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Sterilisation af sundhedsprodukter – Biologiske indikatorer – Del 8: Metode til validering af en reduceret inkubationstid for en biologisk indikator

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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EUROPÄISCHE NORM

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.

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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of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.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.

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

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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.

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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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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).

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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.

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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.

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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

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*