DIN EN ISO 11138-8

ICS 11.080.01

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); English version EN ISO 11138-8:2021, English translation of DIN EN ISO 11138-8:2021-11

Sterilisation von Produkten für die Gesundheitsfürsorge –
Biologische Indikatoren –
Teil 8: Methode zur Validierung einer reduzierten Inkubationszeit eines biologischen Indikators (ISO 11138-8:2021);
Englische Fassung EN ISO 11138-8:2021,
Englische Übersetzung von DIN EN ISO 11138-8:2021-11

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);
Version anglaise EN ISO 11138-8:2021,
Traduction anglaise de DIN EN ISO 11138-8:2021-11

Document comprises 14 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

10.21 3301097

A comma is used as the decimal marker.

National 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” (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was *DIN-Normenausschuss Medizin* (DIN Standards Committee Medicine), Working Committee NA 063-04-08 AA “Indicators”.

The DIN documents corresponding to the documents referred to in this document are as follows:

ISO 11138-1:2017	DIN EN ISO 11138-1:2017-07
ISO 11138-2	DIN EN ISO 11138-2
ISO 11138-3	DIN EN ISO 11138-3
ISO 11138-7:2019	DIN EN ISO 11138-7:2019-11
ISO 18472	DIN EN ISO 18472

For current information on this document, please go to DIN’s website (www.din.de) and search for the document number in question.

National Annex NA
(informative)

Bibliography

DIN EN ISO 11138-1:2017-07, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2017)*

DIN EN ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

DIN EN ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

DIN EN ISO 11138-7:2019-11, *Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)*

DIN EN ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

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)

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)

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

This European Standard was approved by CEN on 24 June 2021.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11138-8:2021 E

Contents

Page