SLOVENSKI STANDARD
SIST EN ISO 11138-5:2017

01-junij-2017

Nadomešča:

SIST EN ISO 11138-5:2006

Sterilizacija izdelkov za zdravstveno nego - Biološki indikatorji - 5. del: Biološki indikatorji za sterilizacijske postopke s paro nizke temperature in formaldehidom (ISO 11138-5:2017)

Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 5: Biologische Indikatoren für Sterilisationsverfahren mit Niedertemperatur-Dampf-Formaldehyd (ISO 11138-5:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 5: Indicateurs biologiques pour la stérilisation à la vapeur d'eau et au formaldéhyde à basse température (ISO 11138-5:2017)

Ta slovenski standard je istoveten z: **EN ISO 11138-5:2017**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11138-5:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 11.080.20

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English Version

Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2017)

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 11138-5:2017) 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 11138-5:2006.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-5:2006:

— 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*

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Endorsement notice

The text of ISO 11138-5:2017 has been approved by CEN as EN ISO 11138-5:2017 without any modification.

INTERNATIONAL STANDARD

ISO 11138-5

Second edition
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Sterilization of health care products — Biological indicators —

Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques — Partie 5: Indicateurs biologiques pour la stérilisation à la vapeur d'eau et au formaldéhyde à basse température

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