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)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11138-8:2021 sisaldab Euroopa standardi EN ISO 11138-8:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11138-8:2021 consists of the English text of the European standard EN ISO 11138-8:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.07.2021.	Date of Availability of the European standard is 28.07.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.01

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

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.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

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*

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, 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 the United Kingdom.

Endorsement notice

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

Contents

Page

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).

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 www.iso.org/iso/foreword.html.

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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A biological indicator incubation time is the minimum period of cultivation required before making a final determination that a biological indicator is negative (shows no growth). The reference incubation time for biological indicators for established sterilization processes such as moist heat and ethylene oxide is 7 d (see ISO 11138-1:2017). In some instances where biological indicator results are needed as part of the product release process, a 7-day incubation time might not be practical. This is especially the case where biological indicators are used to monitor sterilization processes in hospitals or other health care facilities such as dental or general practitioner offices.

The purpose of a reduced incubation time procedure is to demonstrate recovery of the surviving test organisms within the specified reduced incubation time period. The reduced incubation time is a function of the test method and conditions used to establish the incubation time and is independent of the process parameters for the sterilization method used to deliver the lethality.

Biological indicators with an incubation time of less than 7 d (a Reduced Incubation Time, or RIT) have been in use since the 1970s. The methodology to determine the RIT was originally created by the biological indicator manufacturers. Later, the United States Food and Drug Administration published guidance for manufacturers seeking regulatory clearance to market biological indicators to health care facilities in the United States (see Reference [1]). This guidance contained a protocol for validating an incubation time that was less than 7 d. This document was specific to regulations for commercial practices in a single country and did not address requirements for RIT methodology outside of that application. The purpose of this document is to describe an internationally agreed approach to the validation of the reduced incubation time of a biological indicator.

Sterilization of health care products — Biological indicators —

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

1 Scope

1.1 This document specifies the requirements for a test method to be utilized to establish or confirm a reduced incubation time (RIT) that is shorter than the 7-day reference incubation time specified in 7.3.2 of ISO 11138-1:2017 for biological indicators used to monitor moist heat sterilization processes or ethylene oxide (EO) sterilization processes.

NOTE For biological indicators used for EO sterilization, the stated RIT is applicable to 100 % EO processes or processes that use EO blends, regardless of the product load.

1.2 This document is applicable to manufacturers of biological indicators (BIs) and to end users of BIs who intend to, if required by their quality system, establish, validate or confirm a RIT.

1.3 This document does not apply to biological indicators used to monitor dry heat, low temperature steam formaldehyde (LTSF) or vaporized hydrogen peroxide (VH2O2) sterilization processes.

NOTE The method described in this document to establish a RIT for biological indicators used to monitor moist heat or EO sterilization processes has been used extensively for many years. However, there is limited experience in use of this method to establish a RIT for biological indicators used to monitor dry heat, low temperature steam formaldehyde or vaporized hydrogen peroxide sterilization processes. This document, therefore, does not include these sterilization processes.

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

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/