

A close-up, slightly blurred photograph of a medical professional's hands. The person is wearing a white surgical mask, a blue surgical cap, and a blue surgical gown. They are wearing a pair of white, latex-like disposable gloves, with one hand partially visible in the foreground and the other hand being pulled over it by another person's hand.

Testing Services for Disposable gloves

The disposable gloves can be Medical Devices, PPE or both as per European Directive of medical devices and PPEs Regulation.

As a PPE, the gloves are Category III PPE and in addition to certification process by an EU Notified Body, they need to meet one of the following requirement: conformity to type based on internal production control (Module C2) or conformity to type based on quality assurance (Module).

As a Medical Device, if the gloves are nonsterile, they are Class I.

Testing Services for European Market

Intended to be used in medical procedures and circumstances, disposable medical gloves are important equipment to protect users from cross-contamination. There are a number of different standards specifying the requirements for this type of gloves. For European market, disposable gloves which are used to protect the user from chemical or biological risks, must observe the follow standards, according to the *Regulation (EU) 2016/425*:

EN ISO 374-1:2016/A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks

- EN ISO 374-2 Penetration: water leak and air leak
- EN 16523-1 Chemical permeation
- EN ISO 374-4 Chemical degradation

Depending on the number of chemical liquids tested, the classification shall be:

 ISO 374-1/Type A UVWXYZ	Type A: at least level 2 against a minimum of six test chemicals listed in the table
 ISO 374-1/Type B XYZ	Type B: at least level 2 against a minimum of three test chemicals listed in the table
 ISO 374-1/Type C	Type C: at least level 1 against a minimum of one test chemical listed in the table

Table: List of test chemicals for disposable gloves

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 ISO 374-5:2016 - Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

- EN ISO 374-2: Penetration: water leak and air leak
- ISO 16604, Procedure B: Protection against viruses (optional test)



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

- EN 455-1 - Medical gloves for single use. Requirements and testing for freedom from holes
- EN 455-2 - Medical gloves for single use. Requirements and testing for physical properties
- EN 455-3 - Medical gloves for single use. Requirements and testing for 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. Requirements and testing for shelf life determination

Testing Services for U.S. Market

For the U.S. market, however, disposable medical gloves should be tested according to ASTM standards, depending on the type of gloves and its use:

- ASTM D6319 - Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3578 - Specification for Rubber Examination Gloves
- ASTM D5250 - Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D3577 - Specification for Rubber Surgical Gloves

For all of these standards, testing consists of the following:

- Sterility (if applicable)
- Free of holes
- Dimensions
- Physical properties (before aging, after accelerated aging)
- Powder-free residue
- Powder amount (if the glove is powdered)

Additionally, rubber gloves should undergo the below testing:

- Protein content
- Antigenic protein content

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Our PPE team has over 15 years of experience in PPE testing and certification. Their rich knowledge in PPE compliance ensures seamless CE Marking application procedures for every manufacturer, importer, exporter and seller. Our team can provide guidance and advice on technical file compilation among other issues that customers may face.

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