

UNDERSTANDING THE DIFFERENCE BETWEEN MEDICAL EXAMINATION AND INDUSTRIAL GRADE DISPOSABLE GLOVES

With the spread of COVID-19 raising disposable glove use globally, understanding the differences between gloves is critical to ensuring proper protection.

In the United States, disposable gloves are categorized as industrial grade or medical grade, the latter often referred to as “examination.” Industrial grade single use gloves provide protection against industrial hazards, like oils and chemicals, but are not approved for patient contact.

On the other hand, disposable *examination* gloves require a 510(k) premarket authorization, covering required safety testing, product performance testing and claims substantiation data. The additional testing is done to ensure protection between people when blood, bodily fluids and biological hazards like bacteria or viruses may be present.

In some cases, additional testing under ASTM F1671 is done on gloves to ensure protection against bloodborne pathogens, like a virus or bacteria. This certification should be available from the manufacturer.



The European Union takes a different approach, segmenting certifications based on who is being protected. To ensure proper protection when dealing with potential COVID-19 infections, look for these categories.

- **Patient protection: Compliance to Medical Device Directive 93/42/EEC**
 - Look for the MDD symbol on packaging
- **User protection: Compliance to 2016/425 for PPE**
 - Look for the CE mark with four digits behind it for Category III certification
 - Look for the EN ISO 374-5 VIRUS symbol for certified protection against viruses
- **Dual marked products (both MDD and PPE certified) provide protection to both the patient and the user**

Users should refer to the Declaration of Conformity required on all PPE in the European Union to ensure compliance and proper protection against specific needs and environments.



510K Documentation Requirements for Medical Gloves

- Biocompatibility assessment per ISO 10993
- Conformity to industry standards testing
- Substantiation data for any claims
- Legal attestations by manufacturer to truth and accuracy

Outside Certifications

The CE marking indicates conformity with health and safety standards for products sold in the European Union. It is similar in scope to the 510 K certification in the U.S.

Look for the CE mark on the bottom of the box. The numbers next to the mark identify the Notified Body that is used in the certification process for the PPE Category III product.



EN ISO 374 VIRUS Certification

The EN ISO 374-5 VIRUS standard measures the ability of gloves to protect users against bacteria, fungi and viruses. Gloves featuring the EN ISO 374-5 VIRUS marking on packaging have been tested using Bacteriophage X-174, per ISO 16604 testing methods.

EN ISO 374-5:2016

