EESTI STANDARD EVS-EN ISO 11138-1:2006

Bioloogilised süsteemid sterilisaatorite ja sterilisatsiooniprotsesside katsetamiseks. Osa 1: Üldnõuded

Sterilization of health care products - Biological indicators - Part 1: General requirements

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11138-1:2006 sisaldab Euroopa standardi EN ISO 11138-1:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 30.08.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11138-1:2006 consists of the English text of the European standard EN ISO 11138-1:2006. This document is endorsed on 30.08.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa esitab üldised nõuded bioloogiliste süsteemide tootmisele, mida kasutatakse sterilisaatorite ja sterilisatsiooniprotsesside testimisel.	**Scope:** This part of ISO 11138 provides 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.

ICS 11.080.01

Võtmesõnad: bioloogiline proov, bioloogilised indikaatorid, ettevalmistus, meditsiiniaparatuur, pakkimine, sildiga märgistamine, sterilisaatorid, tehnilised andmed, tootmine

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Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2006)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 1: Exigences générales (ISO 11138-1:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 1: Allgemeine Anforderungen (ISO 11138-1:2006)

This European Standard was approved by CEN on 7 June 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 11138-1:2006) 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 January 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

This document supersedes EN 866-1:1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 United Kingdom.

Endorsement notice

The text of ISO 11138-1:2006 has been approved by CEN as EN ISO 11138-1:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11138-1

Second edition
2006-07-01

Sterilization of health care products — Biological indicators —

Part 1: General requirements

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 1: Exigences générales

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Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1
1.1 General ... 1
1.2 Exclusions ... 1

2 Normative references ... 1

3 Terms and definitions ... 2

4 General manufacturing requirements ... 4
4.1 Manufacturing controls ... 4
4.2 Test organism ... 5
4.3 Information supplied by manufacturer (labelling) ... 6
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 ... 8
5.4 Biological indicators ... 8
5.5 Self-contained biological indicators ... 8

6 Determination of resistance ... 8
6.1 General resistance requirements ... 8
6.2 Test organism ... 9
6.3 Population of test organisms ... 9
6.4 Resistance characteristics ... 9
6.5 Test conditions ... 10

7 Culture conditions ... 10
7.1 Incubator ... 10
7.2 Growth medium ... 10
7.3 Incubation ... 10

Annex A (normative) **Determination of viable count** ... 11

Annex B (normative) **Determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes** ... 13

Annex C (normative) D **value determination by survivor curve method** ... 15

Annex D (normative) D **value determination by fraction negative method** ... 19

Annex E (normative) **Survival-kill response characteristics** ... 35

Annex F (informative) **Relationship between components of biological indicators** ... 36

Bibliography ... 37

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 11138-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11138-1:1994), which has been technically revised.

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*

Introduction

This part of ISO 11138 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. Subsequent 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 Annex F. The presentation includes the two types of biological indicator which are covered by ISO 11138. 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 and the effects of the primary package. Advice on selection, use and interpretation of results of biological indicators can be found in ISO 14161[7].

For any individual sterilization process, including those covered in subsequent 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 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 subsequent parts of ISO 11138.

ISO 11138, parts 1 to 5 represent the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing this International Standard.

Biological indicators for specific sterilization processes not covered by reference test conditions in subsequent parts of ISO 11138 should comply with the general requirements in this part, 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,1993[27]) are included in these biological indicators, the appropriate containment and safety levels must be met.

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

NOTE Some countries or regions might 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

1.1 General

1.1.1 This part of ISO 11138 provides 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.

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

NOTE National or regional regulations may apply.

1.2 Exclusions

This part of ISO 11138 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 part of ISO 11138, however, could contain elements relevant to such microbiological test systems.

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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 15223, *Symbols to be used with medical device labels, labelling and information to be supplied*

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.

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

[ISO/TS 11139, definition 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 recognised 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 The manner of incubation may include the temperature, time and any other conditions specified for incubation.

[ISO/TS 11139, definition 2.10]

3.6
D **value**
D_{10} **value**
time or dose required to achieve inactivation of 90 % of a population of the test microorganism under stated dose conditions

[ISO/TS 11139, definition 2.11]

