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 (Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

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ANNEX I

RISK CATEGORIES OF PPE

This Annex lays down the categories of risk against which...

Category I

Category II

Category III

ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

ANNEX III

TECHNICAL DOCUMENTATION FOR PPE

The technical documentation shall specify the means used by the...
The technical documentation shall include at least the following elements:...
a complete description of the PPE and of its intended...

ANNEX IV

INTERNAL PRODUCTION CONTROL (Module A)

1. Internal production control is the conformity assessment procedure whereby the...
2. Technical documentation
3. Manufacturing
4. UK marking and ... declaration of conformity
   - 4.1. The manufacturer shall affix the UK marking to each individual...
   - 4.2. The manufacturer shall draw up a written ... declaration of...
5. Authorised representative

ANNEX V

... TYPE-EXAMINATION (Module B)

1. ... Type-examination is the part of a conformity assessment procedure...
2. ... type-examination shall be carried out by assessment of the...
3. Application for ... type-examination
4. ... Type-examination
5. Evaluation report
6. ... Type-examination certificate
   - 6.1. Where the type meets the applicable essential health and safety...
   - 6.2. The ... type-examination certificate shall contain at least the following...
   - 6.3. The ... type-examination certificate may have one or more annexes...
   - 6.4. Where the type does not satisfy the applicable essential health...
7. Review of the ... type-examination certificate
   - 7.1. The approved body shall keep itself apprised of any changes...
   - 7.2. The manufacturer shall inform the approved body that holds the...
   - 7.3. The manufacturer shall ensure that the PPE continues to fulfil...
   - 7.4. The manufacturer shall ask the approved body to review the...
   - 7.5. The approved body shall examine the PPE type and, where...
   - 7.6. Where the conditions referred to in points (a) and (b) of point 7.4...
   - 7.7. If, following the review, the approved body concludes that the...
8. Each approved body shall inform the Secretary of State concerning...
9. The manufacturer shall keep a copy of the ... type-examination...
10. The manufacturer's authorised representative may lodge the application referred to...

ANNEX VI

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)

1. Conformity to type based on internal production control is the...
2. Manufacturing
3. UK marking and ... declaration of conformity
   - 3.1. The manufacturer shall affix the UK marking to each individual...
   - 3.2. The manufacturer shall draw up a written ... declaration of...
4. Authorised representative

ANNEX VII

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)

1. Conformity to type based on internal production control plus supervised...
2. Manufacturing
3. Application for supervised product checks at random intervals
4. Product checks
   - 4.1. The approved body shall carry out product checks in order...
   - 4.2. The product checks shall be carried out at least once...
   - 4.3. An adequate statistical sample of the manufactured PPE shall be...
   - 4.4. Where the approved body referred to in point 3 is not...
   - 4.5. The acceptance sampling procedure to be applied is intended to...
   - 4.6. If the examination and testing reveal that the production is...
5. Test report
   - 5.1. The approved body shall provide the manufacturer with a test...
   - 5.2. The manufacturer shall keep the test report at the disposal...
   - 5.3. The manufacturer shall, under the responsibility of the approved body,...
6. UK marking and ... declaration of conformity
   - 6.1. The manufacturer shall affix the UK marking and, under the...
   - 6.2. The manufacturer shall draw up a written ... declaration of...
7. Authorised representative

ANNEX VIII

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (Module D)

1. Conformity to type based on quality assurance of the production...
2. Manufacturing
3. Quality system
   - 3.1. The manufacturer shall lodge an application for assessment of his...
   - 3.2. The quality system shall ensure that the PPE is in...
   - 3.3. The approved body shall assess the quality system to determine...
   - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
   - 3.5. The manufacturer shall keep the approved body that has approved...
   - 3.6. The approved body shall authorise the manufacturer to affix the...
4. Surveillance under the responsibility of the approved body
   - 4.1. The purpose of surveillance is to make sure that the...
   - 4.2. The manufacturer shall, for assessment purposes, allow the approved body...
   - 4.3. The approved body shall carry out periodic audits, at least...
   - 4.4. In addition, the approved body may pay unexpected visits to...
5. UK marking and ... declaration of conformity
   - 5.1. The manufacturer shall affix the UK marking and, under the...
   - 5.2. The manufacturer shall draw up a written ... declaration of...
6. The manufacturer shall, for 10 years after the PPE has been...
7. The approved body shall inform the Secretary of State of...
8. Authorised representative

ANNEX IX

... DECLARATION OF CONFORMITY No …

1. PPE (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his...

3. This declaration of conformity is issued under the sole responsibility...

4. Object of the declaration (identification of PPE allowing traceability; where...

5. The object of the declaration described in point 4 is...

6. References to the relevant designated standards used, including the date...

7. Where applicable, the approved body … (name, number) … performed...

8. Where applicable, the PPE is subject to the conformity assessment...

9. Additional information:
   Signed for and on behalf of: …
   (place and date of issue):
   (name, function) (signature):

ANNEX X

CORRELATION TABLE

(**1**) OJ C 451, 16.12.2014, p. 76.

(**2**) Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

(**3**) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

(**4**) OJ C 136, 4.6.1985, p. 1.

(**5**) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

(**6**) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(**7**) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(**8**) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

(**9**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Art. 24(2) substituted by S.I. 2024/504 reg. 17(a)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 3(2) words substituted by S.I. 2019/696 Sch. 35 para. 3(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(3) words substituted by S.I. 2019/696 Sch. 35 para. 3(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(5) substituted by S.I. 2019/696 Sch. 35 para. 3(4)(b) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(b) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 3(5) words substituted in earlier amending provision S.I. 2019/696, Sch. 35 para. 3(4)(b) by S.I. 2020/852 reg. 4(2)Sch. 1 para. 1(u)(ii) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(u)(ii) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- Art. 24(2A) inserted by S.I. 2024/504 reg. 17(b)