Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes

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EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11138-4:2006 sisaldab Euroopa standardi EN ISO 11138-4:2006 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 11138-4:2006 consists of the English text of the European standard EN ISO 11138-4:2006. 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: This part of ISO 11138 provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods intended for use in assessing the performance of sterilization processes employing dry heat as the sterilizing agent at sterilizing temperatures within the range of 120 °C to 180 °C.	**Scope:** This part of ISO 11138 provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods intended for use in assessing the performance of sterilization processes employing dry heat as the sterilizing agent at sterilizing temperatures within the range of 120 °C to 180 °C.

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English Version

Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-4:2006)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 4: Indicateurs biologiques pour la stérilisation à la chaleur sèche (ISO 11138-4:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 4: Biologische Indikatoren für Sterilisationsverfahren mit Heißluft (ISO 11138-4:2006)

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.

CEN members are the national standards bodies of 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 11138-4:2006: E

Foreword

This document (EN ISO 11138-4:2006) 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 866-6:1999.

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 11138-4:2006 has been approved by CEN as EN ISO 11138-4:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11138-4

First edition
2006-07-01

Sterilization of health care products — Biological indicators —

Part 4: Biological indicators for dry heat sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 4: Indicateurs biologiques pour la stérilisation à la chaleur sèche

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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.

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 11138-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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

ISO 11138-1 specifies 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 sterilization processes. This part of ISO 11138 gives specific requirements for those biological indicators intended for use in dry heat sterilization processes.

The intent of providing requirements in the ISO 11138 series of International Standards is to provide general requirements and requirements for test methods. This series of International Standards represents the current "state-of-the-art" according to the experts representing manufacturers, users and regulatory authorities involved in developing the standard. The intent is not to promote the use of biological indicators where such use is not advised, but to provide common requirements for the production of those biological indicators that are known to be in use today.

Standards exist providing general requirements for the validation and control of general sterilization processeses (see ISO 14937)[1)].

NOTE Some countries or regions may have published standards covering requirements for sterilization or biological indicators.

Advice on selection, use and interpretation of results when using biological indicators can be found in ISO 14161.

1) Although ISO/TC 198 has agreed to develop a standard applicable to dry heat processes, it was not available for reference at the time this document was prepared.

Sterilization of health care products — Biological indicators —

Part 4: Biological indicators for dry heat sterilization processes

1 Scope

This part of ISO 11138 provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods intended for use in assessing the performance of sterilization processes employing dry heat as the sterilizing agent at sterilizing temperatures within the range of 120 °C to 180 °C.

NOTE 1 Requirements for validation and control of dry heat sterilization processes are provided by ISO 14937.

NOTE 2 Requirements for work place safety may be provided by national or regional regulations.

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 11138-1:2006, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 18472, *Sterilization of health care products — Biolgical and chemical indicators — Test equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11138-1 apply.

4 General requirements

The requirements of ISO 11138-1 apply.

5 Test organism

5.1 The test organisms shall be spores of *Bacillus atrophaeus* or other strains of microorganisms of demonstrated equivalent performance as required by this part of ISO 11138.

NOTE 1 Some strains of *Bacillus subtilis* have been reclassified as *Bacillus atrophaeus*.

NOTE 2 *Bacillus atrophaeus* CIP 77.18, NCIMB 8058, DSM 675, NRRL B-4418, and ATCC 9372 or *Bacillus subtilis,* DSM 13019 have been found to be suitable.

5.2 If a test organism other than *Bacillus atrophaeus* is used, the suitability of the resistance of that test organism shall be determined.