



**NSAI**  
Standards

Irish Standard  
I.S. EN 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)

**I.S. EN ISO 11138-5:2017**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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## National Foreword

I.S. EN ISO 11138-5:2017 is the adopted Irish version of the European Document EN 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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*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

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**EUROPEAN STANDARD**  
**NORME EUROPÉENNE**  
**EUROPÄISCHE NORM**

**EN ISO 11138-5**

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.



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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*:

- *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.

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# INTERNATIONAL STANDARD

**ISO**  
**11138-5**

Second edition  
2017-03

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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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ISO 11138-5:2017(E)

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



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## ISO 11138-5:2017(E)

### 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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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](http://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.



# 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*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11138-1 and the following 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/>

#### 3.1

##### **low-temperature steam and formaldehyde sterilization**

process incorporating forced air removal, which allows exposure of wrapped goods to steam at sub-atmospheric pressure, and thus at temperatures less than 100 °C, with the admission of formaldehyde gas, keeping the sterilizing agent in a steady state throughout the hold time

### 4 General requirements

The requirements of ISO 11138-1 apply.

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