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Sjukvårdstextilier – Uppdukningsmaterial, operationsrockar och specialarbetsdräkter, avsedda som medicintekniska produkter för patienter, personal och utrustning – Provningsmetod för motstånd mot våt bakteriepenetration (ISO 22610:2006, IDT)

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration
(ISO 22610:2006, IDT)

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English Version

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux, pour les patients, le personnel et les équipements - Méthode d'essai de résistance à la pénétration de la barrière bactérienne à l'état humide (ISO 22610:2006)

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung, zur Verwendung als Medizinprodukte, für Patienten, Klinikpersonal und Geräte - Prüfverfahren für die Widerstandsfähigkeit gegen Keimdurchtritt im feuchten Zustand (ISO 22610:2006)

This European Standard was approved by CEN on 24 May 2006.

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Foreword

This document (EN ISO 22610:2006) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN, 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of an identical text or by endorsement, at the latest by January 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

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 Annex ZA, which is an integral part of this document.

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Introduction

There are numerous examples of situations where bacteria carried by a liquid may migrate through a barrier material in the wet state. The wet penetration of skin flora through a covering material is one example.

European Medical Device regulations specifically place the responsibility for avoiding device-related infections on the manufacturer. In order to demonstrate compliance with this requirement and to describe a product to the user, there is a need to use harmonized and recognized international test methods.

The test method described in this international standard uses microbiological techniques and is therefore intended to be performed exclusively by laboratories experienced in and equipped for such work.

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration

WARNING — The use of this standard may involve hazardous materials, operations and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This International Standard specifies a test method, with associated test apparatus (see Annex A), which is used to determine the resistance of a material to the penetration of bacteria, carried by a liquid, when subjected to mechanical rubbing.

2 Normative references

The following referenced documents are 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.

ISO 139, *Textiles — Standard atmospheres for conditioning and testing*

ISO 6330, *Textiles — Domestic washing and drying procedures for textile testing*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13683, *Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities*

ISO 13934-1, *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method*

ISO 13937-2, *Textiles — Tear properties of fabrics — Part 2: Determination of tear force of trouser-shaped test specimens (Single tear method)*

ISO 15797, *Textiles — Industrial washing and finishing procedures for testing of workwear*

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
agar plate
Petri dish containing sterile nutrient agar medium

NOTE See Annex B for composition of nutrient media.

3.2
carrier material
material used to prepare the donor

3.3
covering material
material, e.g. surgical drapes, used for covering the patient, equipment and certain surfaces to prevent the patient's skin bacteria and/or bacteria from other non-sterile sources from reaching the operation wound

3.4
donor
material that has been contaminated with a known number of viable cells of a defined strain of test bacterium

3.5
finger
part of the apparatus for testing resistance to wet bacterial penetration, used to bring donor and test specimen into contact with the surface of an agar plate

3.6
replicate test
one complete evaluation of a single test piece, from the test specimen, comprising five plate counts directly against the donor and a sixth plate to estimate the residual bacterial challenge on the reverse of the test piece

3.7
test material
piece of covering material, 25 cm × 25 cm, for which the resistance to wet bacterial penetration is being determined

3.8
reference material
standardized material to assess the precision of the laboratory when performing the test for resistance to wet bacterial penetration

3.9
resistance to wet bacterial penetration
the resistance of a barrier to the penetration of bacteria, carried by a liquid, when subjected to mechanical rubbing

4 Principle

A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface.

After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time.

Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique.

The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

The results may be processed in accumulated form in order to characterize the barrier capability and penetration over time of the material (see Annex C).