



Add value.
Inspire trust.

Personal Protective Equipment Certification and Testing service

Assure consumers with proven product safety and reliability



Your challenges

Personal protective equipment (PPE) are products that the user can wear or hold, to be protected against risks either at work, at home or whilst engaging in leisure activities. Statistics on fatal and major work accidents underline the importance of protection and prevention, for which personal protective equipment plays an important role. The stringent regulations imposed by various occupational safety and health organisations such as WHO, ILO in world, OSHA, NIOSH, NFTA in US, HSE in UK, EU-OSHA, ESF in EU have a positive impact on product demand from the end-use industries of PPE, while it is now widely agreed upon that the use of Personal Protective Equipment (PPE), especially face masks can protect health and curb the spread of the pandemic.

As such, consumers require protective equipment with proven reliability and safety performance, and there are various regulatory and legislative requirements covering the safety and performance of PPE products as it is acknowledged crucial to end users. Manufacturers of PPE must be certain that products function correctly and reliably when used for their intended purpose. In addition, manufacturers face challenges in understanding and complying with the international testing standards and follow the conformity assessment procedure that are required to gain access to their target markets.



What is PPE Certification? EU (CE)

According to (EU) 2016/425 Personal Protective Equipment Regulation under new legislative framework (NFL), PPE is classified into three categories: I, II and III according to Annex I of PPER based on the type of risk. An EU Declaration of Conformity is required for each.

PPE Category and Certification requirements:

▪ Category I:

This certification covers PPE products includes exclusively the minimal risks listed in Annex I such as gloves for dishwasher and sunglasses. Manufacturers may obtain the

certification on their own by developing a technical file that includes the manufacturer's Declaration of Conformity.

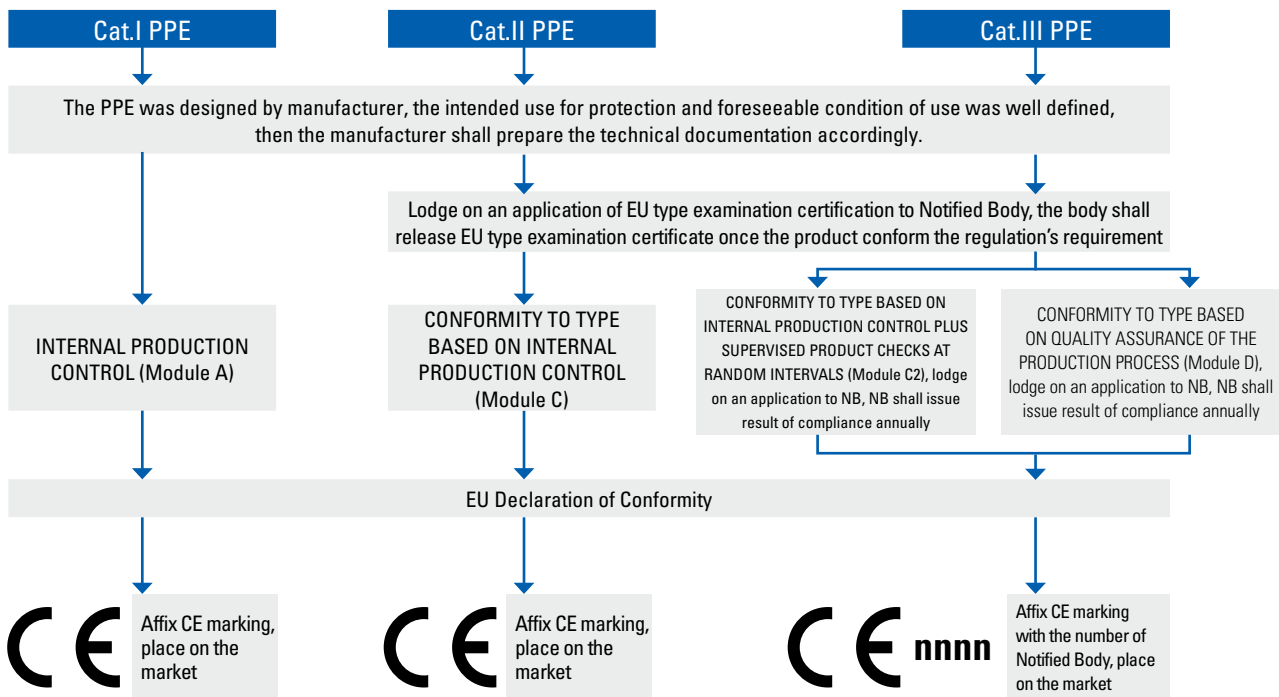
▪ Category II:

Category II includes risks other those listed in Categories I and III, the products covered in this category include safety and sports helmets, safety footwear, high visibility clothing, etc. The certification process requires an EU-type examination by a Notified Body (Module B).

▪ Category III:

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health, covering products such as respiratory equipment, protective clothing providing protection against chemical agent or harmful biological agent, are included in this category. To obtain the certification, an EU Type Examination certificate and ongoing assessment of compliance are required.

After the EU Type Examination assessment of designed product, the manufacturer can choose to have the Notified Body audit the manufacturing annually to ensure that quality management systems are in place to manufacture a compliant product on an ongoing basis (Module D); or they can have the Notified Body select samples annually for compliance testing (Module C2).



CE Certification illustration per different categories of PPE



United States

Although the Occupational Safety and Health Administration (OSHA) and other agencies publish guidance for effective worker protection using PPE, there is currently no single regulatory body, official guidance, or mandating authority for the CA of all PPE. Several PPE Conformity Assessment Programs were developed by different program owner in the United States, and some of them were mandatory while most of them were voluntary, such as head protection was with SEI, CSA, UL, Snell program owners.

In the absence of national policy and guidance, The International Safety Equipment Association (ISEA) created ANSI/ISEA 125-2014 in response to the globalisation of the personal protective equipment (PPE) industry, ANSI/ISEA 125-2014 creates three conformity assessment levels.

- **Level 1** is the least stringent method, which requires suppliers to test products in-house or at third-party labs. The supplier must provide a declaration of conformity with the standards.
- **Level 2** requires suppliers to test their products in ISO 17025 facilities, whether in-house or third-party, and manufacture the products under an ISO 9001-registered quality system. To meet the new ANSE/ISEA 125-2014 standard, the supplier must provide a declaration of conformity with the standards.
- **Level 3** is the most stringent method and requires third-party certification of the entire process from testing to surveillance. To meet Level 3, an accredited third-party certification body must certify and apply its mark to the products.

The guidance provides a description of the appropriate conformity assessment for PPE based on the European Directive 89/686. The standard was updated to 2021 version which addresses improvements and introduces greater flexibility in an effort to promote wider voluntary adoption.

In addition, NIOSH has developed the Framework in 2018 to provide a risk-based, evidence-driven PPE CA approach for occupational use PPE. Which could be found in NIOSH Publications & Products at NIOSH website.

Great Britain (UKCA)

EU Regulation 2016/425 was directly applicable in the UK from 21 April 2018. The enforcement and sanctions system were implemented into UK law by the Personal Protective Equipment (Enforcement) Regulations 2018 (SI 2018 No. 390). The EU Withdrawal Act 2018 preserves these regulations and enables them to be amended so as to continue to function effectively now that the UK has left the EU. Accordingly, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 fix any

deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the GB market.

The UK conformity assessment procedure therefore was generally very close to EU one, PPE that is conformity assessed by a UK approved body should be UKCA marked along with UK Declaration of Conformity to place PPE to Great Britain Market.







What is PPE testing?

PPE testing ensures that the product can reliably protect the wearer's well-being when worn and used as intended. Different standard organisation publishes standards which outlines technical requirement for specific PPE products, manufacturers may have opportunities to use European, international or other national standards and/or industrial technical specifications regarded as important, relevant or useful to cover the applicable essential health and safety requirements of PPE regulation. These tests provide manufacturers with the assurance that based on design, their products are able to safeguard end users from injury. PPE testing services also ensure that the manufacturing equipment meets global standards, thus enabling the manufacturers to access key markets. There are normally own testing and third-party testing program, and third-party testing program was normally the only route for most of certification scheme considering

the impartiality and independence of test result, moreover third party testing program was commonly recognised within supply chain and more acceptable by consumers and market surveillance authority.

How can we help you?

TÜV SÜD is one of the leading players in the testing and certification industry. With our long-standing experience in product quality and safety, we are ready to support all your PPE testing and certification requirements. Our experts apply their knowledge and expertise to ensure that your products will protect consumers and function reliably. Our global roadmap gives your convenience on connecting TÜV SÜD for providing technical service when you are acquiring technical supports, with TÜV SÜD Group, there are three certification bodies who are specialised on PPE service.

<p>UK CA 0168</p>	<p>CE 2443</p>	<p>CE 0123</p>
<p>   TÜV SÜD BABT UNLIMITED </p>	<p>  <small>Danmark</small> TÜV SÜD Danmark Aps </p>	<p>  <small>Product Service</small> TÜV SÜD Product Service GmbH </p>

Our PPE testing services

▪ Testing of sports helmets

TÜV SÜD tests helmets to international standards for functions such as airborne sports, cycling, skateboarding, children's protection, water sports, snow sports and hockey.

▪ Testing of martial arts support equipment

Our experts provide testing as per international norms for protective equipment used in martial arts activities including clamping pads, shin guards, upper body protection, head guards, genital and abdominal protectors, and breast protectors for women.

▪ Testing of mountaineering equipment

We perform safety tests on mountaineering equipment to international standards. Our tests cover equipment such as chocks, carabiners, harnesses, pulleys, tape, slings, rope clamps, fasteners and pitons.

▪ Testing of fall protection equipment

We perform testing to international standards for equipment designed to protect people by preventing falls or preventing injuries due to falling. Our testing for fall protection equipment covers rescue loops, kernmantle ropes, lanyards, height devices, arrest harnesses, connection elements and protection systems.

▪ Testing for the equipment providing foot, leg and anti-slip protection

We provide testing service to safety shoes, protective shoes, insulation shoes, including:

- EN ISO 20345:2022 Safety shoes
- EN ISO 20346:2022 Protective footwear
- EN ISO 20347:2022 Occupational footwear
- EN 50321-1:2018 Insulating footwear and overboots
- EN 13832-2:2018 Footwear protecting against chemicals-Requirements for limited contact with chemicals
- EN 13832-3:2018 Footwear protecting against chemicals- Requirements for prolonged contact with chemicals
- EN 15090:2012 Footwear for firefighters
- EN 13634:2017 Protective footwear for motorcycle riders
- US safety shoe testing standards etc.

▪ Testing for the equipment providing general body protection (clothing)

We provide testing service to High visibility clothing, protective clothing, including:

- EN ISO 20471:2013 High visibility clothing
- EN 17353:2020 Enhanced visibility equipment for medium risk situations etc.

▪ Testing for the equipment providing hand and arm protection

We provide testing service to gloves, including:

- EN 388:2016 Protective gloves against mechanical risks
- EN ISO 21420:2020 Protective gloves - General requirements and test methods
- ANSI/ISEA 138-2019 – American National Standard for Performance and Classification for Impact-Resistant Gloves
- ANSI/ISEA 105-2016 – American National Standard for Hand Protection Classification etc.

▪ CE Marking, UKCA Marking and GS/TÜV Mark

We provide EU-type examination certification for Category II and III products through TÜV SÜD (Notified Body number 0123 & 2443) and annual factory audit (module D) for Category III products through our global auditor network, annual product check at random interval (module C2) through our global network, in certain specific products, we can offer GS/TÜV Mark certification through TÜV SÜD Product Service GmbH if your products can meet more stringent safety requirement.

We can also provide UK conformity assessment service as UK Approval Body (Approval Body Number 0168) to help you on conforming Regulation 2016/425 on personal protective equipment, as amended to apply in Great Britain.



Your business benefits

- **Ensure product quality** – through performance testing in accordance with various global standards.
- **Win customer confidence** – by conducting independent tests to provide assurance of safe and reliable function, thereby enhancing your brand reputation.
- **Gain a competitive edge** – by working with TÜV SÜD, a globally trusted provider of premium certification and testing services.

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. Since 1866, the company has remained committed to its purpose of enabling progress by protecting people, the environment and assets from technology-related risks. Through more than 25,000 employees across over 1,000 locations, it adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

Why choose TÜV SÜD?

A global leader in testing and certification, TÜV SÜD's team of multidisciplinary experts has in-depth experience across most consumer product categories. We offer extensive industry expertise to support our customers in safety testing and meeting laws, directives and standards on safety and quality.

By partnering with us, you will benefit from guided and informed testing services and support throughout the product lifecycle. Our global network of accredited test labs is ready to support you with timely responses to all your testing needs.

* Some of the services listed are provided due to local regulations only and may not be available in other regions. Please contact us for further details.

