



Personal Protective Equipment

SAVING LIVES BY INDEPENDENT, EXPERT TESTING AND CERTIFICATION OF PPE

NOTIFIED BODY



0493



056-PROD



CE



European Union

CE mark

Many products require CE marking before they can be sold in the EU. CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.

The CE marking must be accompanied by the identification number of the notified body¹ that is responsible for the annual monitoring.

US market

Consumer Product Safety Commission

US Federal law requires manufacturers and importers to test many consumer products for compliance with consumer product safety requirements. Based on passing test results, the manufacturer or importer must certify the consumer product as compliant with the applicable consumer product safety requirements in a written or electronic certificate.

Certificates are required to accompany the applicable product or shipment of products covered by the certificate, and a copy must be provided to retailers, distributors and, upon request, to the government.

1 Centexbel is notified body #0493

A hand wearing a white latex glove is holding a white surgical mask. The background is a soft, out-of-focus white and light grey, suggesting a clean, clinical environment. The lighting is bright and even, highlighting the texture of the glove and the pleats of the mask.

Medical Device or PPE?

The amended Medical Device Directive (MDD) 2007/47/EC that came into force in 2010 makes it possible that some products serving a dual purpose may fall under different regulations.

Some products may be intended to be used both as a personal protective equipment and as a medical device. These products thus pursue a double purpose. For example, gloves with a medical purpose in the patient environment are medical devices (e.g. examination gloves), but as they may also be designed to provide protection to the user, they can fall into the definition of personal protective equipment. Masks used by surgeons during operation may also be designed as a filtering respiratory device to protect the user against body liquids or other infective agents. Sunglasses or other protective glasses/goggles or visors with correction are another frequent example of devices with a double purpose.

When the manufacturer wants to market a product as a medical device and also as a personal protective equipment, the essential health and safety requirements of both the PPE Directive and the Medical Device Directive need to be fulfilled.

The amended Article 1(6) MD Directive now reads: *"Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council EU regulation 2016/425 and the MDD, the relevant basic health and safety requirements of EU regulation 2016/425 shall also be fulfilled."* (Article 2(1)f of Directive 2007/47/EC).

With its extended range of testing and certification services, Centexbel enables you to effectively put your products on the market. By being independent of all product suppliers, installers and manufacturers, we can guarantee a confidential and impartial service, and provide you with reliable and objective guidance.

As a BELAC
(056-PROD - EN ISO/IEC 17065:2012)
Accredited Certification Body and Notified
Body #0493 for the PPE Regulation (EU)
2016/425 and other specific Directives and
Regulations, we guide you to meet and demonstrate
compliance of your products with all relevant
standards and legislation.

We guarantee
expertise, quality, safety,
reliability, and accuracy!





MARKING OF PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment (PPE) are products that the user can wear or hold, in order to be protected against hazards either at home, at work 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.

EU Legislation and PPE

The European Union issued a number of regulations to improve health and safety at work and to ensure high quality PPE. The PPE Regulation (EU) 2016/425 covers the manufacturing and marketing of personal protective equipment. It defines legal obligations to ensure that PPE on the European market provides the highest level of protection against hazards.

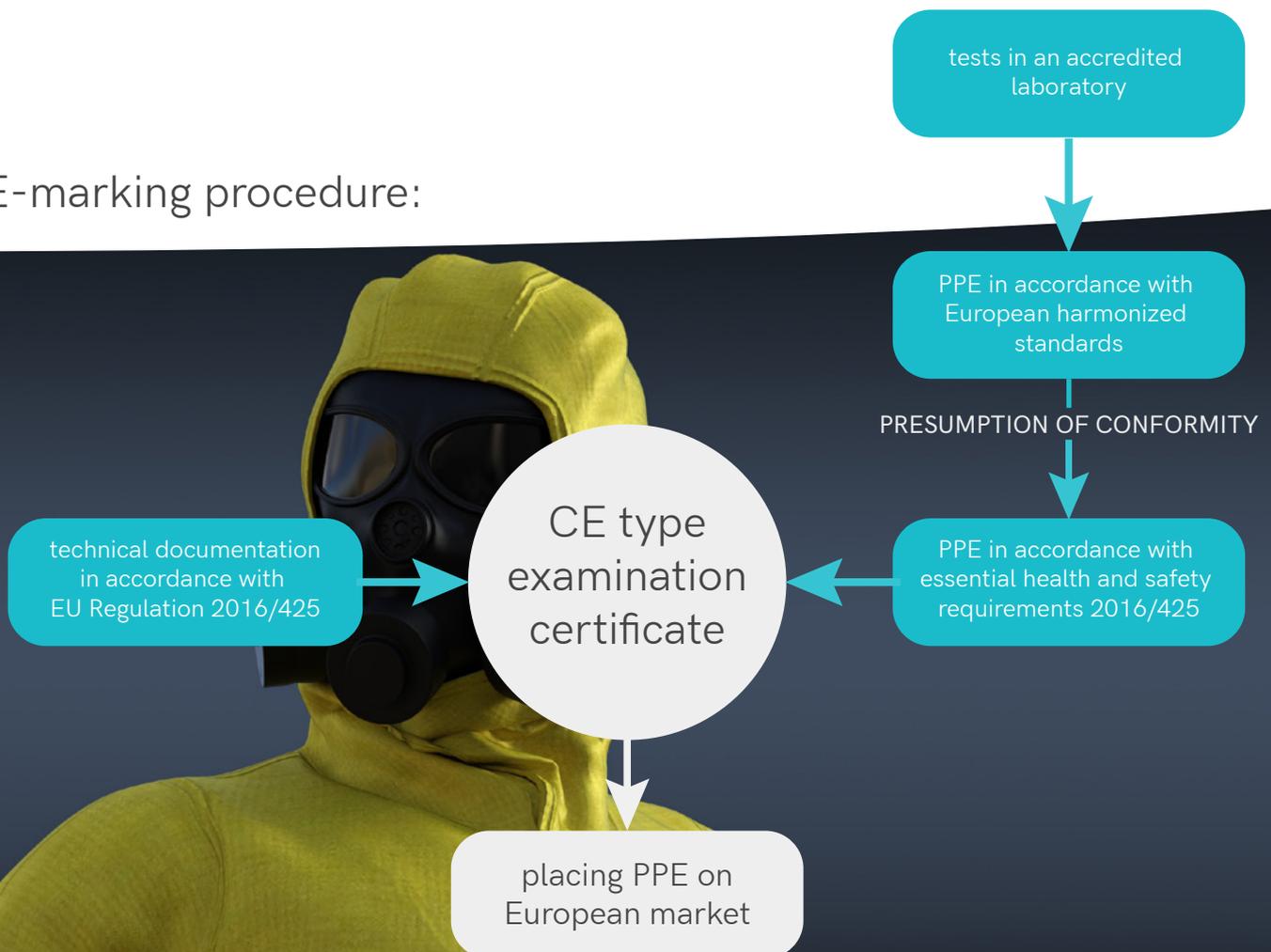
The CE marking affixed to PPE provides evidence of this protection.

As this is a "New Approach" Directive, manufacturers or their authorised representative in the EU can comply with the technical requirements directly or with European Harmonised Standards. The latter provides a presumption of conformity to the essential health and safety requirements.

PPE Regulation (EU) 2016/425

The PPE Regulation is aligned to the New Legislative Framework policy and slightly modifies the scope and the risk categorisation of products. It also clarifies the documentary obligations of economic operators.

CE-marking procedure:



Pictograms

Intended Use



Protection against moving parts



Protection against (high) chemical risk



Protection against static electricity



Protection against heat and flame



Protection against particulate radioactive contamination



Protective clothing used during welding operations



Protective clothing (equipment) for fire fighters



Protection against micro-organisms
EN 374-2



Protection against mechanical risks

Pictograms

Intended Use



Protection against cold



Protection against (low) chemical risk



Protection against chain saws



Protection against cuts and stabs



Protection against microbiological hazards



High visibility protective clothing (equipment)



Protective clothing (equipment) for abrasive blasting operators



Protection against foul weather

Producers and/or

distributors of PPE are

obliged to affix the CE-marking

on the equipment as a visible indication

of conformity with the fundamental requirements. The

EU Regulation 2016/425 appeals to notified bodies for a number of

tasks. This is especially the case for the CE-type examination of PPE belonging to categories

II and III and for the monitoring of PPE of category III. Since 1994, CENTEXBEL is recognized by the Belgian FPS Employment,

Labour and Social Dialogue as a notified body (European notification number 0493) for protective clothing and gloves and for

respiratory protection.

Standards: Protective clothing

EN ISO 13688	Protective clothing - general requirements	EN 13034	Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
EN 342	Protective clothing against cold	EN 13982-1	Protective clothing for use against solid particulates. Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 343	Protective clothing against rain	EN ISO 13998	Protective clothing. Aprons, trousers and vests protecting against cuts and stabs by hand knives
EN 381	Protective clothing for users of hand-held chain saws	EN ISO 14116	Protective clothing. Protection against heat and flame. Limited flame spread materials, material assemblies and clothing
EN 469	Protective clothing for firefighters. Performance requirements for protective clothing for firefighting	EN 14605	Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
EN ISO 20471	High visibility clothing - Test methods and requirements	EN ISO 14877	Protective clothing for abrasive blasting operations using granular abrasives
EN 510	Specification for protective clothing for use where there is a risk of entanglement with moving parts	EN 14126	Protective clothing. Performance requirements and tests methods for protective clothing against infective agents
EN 943-1	Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols - Part 1: Performance requirements for Type 1 (gas-tight) chemical protective suits	EN 13356	Visibility accessories for non-professional use
EN 943-2	Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles - Part 2: Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET)	EN 13758-2	Textiles. Solar UV protective properties. Classification and marking of apparel
EN 1073-1	Protective clothing against radioactive contamination. Requirements and test methods for ventilated protective clothing against particulate radioactive contamination	EN 13911	Protective clothing for firefighters. Requirements and test methods for fire hoods for firefighters
EN 1073-2	Protective clothing against radioactive contamination. Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination	EN 14058	Protective clothing. Garments for protection against cool environments
EN 1149-5	Protective clothing. Electrostatic properties. Material performance and design requirements	EN 14404	Personal protective equipment. Knee protectors for work in the kneeling position
EN 1150	Protective clothing. Visibility clothing for non-professional use. Test methods and requirements	EN 14786	Protective clothing. Determination of resistance to penetration by sprayed liquid chemicals, emulsions and dispersions. Atomizer test
EN 1486	Protective clothing for fire-fighters. Test methods and requirements for reflective clothing for specialized fire-fighting	EN 15614	Protective clothing for firefighters. Laboratory test methods and performance requirements for wildland clothing
EN ISO 11611	Protective clothing for use in welding and allied processes	ISO 15384	Protective clothing for firefighters -- Laboratory test methods and performance requirements for wildland firefighting clothing
EN ISO 11612	Protective clothing. Clothing to protect against heat and flame	IEC 61482-2	Live working - Protective clothing against the thermal hazards of an electric arc - Part 2: Requirements

Standards: Protective gloves

EN 374	Protective gloves against chemicals and micro-organisms	EN 659+A1	Protective gloves for fire-fighters
EN ISO 374-1	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks	EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for microorganisms risks
EN 381-7	Protective clothing for users of hand-held chainsaws - Part 7: Requirements for chainsaw protective gloves	EN 1082	Protective clothing. Gloves and arm guards protecting against cuts and stabs by hand knives
EN 388	Protective gloves against mechanical risks	EN ISO 10819	Mechanical vibration and shock. Hand-arm vibration. Method for the measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand
EN ISO 13997	Protective clothing - Mechanical properties - Determination of resistance to cutting by sharp objects	EN 12477	Protective gloves for welders
EN 407	Protective gloves against thermal risks	EN 14328	Protective clothing. Gloves and arm guards protecting against cuts by powered knives. Requirements and test methods
EN ISO 21420 EN 420	Protective gloves - General requirements and test methods	EN 60903	Live working - Gloves of insulating material
EN 421	Protective gloves against ionizing radiation and radioactive contamination	EN ISO 15383	Protective gloves for firefighters - Laboratory test methods and performance requirements
EN 511	Protective gloves against cold		

Standard: Respiratory protective devices

EN 149	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
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Centexbel

CERTIFICATION & TESTING @ GENT

Technologiepark 70 | BE-9052 Gent | +32 9 220 41 51 | gent@centexbel.be

TESTING @ KORTRIJK | E. Sabbelaan 49 | BE-8500 Kortrijk | +32 56 29 27 00 | kortrijk@centexbel.be

TESTING @ GRÂCE-HOLLOGNE | Rue du Travail 5 | BE-4460 Grâce-Hollogne | +32 4 296 82 00 | g-h@centexbel.be

www.centexbel.be