market on or after 21st April 2018.

(2) These Regulations do not apply to PPE—

(a) designed for the uses specified in Article 2(2)(a) to (d); or

(b) that falls within Article 2(2)(e).

(3) Nothing in these Regulations prevents the showing of PPE at trade fairs, exhibitions, demonstrations or the like, which is not in compliance with the provisions of EU Regulation 2016/425, provided that a visible sign clearly indicates that such PPE does not comply with those provisions and that it is not for sale until it is made compliant.

(4) [<sup>F19</sup>Subject to the modifications made in paragraph (4A),] the 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market before 21st April 2019 <sup>F20</sup>, and in any such case the consequential amendments made by Schedule 5 do not apply.

[<sup>F21</sup>(4A) The modifications referred to in paragraph (4) are as follows—

(a) any reference to “Community” is to be read as including the United Kingdom;

- (b) any reference to “Member State” is to be read as including the United Kingdom;
- (c) in Schedule 7—
  - (i) in paragraph 5—
    - (aa) omit from “The Commission” to “conducted”;
    - (bb) before “file shall be held” insert “ manufacturer's technical ”;
  - (ii) in paragraph 6, omit from “An inspection body” to the end;
- (d) in Schedule 10, in paragraph 2, omit from “with a view” to “the Commission]
- (5) If, before 21st April 2019—
  - (a) an EC type-examination certificate is issued by an approved body under the 2002 Regulations, pursuant to the EC type-examination procedure set out in Schedule 7 to those Regulations, or
  - (b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring EC quality of production by means of monitoring) to the 2002 Regulations, that certificate or decision remains valid until 21st April 2023 <sup>F22</sup>, or until its' expiry date if earlier, for the purpose of satisfying the requirements of an EU declaration of conformity set out in paragraphs 7 or 8 of Annex IX [<sup>F23</sup>of Regulation 2016/425 (pre-exit) or a declaration of conformity set out in paragraphs 7 or 8 of Annex IX ].
- (6) The 2002 Regulations are revoked save to the extent required to give effect to paragraphs [<sup>F24</sup>(4) to (5)].

#### Extent Information

- E4** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Textual Amendments

- F19** Reg. 2(4)(a) inserted (31.12.2020) by S.I. 2019/696, Sch. 35 para. 1(3)(a) (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1))
- F20** Article 47(1) of EU Regulation 2016/425 provides for PPE which is in conformity with Council Directive 89/686/EEC to be placed on the market until 21 April 2019. The 2002 Regulations transposed Council Directive 89/686/EEC.
- F21** Reg. 2(4A) inserted (31.12.2020) by S.I. 2019/696, **Sch. 35 para. 1(3)(b)** (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(ii)**; 2020 c. 1, **Sch. 5 para. 1(1)**)
- F22** Article 47(2) of the EU Regulation 2016/425 provides for EC type-examination certificates and approval decisions issued under Council Directive 89/686/EEC to remain valid until 21 April 2023 unless they expire before that date.
- F23** Words in reg. 2(5) inserted (31.12.2020) by S.I. 2019/696, Sch. 35 para. 1(3)(c) (as substituted by [The Product Safety, Metrology and Mutual Recognition Agreement \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1246), regs. 1(3), **9(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1))
- F24** Words in reg. 2(6) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 35 para. 1(3)(e)** (as amended by S.I. 2020/676, regs. 1(1), 2, 3); 2020 c. 1, Sch. 5 para. 1(1))

**[<sup>F1</sup>Obligations which are met by complying with obligations in Regulation 2016/425 (pre-exit)**

**2A.**—(1) In this regulation, “harmonised standard” has the meaning in Article 3(10) of Regulation 2016/425 (pre-exit).

- (2) Paragraph (3) applies where before placing PPE on the market, the manufacturer—
- (a) ensures that the PPE has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II of Regulation 2016/425 (pre-exit);
  - (b) carries out the applicable conformity assessment procedure referred to in Article 19 of Regulation 2016/425 (pre-exit), or has it carried out;
  - (c) draws up the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit);
  - (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in, or translated into, English;
  - (e) affixes a CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit);
  - (f) draws up an EU declaration of conformity, in accordance with Article 15 of Regulation 2016/425 (pre-exit); and
  - (g) ensures that the EU declaration of conformity is prepared in, or translated into, English.
- (3) Where this paragraph applies—
- (a) the requirements of Articles 8(1) and (2), 15, 16, 17 and 19 are to be treated as being satisfied;
  - (b) Articles 8(3), (4), (7) and (8), 9(2) and regulation 7(1) apply, subject to the modifications in paragraph (8);
  - (c) Article 41 does not apply.
- (4) Paragraph (5) applies, where before placing PPE on the market, the importer ensures that—
- (a) the applicable conformity assessment procedure referred to in Article 19 of Regulation 2016/425 (pre-exit) has been carried out;
  - (b) the manufacturer has drawn up the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit); and
  - (c) the PPE bears the CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit).
- (5) Where this paragraph applies—
- (a) the requirements in Article 10(2), to ensure that—
    - (i) the appropriate conformity assessment procedure referred to in Article 19 has been carried out;
    - (ii) the manufacturer has drawn up the technical documentation;
    - (iii) the PPE bears the UK marking,
 are to be treated as being satisfied; and
  - (b) the second subparagraph of Article 10(2), Article 10(4), (5) and (8), and regulation 7(1) apply, subject to the modifications in paragraph (8).
- (6) Paragraph (7) applies where, before placing PPE on the market, a distributor ensures that the PPE bears the CE marking in accordance with Articles 16 and 17(1) to (4) of Regulation 2016/425 (pre-exit).
- (7) Where this paragraph applies—

- (a) the requirement for the distributor to verify that the PPE bears the UK marking, referred to in Article 11(2), is to be treated as being satisfied; and
  - (b) (excluding the requirement mentioned in sub-paragraph (a)), Article 11(2), 11(3) and regulation 7(1) apply, subject to the modifications in paragraph (8).
- (8) The modifications referred to in subparagraphs (3)(b), (5)(b) and (7)(b) are that—
- (a) any reference to a “declaration of conformity” is to be read as a reference to an EU declaration of conformity, referred to in Article 15 of Regulation 2016/425 (pre-exit);
  - (b) any reference to point 1.4 of Annex II is to be read as a reference to point 1.4 of Annex II of Regulation 2016/425 (pre-exit);
  - (c) any reference to “essential health and safety requirements” is to be read as a reference to the essential health and safety requirements referred to in Annex II of Regulation 2016/425 (pre-exit);
  - (d) any reference to “designated standard” is to be read as a reference to a harmonised standard;
  - (e) any reference to “technical documentation” is a reference to the technical documentation referred to in Annex III of Regulation 2016/425 (pre-exit);
  - (f) in regulation 7(1), any reference to a numbered Article is to be read as a reference to the equivalent Article of Regulation 2016/425 (pre-exit).

#### Textual Amendments

- F1** Regs. 2A, 2B inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 35 para. 1\(4\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2, 3); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Conformity assessment procedure obligation which is met by complying with Regulation 2016/425 (pre-exit)

- 2B.**—(1) Paragraph (2) applies where—
- (a) PPE is classified under Article 18 of Regulation 2016/425 (pre-exit) as falling within risk category II or risk category III, as set out in Annex I to Regulation 2016/425 (pre-exit); and
  - (b) prior to manufacture of that PPE, the manufacturer ensures that the conformity assessment procedure set out in Annex V to Regulation 2016/425 (pre-exit), and referred to in Article 19(b) and (c) of Regulation 2016/425 (pre-exit) as EU type-examination, has been carried out in accordance with Article 19(b) or (c).
- (2) Where this paragraph applies—
- (a) the requirement in Article 19(b) or (c) to follow the conformity assessment procedure referred to in those provisions as type-examination, and set out in Annex V, is to be treated as being satisfied;
  - (b) any reference to “conformity assessment procedure” in Articles 8(2) and 10(2) is to be read as including the conformity assessment procedure referred to in Article 19(b) and (c) of Regulation 2016/425 (pre-exit) as EU type-examination;
  - (c) any reference to “technical documentation” in Articles 8(2), 8(3), 10(2) and 10(8) is to be read as including the technical documentation relating to the design of the PPE as referred to in Annex V to Regulation 2016/425 (pre-exit).]

### Textual Amendments

- F1** Regs. 2A, 2B inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 35 para. 1\(4\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2, 3); 2020 c. 1, Sch. 5 para. 1(1)

### [<sup>F2</sup>Expiry of regulations 2A and 2B

**2C.**—(1) Subject to paragraph (2), regulation 2A ceases to have effect at the end of the period of [<sup>F3</sup>four years] beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 2A—

- (a) any PPE which was placed on the market pursuant to regulation 2A may continue to be made available on the market on or after the expiry of regulation 2A;
- (b) any obligation to which a person was subject under regulation 2A in respect of PPE placed on the market pursuant to regulation 2A continues to have effect after the expiry of regulation 2A, in respect of that PPE.

(3) Subject to paragraph (4), regulation 2B ceases to have effect at the end of the period of [<sup>F4</sup>four years] beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 2B in relation to a product prior to the expiry of regulation 2B, regulation 2B continues to apply in respect of that product where—

- (a) the manufacturer arranges for the EU-Type examination certificate and any annexes to that certificate to be transferred to an approved body;
- (b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and
- (c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) “EU-Type examination certificate” means a certificate issued after the conformity assessment procedure referred to in regulation 2B(1)(b) has been carried out in relation to that PPE, in accordance with Article 19(b) or (c) of Regulation 2016/425 (pre-exit).

### Textual Amendments

- F2** Regs. 2C, 2D inserted (E.W.S.) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [Sch. 35 para. 1\(4\)](#) (as amended (31.12.2020) by [S.I. 2020/1460](#), reg. 1(4), [Sch. 3 para. 24\(2\)](#))
- F3** Words in [reg. 2C\(1\)](#) substituted (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022 \(S.I. 2022/1393\)](#), regs. 1(1), 2, [Sch. 1 para. \(f\)](#)
- F4** Words in [reg. 2C\(3\)](#) substituted (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022 \(S.I. 2022/1393\)](#), regs. 1(1), 2, [Sch. 1 para. \(f\)](#)

### Qualifying Northern Ireland Goods

**2D.**—(1) In this regulation—

“EU Regulation 2016/425 (Northern Ireland)” means Regulation (EU) No. 2016/425 of March 2016 of March 2016 of the European Parliament and of the Council on personal protective



equipment, repealing Council Directive [89/686/EEC](#), as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement;

“applicable conformity assessment procedure” means the conformity assessment procedure applicable to the PPE in accordance with Article 19 of EU Regulation 2016/245 (Northern Ireland);

“CE marking” has the meaning given to it in Article 3(18) of EU Regulation 2016/425 (Northern Ireland);

“qualifying Northern Ireland goods” has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

“technical documentation” means the documentation referred to in Annex III of Regulation 2016/425 (Northern Ireland).

(2) Where paragraph (3) applies—

- (a) PPE is to be treated as being in conformity with the essential safety requirements within the meaning given in EU Regulation 2016/425; and
- (b) each relevant economic operator is to be treated as having complied or as complying with the obligations imposed on them under Chapter II of EU Regulation 2016/425.

(3) This paragraph applies where—

- (a) PPE is—
  - (i) in conformity with the essential requirements within the meaning given in EU Regulation 2016/245 (Northern Ireland); and
  - (ii) qualifying Northern Ireland goods; and
- (b) each relevant economic operator has complied or is complying with the obligations imposed on them under Chapter II of EU Regulation 2016/425 (Northern Ireland); and
- (c) an importer has complied with the obligations set out in paragraph (4).

(4) The obligations referred to in paragraph (3)(c) are that, before placing the PPE on the market, the importer—

- (a) complies with Article 10(3) of EU Regulation 2016/425;
- (b) ensures that—
  - (i) the applicable conformity assessment procedure has been carried out in relation to the PPE;
  - (ii) the manufacturer has drawn up the technical documentation; and
  - (iii) the PPE bears the CE marking.]

#### **Textual Amendments**

- F2** Regs. 2C, 2D inserted (E.W.S.) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [Sch. 35 para. 1\(4\)](#) (as amended (31.12.2020) by [S.I. 2020/1460](#), [reg. 1\(4\)](#), [Sch. 3 para. 24\(2\)](#))

**Changes to legislation:**

There are currently no known outstanding effects for the The Personal Protective Equipment (Enforcement) Regulations 2018, PART 1.