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

GB/T 19971-2026

Replacing GB/T 19971-2015

**Sterilization of health care products - Vocabulary of terms used
in sterilization and related equipment and process standards**

医疗产品灭菌 灭菌相关设备和灭菌过程标准中使用的术语

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces GB/T 19971-2015 "Terminology for Sterilization of Medical and Health Products". Compared with GB/T 19971-2015, except for the structure...

Aside from adjustments and editorial changes, the main technical changes are as follows.

---The terminology related to medical devices has been removed (see section 2.24 of the 2015 edition);

---The following terms have been revised. dosing measurement system (see 3.94, 2.15 of the 2015 edition), medical product (see 3.137,...).

(See 2.20 of the 2015 edition), inactivation curve (see 3.142, 2.51 of the 2015 edition), load (see 3.172, 2.48 of the 2015 edition), Microbial identification (see 3.190, 2.25 of the 2015 edition), microbial inactivation (see 3.192, 2.21 of the 2015 edition), safety techniques Instructions for use (see 3.267, 2.23 of the 2015 edition), sterility test (see 3.333, 2.53 of the 2015 edition);

---The definitions of the following terms have been changed. calibration (see 3.32, 2.4 of the 2015 edition), product (see 3.243, 2.36 of the 2015 edition), and none.

Bacterial examination (see 3.332, 2.54 in the 2015 edition);

---327 new terms and definitions have been added (see Chapter 3).

This document modifies and adopts the terminology used in ISO 11139:2018, "Sterilization of medical products - Sterilization-related equipment and sterilization processes".

This document has undergone significant structural adjustments compared to ISO 11139:2018. A table comparing the structural numbering changes between the two documents is provided.

See Appendix A.

The technical differences between this document and ISO 11139:2018, and the reasons therefor, are as follows.

---The following terms and definitions have been removed. "sterility assurance", "excipients", "BIOLOGICAL value", "flexible sterilization bag", "influence quantity", "wearing".

"Transparency", "Process Development", "Routine Testing", "Storage Cabinet", "Biopharmaceuticals", "Associated Tissues", "Identification", "Finished Product Testing", "Endpoint", "Medical" "Medical institutions", "Implantable medical products", "National standards", "Penetration type testing devices", "Basic standards", "Reference standards for endotoxins" "Statistical process control" and "organization-based products" (see ISO 11139:2018 and Amd1.2024, 3.17 and 3.108).

3.113.4, 3.119, 3.143, 3.194, 3.210, 3.238, 3.289, 3.330, 3.331, 3.334, 3.335, 3.338.3, 3.339 Standards 3.340, 3.356, 3.358, 3.359, 3.365, 3.372, and 3.375), due to the potential transformation of Chinese standards in the field of disinfection and sterilization into national standards.

Not used in international standards;

---The term and definition of "medical device" (see 3.166 of ISO 11139:2018) have been removed to avoid discrepancies with Chinese regulations;

---The definitions of "accompanying information" and "calibration" have been changed (see 3.6, 3.32, and 3.329 of ISO 11139:2018/Amd1.2024).

3.31), conforms to the regulations of metrology in my country;

---The terms "drug-device combination product," "reproducibility conditions," and "repeatability conditions" have been changed (see 3.55, 3.258, 3.259, ISO 11139. (3.54, 3.230, 3.231 in 2018)

---Added "Exposure Time", "Inactive Ingredients", "Low-Temperature Steam Formaldehyde Sterilization", "Sterility Negative Test", "Zero-Effect Reaction Point", and "Sterility Positive Test".

The terms and definitions of "sexual testing" and "testing period" (see 3.117, 3.143, 3.175, 3.202, 3.208, 3.221, 3.330) make this...

The document is more complete.

The following editorial changes have been made to this document.

---Incorporates the amendments to ISO 11139:2018/Amd1.2024, with the relevant clauses' outer margins marked vertically.

The double lines (||) are used to indicate this.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Disinfection Technology and Equipment (SAC/TC200).

1 Scope

This document defines the terms and definitions used in the sterilization of medical products and related equipment and processes.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The equivalent time [in seconds (s)] for killing microorganisms with a z-value of 10K at 80°C is used to represent the microbial activity in moist heat sterilization processes.

Quantitative indicators of killing efficacy.

absolute pressure

Pressure with absolute vacuum as the zero reference.

Absorbed dose

Irradiation is the ionizing radiation energy transferred to a unit mass of matter.

Acceptable range

refers to the range of statistic considered when the process is under control, with a specific probability falling into it.

access device

Methods for accessing restricted areas of the equipment.

Note: This may be a special key, password, or tool.

Information provided with or labeled on a medical device or accessory.

Note 1: Accompanying information is part of the medical device or accessory and includes information about the user or person responsible for the installation, use, maintenance, decommissioning, and disposal of the medical device or accessory.

The required information, especially regarding safe use.

Note 2: Accompanying information includes labels, markings, instructions for use, technical specifications, installation manuals, quick reference guides, etc.

Note 3: Accompanying information is not necessarily a written or printed document; it may be audio, video, or tactile material and multimedia types (such as CDs, flash drives, websites).

Note 4: Labels include information on medical device packaging.

Note 5: Electronic documents include any type of information provided by the manufacturer, in whole or in part.

Note 6: Market information is also known as promotional materials.

[Source. ISO 20417:2021, 3.2, with modifications]