



SLOVENSKI STANDARD
SIST EN ISO 11138-1:2017
01-junij-2017

Nadomešča:
SIST EN ISO 11138-1:2006

Sterilizacija izdelkov za zdravstveno nego - Biološki indikatorji - 1. del: Splošne zahteve (ISO 11138-1:2017)

Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil1: Allgemeine Anforderungen (ISO 11138-1:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 1: Exigences générales (ISO 11138-1:2017)

Ta slovenski standard je istoveten z: EN ISO 11138-1:2017

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
-----------	--	---

SIST EN ISO 11138-1:2017

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11138-1:2017](#)

<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>

EUROPEAN STANDARD

EN ISO 11138-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2017

ICS 11.080.20

Supersedes EN ISO 11138-1:2006

English Version

Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)

Stérilisation des produits de santé - Indicateurs
biologiques - Partie 1: Exigences générales (ISO 11138-
1:2017)

Sterilisation von Produkten für die
Gesundheitsfürsorge - Biologische Indikatoren - Teil 1:
Allgemeine Anforderungen (ISO 11138-1:2017)

This European Standard was approved by CEN on 19 January 2017.

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: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11138-1:2017](https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017)
<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>

European foreword

This document (EN ISO 11138-1:2017) 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 September 2017 and conflicting national standards shall be withdrawn at the latest by September 2017.

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.

This document supersedes EN ISO 11138-1:2006.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-1:2006:

- Normative references and bibliography updated;
- Terms and definitions „ F_{BIO} -value“ und „packaging system“ deleted;
- General manufacturing requirements (clause 4) including Table 1 revised, e.g. requirements on traceability added;
- requirements on carrier and the primary and secondary packaging revised;
- general resistance requirements (6.1.2 and 6.4.3) revised;
- requirements on software validation (7.4) and detection systems (7.5) added;
- for determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes the number of probes was increased and requirements revised (see Annex B).

EN ISO 11138 consists of the following parts, under the general title *Sterilization of health care products — Biological indicators*:

- *Part 1: General requirements*
- *Part 2: Biological indicators for ethylene oxide sterilization processes*
- *Part 3: Biological indicators for moist heat sterilization processes*
- *Part 4: Biological indicators for dry heat sterilization processes*
- *Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

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,

EN ISO 11138-1:2017 (E)

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 11138-1:2017 has been approved by CEN as EN ISO 11138-1:2017 without any modification.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11138-1:2017](https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017)

<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>

INTERNATIONAL
STANDARD

ISO
11138-1

Third edition
2017-03

**Sterilization of health care products —
Biological indicators —**

**Part 1:
General requirements**

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 1: Exigences générales
iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11138-1:2017](https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017)

<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>



Reference number
ISO 11138-1:2017(E)

© ISO 2017

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11138-1:2017](https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017)
<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General manufacturing requirements	4
4.1 Manufacturing controls.....	4
4.1.1 Quality management systems.....	4
4.1.2 Traceability.....	4
4.1.3 Finished product requirements.....	4
4.1.4 Personnel.....	4
4.2 Test organism.....	4
4.2.1 Strain.....	4
4.2.2 Originating inoculum for suspension.....	5
4.2.3 Test organism count.....	5
4.3 Information to be provided by the manufacturer (labelling).....	5
4.4 Storage and transport.....	6
5 Specific manufacturing requirements	7
5.1 Suspensions.....	7
5.2 Carrier, primary and secondary packaging.....	7
5.3 Inoculated carrier.....	7
5.4 Biological indicators.....	8
5.5 Self-contained biological indicators.....	8
6 Determination of population and resistance	8
6.1 General resistance requirements.....	8
6.2 Test organism.....	8
6.3 Population of test organisms.....	8
6.4 Resistance characteristics.....	9
6.5 Test conditions.....	9
7 Culture conditions	10
7.1 Incubator.....	10
7.2 Growth medium.....	10
7.3 Incubation.....	10
7.4 Software validation.....	11
7.5 Incubation time using detection system.....	11
Annex A (normative) Determination of viable count	12
Annex B (normative) Determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes	14
Annex C (normative) D value determination by survivor curve method	17
Annex D (normative) D value determination by fraction negative method	21
Annex E (normative) Survival-kill response characteristics	37
Annex F (informative) Relationship between components of biological indicators	39
Bibliography	40

ISO 11138-1:2017(E)

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 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. (standards.iteh.ai)

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

This third edition cancels and replaces the second edition (ISO 11138-1:2006), which has been technically revised.

A list of all parts of ISO 11138 can be found on the ISO website.

Introduction

This document specifies general requirements for production, labelling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes. Other parts of ISO 11138 provide additional specific requirements for biological indicators for defined sterilization processes.

A graphic description of a biological indicator and its components is presented in [Table F.1](#). The presentation includes the two types of biological indicators which are covered by ISO 11138 (all parts). This shows that inoculated carriers can be presented directly to the sterilizing agent without prior packaging, or included in a primary package that permits access by the sterilizing agent.

The resistance characteristics depend on the type of test organism, its numbers, the method of preparation, the substrate upon which it is inoculated, environmental conditions during inoculation and drying and the effects of the primary package. Advice on selection, use and interpretation of results of biological indicators can be found in ISO 14161.

For any individual sterilization process, including those covered in relevant parts of ISO 11138, the resistance of the biological indicator will also depend on its microenvironment during testing. In theory, this could lead to an infinite variation in the preparation of biological indicators. Moreover, a sterilization process could be manipulated in infinite variety to suit each possible set of conditions to which products could be exposed. It has, therefore, been a routine practice to manufacture biological indicators that, when exposed to a set of conditions in a defined sterilization process, provide resistance characteristics expressed as D values and, where relevant, z values. Such values are set out in the relevant parts of ISO 11138.

The ISO 11138 series represents the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing this document.

Biological indicators for specific sterilization processes not covered by reference test conditions in relevant parts of ISO 11138 should comply with the general requirements in this document, including the resistance testing procedures. Such biological indicators might not be well enough described, or might be used for novel sterilization processes, or might be represented by isolated bioburden microorganisms. If microorganisms other than risk group 1 (WHO 2004) are included in these biological indicators, appropriate safety measures (e.g. containment) are necessary.

Standards exist providing requirements for the validation and control of sterilization processes (see Bibliography).

NOTE It is possible that some countries or regions have published other standards covering requirements for sterilization or biological indicators (see Bibliography).

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11138-1:2017

<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>

Sterilization of health care products — Biological indicators —

Part 1: General requirements

1 Scope

This document specifies general requirements for production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes.

This document specifies basic and common requirements that are applicable to all parts of ISO 11138. Requirements for biological indicators for particular specified processes are provided in the relevant parts of ISO 11138. If no specific subsequent part is provided, this document applies.

NOTE National or regional regulations can apply.

This document does not apply to microbiological test systems for processes that rely on physical removal of microorganisms, e.g. filtration processes or processes that combine physical and/or mechanical removal with microbiological inactivation, such as use of washer disinfectors or flushing and steaming of pipelines. This document, however, can contain elements relevant to such microbiological test systems.

SIST EN ISO 11138-1:2017

[https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-](https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017)

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

ISO 11737-1:2006, *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, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at <http://www.electropedia.org/>

— ISO Online browsing platform: available at <https://www.iso.org/obp/>

ISO 11138-1:2017(E)

3.1
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[SOURCE: ISO/TS 11139:2006, 2.3]

3.2
carrier
supporting material on or in which test microorganisms are deposited

3.3
colony forming unit
CFU
individual visible units of growth of microorganisms arising from a single cell or multiple cells

3.4
culture collection number
unique identification of the test organism allocated by a scientifically recognized service culture collection

3.5
culture conditions
combination of growth media and manner of incubation used to promote germination, growth and/or multiplication of microorganisms

Note 1 to entry: The manner of incubation can include the temperature, time and any other conditions specified for incubation.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SOURCE: ISO/TS 11139:2006, 2.10]

3.6
D value
D₁₀ value
time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

SIST EN ISO 11138-1:2017
<https://standards.iteh.ai/catalog/standards/sist/18ed3341-90c8-4d77-8199-0f1322098e29/sist-en-iso-11138-1-2017>

Note 1 to entry: Other critical process variable(s) exhibiting first order inactivation kinetics can achieve an inactivation of 90 % of a population of the test microorganism under stated conditions.

[SOURCE: ISO/TS 11139:2006, 2.11, modified]

3.7
inactivation
loss of ability of microorganisms to grow and/or multiply

[SOURCE: ISO/TS 11139:2006, 2.21]

3.8
inoculated carrier
supporting material on or in which a defined number of viable test organisms have been deposited

Note 1 to entry: See [Annex F](#).

3.9
nominal population
manufacturer's stated number of viable microorganisms

Note 1 to entry: This is generally expressed in log₁₀ function (e.g. 10⁶).

3.10**primary package**

element of the packaging system which maintains the integrity of the product

Note 1 to entry: The packaging system protects the inoculated carrier from damage and contamination without preventing penetration of the sterilizing agent.

3.11**process challenge device****PCD**

item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

[SOURCE: ISO/TS 11139:2006, 2.33]

3.12**resistometer**

test equipment designed to create defined reference combinations of the physical and/or chemical variables of a sterilization process

[SOURCE: ISO 18472:2006, 3.11, modified]

3.13**secondary package**

container in which biological indicators are packed for transport and storage

3.14**self-contained biological indicator**

biological indicator presented in such a way that the primary package, intended for incubation, contains the incubation medium required for recovery of the test organism

3.15**survival-kill window**

extent of exposure to a sterilization process under defined conditions where there is a transition from all biological indicators showing growth to all biological indicators showing no growth

3.16**survivor curve**

graphical representation of the inactivation of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions

3.17**suspension**

viable test organisms suspended in a fluid

Note 1 to entry: Suspension can be a biological indicator if ready to use in a sealed glass ampoule or may be an intermediate component used to produce an inoculated carrier or biological indicator.

3.18**viable count**

actual number of recoverable colony-forming units or other appropriate units

Note 1 to entry: See [Annex A](#).

3.19**z value**

change in exposure temperature of a thermal sterilization process, which corresponds to a tenfold change in *D* value

Note 1 to entry: See ISO 11138-3 and ISO 11138-4.