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Protection Against Viral Penetration – Sempermed Follows a Stricter Standard

The new norm EN ISO 374-5:2016 defines requirements and test methods for protective gloves with the aim of protecting glove users against harmful microorganisms. This new norm relates to the standard test method ISO 16604:2004, and is very similar to the older ASTM F1671:2004. Both evaluate whether viruses, fungi and bacteria are able to penetrate protective gloves. At Sempermed, we will continue to follow the stricter ASTM F1671:2007. Read on to find out why we decided to do so and still meet the requirements of EN ISO 374-5:2016.

Recognised test methods

There are two globally recognised standard test methods which can be employed to test the resistance of materials used in protective clothing to penetration by blood-borne pathogens: ISO 16604:2004 and ASTM F1671:2007. These methods, which employ Phi-X174-Bakteriophage penetration, are suitable for determining whether protective gloves can resist viral penetration.

With EN 374-1 becoming applicable on an international level, a new norm, EN ISO 374-5:2016, was introduced simultaneously. This norm describes the performance requirements gloves must meet in protecting against bacteria, fungi and viruses.

Since viruses are very small microorganisms, it is necessary to specifically test if gloves protect against viruses. EN ISO 374-5:2016 requires that testing follows the previously mentioned test method based on ISO 16604:2004.

Sempermed's stricter standard

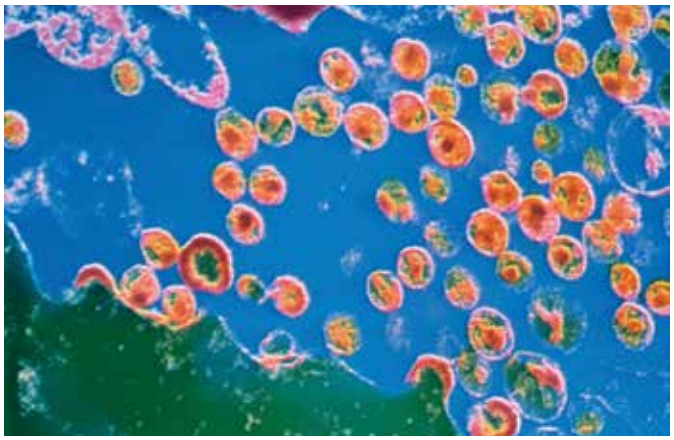
For years, we have been testing and certifying our gloves using the United States' ASTM standard for microorganisms. Approved by the Federal Drug Administration for the testing of medical gloves, this tried and tested standard has been used for decades.

We have achieved that this stricter standard is now accepted by our notified bodies for the EC type examination following the new PSA directive (EU) 2016/425.

This means that Sempermed can continue to conduct viral penetration tests based on the stricter ASTM F1671/F1671M-13.

Comparing the test procedures

The steps involved in the test procedures based on both ASTM F1671:2007 and ISO 16604:2004 are very similar.
First, a material sample is taken and placed securely in a test cell. A solution containing the virus is then applied to the glove's exterior surface. The virus chosen for these tests is the Phi-X174-Bakteriophage, which is approximately 30 nanometers in size. By comparison, at a size of around 120 nanometers, the dangerous HIV type 1 is four times larger than the small Phi-X174-Bakteriophage. After the sample has been conditioned, atmospheric pressure is applied to the exterior surface. The test procedure concludes at this point if ISO 16604 is followed. Meanwhile, ASTM F1671 requires an additional test cycle, which exposes the tested protective gloves to additional pressure.



HIV type 1: 120 nanometres in size

While still in the test cell, the inside of the glove material sample is then examined to see whether viral penetration has occurred.

A control sample, which has been exposed to a sterile solution, ensures that inaccurate results are excluded.

The bottom line

Upon comparing the test procedures side by side, we can see that the two recognised test standards do not differ significantly. However, as has been shown, ASTM F1671 provides for a stricter test procedure.

Our products always need to meet high standards. Therefore, as a manufacturer of quality gloves, we will continue to test our gloves based on the stricter ASTM F1671. Always with quality in mind.

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Publisher and Editor: Semperit Technische Produkte Gesellschaft m. b. H., Division Sempermed, Modecenterstrasse 22, A-1030 Vienna,
Tel. +43 1 79 777-0, Fax: +43 1 79 777-630, E-Mail: sempermed@semperitgroup.com, www.sempermed.com
FN 36912h, Commercial Court Vienna

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