
**Sterilization of health care products —
Biological indicators — Guidance for the
selection, use and interpretation of
results**

*Stérilisation des produits de santé — Indicateurs biologiques —
Directives générales pour la sélection, l'utilisation et l'interprétation des
résultats*



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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 14161 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 14161:2000), which has been technically revised.

Introduction

This International Standard provides guidance regarding the selection, use and interpretation of results of biological indicators when used to develop, validate and monitor sterilization processes. The procedures described in this International Standard are of a general nature and do not, of themselves, constitute a comprehensive development, validation or monitoring programme with regard to the sterilization of health care products. The intent of this International Standard is not to mandate the use of biological indicators in a process but, if they are used, to provide guidance for their proper selection and use in order to obviate misleading results.

In this International Standard, users will find guidance on selection of the correct biological indicator for their particular sterilization process and critical parameters as well as guidance on its appropriate use.

The user should select a biological indicator that is appropriate for the particular process to be used. There is a wide variety of sterilization processes in common use, and biological indicator manufacturers are not able to foresee all possible uses of their product. Manufacturers, therefore, label biological indicators according to their intended use. It is the responsibility of the users of biological indicators to select, use, recover and interpret the results as appropriate for the particular sterilization process used.

The certified performance of a biological indicator can be adversely affected by the conditions of storage and transport prior to its use, by the use of the biological indicator or by the sterilizer process parameters. In addition, the incubation procedure used after exposure to the process, including outgrowth temperature and culture medium type, supplier and specific lot, can affect measured resistance as a function of recovery and growth. For these reasons, the recommendations of the biological indicator manufacturer for storage and use should be followed. After exposure, biological indicators should be aseptically transferred (if applicable) and incubated as specified by the biological indicator manufacturer.

It should be noted that biological indicators are not intended to indicate that the products in the load being sterilized are sterile. Biological indicators are utilized to test the effectiveness of a given sterilization process and the equipment used, by assessing microbial lethality according to the concept of sterility assurance level. Suitably trained personnel should conduct these studies.

Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results

1 Scope

This International Standard provides guidance for the selection, use and interpretation of results from application of biological indicators when used in the development, validation and routine monitoring of sterilization processes. This International Standard applies to biological indicators for which International Standards exist.

NOTE 1 See, for example, the ISO 11138 series.

NOTE 2 The general information provided in this International Standard can have useful application for processes and biological indicators not currently addressed by existing International Standards, e.g., new and developing sterilization processes.

This International Standard does not consider those processes that rely solely on physical removal of microorganisms, e.g., filtration.

This International Standard is not intended to apply to combination processes using, for example, washer disinfectors or flushing and steaming of pipelines.

This International Standard is not intended to apply to liquid sterilization processes.

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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11138-1:2006, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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*

ISO 18472:2006, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

3 Terms and definitions

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

3.1 accreditation
procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

NOTE 1 See ISO/IEC 17011^[3].

NOTE 2 Accreditation does not itself qualify the laboratory to approve any particular product. However, accreditation can be relevant to approval and certification authorities when they decide whether or not to accept data produced by a given laboratory in connection with their own activities.

3.2 aseptic technique
conditions and procedures used to exclude the introduction of microbial contamination

3.3 bioburden
population of viable microorganisms on or in a product and/or sterile barrier system

[ISO/TS 11139, definition 2.2]

3.4 biological indicator
BI
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[ISO/TS 11139, definition 2.3]

3.5 D value
 D_{10} value
time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

[ISO/TS 11139, definition 2.11]

3.6 holding time
period for which the sterilization variable within the sterilizer and at all points within the load are continuously within the limits specified for the sterilization stage

3.7 inoculated carrier
supporting material on or in which a defined number of viable test organisms have been deposited

NOTE 1 See ISO 11138-1.

NOTE 2 The test organism is a microorganism used for the manufacture of inoculated carriers.