

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)

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

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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
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EUROPEAN STANDARD

EN ISO 11138-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2017

ICS 11.080.20

Supersedes EN ISO 11138-5:2006

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)

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)

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

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

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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*: **(standards.iteh.ai)**

- *Part 1: General requirements* [SIST EN ISO 11138-5:2017](https://standards.iteh.ai/catalog/standards/sist/5d6a3b52-60eb-4660-90d0-b0941aca12/sist-en-iso-11138-5-2017)
- *Part 2: Biological indicators for ethylene oxide sterilization processes* <https://standards.iteh.ai/catalog/standards/sist/5d6a3b52-60eb-4660-90d0-b0941aca12/sist-en-iso-11138-5-2017>
- *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 11138-5:2017 has been approved by CEN as EN ISO 11138-5:2017 without any modification.

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INTERNATIONAL
STANDARD

ISO
11138-5

Second edition
2017-03

**Sterilization of health care products —
Biological indicators —**

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

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*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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Reference number
ISO 11138-5:2017(E)

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