SLOVENSKI STANDARD
oSIST prEN ISO 22610:2015

01-december-2015

Operacijska pokrivala, pregrinjala in plašči ter čista oblačila, ki se uporabljajo kot medicinski pripomočki za paciente, zdravstveno osebje in opremo - Preskusne metode za določanje odpornosti proti prodiranju vlažnih bakterij (ISO/DIS 22610:2015)

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/DIS 22610:2015)

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/DIS 22610:2015)

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/DIS 22610:2015)

Ta slovenski standard je istoveten z: **prEN ISO 22610**

ICS:

11.140	Oprema bolnišnic	Hospital equipment
13.340.10	Varovalna obleka	Protective clothing

oSIST prEN ISO 22610:2015 **en,fr,de**

DRAFT INTERNATIONAL STANDARD
ISO/DIS 22610

ISO/TC **94**/SC **13**	Secretariat: **SNV**
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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

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ICS: 13.340.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22610 was prepared by Technical Committee ISO/TC 94, *Personal safety - Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing* and by Technical Committee CEN/TC 205, *Non-active medical devices* in collaboration.

This second edition cancels and replaces the first edition (ISO 22610:2006), which has been significantly revised in order to improve the precision of the test method.

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.

ISO 22610:2006 has been significantly revised in order to improve the precision of the test method.

The primary difference between ISO 22610:2016 and ISO 22610:2006 is that the 2016 version specifies a different bacteria strain and tighter tolerances on material handling and procedure, resulting in more reproducible and accurate measurements.

In order to obtain accurate repeatable and reproducible results, not only does the equipment need to meet the requirements specified in this standard, but also the material handling and test procedure need to be followed precisely and consistently. Minor deviations from the equipment requirements, procedure and/or specimen handling can result in considerable loss of repeatability, reproducibility and accuracy of the measurement.

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.

IMPORTANT — The equipment shall meet the requirements specified in this document and the measurements shall be carried out under the specified conditions with special attention being paid to specimen (pre-)treatment, strictly following the procedure prescribed in this document. Minor deviations from the equipment requirements, procedure and/or specimen handling can result in considerable loss of repeatability, reproducibility and accuracy of the measurement.

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11607, *Packaging for terminally sterilized medical devices*

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

ISO 17665-1, *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

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

3.1
agar plate
petri dish containing sterile agar medium

NOTE See Annex B for composition of nutrient media

3.2
carrier material
material (paper sheet) used to support the donor (polyurethane film) during production and preparation

3.3
donor
material that has been contaminated with a known number of viable cells or spores of a defined strain of test bacterium

3.4
cover film
material used to cover the donor and the test specimen during the test

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 of five plate counts directly in contact with the donor and a sixth plate to estimate the residual bacterial challenge on the reverse of the test piece

3.7
test specimen
piece of 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 material to the penetration of bacteria carried by a donor, when subjected to mechanical rubbing and wetting

4 Principle

A sheet of donor material, of the same size as the test specimen and carrying the bacteria, is placed on the test specimen with the contaminated side facing down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two conical metal rings, close-fitting into each other, hold the three sheets together. The assemblage of materials is placed on an agar plate with the steel rings hanging freely outside the brim, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen into contact with the agar surface. The finger is moved over the entire surface of the plate in less than 15 minutes by means of a pivoted lever moved by an eccentric 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 up from the agar surface, bacteria may pass from the donor material through the test specimen down to the agar surface.

The test is carried out for 15 minutes. After 15 minutes the agar plate is replaced by a fresh one, and the test is repeated with the same assemblage, i.e. the same donor and test specimen. Five consecutive tests are performed with the same assemblage enabling an estimation of the penetration over time.

An estimation of the bacterial contamination on the upper side of the test specimen and the bacterial load remaining on the donor material may be determined by using the same technique.

The agar plates are incubated in order to grow the bacterial colonies, which are then counted.

The results are expressed as a percentage (%) of penetration compared to the bacterial load initially inoculated on the donor.

If the test material contains antimicrobial substances, the result of the wet penetration method expressed in percentage will measure the combined chemical and mechanical effects.

5 Equipment, reagents and materials

Normal laboratory equipment and the following equipment, reagents and materials:

5.1 Biosafety cabinet class II.

5.2 Incubators, capable of maintaining the temperature at (56 ± 2) °C and (37 ± 2) °C.

5.3 Refrigerator, capable of maintaining the temperature at (5 ± 2) °C.

5.4 Water bath, capable of maintaining the temperature at (45 ± 2) °C.

5.5 Bacterial strain suspension, purified spores of Bacillus atrophaeus ATCC 9372 suspended in ethanol 90% at a concentration of about 109 spores/ml1).

5.6 Peptone water, 10 g Peptone, 5 g NaCl and 1 g Polysorbate 80 in 1000 ml Ultrapure water, steam sterilized for 15 minutes at (121 ± 2) °C.

5.7 TGEA agar, 3 g beef extract, 5 g Tryptone, 1 g dextrose, 15 g agar in 1000 ml Ultrapure water, steam sterilized for 15 minutes at (121 ± 2) °C.

5.8 Petri dishes, sterile, 14 cm and 9 cm in diameter, with lid.

5.9 Donor material, five pieces 25 cm x 25 cm polyurethane (PU) film on siliconized carrier paper, film thickness 25 µm - 30 µm, each piece packed in a sterilization bag and steam sterilized at (121 ± 2) °C for 15 minutes[2)].

NOTE Guidance for selecting a suitable donor material: wettable, solvent-cast polyurethane (PU) film of 25 µm - 30 µm thickness, elongation in the machine direction 350 % ± 50 %, and cross direction 400 % ± 75 %, carried on paper

5.10 Cover film, five pieces of 25 cm × 25 cm, or 25 cm in diameter High density Polyethylene (HDPE) film, approximate thickness 10 µm, having a density of approximately 950 kg/m3 and a mass flow rate (190 °C, 5 kg) of 0,027 g/min[3)].

5.11 Reference material, 100% Polyester fabric, type 400–washed[4)].

5.12 Pipettes, 1 ml, 10 ml.

5.13 Micropipettes, 1000 µl and 100 µl, with suitable sterile tips.

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1) The spore suspension in alcoholic suspension can be bought at SIMICON Gmbh – München. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

2) Suitable donor material is available from Gerlinger (reference: 4220 M or 4220) and Schütt Labortechnik. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

3) Available from Schütt Labortechnik, Rudolf-Wissel-Straße 11, D-37079 Göttingen, Germany. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

4) Available from Rotecno AG, Via Vite 3, CH-6855 Stabio, Switzerland. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.