

Personal Protective Equipment Directive 89/686/EEC

What does it cover?

So should my Protective Equipment be CE marked if it falls under the directive? And how do I get the CE mark?

What should be the contents of the Technical File?

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What does it cover?

The PPED (*Personal Protective Equipment Directive*) covers any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

PPED also applies to:

(a) a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;

(b) a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;

(c) interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment.



However the PPED **does not apply to:**



1. PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).

2. PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.).

3. PPE designed and manufactured for private use against:

— adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.),

— damp and water (dish-washing gloves, etc.),

— heat (gloves etc.).

4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.

5. Helmets and visors intended for users of two- or three-wheeled motor vehicles.



So should my Protective Equipment be CE marked if it falls under the directive? And how do I get the CE mark?

Yes, it should be CE marked if it falls within the scope of the directive.

First of all the manufacturer must create a **technical file**.

Then, if the product is to be manufactured in series, an **EC type-examination** is required. This EC type declaration *shall not be required* in the case of PPE models of simple design where the designer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time. This category shall cover exclusively PPE intended to protect the wearer against:

- mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),
- cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),
- 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, etc.),
- atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),
- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),
- sunlight (sunglasses).

In the case of PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the PPE will be subject to either **‘EC’ quality control system for the final product** or **System for ensuring EC quality of production by means of monitoring** and to an **EC declaration of conformity**.

What should be the contents of the Technical File?

The **Technical File** shall consist of:

1. Overall and detailed plans of the PPE accompanied, if appropriate, by calculation notes and the results of prototype tests in so far as is necessary for the verification of compliance with the Basic Requirements (Annex II of the PPE Directive).

2. An exhaustive list of the basic safety requirements and of the harmonized standards or other technical specifications used to demonstrate compliance with the Basic Requirements.

Other technical documentation that should be included, although not strictly part of the 'Technical File' is:

1. A copy of the User Information or Instructions for Use supplied with the product;
2. A description of the control and test facilities to be used in the manufacturer's plant to check compliance of production PPE with the harmonized standards or other technical specification.

Relevant Legal Notices

LEGAL NOTICE 371 of 2002 - Personal Protective Equipment Regulations

<http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/427/38.pdf>

Relevant Guidance documents

http://ec.europa.eu/enterprise/mechan_equipment/ppe/ppe_guidelines.pdf

http://ec.europa.eu/enterprise/mechan_equipment/ppe/guide.htm