PERSONAL PROTECTIVE EQUIPMENT

SAVING LIVES BY INDEPENDENT, EXPERT PPE TESTING & CERTIFICATION

CENTEX BEL

MEDICAL DEVICE OR PPE?

SOME PRODUCTS SERVING A DUAL PURPOSE MAY FALL UNDER DIFFERENT REGULATIONS.

Some products may be intended to be used both as personal protective equipment and as a medical device. These products therefore have a dual 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 protect to the user, they can fall within the definition of personal protective equipment. Masks used by surgeons during surgery 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 common example of dual-purpose devices.

If a manufacturer wants to market a product as both a medical device and personal protective equipment, it must meet the essential health and safety requirements of both the PPE and medical device regulations.

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.

If applicable, the CE marking must be accompanied by the identification number of the Notified Body that is responsible for the annual surveillance.

Centexbel is Notified Body #0493

Centexbel offers a wide range of **testing and certification services** to help you effectively market your products. As we are **independent** of all product suppliers, installers and manufacturers, we guarantee a **confidential and impartial service** and provide **reliable and objective information to support compliance with Regulation (EU) 2016/425.**

Centexbel is a **BELAC-accredited Certification Body (056-PROD, EN ISO/IEC 17065:2012)** and T**esting Laboratory (056-TEST, EN ISO/IEC 17025:2017)** as well as **Notified Body #0493 for the PPE Regulation (EU) 2016/425** and other relevant Directives and Regulations.

We guide you to meet and demonstrate compliance of your products with all relevant standards and legislation.

We also provide full conformity assessment services, including:

Module C2: EU type examination based on supervised product checks at random intervals
Module D: EU type examination based on quality assurance of the production process

With Centexbel's expertise and support, you can ensure your products comply with all regulations, maintain high quality and reliability, and access the European market with confidence.

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

PPE MARKING

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 has issued a number of regulations to improve health and safety at work and to ensure high quality PPE. 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.

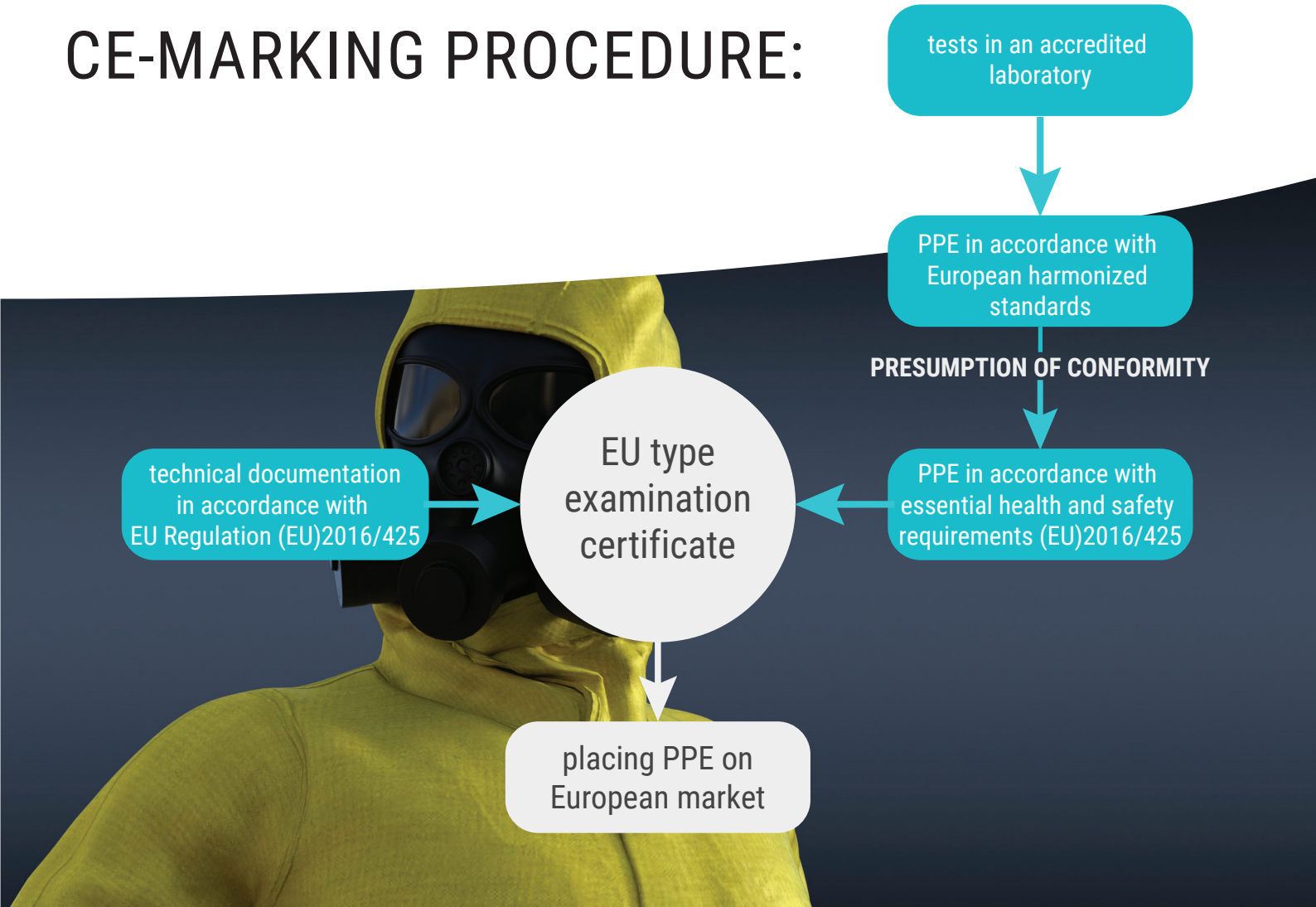
The CE marking affixed to PPE provides evidence of this compliance.

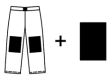
As this is a “New Approach” legislation, manufacturers or their authorised representative in the EU can comply with the technical requirements directly or with European Harmonised Standards. The latter provides a presumption of conformity to the essential health and safety requirements.

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 mechanical risks
	Knee protection
	Protection against chain saws
	Protection against cuts and stabs
	Mechanical Vibration and shock - Hand-Arm vibration
	Protection against cold
	Protection against rain
	Protection against UV-radiation
	High visibility protective clothing (equipment)
	Enhanced visibility equipment

Pictograms	Intended Use
	Protection against heat and flame
	Protective clothing for use in welding and allied processes
	Protective clothing against the thermal hazards of an electric arc
	Protective equipment for fire fighters
	Wildland firefighting clothing
	Protection against static electricity
	Protection against (high) chemical risks
	Protection against microbiological hazards and micro-organisms
	Protective equipment for pesticide operators applying pesticides and for re-entry workers
	Protection against particulate radioactive contamination

Producers and distributors of personal protective equipment (PPE) are required to affix the CE marking to their products as visible proof of compliance with essential health and safety requirements. Under EU Regulation (EU) 2016/425, notified bodies play a key role, especially in conducting EU type examinations for PPE in categories II and III, and in the ongoing surveillance of category III PPE. Since 1994, Centexbel has been recognized by the FPS Economy (Federal Public Services) as a Notified Body (European notification number 0493) for protective clothing, gloves, and respiratory protection.

Standards: Protective clothing

EN ISO 13688	Protective clothing - general requirements
EN 510	Specification for protective clothing for use where there is a risk of entanglement with moving parts
EN 14404 -1,3,4	Personal protective equipment. Knee protectors for work in the kneeling position
EN ISO 11393-1,2,6	Protective clothing for users of hand-held chain saws
EN 342	Protective clothing against cold
EN 343	Protective clothing against rain
EN 14058	Protective clothing - Garments for protection against cool environments
EN 13758-2	Textiles - Solar UV protective properties - Part 2: Classification and marking of apparel
EN ISO 20471	High visibility clothing - Test methods and requirements
EN 17353	Protective clothing - Enhanced visibility equipment for medium risk situations - Test methods and requirements
NF S 74-567	Protective clothing - Visibility hunting clothing and textile articles - requirements and test methods
RIS-3279-TOM	High Visibility Clothing - Railway Group
EN ISO 11611	Protective clothing for use in welding and allied processes
EN ISO 11612	Protective clothing — Clothing to protect against heat and flame — Minimum performance requirements
EN ISO 14116	Protective clothing - Protection against flame - Limited flame spread materials, material assemblies and clothing
EN 61482-2	Live working - Protective clothing against the thermal hazards of an electric arc - Part 2: Requirements
EN 469	Protective clothing for firefighters - Performance requirements for protective clothing for firefighting
EN ISO 15384	Protective clothing for firefighters - Laboratory test methods and performance requirements for wildland firefighting clothing
EN 16689	Protective clothing for firefighters - Performance requirements for protective clothing for technical rescue
ISO 21942	Station uniform for firefighters
EN 1486	Protective clothing for firefighters - Test methods and requirements for reflective clothing for specialised fire-fighting
ISO 15538	Protective clothing for firefighters — Laboratory test methods and performance requirements for protective clothing with a reflective outer surface
EN 13911	Protective clothing for firefighters - Requirements and test methods for fire hoods for firefighters
EN 1149-5	Protective clothing - Electrostatic properties - Part 5: Material performance and design 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 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 14126	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN ISO 13982-1	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 1073-2	Protective clothing against radioactive contamination - Part 2: Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination
EN ISO 27065	Protective clothing - Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers
EN ISO 13998	Protective clothing - Aprons, trousers and vests protecting against cuts and stabs by hand knives
NIJ 0115.00	Stab Resistance of Personal Body Armor
NIJ 0101.07	Ballistic Resistance of Body Armor
TR Ballistics	Body Armor Technical Guideline (TR) Ballistic protective vests
VPAM BSW 2006	Ballistic Protective Vests
HOSDB 2017	HOSDB: Home Office Body Armour Standard CAST Publication
Stanag 2920PPS (edition 2)	Ballistic test method for personal armour materials and combat clothing

Standards: Protective gloves

EN ISO 21420	Protective gloves - General requirements and test methods
EN 16350	Protective gloves - Electrostatic properties
EN 388	Protective gloves against mechanical risks
EN 407	Protective gloves and other hand protective equipments against thermal risks (heat and/or fire)
EN 12477	Protective gloves for welders
EN 659	Protective gloves for fire-fighters
EN 511	Protective gloves against cold
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 421	Protective gloves against ionizing radiation and radioactive contamination
ISO 18889	Protective gloves for pesticide operators and re-entry workers - Performance requirements
EN 60903	Live working - Gloves of insulating material
EN ISO 10819	Mechanical vibration and shock - Hand-arm vibration - Measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand
EN ISO 11393-4	Protective clothing for users of hand-held chainsaws - Part 4: Performance requirements and test methods for protective gloves
EN 1082-1	Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 1: Chain mail gloves and arm guards
EN 1082-2	Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 2: Gloves and arm guards made of material other than chain mail

Standard: Respiratory protective devices

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

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