SLOVENSKI STANDARD

SIST EN ISO 11138-2:2017

01-junij-2017

Nadomešča:

SIST EN ISO 11138-2:2009

Sterilizacija izdelkov za zdravstveno nego - Biološki indikatorji - 2. del: Biološki indikatorji za sterilizacijske postopke z etilenoksidom (ISO 11138-2:2017)

Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 2: Biologische Indikatoren für Sterilisationsverfahren mit Ethylenoxid (ISO 11138-2:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène (ISO 11138-2:2017)

Ta slovenski standard je istoveten z: EN ISO 11138-2:2017

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11138-2:2017 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11138-2

March 2017

ICS 11.080.20

Supersedes EN ISO 11138-2:2009

English Version

Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène (ISO 11138-2:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 2: Biologische Indikatoren für Sterilisationsverfahren mit Ethylenoxid (ISO 11138-2:2017)

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

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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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Ref. No. EN ISO 11138-2:2017 E

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European foreword

This document (EN ISO 11138-2:2017) 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 11138-2:2009.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-2:2009:

— requirements on population and resistance (clause 9) revised, e.g. information to minimum *D*-value at 30 °C deleted;

— Annex A, in particular A.2.4 step 6 revised;

— informative Annex B on rationale for the inclusion of a second *D*-value and deletion of the requirement for a minimum D-value at 30 °C added;

— 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*

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Endorsement notice

The text of ISO 11138-2:2017 has been approved by CEN as EN ISO 11138-2:2017 without any modification.

INTERNATIONAL STANDARD

ISO 11138-2

Third edition
2017-03

Sterilization of health care products — Biological indicators —

Part 2: Biological indicators for ethylene oxide sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques — Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène

Reference number
ISO 11138-2:2017(E)

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