TERVISHOIUTOODETE STERILISEERIMINE. BIOLOOGILISED INDIKAATORID. OSA 1: ÜLDNÕUDED

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11138-1:2017 sisaldab Euroopa standardi EN ISO 11138-1:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11138-1:2017 consists of the English text of the European standard EN ISO 11138-1:2017.
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 29.03.2017.	Date of Availability of the European standard is 29.03.2017.
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 11.080.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11138-1

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

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Ref. No. EN ISO 11138-1:2017 E

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,

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.

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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 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.

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).

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.

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/