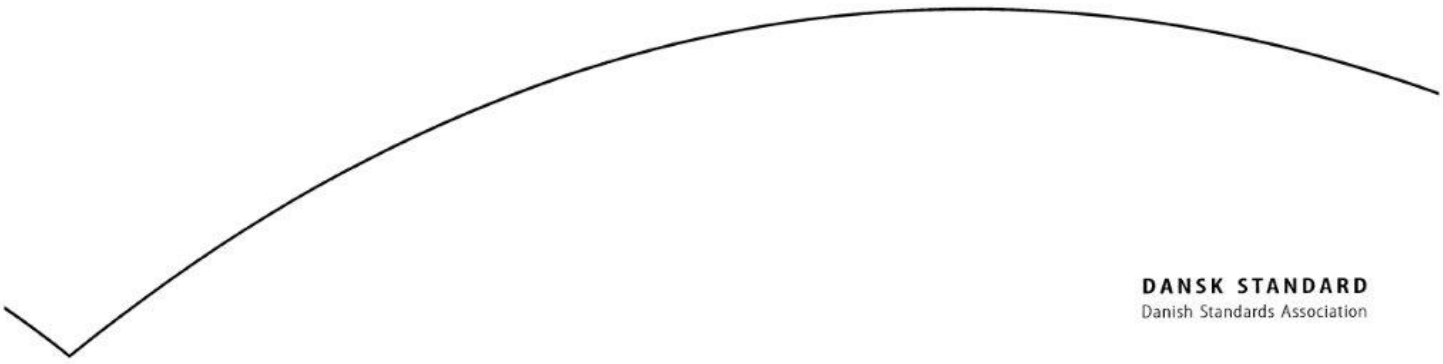
2017-04-04

Sterilisation af sundhedsplejeprodukter – Biologiske indikatorer – Del 3: Biologiske indikatorer for sterilisationsprocesser med fugtig varme

Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)



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ICS: 11.080.20

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EUROPEAN STANDARD **EN ISO 11138-3**

NORME EUROPÉENNE

EUROPÄISCHE NORM March 2017

ICS 11.080.20 Supersedes EN ISO 11138-3:2009

English Version

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide (ISO 11138-3:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (ISO 11138-3:2017)

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

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11138-3:2017 E

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European foreword

This document (EN ISO 11138-3:2017) 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of an identical text or by endorsement, at the latest by September 2017 and conflicting national standards shall be withdrawn at the latest by September 2017.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 11138-3:2009.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-3:2009:

— requirements on population and resistance (clause 9) revised;

— Annex A, in particular A.2.4 step 4 revised;

— informative Annex ZA respective relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered was deleted.

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 11138-3:2017 has been approved by CEN as EN ISO 11138-3:2017 without any modification.

Third edition
2017-03

Sterilization of health care products — Biological indicators —

Part 3: Biological indicators for moist heat sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide

Reference number
ISO 11138-3:2017(E)

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Contents

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 11138-3:2006), which has been technically revised.

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

Introduction

This document specifies 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. This document gives specific requirements for those biological indicators intended for use in moist heat sterilization processes.

Moist heat as the sterilizing agent is defined in this document as dry saturated steam. While air-steam mixtures can be used in moist heat sterilization processes, the methods and performance requirements of this document might not be applicable for biological indicators used in such processes.

The ISO 11138 series 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 known to be in use today.

Standards exist providing requirements for the validation and control of moist heat sterilization (see ISO 17665 series).

NOTE It is possible that some countries or regions have published other 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.

Sterilization of health care products — Biological indicators —

Part 3: Biological indicators for moist heat sterilization processes

1 Scope

This document specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilization processes employing moist heat as the sterilizing agent.

NOTE 1 Requirements for validation and control of moist heat sterilization processes are provided by the ISO 17665 series.

NOTE 2 National or regional regulations can provide requirements for work place safety.

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 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 18472, *Sterilization of health care products — Biological 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.

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 http://www.iso.org/obp

4 General requirements

The requirements of ISO 11138-1 apply.

5 Test organism

5.1 The test organisms shall be spores of *Geobacillus stearothermophilus* or other strains of microorganism of demonstrated equivalent performance as required by this document.

NOTE 1 *Bacillus stearothermophilus* has been reclassified as *Geobacillus stearothermophilus*.