

# The Personal Protective Equipment Regulations

## *A Guide for Manufacturers and Importers*



The Personal Protective Equipment Regulations implement the European Directive on Personal Protective Equipment (PPE), and affect manufacturers, importers, and distributors of PPE. The Directive is one of the European 'new approach' Directives. The intention of such Directives is to harmonise laws in the European Union and assist European Community trade.

This guide has been prepared to assist businesses to meet the requirements of the Regulations. It is not an exhaustive document, but it does try to cover most aspects of the regulations. In particular, advice is given on:

- Product categorisation;
- Demonstrating compliance;
- Documentation;
- CE marking

The advice contained in this leaflet is based on the best information currently available. Every effort has been made to ensure the accuracy of this guide, but you are advised to seek more detailed advice before applying a CE mark to your product.



This is one of a series of leaflets prepared by the Wales Heads of Trading Standards Group. For details of other leaflets in the series, please contact your local Trading Standards Department - contact details are provided at the end of this leaflet.

## Introduction

### What is PPE?

PPE means '*any device or appliance designed to be worn or held by an individual for protection against one or more health & safety hazards*'.

The definition extends to any system placed on the market in conjunction with PPE for its connection to another external additional device.

### Exemptions From the Regulations

Items specifically excluded from the scope of the Regulations include:-

- PPE manufactured for use in a country outside the Community, or imported into the Community for re-export to a country outside the Community
- Non-compliant PPE for presentation at trade fairs, exhibitions and the like, provided that an appropriate notice is displayed drawing attention to the fact that;
  - the PPE is not in conformity with the provisions of the Directive; and
  - it may not be acquired or used until it has been brought into conformity by the manufacturer or his authorised representative established in the community.
- PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields etc)
- PPE for self-defence (e.g. aerosol canisters, personal deterrent weapons etc).
- PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.
- Helmets and visors intended for users of two or three-wheeled motor vehicles.
- Second-hand PPE, except for that which, since its last use, has been subjected to further manufacture or refurbished and resold as new PPE.
- PPE covered by another Directive, designed to achieve the same objectives as the PPE Directive with regard to placing on the market, free movement of goods and safety of PPE.

## Product Categorisation

PPE is categorised into three different types – simple, intermediate and complex. The distinction is an important one as it affects the way in which manufacturers and importers are able to demonstrate compliance with the Regulations. This is explained later in this guide.

### 1. 'Simple' Design

PPE models of '*simple*' design are those where the designer assumes that the user can himself assess the level of protection provided against the minimal risks concerned, the affects of which, when they are gradual, can be safely identified by the user in good time.

This type of PPE is intended to protect the wearer exclusively against:

- Mechanical action whose effects are superficial (gardening gloves, thimbles);
- Cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergents);
- Risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C, or to dangerous impacts (gloves, aprons for professional use);
- Atmospheric agents of neither exceptional nor extreme nature (headgear, seasonal clothing, footwear);
- Minor impacts and vibrations etc which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear);
- Sunlight (sunglasses). However this does not include PPE used for high reflecting environment or in altitude.

### 2. 'Intermediate' Design

This comprises all models of PPE, which are neither covered by the '*simple*' design type nor the '*complex*' design type.

### 3. 'Complex' Design

PPE models of '*complex*' design are intended to protect against mortal danger, or against dangers that may seriously and irreversibly harm health, the immediate effects of which the designer assumes that the user cannot identify in sufficient time.

This type of PPE covers exclusively:

- Filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;
- Respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;
- PPE providing only limited protection against chemical attack or against ionising radiation;
- Emergency equipment for use in high-temperature environments, the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten materials;
- Emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less;
- PPE to protect against falls from a height;
- PPE to protect against electrical risks and dangerous voltages or that used as insulation in high-tension work.

### What Do the Regulations Require?

**Manufacturers** of PPE must decide in light of all the available information whether their product is covered by the regulations and if so whether it is PPE of a '*simple*', '*intermediate*' or '*complex*' design. This distinction is important as it will dictate the appropriate conformity procedures that must be followed to demonstrate compliance with the Regulations. This is illustrated in the chart overleaf.

The PPE Directive gives manufacturers the option of complying with its requirements by manufacturing either directly in accordance with the basic health and safety requirements, or to harmonised European standards, which have been developed specifically to allow a presumption of conformity with those requirements.

**Importers** of PPE directly into the European Community, with a view to placing it on the Community market should ensure it has been manufactured in accordance with the requirements of the Regulations, and bears the CE mark.

**Distributors** of PPE (eg wholesalers, retailers) have a statutory duty to ensure the PPE satisfies the safety requirements and bears the CE marking.

## Demonstrating Compliance – Conformity Assessment

	Simple PPE	Intermediate PPE	Complex PPE
<b>Step 1 : Draw up necessary technical documentation:-</b>	This might include:- <ul style="list-style-type: none"> <li>● Description of and/or sample of the PPE to which it relates;</li> <li>● List of basic health &amp; safety requirements for the PPE, &amp; the means used to satisfy those requirements, including:-                             <ul style="list-style-type: none"> <li>➢ Details of any harmonised standards employed in the PPE's manufacture</li> <li>➢ Details of any other national or other standards, or recognised specifications, employed in the PPE's manufacture;</li> <li>➢ Any other technical specifications to be taken into account</li> </ul> </li> <li>● Performance characteristics and details of intended use</li> </ul>	As for <i>Simple PPE</i> , but documentation must also include a <b>technical file</b> comprising:- <ul style="list-style-type: none"> <li>a) Overall &amp; detailed plans of the PPE in question, results of testing &amp; the testing facilities used</li> <li>b) A complete list of the basic health and safety requirements, national standards (if any) and other technical specifications taken into account in its design</li> </ul>	As for <i>Intermediate PPE</i>
<b>Step 2 : Declaration of Conformity</b>	↓ ✓ Prepare an EC Declaration of Conformity	↓ ✓ Submit to an approved body for EC type examination ✓ Prepare Declaration of Conformity	↓ ✓ Submit to an approved body for EC type examination ✓ Apply Quality Control procedures ✓ Prepare Declaration of Conformity
<b>Step 3 : CE Mark</b>	↓ Affix the CE mark to the product	↓ Affix the CE mark to the product	↓ Affix the CE mark to the product (ID no. of Approved Body to be marked adjacent)

**Note:** This chart is only an outline of the process and the relevant components of the chart are discussed in more detail overleaf



## Documentation – The Declaration of Conformity

The Regulations require a manufacturer to create and sign a Declaration of Conformity for each type of product and its variants. The example given below outlines the content of such a declaration. It should be in English and must be signed by a representative of the manufacturer. This might be a director of the company. In the event of a false declaration being made, action may be taken against the person who has signed the declaration as well as the manufacturer.

### Example of a Declaration of Conformity

The manufacturer, or his authorised representative in the Community

*Company Name/Address etc.*

.....  
.....  
.....

Declares that the new PPE described below

Product make and model .....

Serial number .....

Category (*Simple / Intermediate / Complex*) .....

\* Is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, the national standard transposing harmonized standard

*(State which standard used).....*

\* Is identical to the PPE which is the subject of the EC certificate of conformity no.....issued by

*(State name and address of approved body).....*

\*Is subject to the procedure set out in Article 11 Point A\* or Point B\* of Directive 89/686/EEC, under the supervision of

*(State name and address of approved body)*

**Signed:** .....

**Position:** .....

**Date:** .....

\*Delete as appropriate

## The Basic Health and Safety Requirements

The regulations specify the health and safety requirements that PPE must meet. You should read them in full by consulting the regulations themselves. To summarise, the requirements fall into three categories:-

- General – e.g. design principles, instructions for use
- Product specific
- Risk specific

## EC Type Examination Procedures

The regulations require that all PPE, other than simple PPE, is subject to an EC type examination by an approved body (ie government approved to carry out conformity assessment procedures for PPE). The manufacturer or his authorised representative must apply to the approved body, and provide sufficient samples of the item in question, together with manufacturing details, and the relevant technical file.

If the approved body is satisfied that the PPE samples provided meet fully the appropriate requirements of the Regulations, it will prepare an EC type-examination certificate which it will issue to the applicant.

## Quality Control Procedures

In addition to the EC type examination process, PPE of *complex design* must also be subject to one of two quality control systems. This is to ensure that manufactured PPE does in fact meet the quality and safety of the samples originally submitted for EC type examination. The two types of system are:-

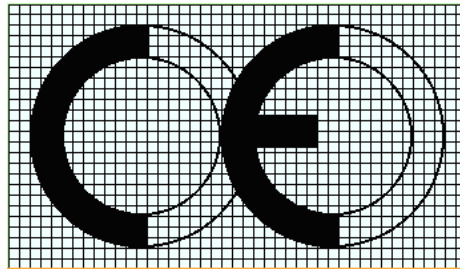
- **Final product checks by approved body ('Point A' in the Directive)** – the manufacturer appoints an approved body (which may be the same one used for the EC type examination). At least once a year, the approved body makes the necessary checks to ensure that the PPE conforms with the pre-production PPE for which the EC type examination certificate was issued, and that it meets the basic health and safety requirements.
- **Quality system adopted by manufacturer ('Point B' in the Directive)** – the manufacturer must check each item of PPE under a quality control system that is approved and audited by a suitably qualified approved body.

## Applying the CE Mark

The application of the CE mark by the manufacturer is taken as a claim that the product satisfies all of the relevant directives. You must be aware of any other European Directives that apply to your product and meet their requirements **before** applying the CE mark.

The CE marking must be affixed to each piece of PPE so as to be visible, legible and indelible throughout the expected life of the PPE; however, if this is not possible in view of the characteristics of the product, the CE marking may be affixed to the packaging.

The CE mark must be at least 5mm high and in the font style given in the Regulations.



## Where can I get more information?

- The Trading Standards Service of your local authority should be able to help with most of your queries. You can contact your local Trading Standards at:-



### Trading Standards

Torfaen County Borough Council

County Hall

Cwmbran NP44 2WN

[trading\\_standards@torfaen.gov.uk](mailto:trading_standards@torfaen.gov.uk)

tel: 01633 648384

- The Dti

The Standards and Technical Regulations Directorate are the lead body within the UK for most of the CE marking directives (but not all). The Dti produce a number of in-depth guidance notes on the various regulations, most of which can be obtained from your Local Trading Standards Department. Alternatively you can contact the Dti directly on 0207 215 5000 or by writing to 151 Buckingham Palace Road, London, SW1W 9SS.