SVENSK STANDARD
SS-EN ISO 11138-4:2017

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Sterilisering av medicintekniska produkter – Biologiska indikatorer –
Del 4: Biologiska indikatorer för steriliseringsprocesser med torr värme (ISO 11138-4:2017)

Sterilization of health care products – Biological indicators –
Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-4:2017)

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Europastandarden EN ISO 11138-4:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11138-4:2017.

Denna standard ersätter SS-EN ISO 11138-4:2006, utgåva 1.

The European Standard EN ISO 11138-4:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 11138-4:2017.

This standard supersedes the Swedish Standard SS-EN ISO 11138-4:2006, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11138-4

March 2017

ICS 11.080.20

Supersedes EN ISO 11138-4:2006

English Version

Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-4:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 4: Indicateurs biologiques pour la stérilisation à la chaleur sèche (ISO 11138-4:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 4: Biologische Indikatoren für Sterilisationsverfahren mit Heißluft (ISO 11138-4:2017)

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.

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European foreword

This document (EN ISO 11138-4:2017) 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 11138-4:2006.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-4:2006:

— requirements on determination of resistance characteristics (9.6) revised.

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 11138-4:2017 has been approved by CEN as EN ISO 11138-4:2017 without any modification.

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 document gives specific requirements for those biological indicators intended for use in dry heat sterilization 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 that are known to be in use today.

A standard exists providing general requirements for the validation and control of dry heat sterilization processeses (see ISO 20857).

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 4: Biological indicators for dry 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 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 20857.

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

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 https://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 *Bacillus atrophaeus* or other strains of microorganisms of demonstrated equivalent performance as required by this document.

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[1)].

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

6 Suspension

The requirements of ISO 11138-1 apply.

7 Carrier and primary packaging

7.1 The suitability of the carrier and primary packaging materials for biological indicators for use in dry heat sterilization processes shall be demonstrated in accordance with the requirements of ISO 11138-1:2017, 5.2 and Annex B.

7.2 The exposure conditions to determine compliance shall be the following:

a) minimum exposure temperature: greater than or equal to 5 °C above the manufacturer's stated maximum temperature;

b) sterilizing agent: dry heat in ambient air;

c) maximum exposure temperature: as stated by the manufacturer; if not stated by the manufacturer, the maximum exposure temperature shall be greater than or equal to 180 °C;

d) exposure time: greater than or equal to 30 min.

NOTE These conditions have been selected to represent a realistic challenge to the carrier while remaining within the practical limits of a dry heat sterilization process.

8 Inoculated carriers and biological indicators

The requirements of ISO 11138-1 apply.

9 Population and resistance

9.1 The manufacturer shall state the resistance characteristics according to ISO 11138-1:2017, 6.4.

9.2 The viable count shall be stated with increments less than or equal to $0{,}1 \times 10^{n}$ per unit (e.g. per ml of suspension, per inoculated carrier or per biological indicator).

9.3 For inoculated carriers and biological indicators, the viable count shall be greater than or equal to $1{,}0 \times 10^{6}$.

9.4 The resistance shall be expressed as the *D* value in minute at 160 °C. The *D* value of each batch/lot of biological indicators or inoculated carriers shall be stated in minutes to one decimal place at 160 °C.

9.5 Suspensions, inoculated carriers or biological indicators containing *Bacillus atrophaeus* spores shall have a D_{160} value of not less than 2,0 min when tested according to the conditions in Annex A. Other microorganisms shall have *D* values supporting the application. The *z* value of the test organisms in the suspension, on the inoculated carrier or in the biological indicator shall be determined at not less than

1) These are examples of suitable products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

three temperatures, in the range of 150 °C to 180 °C. These data shall be used to calculate the *z* value, which shall be greater than or equal to 20 °C (see Annex B).

9.6 The resistance characteristics specified in this document and any other document shall be defined using the specific critical variables associated with the referenced sterilization process.

9.7 *D* values are determined according to methods given in ISO 11138-1:2017, Annexes C and D.

9.8 Determination of *D* value and survival-kill response characteristics require the use of a resistometer applying the reference resistometer process parameters (see Annex A).

NOTE The values stated above would fit a dry heat sterilizer with forced air distribution, running a cycle of 160 °C with a holding time of 2 h.

9.9 The survival-kill window should be calculated using the formulae in ISO 11138-1:2017, Annex E.

NOTE This information can be of value to the user when comparing different batches from the same manufacturer.

EXAMPLE Using the formulae in ISO 11138-1:2017, Annex E, with the minimum population and minimum *D* value requirements specified in this document, the survival-kill response characteristics are

— at 160 °C: survival time greater than or equal to 8 min and kill time less than or equal to 20 min.