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Interested committees:

Title: Draft BS ISO 22610 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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Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 22610

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

ICS: 13.340.10; 11.140

ISO/TC 94/SC 13

Secretariat: **SNV**

Voting begins on:
2025-07-01

Voting terminates on:
2025-09-23

This document is circulated as received from the committee secretariat.

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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.

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).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 22610:2018), which has been technically revised.

The main changes are as follows:

- different strain of bacterial species;
- minor adjustments to the test procedure;
- different expression of the results.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 D](#)).

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.

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.

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 — 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