SLOVENSKI STANDARD
SIST EN ISO 11138-8:2021

01-oktober-2021

Sterilizacija izdelkov za zdravstveno oskrbo - Biološki indikatorji - 8. del: Metoda za validacijo skrajšanega časa inkubacije biološkega indikatorja (ISO 11138-8:2021)

Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator (ISO 11138-8:2021)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 8: Methode zur Validierung einer reduzierten Inkubationszeit eines biologischen Indikators (ISO 11138-8:2021)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 8: Méthode pour la validation d'un temps d'incubation réduit pour un indicateur biologique (ISO 11138-8:2021)

Ta slovenski standard je istoveten z: **EN ISO 11138-8:2021**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11138-8:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11138-8

July 2021

ICS 11.080.01

English Version

Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator (ISO 11138-8:2021)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 11138-8:2021) 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of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

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.

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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*
- Part 6: *Biological indicators for hydrogen peroxide sterilization processes*
- Part 7: *Guidance for the selection, use and interpretation of results*
- Part 8: *Method for validation of a reduced incubation time for a biological indicator*

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Endorsement notice

The text of ISO 11138-8:2021 has been approved by CEN as EN ISO 11138-8:2021 without any modification.

INTERNATIONAL STANDARD

ISO 11138-8

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Sterilization of health care products — Biological indicators —

Part 8: Method for validation of a reduced incubation time for a biological indicator

Stérilisation des produits de santé — Indicateurs biologiques — Partie 8: Méthode pour la validation d'un temps d'incubation réduit pour un indicateur biologique

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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

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