

ICS 11.080.01
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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 18281.8-2024

**Sterilization of health care products - Biological indicators -
Part 8: Method for validation of a reduced incubation time for a
biological indicator**

医疗保健产品灭菌 生物指示物 第8部分：缩短生物指示物培养时间的确认方法
(English Translation)

Issued on: November 28, 2024

Implemented on: June 1, 2026

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting is required.

This document is Part 8 of GB/T 18281 "Biological indicators for sterilization of healthcare products". GB/T 18281 has been published the following parts.

Part 1: General;-

Part 2: Biological indicators for ethylene oxide sterilization;

Part 3: Biological indicators for moist heat sterilization;

Part 4: Biological indicators for dry heat sterilization; -Part 5: Biological indicators for low temperature steam formaldehyde sterilization;

Part 7: Guidance for the selection, use and interpretation of biological indicators;

Part 8: Confirmation methods for shortening the incubation time of biological indicators.

This document is equivalent to ISO 11138-8:2021 "Biological indicators for sterilization of healthcare products - Part 8: Shortened biological indicators" "Method for Confirming the Cultivation Time of Plants".

Introduction

GB/T 18281 "Biological Indicators for Sterilization of Healthcare Products" is a general and specific standard for biological indicators.

It is intended to consist of eight parts, providing requirements for biological indicators, guidelines for selection, use and result interpretation, as well as methods to shorten incubation time.

Part 1: General. The purpose is to provide common requirements for biological indicators.

Part 2: Biological indicators for ethylene oxide sterilization. The purpose is to provide specific biological indicators for ethylene oxide sterilization.

Require.

Part 3: Biological indicators for moist heat sterilization. The purpose is to provide specific requirements for biological indicators for moist heat sterilization.

Part 4: Biological indicators for dry heat sterilization. The purpose is to provide specific requirements for biological indicators for dry heat sterilization.

Part 5: Biological indicators for low temperature steam formaldehyde sterilization. The purpose is to provide biological indicators for low temperature steam formaldehyde sterilization.

Special requirements.

Part 6: Biological indicators for hydrogen peroxide sterilization. The purpose is to provide specific biological indicators for hydrogen peroxide sterilization.

Require.

Part 7: Guidance on the selection, use and result interpretation of biological indicators. The purpose is to provide guidance on the correct selection and use of biological indicators.

Guide for use.

Part 8: Confirmation method for shortening the incubation time of biological indicators.

Recognize the method.

GB/T 18281.1 specifies the use of biological indicators (including contaminated carriers and bacterial suspensions) for monitoring the sterilization process in production and standardization.

This document specifies the general requirements for the establishment or validation of a reduced incubation time (RIT).

Test method requirements.

The biological indicator culture time refers to the shortest culture week required before the biological indicator is finally determined to be negative (i.e., sterile growth).

For the recognized sterilization processes such as moist heat sterilization and ethylene oxide sterilization, the standard incubation time of biological indicators is 7 days (see GB/T 18281.1-2024). However, in some cases, especially in hospitals or other medical institutions (such as dental or other clinics), If biological indicators are used to monitor the sterilization process in places such as laboratories, and if the results of biological indicators are used as one of the conditions for product release, then the 7-day culture time is not suitable.

The purpose of the shortened bioindicator incubation time method is to demonstrate that viable test bacteria can be recovered within a specific shortened incubation time.

The shortened incubation time is related to the experimental conditions and methods used to determine the incubation time, and to the sterilization method and process parameters used to kill microorganisms.

The number doesn't matter.

Since the 1970s, bioindicators with incubation times of less than 7 days have been used.

Initially, these were developed by the manufacturers of biological indicators. Later, reference [6] provided guidelines for manufacturers who had applied for regulatory approval.

The guidance contains protocols for confirming that the incubation time is less than 7 days.

This document does not address requirements related to methods of shortening incubation times for applications other than this one. The purpose of this document is to present an internationally recognized Method for confirming the cultivation time of biological indicators.

Sterilization biological indicators for healthcare products Part 8: Shortening of biological indicators Method for confirming the culture time

1 Scope

1.1

This document specifies the requirements for test methods used to establish or determine shortened incubation times for biological indicators.

The time is less than that specified in 7.3.2 of GB 18281.7-2024 for monitoring biological indicators in moist heat or ethylene oxide (EO) sterilization processes 7 d is the reference culture time.

NOTE: For biological indicators used to monitor ethylene oxide sterilization processes, the reduced incubation times described apply to both 100% ethylene oxide sterilization and Sterilization process, also suitable for ethylene oxide mixed gas sterilization process.

1.2

This document applies to manufacturers and end users of biological indicators (BIs). If the user's quality system requires it, it must be specified in accordance with the regulations.

Establish, validate, or determine shortened culture times.

1.3

This document is not applicable to monitoring of biological products during dry heat, low temperature steam formaldehyde (LTSF) and vaporized hydrogen peroxide (VH₂O₂) sterilization processes.

Indicator.

NOTE: The reduced incubation time for biological indicators described in this document for monitoring moist heat or ethylene oxide (EO) sterilization processes has been widely used for many years.

This method was used to develop biological indicators for monitoring dry heat, low temperature steam formaldehyde (LTSF), and vaporized hydrogen peroxide (VH₂O₂) sterilization processes.

There is limited experience with incubation times. Therefore, these sterilization processes are not covered in this document.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies.

in this document.

ISO 18472 Sterilization of health care products Biological and chemical indicator test equipment products-Biological and chemical indicators-Test equipment) Note. GB/T 24628-2009 Sterilization of healthcare products - Biological and chemical indicators - Test equipment (ISO 18472:2006, IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

ISO and IEC maintain terminology databases for standardization at the following URLs.

biological indicator; BI A test system containing viable microorganisms that has a specific