

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14161:2009 sisaldab Euroopa standardi EN ISO 14161:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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English Version

**Sterilization of health care products - Biological indicators -  
Guidance for the selection, use and interpretation of results (ISO  
14161:2009)**

Stérilisation des produits de santé - Indicateurs biologiques  
- Directives générales pour la sélection, l'utilisation et  
l'interprétation des résultats (ISO 14161:2009)

Sterilisation von Produkten für die Gesundheitsfürsorge -  
Biologische Indikatoren - Leitfaden für die Auswahl,  
Verwendung und Interpretation von Ergebnissen (ISO  
14161:2009)

This European Standard was approved by CEN on 31 July 2009.

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## Foreword

This document (EN ISO 14161:2009) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers for medical purposes" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

### Endorsement notice

The text of ISO 14161:2009 has been approved by CEN as a EN ISO 14161:2009 without any modification.

# Contents

Page

Foreword .....	v
Introduction .....	vi
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	2
4 General .....	5
5 Characteristics of biological indicators .....	7
5.1 General .....	7
5.2 Test organism suspension for direct inoculation of products .....	7
5.3 Inoculated carriers .....	8
5.4 Self-contained biological indicators .....	8
5.5 Other biological indicators .....	9
6 Selection of supplier .....	9
6.1 General .....	9
6.2 Documentation .....	10
7 Biological indicators in process development .....	11
7.1 General .....	11
7.2 Overkill approach .....	12
7.3 Combined biological indicator and bioburden method .....	12
7.4 Bioburden method .....	13
8 Biological indicators in sterilization validation .....	14
8.1 General .....	14
8.2 Placement and handling of biological indicators .....	14
8.3 Sterilizer qualification .....	14
8.4 Performance qualification .....	14
8.5 Review and approval of validation .....	15
8.6 Requalification .....	15
9 Biological indicators in routine monitoring .....	15
9.1 General .....	15
9.2 Placement and handling of biological indicators .....	15
9.3 Process challenge device (PCD) .....	16
10 Results .....	16
10.1 General .....	16
10.2 Interpretation of results .....	16
11 Application of biological indicator standards .....	17
11.1 General assessment of biological indicator performance by the user .....	17
11.2 Nominal population of test organism .....	17
11.3 Resistance determination .....	18
11.4 $z$ value determination .....	20
11.5 $F_{(T, z)}$ equivalent sterilization value determination .....	22
11.6 Establishing spore-log-reduction (SLR) .....	23
11.7 Sterility assurance level (SAL) calculation .....	23
11.8 Test equipment .....	24
12 Culture conditions .....	24
12.1 General .....	24
12.2 Incubation temperature .....	24

12.3	Incubation period .....	25
12.4	Choice of growth medium .....	25
13	Third-party requirements .....	26
13.1	General .....	26
13.2	Minimum requirements for replicates and total number of biological indicators .....	26
13.3	Test equipment .....	26
14	Personnel training .....	27
15	Storage and handling .....	27
16	Disposal of biological indicators .....	27
Annex A (informative) Microbiological inactivation kinetics and enumeration techniques .....		28
Annex B (informative) Process challenge devices .....		34
Annex C (informative) Formulae for fraction negative methods for <i>D</i> value calculations .....		35
Annex D (informative) Examples of documentation for biological indicators prepared by the user .....		50
Annex E (informative) Calculation of <i>z</i> value .....		54
Annex F (informative) <i>D</i> value determination by survivor curve method .....		57
Annex G (informative) Survival-kill response characteristics .....		61
Bibliography .....		62

## 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<sup>[3]</sup>.

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<sub>10</sub> 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.