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CE marking and the Personal Protective Equipment (PPE) Directive, 89/686/EEC

Category III PPE

The Personal Protective Equipment Directive requires PPE to be CE marked by the manufacturer before being sold in Europe (the EEA). Complex design PPE (known as Category III) includes the following:

- Respiratory devices
- Chemical protective equipment and clothing
- High-temperature protection (e.g. firefighter's PPE, arc flash, molten metal splash protection)
- Low-temperature PPE (below -50 °C)
- PPE to protect against falls from a height,
- High-voltage protective equipment

ARTICLE 10

Category III PPE must be examined by a Notified Body, according to Article 10. The Notified Body issues an EC Type-Examination Certificate for the PPE product. Certificates without expiry dates remain valid as long as the PPE and the production do not change. New Article 10 Certificates from BTTG expire after 5 years, but can be extended if the referenced standard has not been updated.

ARTICLE 11

A Manufacturer making Category III PPE must apply to a Notified Body for Article 11 (Quality Assurance Assessment). This must be carried out every year. The Notified Body issues a Quality Assurance Assessment Certificate for the manufacturing site (or one for each site, if made in more than one place). This will be valid for 1 year if Article 11(A), or 3 years if Article 11(B).

EC DECLARATION OF CONFORMITY

When Article 10 has been completed, and Article 11 has been carried out or agreed with a Notified Body, the Manufacturer writes their EC Declaration of Conformity.

THE 'CE' MARK

The CE mark is the graphical equivalent of the EC Declaration of Conformity. Category III PPE must have the Identification Number of the Notified Body conducting the annual Article 11 assessment beside, or beneath, the CE Mark.

CE XXXX or CE XXXX

Category III PPE cannot be sold in Europe unless both Article 10 and Article 11 are carried out.

Summary of Article 10 and Article 11

EC-TYPE EXAMINATION (ARTICLE 10)

- The manufacturer applies to a Notified Body, such as BTTG, for EC Type-Examination of their PPE.
- An Application Form, Technical File, and samples of the PPE must be submitted to the Notified Body.
- The Notified Body examines the PPE against the relevant product standard, and carries out any testing required. The Technical File is also examined, including the Labelling and User Information.
- Once the Notified Body is satisfied that the PPE and the Technical File meet the requirements of the Directive and relevant standards, it issues an EC Type-Examination Certificate.

QUALITY ASSURANCE ASSESSMENT (ARTICLE 11)

For Category III PPE, the manufacturer must apply to a Notified Body for Quality Assurance assessment using either Article 11(A) or 11(B). This can be the same Notified Body that carries out Article 10, or a different body. The Manufacturer can change between 11(A) and 11(B), and can change Notified Bodies.

Article 11(A)

Article 11(A) is suitable for manufacturers with a limited range of PPE. The Notified Body selects samples of PPE and conducts sufficient tests to show that the PPE has been produced to the same level as the sample that was certified to Article 10. In addition, the Notified Body will either:

(i) Once per year, carry out an on-site review of company production and test records.

(ii) Once per year, carry out an on-site audit of the production control.

(iii) Once per year, take sufficient samples to conduct statistical analysis of production homogeneity.

(iv) Select samples throughout the year, each sample smaller in size than in (iii), based upon production information supplied by the manufacturer, to assess production homogeneity.

Each production site is visited by the Notified Body for (i) and (ii). For (iii) and (iv), samples may be selected from a convenient location by the Notified Body, e.g. from a distributor. All production sites must be covered by the selection. This is repeated annually.

Article 11(B)

Article 11(B) is suitable for manufacturers with a considerable range of PPE. The Notified Body visits the production site, and assesses the quality system to ensure that the manufacturer can produce the PPE to the same level as the sample that was certified to Article 10. The Notified Body then audits the quality system annually. Each production site must be separately assessed by a Notified Body.

An ISO 9000 Certificate does not replace Article 11(B). The Manufacturer must obtain a separate Article 11(B) Certificate.

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