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ICS 11.080.01

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 18281.1-2024

Sterilization of health care products-Biological indicators-Part 1: General requirements

医疗保健产品灭菌 生物指示物 第1部分：通则

(English Translation)

Issued on: December 10, 2015

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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1 Foreword

GB/T 18281.1-2024 was issued by State Administration for Market Regulation; Standardization Administration of the PRC on 10 December 2015.

It is one of 7 parts of the GB/T 18281 series.

The GB/T prefix marks a recommended standard. It is not law in itself: it becomes binding when a contract names it, when a regulation or a mandatory standard refers to it, or when a producer declares conformity with it.

2 Scope Preview

This document specifies general requirements for production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and test suspensions, and their components, to be used in the validation and monitoring of sterilization processes. This document specifies basic requirements that are applicable to all parts of GB/T 18281. Requirements for biological indicators for particular specified processes are provided in the relevant parts of GB/T 18281. For biological indicators for which no specific requirements are given, this document applies. Note: National or regional

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regulations can apply. This document does not apply to microbiological test systems for processes that rely on physical removal of microorganisms, e.g. filtration processes or processes that combine physical and/or mechanical removal with microbiological inactivation, such as use of washer disinfectors or flushing and steaming of pipelines. This document, however, can contain elements relevant to such microbiological test systems.

GB/T 18281.1-2024 falls under ICS 11.080.01, in the field of health care technology.

This catalogue holds 845 other GB/T standards in that field.

In this catalogue, GB/T standards carry edition years from 1963 to 2026.

3 Normative references

GB/T 19973.1-2023 - Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018, IDT)

ISO 11135 - Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11138 - -2 Sterilization of health care products - Biological and chemical indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

ISO 14937 - Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO 17665 - -1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

4 Where this standard sits

3 other standards in this catalogue cite it, among them GB/T 18281.2-2024, GB/T 18281.3-2024, GB/T 18281.4-2024.

It is one part of the GB/T 18281 series, of which this catalogue holds 7 parts.

5 About this standard

Issued by: State Administration for Market Regulation; Standardization Administration of the PRC

English translation: about 15 pages (approximate)

6 Related standards

Other parts of this standard:

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GB/T 18281.2-2024 - Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

GB/T 18281.3-2024 - Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes

GB/T 18281.4-2024 - Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes

GB/T 18281.5-2024 - Sterilization of health care products-Biological indicators-Part 5:Biological indicators for low-temperature steam and formaldehyde sterilization processes

GB/T 18281.7-2024 - Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results

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

7 Classification and status

International classification (ICS): 11.080.01

Chinese Standard Classification (CCS): C 47

Prefix GB/T: recommended standard.

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