Disposable protective gloves are personal protective equipment (PPE), the purpose of which is to protect the user and their skin during a variety of tasks. Gloves must provide adequate protection against potential hazards and material must adapt to the wearer in relation to size.

Product and regulatory scenario in Europe

Disposable protective gloves are personal protective equipment (PPE), which should never be used as a substitute for handwashing or the use of disinfectants. Gloves are generally effective, providing the user with good sensitivity and freedom of movement, but they are less resistance to chemical stress.

In Europe, PPE gloves are subject to Regulation EU 2016/425 (PPE) and must meet the requirements of standards applicable to types of gloves and must bear a CE certification mark.

Manufacturers are liable for these gloves to comply with the safety and effectiveness requirements of relevant regulation. Importers and brand owners bear the same responsibility if a product is manufactured abroad.

Eurofins can support you to ensure your products’ safety, functionality and compliance.

Service scope

Testing services

Protective gloves against dangerous chemicals and micro-organisms
- EN 420 – Protective gloves - General requirements
- EN ISO 374-1 Protective gloves against dangerous chemicals
- EN ISO 374-5 – Protective gloves against micro-organisms
- EN 374-2 Determination of resistance to penetration
- EN 16523-1 Permeation by liquid chemicals under conditions of continuous contact
- EN 374-4 Determination of resistance to degradation by chemicals
- ISO 16604 Procedure B: Protection against viruses

Food contact gloves

Plasticisers and other substances may migrate into food, compromising it.
- EN 1186; we offer migration testing in accordance with EN 1186 for different food simulants. Overall migration can be determined, as well as migration of specific substances.
Innocuousness criteria

- Gloves must offer the greatest possible degree of protection
- If the glove has seams, they should not reduce the performance of the glove
- pH levels should be between 3.5 and 9.5 (ISO 4045 leather; ISO 3071 textile)
- Chromium (VI) Content should be below detection (<3ppm) (ENISO 17075:2007)
- Natural rubber gloves should be tested for extractable proteins, to mitigate allergic reactions of wearers (EN 455-3)
- If cleaning instructions are provided, the level of performance of the product must not reduce, even after the maximum number of washes outlined in cleaning instructions

<table>
<thead>
<tr>
<th>Europe</th>
<th>Disposable Protective Gloves</th>
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<tbody>
<tr>
<td>Legislation</td>
<td>Regulation (EU) 2016/425</td>
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</table>
| Standards | • EN 420 (General requirements)  
 | | • EN ISO 374-5 (Gloves against microorganisms)  
 | | • EN ISO 374-1 (Only if the glove is, in addition, intended for chemical protection)  
 | | • EN ISO 374-2 (Absence of holes)  
 | | • EN 16523 (Resistance to permeation in the event that the glove is, in addition, intended for chemical protection)  
 | | • ISO 16604 (Resistance to virus penetration, optional)  |
| Fields of use | 3 (liquid drops, admits direct ventilation) depending on tightness required |
| Category | Category III if biological agents are harmful |
| Marking | The CE marking will be followed by the number of the Notified Body that participates in the relevant compliance procedures |
| Evaluation process | • Technical documentation and product conformity assessment procedure.  
 | | • EU declaration of conformity |
| EU type examination certificate by a notified body | Module B set out in Annex V.  
 | | • Annual PPE surveillance by a Notified Body (Module C2 or D)  
 | | • Affix the number of the Notified Body to CE marking |

Relevant Notified bodies

CE-marking is a mandatory conformity mark which is 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 a Notified Body n. 2865 for Personal Protective Equipment (PPE), with focus on protective clothing and footwear, providing both, testing and certification services to ensure the compliance of your gloves –among other PPE products- against the concerned European regulation EU 2016(425).

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.

Quality Assurance and Control throughout the Supply Chain

Whichever your role in the supply chain, you need to safeguard the reputation of your brand and/or that of your client.

From supplier assessment and R&D support to regulatory guidance and supply chain mapping, all the way through to compliance, bespoke testing and QC inspections and down to failure analysis and market surveillance, we cover every stage of your product’s quality journey.

www.eurofins.com/covid-19-product-testing