Second edition
2018-09

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

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 94, *Personal safety — Protective clothing and equipment*, SC 13, *Protective clothing*.

This second edition cancels and replaces the first edition (ISO 22610:2006), which has been technically and editorially revised.

Although the same principle applies as for ISO 22610:2006, this revised test method should be considered technically as a new test method.

The main differences between this document and ISO 22610:2006 are:

— Different strain of bacterial species;

— More detailed description of equipment, reagents and materials;

— Tighter tolerances on equipment requirements;

— Tighter tolerances on specimen (pre)treatment, preparation of the agar plates, bacterial inoculum and donor;

— Strict protocol for the test procedure.

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 (see Annex E).

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 this document and ISO 22610:2006 is that this document specifies a strain of a different bacterial species 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 document, 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.