

CE Program

Notified Body Services

CE 认证 - 公告机构服务

For PPE Products

个人防护用品

Directive 89/686/EEC

指令 89/686/EEC

PPE – Personal Protective Equipment

个人防护用品

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

所有出口到或者在欧盟国家销售个人防护用品的公司都将面临着挑战，即对其产品所需要遵从的法律要求的理解。

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 是一家经批准的欧盟公告机构，在指令 89/686/EEC 的要求下对个人防护用品 CE 标志的符合性进行评估。

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 在个人防护用品领域的认证服务有 40 多年的历史，覆盖了 50 多个国家。请让 SAI Global 以简单而直接的方式来帮您完成产品符合性及质量保证要求。

SAI Global Notified Body Scope for CE Marking PPE Products



SAI Global 公告机构个人防护用品 CE 认证的产品范围

- Eye protection
护目用具
- Fall from height equipment (including safety and rescue harnesses)
高空下坠设备 (包括安全与急救扣具)
- Foot and leg protection
腿和脚的护具
- Hand protection (gloves)
护手用具 (手套)
- Head protection (helmets)
头部护具 (头盔)
- Hearing protection
听力护具
- High visibility garments
高可见性服装
- Life jackets and buoyancy aids
救生衣以及助浮救生工具
- Protective clothing
防护服
- Respiratory protection devices
呼吸防护用品
- Safety devices for diving
潜水安全装置
- Sports equipment
运动器械

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What is CE Marking?

什么是 CE 标志?

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 标志是一种由制造商标识在其产品上的标志，用来表明其产品符合所有适用的欧盟新方法指令。

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

CE 标志向官方表明该产品可以在欧盟经济区内的任何国家合法销售。

How to affix CE Marking?

如何粘贴 CE 标志?

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

在粘贴 CE 标志之前，制造商必须完成产品的符合评定过程。包括：

- Preparation of a Technical File
技术文件的准备
- Development of a Risk Assessment
风险评估的开展
- Conducting independent and/or in-house product testing
第三方的和/或内部的产品测试

- Drawing up and signing a Declaration of Conformity
起草并签署符合性声明
- Verification by an externally accredited Notified Body, such as SAI Global

认可的公告机构的验证，例如 SAI Global

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

制造商有责任确保其个人防护用品符合适用指令的要求。

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.

按照欧盟公布的新方法指令的要求，与由某一公告机构进行独立评估的自我声明不同，不同的产品有着不同的合格评定途径。

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

什么是 PPE 指令 89/686/EEC 的要求?

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

在指令 89/686/EEC 里，对于个人防护用品，有三种产品类别：

- Category I (Low Risk) – Simple Design
(such as, gardening gloves, sunglasses,

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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'.

类别一（低风险）– 简单设计（比如园艺工人手套、太阳镜、轻便靴子，使用者可以自行判定产品所提供的能够应对最低风险的防护级别）。这个类别被称作“自我声明”。

- Category II (Medium Risk) – Products outside of categories I and III (such as, life jackets, high visibility garments, hearing protection, eye protection).

类别二（中等风险）– 在类别一和类别三涉及范围之外的产品（例如救生衣、高可见性服装、听力护具、护目用具）。

- 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).

类别三（高风险）– 预期用于对致命风险提供保护，或者对使用者不能识别的重大危害提供保护的复杂产品（比如防坠栓，呼吸防护用品、头部护具）

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.

对于归于类别二和类别三的个人防护用品而言，公告机构如 SAI Global，作为独立的验证者必须参与合格评定过程。

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.

属于类别一的个人防护用品需要包括符合性声明在内的技术文件。SAI Global 提供技术文件评审和差距分析服务。

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.

属于类别二的个人防护用品需要一份由公告机构颁发的 EC 型式检验证书（条款 10）。认证包括技术文件和第三方的测试报告。SAI Global 提供测试和 EC 型式检验、技术文件评审和差距分析服务。

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

属于类别三的个人防护用品需要一份由认证机构颁发的 EC 型式检验证书（条款 10）和持续符合性评估（条款 11）。根据条款 11，顾客可以选择公告机构。

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

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每年审核工厂以确保质量管理体系的有效性，生产持续符合要求的产品；或者：

- Select samples annually for compliance testing
每年挑选一些样品做符合性测试。

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

作为公告机构，SAI Global 提供针对类别三的两种合格评定服务。

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

符合相关的协调化标准是证明产品符合基本健康和
安全要求 (EHSRs) 的途径。

General Steps in CE Marking

申请 CE 标志的一般步骤

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

总的来讲，以下步骤说明了制造商在适当的指令要求下所必须遵从的方面：

- Identify the applicable Directive(s) or Regulations for the product concerned
识别相关产品的适用指令或法规
- Meet the requirements of the applicable Directive(s) that deal with specific risk
满足适用指令的风险管理要求。
- Comply with the Essential Health and Safety Requirements (EHSRs)



符合基本健康和
安全要求 (EHSRs)

- Carry out testing to European Harmonised Standard(s)

按照欧洲协调化标准进行检测

- Provide information on the use, safety, maintenance, training, supervision and PPE requirements

提供关于使用、安全、维护、培训、监管以及 PPE 要求等方面的信息。

- Compile and keep available a Technical File
编写并保持技术文件的有效性。

- Make a Declaration of Conformity
制定符合性声明。

- Provide labeling information, such as maker's name, on the product in accordance with the Directive (s)

提供标识信息，例如按照指令要求在产品上标注
制造商名称。

- Affix CE Mark on the product in accordance with the Directive(s)

按照指令要求在产品上粘贴 CE 标志

Overview of SAI Global Product Certification

SAI Global 产品认证的概述

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.

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SAI Global 产品认证服务保证特定的产品满足适用的指令/产品标准的要求。对于终端用户，SAI Global 提供了高程度的信任度，即产品将以符合指定标准的方式运行。

SAI Global Product Certification:

SAI Global 产品认证：

- Issues over 3000 product certificates
已经颁发了超过 3000 张证书
- Certifies clients in over 50 countries
客户遍布 50 多个国家
- Certifies in over 500 ISO, EN, Australian and other standards
认证涉及 500 多个国际标准、欧洲标准、澳大利亚标准及其他标准
- Has more than 40 years of product certification expertise
拥有超过 40 年的产品认证专业经验

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

SAI Global 能颁发众多的认证标志，例如：



The main Product Certification areas include:

主要产品认证领域包括：

- Personal Protective Equipment
个人防护用品
- Electrical Safety
电气安全
- Plumbing Products
管道产品
- Fire Safety Products
防火产品
- Building Products
建筑产品
- Gas Appliances and Components
气体装置及其部件
- Horticulture, Water and Waste Treatment
园艺,水处理以及废物处理

SAI Global staff capability

SAI Global 团队的实力

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

所有的 SAI Global 的技术经理和审核员们都经过充分的培训，并且对其审核的产品及其标准必须具有丰富的经验，包括 ISO，EN 以及其他标准。SAI Global 提供

- Strong technical management, auditor & standards development expertise base
强大的技术管理，审核以及标准开发的专业知识平台

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- Advanced audit management systems technology
先进的审核管理体系

SAI Global certifying PPE

SAI Global 认证的个人防护用品

Some specific examples of current product certifications globally include

在全球范围内，产品认证具体范例包括：

Respiratory protective devices

呼吸保护装置

- All respiratory products in over 85 manufacturing locations
来自超过 85 个制造地点的呼吸保护产品
- 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.
SAI Global 还提供按照美国联邦法规 42 CFR 84 要求所执行的审核，在美国该法规被用为呼吸保护装置控制和批准的基础。

Protective helmets for vehicle users

车用防护头盔

Industrial safety helmets

工业安全帽

Fire fighting helmets

救火安全帽

Lightweight protective helmets (pedal cycling)

轻型防护头盔 (休闲脚踏车用)



Horse riding helmets

骑马防护头盔

Cricket helmets

板球防护头盔

- Certifications in over 185 manufacturing locations
已经为超过 185 个制造地点办理了认证

Hearing protectors

听力护具

- Certifications in over 30 manufacturing locations
已经为超过 30 个制造地点办理了认证

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

护目用品 - 焊接，车辆用户，个人用户，防护面罩

- Certifications in over 60 manufacturing locations
已经为超过 60 个制造地点办理了认证

Fall from height equipment (including safety and rescue harnesses)

高空下坠设备 (包括安全与急救扣具)

- Certifications in 8 manufacturing locations
已经为 8 个制造地点办理了认证

Personal Flotation Devices (Life Jackets)

个人漂浮装置 (救生衣)

- Certifications in 44 manufacturing locations
已经为 44 个制造地点办理了认证

Clothing and Safety Footwear

工作服及安全鞋

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- Certifications in over 53 manufacturing locations

已经为超过 53 个制造地点办理了认证

SAI Global background

SAI Global 的背景

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.

SAI Global 在产品和体系认证方面有 40 多年的历史，从最初的作为澳大利亚国家标准机构的一员，到 2003 年成为一家在全球各大市场和主要国家拥有 50 家办事处的上市公司。

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.

除了提供极具公信力的产品与体系认证服务之外，SAI Global 为了满足您在保险和风险管理方面的要求还提供了定制的评估和检查服务。

Inform...Train...Assess



咨询服务...培训服务...评估服务

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

不论您是需要满足合约要求，展示法律法规的符合性，提高内部管理流程，还是加强您的竞争力，SAI 国际集团都能提供帮助。

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.

如果您希望了解更多关于CE贴标服务的内容，或是想了解是否需要欧盟认可的公告机构来为您做一个评估，还是希望购买标准（包括欧标），请访问网站www.saiglobal.com/assurance.

Let SAI Global look after your assurance needs. We welcome your contact via product@saiglobal.com

SAI 国际集团将竭诚为您服务。欢迎通过下面的邮件联系我们：

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