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

GB/T 19633.1-2024

**Packaging for terminally sterilized medical devices - Part 1:
Requirements for materials, sterile barrier systems and
packaging systems
(English Translation)**

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 1 of GB/T 19633 Packaging for Terminally Sterilized Medical Devices.

GB/T 19633 has published the following parts.

--- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems;

--- Part 2: Validation Requirements for Forming, Sealing and Assembly Processes.

This Document replaced GB/T 19633.1-2015 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.

Compared with GB/T 19633.1-2015, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications.

--- Change the description of scope (see Clause 1 of this Edition; Clause 1 of the 2015 Edition);

--- Add the terms "control", "supervision", "terminally sterilized", "expiration date", "hazard", "intended use", "intended purpose", "process", "reasonably foreseeable misuse", "risk" and their definitions (see 3.5, 3.10, 3.28, 3.29, 3.32, 3.33, 3.34, 3.35 and 3.36 of this Edition);

--- Delete the terms "packaging material" and "recycled material" and their definitions (see 3.9 and 3.14 of the 2015 Edition);

--- Add the requirements for risk management (see 4.2, Annex F of this Edition);

--- Add the sampling requirements for materials and sterile barrier systems (see 4.3 of this Edition);

--- Add the requirements for the microbial barrier properties of materials [see 5.1.7h) of this Edition];

--- Add the requirements for confirming compliance with ISO11607-2 and the sub-clause for reversible seals or closures [see 5.1.9 a), f) of this Edition];

--- Add requirements for aseptic access (see 6.1.2 of this Edition);

--- Add performance evaluation requirements for selection and confirmation of materials and preformed aseptic barrier systems (see 6.2.2 of this Edition);

--- Add labeling requirements on protective packaging of aseptic liquid products (see 6.2.5 of this Edition);

--- Add requirements for usability evaluation of aseptic access (see Clause 7 of this Edition);

--- Add general requirements for performance and stability of packaging systems (see 8.1 of this Edition);

--- Change the test objects of performance tests (see 8.2.2 of this Edition; 6.3.4 of the 2015 Edition);

- Add requirements for forming documents to determine the worst-case principle (see 8.2.3 of this Edition);
- Change the time when real-time aging starts (see 8.3.4 of this Edition; 6.4.4 of the 2015 Edition);
- Add packaging system validation and changes (see Clause 9 of this Edition);
- Add requirements for inspection immediately prior to aseptic presentation (see Clause 10 of this Edition).

This Document equivalently adopted ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.

The following minimal editorial changes were made to this Document.

- Incorporate the amendments of ISO11607-1:2019/Amd.1:2023, and the outer margins of the involved clauses are marked with vertical double lines (||);
- Add NOTE 2 to 3.8;
- Adjust the format of Table B.1, adding a column "Chinese standard number corresponding to the reference standard", and merged "reference standard" and "name" into one column;
- Added NOTE to Annex E;
- Change the numbers of the NOTES in F.2 and F.7.

Please note some contents of this Document may involve patents. The issuing agency of this document shall not assume the responsibility to identify these patents.

This Document was proposed by National Meical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Disinfection Technology and Equipment of Standardization Administration of China (SAC/TC 200).

Drafting organizations of this Document. Guangdong Medical Devices Quality Surveillance and Test Institute; Shanghai MicroPort Medical (Group) Co., Ltd.; DuPont (China) Research & Development and Management Company Limited; Micro-Tech (Nanjing) Co., Ltd.; Shanghai Jianzhong Medical Packaging Co., Ltd.; and Amcor Group, Bemis Flexible Packaging (Suzhou) Co., Ltd.

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The historical editions replaced by this Standard are as follows.

--- GB/T 19633-2005 Packaging for Terminally Sterilized Medical Devices was first-time published in 2005;

--- It was first-time revised in 2015; the standard number and name was adjusted into GB/T 19633.1-2015 Packaging for Terminally Sterilized Medical Devices - Part 1.

Requirements for Materials, Sterile Barrier Systems and Packaging Systems.

1 Scope

This Document specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

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.

ISO 5636-5 Paper and board - Determination of air permeance (medium range) - Part 5.

Gurley method

3.1 Aseptic presentation

Transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination.

3.2 Bioburden

Population of viable microorganisms on or in product and/or sterile barrier system.

4.1 Quality systems

The activities described within this document shall be carried out within a formal quality system.

4.2 Risk management

A risk management process conforming with the requirements of Annex F shall be implemented.