

ICS 11.080.01



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

GB/T 18281.2-2024

**Sterilization of health care products - Biological indicators -
Part 2: Biological indicators for ethylene oxide sterilization
processes**

医疗保健产品灭菌 生物指示物 第2部分：环氧乙烷灭菌用生物指示物
(English Translation)

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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 sterilizer and sterilization process use pure ethylene oxide gas or a mixture of ethylene oxide gas and dilution gas, with a sterilization temperature range of 29 °C to 65 °C.

NOTE 1: Requirements for validation and control of ethylene oxide sterilization are found in ISO 11135 and ISO 14937.

NOTE 2: Some national or regional regulations may specify workplace safety requirements.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) 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

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in ISO 11138-1 apply.

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

--- ISO Online Browsing Platform. <http://www.iso.org/obp/>.

4 General Requirements

The requirements in ISO 11138-1 apply.

5 Test Microorganisms

5.1

The test microorganism shall be a *Bacillus atrophaeus* spore, *Bacillus subtilis* spore, or other microbial strains that demonstrate equivalent performance to the requirements of this Document.

NOTE 1: Some strains of *Bacillus subtilis* have been reclassified as *Bacillus atrophaeus*.

NOTE 2: *Bacillus atrophaeus* ATCC 9372, NCTC 10073, NCIMB 8058, DSM 2277, NRRL B-4418, and ICP77.18 have been found to be suitable strains¹).

5.2

If a test microorganism other than *Bacillus atrophaeus* is used, the suitability of the resistance of the test microorganism shall be determined.

6 Bacterial Suspensions

The requirements in ISO 11138-1 apply.

7.1 The suitability of carriers and primary packaging materials used for biological indicators

for ethylene oxide sterilization shall be demonstrated to meet the requirements of 5.2 and Appendix B in GB/T 18281.1-2024.

7.2 The exposure conditions for determining compliance shall be.

- a) Minimum exposure temperature. ≥ 55 °C;
- b) Sterilization factor. Ethylene oxide gas mass concentration ≥ 800 mg/L at relative humidity $\geq 70\%$;

c) Maximum exposure temperature. As stated by the biological indicator manufacturer;

1) *Bacillus atrophaeus* ATCC 9372, NCTC 10073, NCIMB 8058, DSM 2277, NRRL B-4418, and CIP 77.18 are several examples of suitable commercially available products. This information is provided for the convenience of users of this Document and does not imply endorsement of these products.

d) Exposure time. ≥ 6 h.

NOTE: Although within the practical limitations of the ethylene oxide sterilization process, the exposure conditions shall also represent a realistic challenge to the carrier.

8 Contaminated Carriers and Biological Indicators

The requirements in ISO 11138-1 apply.

9 Bacterial Count and Resistance

9.1

The manufacturer shall declare that the resistance characteristics of the biological indicator meet the requirements of 6.4 in GB/T 18281.1-2024.

9.2

The increment of viable count per unit on the biological indicator shall be nominally stated as an integer multiple of $\leq 0.1 \times 10^n$ (e.g., per milliliter of bacterial suspension, per contaminated carrier, or per biological indicator).

9.3

The viable count on the contaminated carrier and biological indicator shall be $\geq 1.0 \times 10^6$.

9.4

Resistance shall be expressed as the D value at 54 °C, in min. The D value of each batch of biological indicator or contaminated carrier shall be nominally stated as the D value at 54 °C (in min), rounded-off to one digit after the decimal point.

9.5

When testing with a mixed test gas (see Appendix B) under the conditions of Appendix A, the D value of suspensions, contamination carriers, or biological indicators containing *Bacillus atrophaeus* spores shall be ≥ 2.5 min at 54 °C. The D value for other microorganisms shall support their application.

9.6

When testing with 100% ethylene oxide test gas (see Appendix B) under the conditions of Appendix A, the D value of suspensions, contamination carriers, or biological indicators

containing *Bacillus atrophaeus* spores shall be ≥ 2.0 min at 54 °C. The D value for other microorganisms shall support their application.

9.7

The resistance characteristics specified in this Document and any other part of ISO 11138 shall be defined using the specific key variables of the used sterilization process.

9.8

The D value shall be determined according to the methods in Appendixes C and D of GB/T 18281.1-2024.

9.9

The determination of D value and survival-kill reaction characteristics requires the use of a resistance meter, and application shall be conducted under specified process parameters (see

Appendix A).

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