NEWSLETTER
MAY 2016

BTTG Testing & Certification Ltd.

Revision of the PPE Directive – Regulation on Personal Protective Equipment EU 2016/425

The PPE Regulation has now been published and is available at the following link:
http://eur-lex.europa.eu/legalcontent/EN/TXT/?toc=OJ%3AL%3A2016%3A081%3ATOC&uri=uriserv%3AOJ.L_.2016.081.01.0051.01.ENG

This regulation replaces the PPE Directive EC 89/686, and the key dates are as follows:

- **21st April 2016**
  Enters into force; **Article 48**

- **21st April 2018**
- PPE Directive EC 89/686 is repealed and the PPE Regulation is now applied; **Article 46**

- **21st April 2018 – 21st April 2019**
  Manufacturers have 1 year after the Directive is repealed to place new products on the market, which were certified under the PPE Directive; **Article 47**

- **21st April 2019**
  Any new product placed on the market must conform to the Regulation; **Article 47**

- **21st April 2023**
  All Certificates issued under the PPE Directive, including those with no expiry date, will expire.
  All PPE made available on the EU market must conform to the Regulation; **Article 47.**

Summary of key requirements and changes

Chapter II – Obligations of economic operators

Covers manufacturers, importers, distributors and authorised representatives.

General – economic operators to retain a series of records and documents, e.g. EU declaration.

Article 8 – Obligations of Manufacturers.

Total of 10 bullet points.

5. PPE to have type, batch or serial number marked. If not possible, can be on packaging or accompany documentation.

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The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Our laboratories are accredited to EN ISO/IEC 17025.
Our Certification Services are accredited to EN ISO/IEC 17021.

Article 10 – Obligations of importers.

Total of 9 bullet points.

1. Only compliant PPE to be placed on the market.

3. Importer details to either be marked on the product or if too small, on accompanying packaging / documentation.

Chapter III – Conformity of the PPE

Article 14 – presumption of conformity.

PPE that complies with harmonised standards, or parts thereof, can be presumed to be in conformity with the Essential Health and Safety Requirements (EHSRs) in Annex II that are covered by the standard(s)

Article 16 – CE marking

General principles of article 30 of Regulation 765/2008 to apply.

Chapter IV – Conformity assessment

Article 18 - Risk categories of PPE

Introduces risk categories and refers to annex I.

Article 19 - Conformity assessment procedures

Category I – Internal production control as Annex IV (module A); no NB involvement.

Category II – Type-examination as Annex V (module B) – NB involvement + internal production control as Annex VI (module C) – no NB involvement

Category III - Type-examination as Annex V (module B) – NB involvement + either:
Conformity to type as Annex VII (module C2) – NB involvement
OR
Conformity to type quality assurance as Annex VIII (module D) – NB involvement

Category III PPE produced as a single unit to fit induvial user to be treated as category II

Chapter VII Delegated and implementing acts

Article 42 - Delegated power

Enables the commission to either add or amend Annex I by reclassifying PPE from one category to another.

Annexes

Annex I Risk categories of PPE

Category I – Minimal risks, exclusive list
Category II – All risks not listed under I or III.
Category III – Very serious consequences, exclusive list.

New to category III:
- Drowning
- Cut by hand held chain saws.
- High pressure jets
- Bullet wounds or knife stabs
- Harmful noise

For further information on the changes, or to find out more about the services we offer please visit our website www.bttg.co.uk or email onestopshop@bttg.co.uk

Annex II Essential health and safety requirements (EHSRs)

EHSRs have not changed much from PPE Directive 89/686

Section 1.General / Applicable to all PPE.

- 1.4 (j) Name and address of all NBs involved, therefore for category III products can be more than one NB.
- 1.4 (l) Internet address where the EU declaration can be accessed.

Annex III Technical documentation for PPE.

Applications for type-examination have to include all technical documentation

Has to include at least the following.

(b) An assessment of the risks against which the PPE is intended to protect;

(j) For PPE produced as a single unit to fit an individual user, instructions for manufacturing such PPE on the basis of the approved basic model;

(k) For PPE produced in series where each item is adapted to fit an individual user, the measures to be taken during the fitting and production process to ensure that each item of PPE complies with the approved type.

Annex IV – Internal production control (Module A)

New annex applicable to category I PPE.

Annex V - EU Type-examination (Module B). Compare article 10 PPE Directive.

6.1 Certificate to have a maximum validity of 5 years.
6.2 Minimum content of certificate specified.

7. Review.

7.1 NB to maintain current knowledge and monitor if any changes could invalidate existing certificates.

7.2 Manufacturer to inform NB if changes are made to documents or products that could affect compliance with EHSRs. Certificate to be amended in such cases.

7.4 Manufacturer to ask NB to review certificate:
(a) PPE is modified
(b) Changes to state of the art
(c) Before expiry of the certificate, providing manufacturer wants it renewed
Request for renewal to be made at the earliest 12 months before expiry and no later than 6 months.

7.5 NB carries out examination and if necessary arranges for the PE to be tested. If satisfied with continued compliance, certificate is renewed. NB to ensure procedure is finalised before certificate expiry.

7.6 If no product changes have been made and no change in state of the art, e.g. standard has not changed, simplified renewal process to be followed.

Annex VI - Conformity to type based upon internal production control (Module C)

New annex applicable to category II PPE / no NB involvement.

Annex VII – Conformity to type based upon internal production control plus supervised product checks at random intervals (Module C2). Compare article 11A PPE Directive

4.3 Adequate statistical sample to be taken, tests carried out to verify compliance with standards and EHSRs.

4.5 Sampling procedure applied to determine if production is homogeneous; compare with 4.3.

4.6 If examination / testing reveals production is not homogeneous or PPE is non-compliant, NB to take action and to inform notifying authority.

NOTE: No additional assessment is required as per recommendation for use sheet 125.

Annex VIII - Conformity to type based upon quality assurance of the production process (Module D). Compare article 11B PPE Directive.

2. Quality system to cover production and final product inspection and testing