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

**GB/T 18281.7-2024**

Replacing GB/T 19972-2018

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**Sterilization of health care products - Biological indicators -  
Part 7: Guidance for the selection, use and interpretation of  
results**

医疗保健产品灭菌 生物指示物 第7部分：选择、使用和结果判断指南  
(English Translation)

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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.

This document is part 7 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 selection, use and result judgment;
- Part 8: Confirmation method for shortening the incubation time of biological indicators.

This document replaces GB/T 19972-2018 "Guidelines for the selection, use and result judgment of biological indicators for sterilization of medical products" Compared with GB/T 19972-2018, in addition to structural adjustments and editorial changes, the main technical differences are as follows.

- Changed the contents not specifically specified in this document (see Chapter 1, Chapter 1 of the 2018 edition);
- Deleted some terms and definitions (see Chapter 3, Chapter 3 of the 2018 edition)
- Added the content of self-contained biological indicators (see Chapter 4);
- Deleted other indicators (see 5.5 of the 2018 edition);
- Changed the relevant content of supplier selection (see Chapter 6, Chapter 6 of the 2018 edition);
- Changed the relevant content of biological indicators in process development (see Chapter 7, Chapter 7 of the 2018 edition);
- Changed the relevant content of the treatment of biological indicators (see Chapter 16, Chapter 16 of the 2018 edition).

This document is equivalent to ISO 11138-7:2019 "Biological indicators for sterilization of health care products - Part 7: Selection, use and conclusion" Results Judgment Guide.

## Introduction

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

GB/T 18281 aims to provide requirements for biological indicators, guidelines for selection, use and result judgment, as well as methods for shortening the incubation time.

It consists of eight parts.

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

--- Part 2: Biological indicators for ethylene oxide sterilization. The purpose is to provide a dedicated biological indicator 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 for

--- Part 6: Biological indicators for hydrogen peroxide sterilization. The purpose is to provide a dedicated biological indicator for hydrogen peroxide sterilization Require.

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

Broken guide.

--- Part 8: Confirmation method for shortening the incubation time of biological indicators. The purpose is to provide a method for shortening the incubation time of biological indicators.

Confirmation method.

This document provides guidance on the selection, use and interpretation of biological indicators when applied to the development, validation and monitoring of sterilization processes.

The steps described in this document are of a general nature and are not intended by themselves to be a comprehensive process for the development, validation, and monitoring of sterilization of healthcare products.

The purpose of this document is not to mandate the use of biological indicators in a process, but rather to provide guidance on the correct selection of biological indicators if they are used.

provide guidance for selection and use to avoid misleading results.

In this document, biological indicator users (hereinafter referred to as users) can obtain biological indicators for specific sterilization processes and key parameters.

Guidelines for selecting indicators and for the correct use of such indicators.

Users should select biological indicators that are appropriate for the specific sterilization process they are using.

It is difficult for a manufacturer of a biological indicator (hereinafter referred to as the manufacturer) to foresee all possible uses of its products. Therefore, the manufacturer can only mark its biological indicator for use in a certain Specific use. The appropriate selection, use, recovery and interpretation of the results for the specific sterilization process employed should be the responsibility of the user.

Storage and transport conditions before use of biological indicators, use of biological indicators, or sterilizer process parameters may affect the biological indicators.

In addition, exposure to post-process culture techniques, including culture temperature, culture medium type, manufacturer, and specific batches, may also affect Therefore, the manufacturer's recommendations for storage and use should be followed.

Materials should be transferred aseptically (if applicable) and cultured as specified by the manufacturer.

It should be pointed out that biological indicators are not used to indicate that the sterilized items are indeed sterile, but to test a known sterilization process and the the effectiveness of sterilization equipment is evaluated by the principle of evaluating the lethality of microorganisms according to the sterility assurance level.

The study should be conducted by appropriately trained personnel.

**NOTE:** This document provides general information that also applies to processes and biological indicators not covered by current national standards, such as new and under-development sterilization process.

Sterilization biological indicators for healthcare products Part 7: Guidance for selection, use and interpretation of results

## 1 Scope

This document provides guidance on the selection, use, and interpretation of biological indicators for the development, validation, and routine monitoring of sterilization processes.

Guide.

This document applies to all biological indicators.

This document does not consider processes that rely solely on physical means to remove microorganisms, such as filtration.

This document is not applicable to the use of combined processes such as flushing and steaming of washer-disinfectors or pipes.

This document does not specify biodecontamination equipment for use in monitoring