INTERNATIONAL STANDARD

ISO 22610

First edition
2006-07-01

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

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

Reference number
ISO 22610:2006(E)

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Published in Switzerland

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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 the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.

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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.