

# LEAFLET

## European and National Requirements PPE

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### **European and national requirements for Personal Protection Equipment (PPE)**

Eye protection equipment is divided into three categories according to the European PPE Directive 89/686/EEC. The categorization is based in each case on the protection function and the potential risk to the user due to external chemical, optical or mechanical influences:

#### **Category 1:**

Simple PPE products where the user is protected against minor risks (e.g. sunglasses and ski goggles).

#### **Category 2:**

PPE products which must be used for protection in case of high risk (all products for occupational health and safety fall under this category. for example, welding helmets and protective eyewear).

#### **Category 3:**

PPE products designed for protection against fatal risks where the user cannot identify the direct effect of the risk in good time.

The European PPE Directive 89/686/EEC has been implemented in national law by all Member States of the European Union; marketers thus need to consider the Directive in each country. Various authorities, such as market surveillance bodies or customs monitor compliance with the requirements of the Directive. Failure to observe the requirements can result in a product recall or fines.

As a notified body for personal protective equipment we have worked intensively for the European market for many years. We are your partner and help you to access the European market. We offer you advice and assistance.

Below we have summarized the most important requirements of the PPE Directive for you.

**Before marketing PPE in Europe, or importing it into Europe, the following conditions must be met:**

**Category 1:**

1. The PPE must meet the safety requirements of the PPE Directive. The requirements must be validated on the basis of test reports. The reports must completely cover the harmonised product standards.
2. The importer must demonstrate the existence of technical documentation.
3. The product must be accompanied by complete operating instructions.
4. The importer must issue a Declaration of Conformity and affix the CE mark.

**Category 2:**

1. The PPE must meet the safety requirements of the PPE Directive. The requirements must be validated on the basis of test reports. The reports must completely cover the harmonised product standards.
2. The importer must demonstrate the existence of technical documentation.
3. An EC type-examination of the product must be performed by a notified body (including an EC type-examination certificate).
4. In case of proprietary brands or rebadged products an EC type-examination certificate must be issued for the importer. When importing from outside Europe, the importer always needs an EC type-examination certificate with its name.
5. The product must be accompanied by complete operating instructions.
6. The importer must issue a Declaration of Conformity and affix the CE mark.

**Category 3:**

1. The PPE must meet the safety requirements of the PPE Directive. The requirements must be validated on the basis of test reports. The reports must completely cover the harmonised product standards.
2. The importer must demonstrate the existence of technical documentation.
3. An EC type-examination of the product must be performed by a notified body (including an EC type-examination certificate).
4. In case of proprietary brands or rebadged products an EC type-examination certificate must be issued for the importer. When importing from outside Europe, the importer always needs an EC type-examination certificate with its name.
5. Manufacturing of the product or the product itself is subject to an annual audit by the notified body.
6. The product must be accompanied by complete operating instructions.
7. The importer must issue a Declaration of Conformity and affix the CE mark.

We can support your customers in introducing your products onto the market. Do you have all the necessary documents, or we can assist you in compiling them? Do you possess a valid EC type-examination certificate issued in your customer's name?

**Do you have any other questions? We look forward to helping you!**