

# SVENSK STANDARD

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**Sterilisering av medicintekniska produkter – Biologiska indikatorer – Vägledning för val, användning och tolkning av resultat (ISO 11138-7:2019)**

**Sterilization of health care products – Biological indicators – Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)**

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Europastandarden EN ISO 11138-7:2019 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11138-7:2019.

Denna standard ersätter SS-EN ISO 14161:2009, utgåva 2

The European Standard EN ISO 11138-7:2019 has the status of a Swedish Standard. This document contains the official version of EN ISO 11138-7:2019.

This standard supersedes the SS-EN ISO 14161:2009, edition 2

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Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

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EUROPEAN STANDARD

**EN ISO 11138-7**

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2019

ICS 11.080.01

Supersedes EN ISO 14161:2009

English Version

**Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)**

Stérilisation des produits de santé - Indicateurs biologiques - Partie 7: Directives générales pour la sélection, l'utilisation et l'interprétation des résultats (ISO 11138-7:2019)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 7: Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (ISO 11138-7:2019)

This European Standard was approved by CEN on 4 February 2019.

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.

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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 11138-7:2019) 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 October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14161:2009.

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 11138-7:2019 has been approved by CEN as EN ISO 11138-7:2019 without any modification.



## Introduction

This document provides guidance regarding the selection, use and interpretation of results of biological indicators used to develop, validate and monitor sterilization processes. The procedures described in this document are of a general nature and do not, of themselves, constitute a comprehensive development, validation or monitoring programme with regard to the sterilization of health care products. The intent of this document is not to stipulate the use of biological indicators in a process but, if they are used, to provide guidance for their proper selection and use in order to avoid misleading results.

In this document, users will find guidance on selection of the correct biological indicator for their particular sterilization process (see the ISO 11138 series) and critical parameters as well as guidance on its appropriate use.

The selection of an appropriate biological indicator for the particular process used is critical. There is a wide variety of sterilization processes in common use, and biological indicator manufacturers are not able to foresee all possible uses of their product. Manufacturers, therefore, label biological indicators according to their intended use. It is the responsibility of the users of biological indicators to select, use, recover and interpret the results as appropriate for the particular sterilization process used.

The performance of a biological indicator can be adversely affected by the conditions of storage and transport prior to its use, by inappropriate/non-indicated use of the biological indicator or by the sterilizer process parameters. In addition, the incubation procedure used after exposure to the process, including incubation temperature and culture medium type, supplier and specific batch, can affect measured resistance as a function of recovery and growth. For these reasons, the recommendations of the biological indicator manufacturer for transportation, storage and use should be followed. After exposure, the aseptic transfer (if applicable) and incubation of biological indicators as specified by the biological indicator manufacturer is critical for obtaining correct results.

It is important to note that biological indicators are not intended to indicate that the products in the load being sterilized are sterile. Biological indicators are utilized to test the effectiveness of a given sterilization process and the equipment used, by assessing microbial lethality according to the concept of sterility assurance level. Suitable training is necessary for personnel conducting these studies.

**NOTE** The general information provided in this document can have useful application for processes and biological indicators not currently addressed by existing International Standards, e.g. new and developing sterilization processes.



# Sterilization of health care products — Biological indicators —

## Part 7: Guidance for the selection, use and interpretation of results

### 1 Scope

This document provides guidance for the selection, use and interpretation of results from application of biological indicators when used in the development, validation and routine monitoring of sterilization processes.

It does not consider those processes that rely solely on physical removal of microorganisms, e.g. filtration.

It is not applicable to combination processes using, for example, washer-disinfectors or flushing and steaming of pipelines.

It does not specify requirements for the selection and use of biological indicators intended to monitor vaporised hydrogen peroxide processes for isolator and room biodecontamination processes at atmospheric pressure.

It is not applicable to liquid immersion sterilization processes.

### 2 Normative references

There are no normative references in this document.

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **aseptic technique**

conditions and procedures used to minimize the risk of the introduction of microbial contamination

[SOURCE: ISO 11139:2018, 3.16]

#### 3.2

##### **bioburden**

population of viable microorganisms on or in a product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]