CARE WHAT YOU WEAR

The Risks of Non-Medical-Grade Gloves

Healthcare professionals should be able to depend on their exam gloves for vital protection against bacteria, viruses and other harmful microorganisms.

In an increasingly commoditised and price-driven exam glove marketplace where suppliers are constantly trying to reduce costs, there is a high risk that some gloves are not providing the proper level of protection. Exam gloves are class I non-sterile medical devices that suppliers can CE mark themselves, which eliminates the need for review by a notified body. Adding to this problem, many hospitals are not evaluating all of the proper criteria to ensure trusted quality before making their purchasing decisions. Hospitals need to take matters into their own hands and ask the right questions in order to get reliable and trusted information from suppliers.

WHAT ARE THE RISKS?

Medical grade gloves are separated from industrial or food service gloves by the requirement that they must meet the **EN standards** listed below, which are designed to ensure a higher level of protection.

- EN 455 Part 1
- EN 455 Part 2
- EN 455 Part 3
- EN 455 Part 4

EN 455 Part 1

This part of the standard concerns requirements and testing for freedom from holes. This standard specifies requirements and gives the test method for single-use medical gloves in order to determine freedom from holes. The compliance level for freedom from holes shall be an AQL of 1.5 or lower.

Simply put, the lower the AQL value, the higher the level of barrier protection guaranteed by this glove. AQL is a statistical sample analysis of a large batch of products. For example, testing 200 gloves out of a batch of 5 million is the most common practice among exam glove suppliers. While this is statistically significant, the real task is making sure that this level of AQL is maintained in **every lot** shipped, not just in one report or one lot. With Medline exam gloves, you have the guarantee that Medline-employed inspectors are inspecting **every lot** of product before it ships to the customer, and in many cases we are shipping products with an AQL even lower than 1.5 or 1.0.

Medical grade gloves have a maximum value of 1.5, where industrial and food service gloves can go as high as AQL 4.0. **This means accepting gloves that are two times more defective per batch, which significantly increases the risk of harmful transmissions for healthcare professionals.** Medline offers a select range of AQL 1.0 gloves to offer protection beyond what is required.

EN 455 Part 2

Part 2 deals with requirements and testing for physical properties. This standard specifies requirements and gives test methods for physical properties of single-use medical gloves in order to ensure that they provide and maintain an adequate level of protection from cross-contamination for both patient and user while in use.

Simply put, exam gloves have to meet certain length and force-at-break (FAB) requirements. Gloves should measure a minimum of 240 mm in length, and nitrile/latex gloves should achieve 6N FAB, whereas vinyl should achieve 3.6N. **Gloves that do not meet these standards increase risk to healthcare professionals by increasing skin exposure and having a higher probability of ripping and tearing during use.** EN standards do not require any testing on weight, elongation or thickness of exam gloves.

EN 455 Part 3

This part covers requirements and testing for biological evaluation. This standard specifies requirements for the evaluation of biological safety for single-use medical gloves. It gives requirements for labelling and disclosure of information relevant to the test methods used.

Simply put, exam gloves should cause minimal adverse skin reactions. This is monitored by controlling and tracking the content of latex proteins and the powder content in the gloves on a regular basis. **Gloves not certified to this standard have the risk of causing allergic reactions among users.**

EN 455 Part 4

Part 4 addresses requirements and testing for shelf life determination. This standard specifies requirements for shelf life for single-use medical gloves. It also specifies the requirements for labelling and the disclosure of information relevant to the test methods used.

Simply put, exam gloves need to maintain quality minimums set forth in EN 455-1,2,3 for the entire shelf life of the product. This test ages the gloves artificially and then conducts EN 455-1,2,3 testing to ensure quality standards are met. **Gloves not certified to this standard have the risk of providing subpar protection after being stored.**

WHAT CAN YOU DO?

There are several steps you can take with your exam glove supplier to ensure you get the proper quality medical grade exam gloves you need for your hospital. Medline offers 100% of the safety measures mentioned below, and we are here to help you demand the quality you deserve.

1. REQUEST THE RIGHT DOCUMENTATION.

a. Test reports referencing the correct brand name
b. Test reports from a third-party laboratory
c. Test reports issued less than 3 years ago

2. TEST THE GLOVES TO EN 455 YOURSELF IN-HOUSE OR AT A THIRD-PARTY LAB.

a. Surgical Materials Testing Laboratory (SMTL)

SURGICAL MATERIALS TESTING LABORATORY SMTL Phone: +44 1656 752820

b. Akron Rubber Development Laboratory (ARDL)

ARDL AKRON RUBBER DEVELOPMENT LABORATORY, INC. Phone: +1 330 794 6600

3. REQUIRE QUALITY TRENDING DATA TO MAKE SURE THE GLOVES YOU GET ON DAY 1 HAVE THE SAME QUALITY AS THE GLOVES YOU GET ON DAY 500 AND BEYOND.

a. Medline provides our 'Sure Hands Supervision' service to ensure consistency in quality. At the beginning of the business relationship, we will establish intervals that you would like to receive your quality trending data. Contact your local sales representative for more information.

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