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GB/T 18281.3-2024

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes

医疗保健产品灭菌 生物指示物 第3部分：湿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 3 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 18281.3-2015 Sterilization of Health Care

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Products - Biological Indicators - Part 3.Biological Indicators for Moist Heat Sterilization Processes. In comparison with GB 18281.3-2015, apart from structural adjustments and editorial modifications, the main technical changes are as follows.

---The temperature range for z value determination is modified (see 9.5; 9.5 of Version 2015);

---The expression of FBIO value is deleted (see 9.6 of Version 2015).

This document identically adopts ISO 11138-3.2017 Sterilization of Health Care Products - Biological Indicators - Part 3.Biological Indicators for Moist Heat Sterilization.

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 SHINVA Medical Instrument Co., Ltd.;

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Sterilization of Health Care Products - Biological Indicators

- Part 3.Biological Indicators for Moist Heat Sterilization

Processes

1 Scope

This document specifies the requirements for test microorganisms, bacterial suspensions, contaminated carriers, biological indicators and test methods intended for evaluating the performance of moist heat as a sterilization factor in the sterilization processes.

NOTE 1: requirements for validation and routine control of moist heat sterilization are given in ISO 17665.

NOTE 2: regulations in some countries or regions may have provided the safety requirements for workplaces.

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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.

b) Sterilization factor. dry saturated steam. If the biological indicator is used in a moist heat sterilization process without the use of dry saturated steam, for example, an air / steam mixture is used, an appropriate air / steam mixture should be selected and indicated to distinguish it from this document.

c) Maximum exposure temperature. specified by the manufacturer; if not specified by the manufacturer, 140 °C shall be used;

d) Exposure time. >= 30 min.

NOTE: while within the practical limitations of the moist heat sterilization processes, the exposure

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conditions also need to represent realistic challenges for the carriers.

8 Contaminated Carriers and Biological Indicators

The requirements of ISO 11138-1 apply.

9 Bacterial Count and Resistance

9.1

The manufacturer shall declare that the resistance characteristics of the biological indicators

meet the requirements of 6.4 in GB/T 18281.1-2024.

9.2

The increment of each unit of viable bacteria on the biological indicators shall be specified

as integer multiples of <= 0.1 x 10n (for example, per milliliter of bacterial suspension, per

contaminated carrier or per biological indicator).

9.3 The viable bacterial count of the contaminated carriers and the biological indicators shall

be >= 1.0 x 105.

9.4 Resistance shall be expressed as the D value at 121 °C in minutes (min). The manufacturer

may select other temperatures. The D value of each batch of biological indicators or

contaminated carriers shall be specified as the D value [in minutes (min)] at 121 °C, with one

decimal place retained.

9.5 When tested in accordance with Appendix A, the D value at 121 °C of the bacterial

suspensions containing Bacillus stearothermophilus spores, the contaminated carriers or other

biological indicators shall be >= 1.5 min. Other microorganisms shall have a D value that

supports their application. The z value of the test microorganisms in the bacterial suspensions,

and on the contaminated carriers and the biological indicators shall be determined at no

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