# Protective gloves | Safety & Compliance

**Protective gloves are used in many situations to save human skin from damage during wet work or against mechanical or thermal injury, infections, or chemicals and drugs, thus reducing the risk to human health significantly.**

**Eurofins can help product developers, manufacturers, brand owners and retailers to design, produce and market the right gloves for each particular need, by defining the appropriate testing protocols based on the regulatory requirements of the destination markets and the performance benchmark as per the intended use.**

## Product and regulatory scenario in Europe

Disposable gloves can be Medical Devices, Personal Protective Equipment (PPE), or both, as per the Medical Devices Directive 93/42/EEC[1] and PPEs Regulation EU 2016/425. When forming part of PPE, gloves fall under Category III PPE and, in addition to undergoing a certification process by an EU Notified Body, they need to meet one of the following requirements: conformity to type based on internal production control (Module C2), or conformity to type based on quality assurance (Module D).

## Service scope

Eurofins can support those responsible for their products' quality, whether that's manufacturers, importers or brand owners, to ensure safety, functionality, performance and compliance, through testing, certification, inspection and regulatory services provided from our worldwide laboratory network. Eurofins' network of laboratories provides high expertise in different fields, making the Eurofins Group uniquely placed to design and perform glove testing tailored to many specific needs.

[1] MD Directive to be replaced by Regulation (EU) 2017/745 as from May 26th 2021.

## Testing services

**Disposable protective gloves under EU 216/425 (PPE)**

Testing service against dangerous chemicals and microorganisms:

- EN ISO 21420 – Protective gloves - General requirements
  Restricted substances: Our chemical tests focus on whether your product contains certain substances, and where it does, that these substances are under restriction limits.

Some of the chemical tests offered include (but are not limited to): REACH Annex XVII and SVHC, allergenic and carcinogenic dyestuff, APEO, azo-dyes, chromium VI, flame retardant, PCP, formaldehyde, nickel release, phthalates, total cadmium and total lead.
Eurofins chemical services cover many different market destinations and regulations.
Volatile organic compounds (VOCs): We offer testing for the permeation of volatile organic compounds (VOC) through PPE gloves. We have developed adaptations of standard test methods for collecting data for difficult-to-monitor substances.

- EN ISO 374-1 Protective gloves against dangerous chemicals. Under EN 374-1, protective gloves are classified as Type A, B or C, depending on their performance level with permeation testing against a list of 18 chemicals. The standard requires that chemical protective gloves are tested for their resistance to degradation.

| Code letter | Chemical | CAS | Class |
|---|---|---|---|
| **A** | Methanol | 67-56-1 | Primary alcohol |
| **B** | Acetone | 67-64-1 | Ketone |
| **C** | Acetonitrile | 75-05-8 | Nitrile compound |
| **D** | Dichloromethane | 75-09-2 | Chlorinated hydrocarbon |
| **E** | Carbon disulphide | 75-15-0 | Sulphur containing organic compound |
| **F** | Toluene | 108-88-3 | Aromatic hydrocarbon |
| **G** | Diethylamine | 109-89-7 | Amine |
| **H** | Tetrahydrofuran | 109-99-9 | Heterocyclic and ether compound |
| **I** | Ethyl acetate | 141-78-6 | Ester |
| **J** | n-Heptane | 142-82-5 | Saturated hydrocarbon |
| **K** | Sodium hydroxide 40% | 1310-73-2 | Inorganic base |
| **L** | Sulphuric acid 96% | 7664-93-9 | Inorganic mineral acid, oxidising |
| **M** | Nitric acid 65% | 7697-37-2 | Inorganic mineral acid, oxidising |
| **N** | Acetic acid 99% | 64-19-7 | Organic acid |
| **O** | Ammonium hydroxide 25% | 1336-21-6 | Organic base |
| **P** | Hydrogen peroxide 30% | 7722-84-1 | Peroxide |
| **S** | Hydrofluoric acid 40% | 7664-39-3 | Inorganic mineral acid |
| **T** | Formaldehyde 37% | 50-00-0 | Aldehyde |

- EN 374-1:2016/A1:2018 (superseding EN 374-1:2003), relates breakthrough time with permeation performance levels as follows:

| Breakthrough Time (min) | Performance Level |
|---|---|
| >10 | Level 1 |
| >30 | Level 2 |
| >60 | Level 3 |
| >120 | Level 4 |
| >240 | Level 5 |
| >480 | Level 6 |

- EN 374-2 - Determination of resistance to penetration.
- EN 16523-1 – Chemical permeation by liquid chemicals under conditions of continuous contact, for both water insoluble and non-volatile, such as epoxy resins, polyurethane (isocyanates) and high-boiling mineral oils.
- ASTM and EN standards, including EN 16523-1 (superseding EN 374-3), ASTM F739 and ISO 6529 – Permeation of chemicals through PPE gloves.
- EN 374-4 - Determination of resistance to degradation by chemicals.
  Depending on the number of chemical liquids to be tested, ISO 374 considers the following classification:
  - Type a: at least level 2 against a minimum of 6 test chemicals listed.
  - Type B: at least level 2 against a minimum of 3 test chemicals listed.
  - Type C: at least level 1 against a minimum of 1 test chemical listed.
- EN ISO 374-5 – Protective gloves against micro-organisms.
- ISO 16604 - Procedure B (optional): Protection against viruses.

## Food contact gloves testing

Framework Regulation (EC) no. 1935/2004 sets the general requirements to ensure that gloves in contact with food do not have a negative influence on the food or cause a threat to human health.

Plasticisers and other substances may migrate from the gloves into the handled food, compromising it.

- Overall migration according to the EN 1186-series, as well as specific migration according to the EN 13130, provided that the gloves contain substances restricted by specific migration limits.

## Functionality and innocuousness

Gloves must be safe and functional according to EN ISO 21420:

- pH levels should be between 3.5 and 9.5 (ISO 4045 leather; ISO 3071 textile).
- Chromium (VI) content should be below detection (< 3 ppm) (EN ISO 17075-1:2018).
- Restricted substances: Some of the chemical tests offered include (but are not limited to): Polycyclic aromatic hydrocarbons (PAHs), azo colourants, dimethylformamide (DMFa), nickel release (applicable to metallic components in prolonged contact with skin).

## Gloves and skin health

Our testing offer includes, among other:

- EN 455-3 - Sensitizing proteins.
- EN ISO 21420, ISO 17075-1 - Chromium VI.
- Testing for potential allergens and hazardous chemicals such as N-nitrosamines, azo dyes, aromatic amines, PCP, etc.
- Non-sterile Medical Device gloves, falling under Class I.

Disposable medical gloves used to prevent the spread of infection or illness must observe the following standards, according to Medical Devices Directive 93/42/EEC[2]:

- EN 455-1 - Medical gloves for single use - Freedom from holes.
- EN 455-2 - Medical gloves for single use - Physical properties.
- EN 455-3 - Medical gloves for single use - Biological evaluation:
  - Residual powder.
  - Extractable protein (if natural rubber or latex glove).
  - Bacterial endotoxins (if sterile glove).
- EN 455-4 - Medical gloves for single use - Shelf life determination.

## Bespoke testing

Chemical permeation standards may not always represent the actual working environment or the dangerous chemicals (often chemical mixtures) to which you are being exposed. To help test the chemical barrier effect and ensure chemical protections against such chemical mixtures, Eurofins offers a flexible approach, with unique method adaptations and a method development team to cater our analytical and testing services specifically to your chemical safety and protection.

[2] MD Directive to be replaced by Regulation (EU) 2017/745 as from May, 26th 2021.

## Notified body service

CE-marking is a mandatory conformity mark, required for PPEs in Europe. It signals that products are safe and compliant with European Regulation (EU) 2016/425.

Eurofins Textile Testing Spain, S.L., is accredited as a Notified Body (2865) under Regulation (EU) 2016/425 for the certification of hand and arm protection equipment (protectives gloves) Category II and III, including services for module C2 and D. Our PPE team has over 15 years of experience in ensuring a seamless CE Marking application procedure for every manufacturer, importer and exporter.

## On-site inspections and audits

Assessing manufacturing sites before initiating mass production and checking product quality prior to shipment are key parts of the quality control process, and vital to ensure that production is carried out according to the quality standards and expectations of destination markets.