

ICS 11.080.01



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

GB/T 18281.4-2024

**Sterilization of health care products - Biological indicators -
Part 4: Biological indicators for dry heat sterilization processes**

医疗保健产品灭菌 生物指示物 第4部分：干热灭菌用生物指示物

(English Translation)

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Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives

for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This document is Part 4 of GB/T 18281 Sterilization of Health Care Products - Biological Indicators. GB/T 18281 has issued the following parts.

- 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 7.Guidance for the Selection, Use and Interpretation of Results;
- Part 8.Method for Validation of a Reduced Incubation Time for a Biological Indicator.

This document serves as a replacement for GB 18281.4-2015 Sterilization of Health Care

Products - Biological Indicators - Part 4. Biological Indicators for Dry Heat Sterilization Processes. In comparison with GB 18281.4-2015, apart from structural adjustments and editorial modifications, the main technical changes are as follows.

---The requirements for D160 value are modified (see 9.5; 9.5 of Version 2015);

---The requirements for resistance characteristics are modified (see 9.6; 9.6 of Version 2015).

This document identically adopts ISO 11138-4:2017 Sterilization of Health Care Products - Biological Indicators - Part 4. Biological Indicators for Dry Heat Sterilization Processes.

Please be noted that certain content of this document may involve patents. The institution issuing this document does not undertake the responsibility of identifying these patents.

This document was proposed by National Medical Products Administration.

This document shall be under the jurisdiction of National Technical Committee 200 on Sterilization Techniques and Equipment of Standardization Administration of China (SAC/TC 200).

The drafting organizations of this document. Shandong BIOBASE Disinfection Equipment Co.,

Ltd.; Guangdong Medical Devices Quality Surveillance and Test Institute; Shandong SHINVA

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Sterilization of Health Care Products - Biological Indicators

- Part 4. Biological Indicators for Dry Heat Sterilization

Processes

1 Scope

This document specifies the requirements and test methods for test microorganisms, bacterial

suspensions, contaminated carriers and biological indicators to be used in evaluating the performance of sterilizers and sterilization processes. The sterilizers and sterilization processes

use dry hot air with a sterilization temperature range of 120 °C ~ 180 °C.

NOTE 1: for validation and routine control of dry heat sterilization processes, see ISO 20857.

NOTE 2: for workplace safety, refer to relevant national or regional regulations.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only

versions with a specified date are applicable to this document. In terms of references without a

specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 18281.1-2024 Sterilization of Health Care Products - Biological Indicators - Part 1.

General Requirements (ISO 11138-1:2017, IDT)

ISO 11138-1 Sterilization of Health Care Products - Biological Indicators - Part 1. General Requirements

ISO 18472 Sterilization of Health Care Products - Biological and Chemical Indicators - Test Equipment

NOTE: GB/T 24628-2009 Sterilization of Health Care Products - Biological and Chemical Indicators - Test Equipment (ISO 18472:2006, IDT)

3 Terms and Definitions

The terms and definitions defined in ISO 11138-1 are applicable to this document.

The URLs of the terminology databases maintained by ISO and IEC for standardization are as

follows.

4 General Requirements

The requirements of ISO 11138-1 apply.

5.1 The test microorganisms shall be spores of *Bacillus atrophaeus* or other microbial strains

that have been proven to have equivalent performance meeting the requirements of this

document.

NOTE 1: some strains of *Bacillus subtilis* have been re-classified as *Bacillus atrophaeus*.

NOTE 2: *Bacillus atrophaeus* CIP 77.18, NCIMB 8058, DSM 675, NRRL B-4418 and ATCC 9372 or *Bacillus subtilis* DSM 13019 have been found to be suitable strains¹⁾.

5.2 If test microorganisms other than *Bacillus atrophaeus* is used, the applicability of the

resistance of the test microorganisms shall be determined.

6 Bacterial Suspensions

The requirements of ISO 11138-1 apply.

7 Carriers and Primary Packaging

7.1

The applicability of materials for the carriers and primary packaging of biological indicators for dry heat sterilization shall be proven to comply with the requirements of 5.2 and Appendix

B in GB/T 18281.1-2024.

7.2 The exposure conditions for determining compliance shall be as follows.

a) Minimum exposure temperature. 5 °C or above the nominal maximum temperature specified by the manufacturer;

b) Sterilization factor. dry hot air;

c) Maximum exposure temperature. specified by the manufacturer; if not specified by the manufacturer, the maximum exposure temperature should be ≥ 180 °C;

d) Exposure time. ≥ 30 min.

1) *Bacillus atrophaeus* CIP 77.18, NCIMB 8058, DSM 675, NRRL B-4418 and ATCC 9372 or *Bacillus subtilis* DSM

13019 are examples of suitable commercially available products. This information is given for the convenience of

the users of this document and does not constitute an endorsement of these products.

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