**Draft for Comments Only** **Doc: TXD 36 (14511)**

**BUREAU OF INDIAN STANDARDS**

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*Draft Indian Standard*

# 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 [First revision of IS 16549]

Technical Textiles for Medtech Application Sectional Committee, TXD 36

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 22610 : 2018 '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' issued by the International Organization for Standardization (ISO).

This standard was originally published in 2016. The first revision of this standard has been undertaken to harmonize it with the latest version of ISO 22610 : 2018.

The text of ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appears referring to this standard, they should be read as `Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place, are listed below along with their degree of equivalence for the editions indicated:

| *International Standard* | *Corresponding Indian Standard* | *Degree of Equivalence* |
|---|---|---|
| ISO 11607-1[1)] Packaging for | IS/ISO 11607 -1 : 2006 Packaging for | Identical with |

| | | |
|---|---|---|
| terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems | terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems | ISO 11607-1 : 2006 |
| ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories | IS/ISO/IEC 17025 : 2017 General requirements for the competence of testing and calibration laboratories (*second revision*) | Identical with ISO/IEC 17025 : 2017 |

The technical committee has reviewed the provision of the following International Standard referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard:

| *International Standard* | *Title* |
|---|---|
| ISO 17665 -1 : 2006 | Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices |

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounding off in accordance with IS 2 : 1960 'Rules for rounding off numerical values *(revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1) Since revised in 2019.

**Extract of ISO 22610 : 2018, 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 document may involve hazardous materials, operations and equipment. This document does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this document to establish appropriate safety and health practices prior to the application of this document and to comply with the legal requirements for this purpose.
IMPORTANT — This test method has been technically and editorially significantly revised. 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 document specifies a test method, with associated test apparatus, 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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 11607-1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

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.
ISO and IEC maintain terminological databases for use in standardization at the following addresses:
— ISO Online browsing platform: available at https://www.iso.org/obp
— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**carrier material**
material (paper sheet) used to support the donor (polyurethane film) during production and preparation

**3.2**
**donor**

material made of polyurethane film that has been inoculated with a known number of viable spores of a defined strain of test bacterium

**3.3**
**cover film**
HDPE material used to cover the donor and the test specimen during the test

**3.4**
**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

**3.5**
**replicate test**
one complete evaluation of a single test specimen, cut from the sample (e.g. gowns, drapes), comprising of five plate counts directly in contact with the donor

**3.6**
**test specimen**
piece of material, for which the resistance to wet bacterial penetration is being determined

**3.7**
**reference material**
standardized material to assess the precision of the laboratory when performing the test for resistance to wet bacterial penetration

**3.8**
**resistance to wet bacterial penetration**
resistance of a barrier material to the penetration of bacteria carried by a donor, when subjected to mechanical rubbing and wetting

**3.9**
**bacterial challenge**
number of spores per ml of the suspension of Bacillus atrophaeus as used for inoculation of donor material

**3.10**
**bacterial inoculum**
suspension of Bacillus atrophaeus with a verified concentration
Note 1 to entry: The concentration is between 5,0 × 103 and 1,5 × 104 spores/ml.

## 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 HDPE cover 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 min 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 given 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 min. After 15 min 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 material tested contains an antimicrobial substance it should be inactivated before testing. If it is not possible to inactivate the antimicrobial substance or if there is an assumption that the material contains an antimicrobial substance, additionally the remaining antibacterial activity should be determined. Information about any antimicrobial treatment, the results of the penetration test and the additional test should be included in the report.

## FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clause/sub clause/table/fig etc. be started on a fresh box. Information in column 3 should include reasons for the comments and suggestions for modified working of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

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NAME OF THE COMMENTATOR/ORGANIZATION:

**DOCUMENT NO:** TXD 36 (14511)
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| **Item, Clause Sub-Clause No. Commented upon (Use Separate Box afresh)** | **Comments** | **Specific Proposal (Draft clause to be add/amended)** | **Remarks** | **Technical References and justification on which (2), (3), (4) are based** |
|---|---|---|---|---|
| **(1)** | **(2)** | **(3)** | **(4)** | **(5)** |
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