

CE MARKING FOR PERSONAL PROTECTIVE EQUIPMENT (PPE)



About personal protective equipment

Personal protective equipment (PPE) affords the user protection from hazards **encountered at work, at home or during leisure activities**. In the professional context, they are instruments for achieving what the EU considers a fundamental right, that of health and safety in the workplace.

European Union policy with regard to PPE is aimed to define the **basic health and safety requirements** to be fulfilled by manufacturers and **remove barriers to trade** in these products within the internal market.

The presence of the **CE marking** on PPE is an indication that it meets these harmonised requirements and can be **sold anywhere in the European Economic Area** (made up of the EU countries plus Norway, Iceland and Liechtenstein) as well as in Turkey. This also applies to products manufactured in third countries.

CE marking and the Directive on Personal Protective Equipment

Directive 89/686/EEC **defines** PPE as ‘any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards’.

The Directive makes a **distinction** between PPE of “**simple design**”, “**complex design**” and **neither of these, the last being the third Category**. Whilst the Directive does not explicitly define these three groups as Categories, it is common practice to use the terms cate-

gory I, III and II respectively. Category I is listed in Article 8.3 and consists of products designed to protect the user against gradual or unexceptional risks. They include, among other things, sunglasses, gardening gloves and thimbles. Category III is listed in Article 8.4 and includes for example emergency equipment for use in very high or very low temperatures, respiratory devices and PPE to protect against falls from a height. Category II PPE includes PPE not defined in the above two Articles.

The Directive **does not apply** to PPE designed for use by the armed forces and police, for self-defence or for rescue operations on aircraft or ships. It also does not apply to helmets or visors intended for users of two or three-wheeled motor vehicles, or PPE for simple private use such as umbrellas or dish-washing gloves.

The **health and safety requirements** that PPE must meet in order to be sold in the EU are set out in detail in Annex II of the Directive.

On the road to CE marking – conformity assessment

The manufacturer (or his authorised representative established in the EU) has the obligation to put together technical documentation regardless the category of PPE. The content of this documentation is prescribed in Annex III.

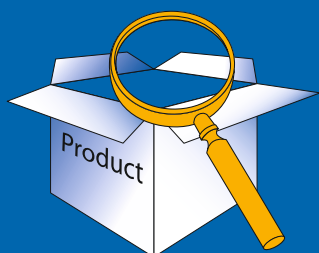
To confirm that PPE of simple design complies with the safety requirements of the

Directive, the manufacturer is required to complete the **EC Declaration of Conformity** only.

For PPE of **categories II, III**, a two-stage conformity assessment procedure must be followed. Firstly, the PPE must undergo the **EC type-examination**, which is carried out by a **Notified Body**. Secondly, the manufac-

turer must choose between either the 'EC quality control system for the final product', or the 'system for ensuring EC quality of production by means of monitoring'. The details of these two options are set out in Article 11 of the Directive.

Once the appropriate certification process has been completed, the manufacturer (or his authorised representative in the EU) must **affix the CE marking to the PPE**. If for practical reasons the marking cannot be affixed to the PPE itself, it can appear on the packaging. Where appropriate, the CE marking must be accompanied by the **identification number of the Notified Body** involved in the conformity assessment process. The CE marking must be **'visible, legible and indelible'** throughout the expected life of the PPE.



Notified Bodies for simple pressure vessels

To find the Notified Bodies appointed by the Member States for conformity assessment of PPE, manufacturers can use NANDO – the New Approach Notified and Designated Organisations database. Notified Bodies can be located by Directive or by country via the NANDO homepage.

Finding the relevant European Harmonised Standards

The first step a manufacturer should take to ensure that PPE will be compliant with the Directive is to check which **European Harmonised Standards** are applicable. A list of harmonised standards for PPE can be found on the European Commission's Enterprise and Industry website.

Where can I find the legal texts and explanatory information?

The Directive can be downloaded from the relevant section of the European Commission's Enterprise and Industry website, where information on other health and safety policies can also be found.

Need more information?

The European Commission has launched a one-stop-shop web portal with all the information you need on CE marking: www.ec.europa.eu/CEmarking

Economic operators can also contact the Enterprise Europe Network at www.enterprise-europe-network.ec.europa.eu.

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