

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

Article 1	Subject matter
Article 2	Scope
Article 3	Definitions
Article 4	Making available on the market
Article 5	Essential health and safety requirements
Article 6	Provisions concerning the use of PPE
Article 7	Making available, putting into service and exhibition at trade fairs, etc
Article 7A	Designated standard

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8	Obligations of manufacturers
Article 9	Authorised representatives
Article 10	Obligations of importers
Article 11	Obligations of distributors
Article 12	Cases in which obligations of manufacturers apply to importers and distributors
Article 13	Identification of economic operators

CHAPTER III

CONFORMITY OF THE PPE

Article 14	Presumption of conformity of PPE
Article 15	... Declaration of conformity
Article 16	General principles of the UK marking
Article 17	Rules and conditions for affixing the UK marking

CHAPTER IV

CONFORMITY ASSESSMENT

Article 18	Risk categories of PPE
Article 19	Conformity assessment procedures

*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. (See end of Document for details) View outstanding changes

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## CHAPTER V

### APPROVAL OF CONFORMITY ASSESSMENT BODIES

Article 20	Approved bodies
Article 21	Approval of conformity assessment bodies
Article 22	UK national accreditation body
Article 23	Monitoring obligations
Article 24	Approved body requirements
Article 25	Presumption of conformity of approved bodies
Article 26	Subsidiaries of, and subcontracting by approved bodies
Article 27	Application for notification
Article 28	Notification procedure
Article 29	Identification numbers and register of approved bodies
Article 30	Restriction, suspension or withdrawal of approval
Article 31	Challenge of the competence of notified bodies
Article 32	Operational obligations of approved bodies
Article 33	Appeal against decisions of approved bodies
Article 34	Information obligation on approved bodies
Article 35	Exchange of experience
Article 36	Coordination of notified bodies

## CHAPTER VI

### MARKET SURVEILLANCE AND CONTROL OF PPE ENTERING THE UNITED KINGDOM MARKET

Article 37	Market surveillance and control of PPE entering the United Kingdom market
Article 38	Procedure ... for dealing with PPE presenting a risk
Article 39	Union safeguard procedure
Article 40	Compliant PPE which presents a risk
Article 41	Formal non-compliance

## CHAPTER VII

### DELEGATED AND IMPLEMENTING ACTS

Article 42	Regulation making powers
Article 43	Exercise of the delegation
Article 44	Committee procedure

## CHAPTER VIII

### TRANSITIONAL AND FINAL PROVISIONS

Article 45	Penalties
Article 46	Repeal
Article 47	Transitional provision in relation to EU exit
Article 48	Entry into force and application Signature

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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

### PRELIMINARY REMARKS

1. The essential health and safety requirements laid down in this...
2. Obligations related to essential health and safety requirements apply only...
3. The essential health and safety requirements are to be interpreted...
4. The manufacturer shall carry out a risk assessment in order...
5. When designing and manufacturing the PPE, and when drafting the...

### 1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

- 1.1. Design principles
  - 1.1.1. Ergonomics
  - 1.1.2. Levels and classes of protection
    - 1.1.2.1. Optimum level of protection
    - 1.1.2.2. Classes of protection appropriate to different levels of risk
- 1.2. Innocuousness of PPE
  - 1.2.1. Absence of inherent risks and other nuisance factors
    - 1.2.1.1. Suitable constituent materials
    - 1.2.1.2. Satisfactory surface condition of all PPE parts in contact with...
    - 1.2.1.3. Maximum permissible user impediment
- 1.3. Comfort and effectiveness
  - 1.3.1. Adaptation of PPE to user morphology
  - 1.3.2. Lightness and strength
  - 1.3.3. Compatibility of different types of PPE intended for simultaneous use...
  - 1.3.4. Protective clothing containing removable protectors
- 1.4. Manufacturer's instructions and information

### 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

- 2.1. PPE incorporating adjustment systems
- 2.2. PPE enclosing the parts of the body to be protected...
- 2.3. PPE for the face, eyes and respiratory system
- 2.4. PPE subject to ageing
- 2.5. PPE which may be caught up during use
- 2.6. PPE for use in potentially explosive atmospheres
- 2.7. PPE intended for rapid intervention or to be put on...
- 2.8. PPE for intervention in very dangerous situations

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- 2.9. PPE incorporating components which can be adjusted or removed by...
  - 2.10. PPE for connection to complementary equipment external to the PPE...
  - 2.11. PPE incorporating a fluid circulation system
  - 2.12. PPE bearing one or more identification markings or indicators directly...
  - 2.13. PPE capable of signalling the user's presence visually
  - 2.14. Multi-risk PPE
3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS
- 3.1. Protection against mechanical impact
    - 3.1.1. Impact caused by falling or ejected objects and collisions of...
    - 3.1.2. Falls
      - 3.1.2.1. Prevention of falls due to slipping
      - 3.1.2.2. Prevention of falls from a height
    - 3.1.3. Mechanical vibration
  - 3.2. Protection against static compression of a part of the body...
  - 3.3. Protection against mechanical injuries
  - 3.4. Protection in liquids
    - 3.4.1. Prevention of drowning
    - 3.4.2. Buoyancy aids
  - 3.5. Protection against the harmful effects of noise
  - 3.6. Protection against heat and/or fire
    - 3.6.1. PPE constituent materials and other components
    - 3.6.2. Complete PPE ready for use
  - 3.7. Protection against cold
    - 3.7.1. PPE constituent materials and other components
    - 3.7.2. Complete PPE ready for use
  - 3.8. Protection against electric shock
    - 3.8.1. Insulating equipment
    - 3.8.2. Conductive equipment
  - 3.9. Radiation protection
    - 3.9.1. Non-ionising radiation
    - 3.9.2. Ionising radiation
      - 3.9.2.1. Protection against external radioactive contamination
      - 3.9.2.2. Protection against external irradiation
  - 3.10. Protection against substances and mixtures which are hazardous to health...
    - 3.10.1. Respiratory protection
    - 3.10.2. Protection against cutaneous and ocular contact
  - 3.11. Diving equipment

### 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...

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## ANNEX IV

### INTERNAL PRODUCTION CONTROL

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

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

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

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## ANNEX VII

### CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS

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

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

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## 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

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- (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](#)).



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**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\(b\)](#)