ICS 11.080.01, 11.080.20 SLOVENSKÁ TECHNICKÁ NORMA September 2017

STN	**Sterilizácia výrobkov zdravotnej starostlivosti Biologické indikátory Časť 5: Biologické indikátory pre sterilizačné procesy nízkoteplotnou parou a formaldehydom (ISO 11138-5: 2017)**	**STN EN ISO 11138-5** 85 5015

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/17

Obsahuje: EN ISO 11138-5:2017, ISO 11138-5:2017

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 11138-5

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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.

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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 11138-5:2017 E

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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*

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.

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

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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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 second edition cancels and replaces the first edition (ISO 11138-5:2006), which has been technically revised.

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

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 low-temperature steam and formaldehyde sterilization processes.

Annex B gives rationale for the liquid-phase test method for low-temperature steam and formaldehyde biological indicators.

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 low-temperature steam and formaldehyde sterilization processes (see ISO 25424).

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.

INTERNATIONAL STANDARD **ISO 11138-5:2017(E)**

Sterilization of health care products — Biological indicators —

Part 5: Biological indicators for low-temperature steam and formaldehyde 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 low-temperature steam and formaldehyde as the sterilizing agent.

NOTE 1 Requirements for validation and control of low-temperature steam and formaldehyde sterilization processes are provided by ISO 14937.

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*