

## CE Program

### Notified Body Services For PPE Products

Directive 89/686/EEC



#### PPE -

#### Personal Protective Equipment

All companies exporting to or selling in the European Union PPE products will face the challenge of understanding the legal requirements for product compliance.

SAI Global is an approved European Notified Body to provide CE Marking conformity assessment services for Personal Protective Equipment under Directive 89/686/EEC.

SAI Global has been certifying Personal Protective Equipment (PPE) over 40 years in over 50 countries. Let SAI Global look after your compliance and assurance requirements in a simple and straight forward manner.

#### SAI Global Notified Body Scope for CE Marking PPE Products

- Eye protection
- Fall from height equipment (including safety and rescue harnesses)
- Foot and leg protection
- Hand protection (gloves)
- Head protection (helmets)
- Hearing protection
- High visibility garments
- Life jackets and buoyancy aids
- Protective clothing
- Respiratory protection devices
- Safety devices for diving
- Sports equipment

#### What is CE Marking?

CE Marking is a mark affixed to a product by the manufacturer to demonstrate that the product complies with all applicable European New Approach Directives.



CE Marking indicates to officials that the product may be legally offered for sale in any country within the European Economic Area.

#### How to affix CE Marking?

Before affixing CE Marking, manufacturers must complete a conformity assessment process for the product. This may involve:

- Preparation of a Technical File
- Development of a Risk Assessment
- Conducting independent and/or in-house product testing
- Drawing up and signing a Declaration of Conformity
- Verification by an externally accredited Notified Body, such as SAI Global

It is the responsibility of the manufacturer to ensure that the PPE complies with the requirements specified in the applicable directive(s).

Different products have different conformity assessment routes, as specified in the New Approach Directives published by the European Union, varying from self declaration to ongoing independent assessment by a Notified Body.

#### What are the PPE Directive 89/686/EEC Requirements?

Within the Directive 89/686/EEC there are three product categories for personal protective equipment:

- Category I (Low Risk) – Simple Design (such as, gardening gloves, sunglasses, light footwear, where the user can himself assess the level of protection provided against the minimal risks). This Category is referred to as ‘Self Declaration’.
- Category II (Medium Risk) – Products outside of categories I and III (such as, life jackets, high visibility garments, hearing protection, eye protection).
- Category III (High Risk) – Complex Design intended to provide protection against mortal danger or protection against serious injury where the user cannot identify in sufficient time (such as, fall arrest harnesses, respiratory products, head protection).

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For PPE Products that fall into Category II and III a Notified Body, such as SAI Global, must be involved in the conformity assessment process as an independent verifier.

Category I requires the development of a Technical File including manufacturer's Declaration of Conformity. SAI Global can provide a review / gap-analysis of your information.

Category II requires an EC Type Examination certificate issued by a Notified Body (Article 10). This is a development of a Technical File with independent testing. SAI Global can facilitate testing and the EC Type Examination as well as provide a review / gap-analysis of your information.

Category III requires an EC Type Examination certificate (Article 10) and ongoing assessment of compliance (Article 11). Under Article 11 the client can choose to have the Notified Body

- Audit the manufacturing site annually to ensure that quality management systems are in place to product a compliant product on an ongoing basis; or
- Select samples annually for compliance testing

SAI Global offers both of these services as Notified Body for category III conformity assessments.

Conformity to the Essential Health and Safety Requirements (EHSRs) can be demonstrated by compliance with the relevant harmonized standards.

### General Steps in CE Marking

The following steps show the areas that the manufacturer must comply, in general, with the appropriate Directive(s) requirements:

- Identify the applicable Directive(s) or Regulations for the product concerned
- Meet the requirements of the applicable Directive(s) that deal with specific risk
- Comply with the Essential Health and Safety Requirements (EHSRs)
- Carry out testing to European Harmonised Standard(s)

- Provide information on the use, safety, maintenance, training, supervision and PPE requirements
- Compile and keep available a Technical File
- Make a Declaration of Conformity
- Provide labeling information, such as maker's name, on the product in accordance with the Directive (s)
- Affix CE Mark on the product in accordance with the Directive(s)

### Overview of SAI Global Product Certification

SAI Global Product Certification services provide third party assurance that a particular product fulfils the specified requirements of a nominated Directive(s)/Product Standard(s). For the end users it provides a high degree of confidence that the product will perform according to the specified standard.

SAI Global Product Certification:

- Issues over 3000 product certificates
- Certifies clients in over 50 countries
- Certifies in over 500 ISO, EN, Australian and other standards
- Has more than 40 years of product certification expertise

SAI Global issues a number of approval marks, such as:



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#### The main Product Certification areas include:

- Personal Protective Equipment
- Electrical Safety
- Plumbing Products
- Fire Safety Products
- Building Products
- Gas Appliances and Components
- Horticulture, Water and Waste Treatment

### SAI Global staff capability

All SAI Global Technical Managers and Auditors are fully trained and must have high levels of experience in the products and standards to which they certify the products, including ISO, EN and other standards. SAI Global offers

- Strong technical management, auditor & standards development expertise base
- Advanced audit management systems technology

### SAI Global certifying PPE

Some specific examples of current product certifications globally include

#### Respiratory protective devices

- All respiratory products in over 85 manufacturing locations
- SAI Global can also perform audits to the American 42 CFR part 84 legislative requirements, which is used as the basis for the control and approval of respiratory protective devices in the United States of America.

#### Protective helmets for vehicle users

##### Industrial safety helmets

##### Fire fighting helmets

##### Lightweight protective helmets (pedal cycling)

##### Horse riding helmets

##### Cricket helmets

- Certifications in over 185 manufacturing locations

#### Hearing protectors

- Certifications in over 30 manufacturing locations

#### Eye protection - welding, vehicle users, personal use, protective visors

- Certifications in over 60 manufacturing locations

#### Fall from height equipment (including safety and rescue harnesses)

- Certifications in 8 manufacturing locations

#### Personal Flotation Devices (Life Jackets)

- Certifications in 44 manufacturing locations

#### Clothing and Safety Footwear

- Certifications in over 53 manufacturing locations

### SAI Global background

SAI Global has been assessing products and systems for over 40 years, initially as part of a national Standards Body, and since 2003, as a publicly listed assurance provider with offices in 50 global locations, in all major markets and countries.

Besides the accredited certification services for products and systems, SAI Global offers customised assessment and inspection services to meet your requirements for assurance and risk management.

### Inform...Train...Assess

Whether you need to satisfy contractual agreements, demonstrate regulatory compliance, improve internal processes, or enhance your competitive edge, SAI Global can help.

To learn more about our CE Marking Services, to determine whether you need an assessment by an approved European Notified Body, or to purchase standards including European Norms, please visit us at [www.saiglobal.com/assurance](http://www.saiglobal.com/assurance).

Let SAI Global look after your assurance needs. We welcome your contact via [product@saiglobal.com](mailto:product@saiglobal.com)