

TERVISHOIUTOODETE STERILISEERIMINE.
BIOLOOGILISED INDIKAATORID. OSA 7: VALIKU,
KASUTAMISE JA TULEMUSTE TÕLGENDAMISE JUHISED

Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11138-7:2019 sisaldab Euroopa standardi EN ISO 11138-7:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11138-7:2019 consists of the English text of the European standard EN ISO 11138-7:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 17.04.2019.	Date of Availability of the European standard is 17.04.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.01

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD

EN ISO 11138-7

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2019

ICS 11.080.01

Supersedes EN ISO 14161:2009

English Version

**Sterilization of health care products - Biological indicators
- Part 7: Guidance for the selection, use and interpretation
of results (ISO 11138-7:2019)**

Stérilisation des produits de santé - Indicateurs
biologiques - Partie 7: Directives générales pour la
sélection, l'utilisation et l'interprétation des résultats
(ISO 11138-7:2019)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Biologische Indikatoren - Teil 7:
Leitfaden für die Auswahl, Verwendung und
Interpretation von Ergebnissen (ISO 11138-7:2019)

This European Standard was approved by CEN on 4 February 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 11138-7:2019) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" 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 October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

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

This document supersedes EN ISO 14161:2009.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11138-7:2019 has been approved by CEN as EN ISO 11138-7:2019 without any modification.

Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 General.....	4
5 Characteristics of biological indicators.....	6
5.1 General.....	6
5.2 Test organism suspension for direct inoculation of products.....	7
5.3 Inoculated carriers.....	7
5.4 Self-contained biological indicators.....	8
6 Selection of supplier.....	8
6.1 General.....	8
6.2 Documentation.....	9
6.2.1 General.....	9
6.2.2 Manufacturer audit.....	10
7 Biological indicators in process development.....	11
7.1 General.....	11
7.2 Overkill approach.....	11
7.3 Combined biological indicator and bioburden method.....	12
7.4 Bioburden method.....	13
8 Biological indicators in sterilization validation.....	13
8.1 General.....	13
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.....	16
9.3 Process challenge device.....	16
10 Interpretation and acceptance criteria.....	17
10.1 General.....	17
10.2 Interpretation of results.....	17
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.....	18
11.3 Resistance determination.....	19
11.3.1 General.....	19
11.3.2 Survivor curve method.....	19
11.3.3 Fraction-negative method.....	19
11.3.4 Survival-kill response characteristics.....	20
11.4 z value determination.....	20
11.4.1 General.....	20
11.4.2 Graphically plotting the z value.....	20
11.4.3 Mathematically calculating the z value.....	21
11.4.4 Correlation coefficient, <i>r</i> , for the z value.....	22
11.5 $F_{(T, z)}$ equivalent sterilization value determination.....	22
11.6 Establishing spore-log-reduction.....	22

11.7	Sterility assurance level calculation	23
11.8	Test equipment	23
12	Culture conditions	24
12.1	General	24
12.2	Incubation temperature	24
12.3	Incubation period	24
12.4	Choice of growth medium	25
13	Third-party considerations	25
13.1	General	25
13.2	Minimum requirements from ISO 11138-1 for replicates and total number of biological indicators	26
13.3	Test equipment	26
14	Personnel training	26
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		33
Annex C (informative) Formulae for <i>D</i> value determination by fraction-negative method		34
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		63

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).

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 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 198, *Sterilization of health care products*.

This first edition cancels and replaces ISO 14161:2009, which has been technically revised.

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

This document provides guidance regarding the selection, use and interpretation of results of biological indicators used to develop, validate and monitor sterilization processes. The procedures described in this document 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 document is not to stipulate 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 avoid misleading results.

In this document, users will find guidance on selection of the correct biological indicator for their particular sterilization process (see the ISO 11138 series) and critical parameters as well as guidance on its appropriate use.

The selection of an appropriate biological indicator for the particular process used is critical. 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 performance of a biological indicator can be adversely affected by the conditions of storage and transport prior to its use, by inappropriate/non-indicated use of the biological indicator or by the sterilizer process parameters. In addition, the incubation procedure used after exposure to the process, including incubation temperature and culture medium type, supplier and specific batch, can affect measured resistance as a function of recovery and growth. For these reasons, the recommendations of the biological indicator manufacturer for transportation, storage and use should be followed. After exposure, the aseptic transfer (if applicable) and incubation of biological indicators as specified by the biological indicator manufacturer is critical for obtaining correct results.

It is important to note 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. Suitable training is necessary for personnel conducting these studies.

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

Sterilization of health care products — Biological indicators —

Part 7: Guidance for the selection, use and interpretation of results

1 Scope

This document 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.

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

It is not applicable to combination processes using, for example, washer-disinfectors or flushing and steaming of pipelines.

It does not specify requirements for the selection and use of biological indicators intended to monitor vaporised hydrogen peroxide processes for isolator and room biodecontamination processes at atmospheric pressure.

It is not applicable to liquid immersion sterilization processes.

2 Normative references

There are no normative references in this document.

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 <http://www.electropedia.org/>

3.1

aseptic technique

conditions and procedures used to minimize the risk of the introduction of microbial contamination

[SOURCE: ISO 11139:2018, 3.16]

3.2

bioburden

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

[SOURCE: ISO 11139:2018, 3.23]