EESTI STANDARD EVS-EN ISO 22612:2005

Nakkusohtlike osakeste kaitseriietus. Kuivbakterite läbilaskekindluse katsemeetod

Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 22612:2005 sisaldab Euroopa standardi EN ISO 22612:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 30.05.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 22612:2005 consists of the English text of the European standard EN ISO 22612:2005. This document is endorsed on 30.05.2005 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.	**Scope:** This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.

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Võtmesõnad:

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English version

Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration (ISO 22612:2005)

Vêtements de protection contre les agents infectieux - Méthode d'essai de la résistance à la pénétration microbienne par voie sèche (ISO 22612:2005)

Schutzkleidung gegen infektiöse Agenzien - Prüfverfahren zur Beständigkeit gegen mikrobielle Penetration im trockenen Zustand (ISO 22612:2005)

This European Standard was approved by CEN on 16 August 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN ISO 22612:2005) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 94 “Personal safety - Protective clothing and equipment”.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are integral parts of this document. For international equivalents of cross-references to European Standards see Annex ZC.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

There are numerous examples of situations where bacteria may migrate through a barrier material in the dry state carried by organic or inorganic particles. The dry penetration of bacteria-carrying skin scales through an operating gown or a clean air suit is one example. Penetration through a packaging material during storage is another.

This document EN ISO 22612 describes a test method, with the associated equipment, that may be used to determine a material's resistance to dry penetration of bacteria on particles in the size range most typical for human skin scales

1 Scope

This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.

NOTE Due to its complexity, this EN ISO 22612 cannot be considered as a useful method for routine quality control but may suit the needs when a material is assessed for compliance with the requirements of current regulations such as EU Directive 93/42/EEC.

2 Normative references

The following referenced document is indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13795-1:2002, *Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – Part 1: General requirements for manufacturers, processors and products.*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13795-1:2002 apply.

4 Principle

The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with *Bacillus subtilis* is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece.

The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate. The sedimentation plates are removed and incubated.

The numbers of colonies produced are counted.

This document specifies two levels of challenge by means of giving two concentrations of bacterial cells on the talc particles and two times during which the barrier is subjected to vibration. The conditions for testing differ among product types and will be specified in other standards where this test method is applied such as in prEN 13795-3.

5 Testing conditions

Condition the samples and test at (20 ± 2) ºC and (65 ± 5) % relative humidity.

6 Equipment

6.1 General lay-out

NOTE See Figure 1.