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

GB/T 19633.2-2024

**Packaging for terminally sterilized medical devices - Part 2:
Validation requirements for forming, sealing and assembly
processes**

(English Translation)

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

Directives for standardization - Part 1.Rules for the structure and drafting of
standardizing documents.

This document is Part 2 of GB/T 19633 Packaging for terminally sterilized medical
devices. GB/T 19633 has been published in 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 replaces GB/T 19633.2-2015 Packaging for terminally sterilized
medical devices - Part 2.Validation requirements for forming, sealing and assembly
processes. Compared with GB/T 19633.2-2015, in addition to structural adjustments
and editorial changes, the main technical changes are as follows.

- The description of the scope has been changed (see Chapter 1; see Chapter 1 of
the 2015 edition);

- The terms "aseptic presentation", "closure", "control", "medical device", "microbial barrier", "monitoring", "process parameter", "process specification", "process variable", "seal", "seal strength", "sterile", "terminally sterilized", "hazard", "process" and "risk" and their definitions have been added (see 3.1, 3.2, 3.3, 3.7, 3.8, 3.9, 3.14, 3.15, 3.16, 3.22, 3.23, 3.24, 3.27, 3.29, 3.30 and 3.31);
- The term "process development" and its definition have been deleted (see 3.8 of the 2015 edition);
- The risk management requirements have been added (see 4.2 and Appendix B);
- The sampling requirements for materials and sterile barrier systems have been added (see 4.3);
- The requirements for determining process specifications have been added (see 5.1.3);
- The requirement that the production of preformed sterile barrier systems and sterile barrier systems shall meet the predefined sealing strength has been added in operational qualification (see 5.3.2);
- The requirements for medical devices with sterile fluid circuits marked have been deleted (see 8.2 of the 2015 edition).

This document is identical to ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2. Validation requirements for forming, sealing and assembly processes.

The following minimal editorial changes are made to this document.

- The amendments to ISO 11607-2:2019/Amd.1:2023 are incorporated, and the outer margins of the clauses involved are marked with vertical double lines (||);
- The NOTE 2 is added to 3.7;
- The note numbers in B.2 are changed.

2 Validation requirements for forming, sealing and assembly processes;

-- This is the second revision.

1 Scope

This document specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes the requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 19633.1-2024 Packaging for terminally sterilized medical devices - Part 1. Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019, IDT)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses.

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

4 General requirements

The sampling plans used for the selection and testing of materials, sterile barrier systems or packaging systems shall be applicable to materials, sterile barrier systems or packaging systems being evaluated. Sampling plans shall be based upon statistically

valid rationale.

5 Validation of packaging processes

The documentation shall summarize and reference all protocols and results, and state conclusions regarding the validation status of the process.

Processes concerning forming, assembly, sealing or closing shall be covered by a change-control procedure for documenting, verifying and authorizing changes.

6 Assembly

Packaging systems shall be assembled and filled according to the instructions based on a validated process that enables sterilization in a defined sterilization process. These instructions should include the configuration of contents and organizing inserts, total weight, inner wrapping and absorbent materials.

7 Use of reusable sterile barrier systems

In addition to the requirements listed in Chapter 6, provisions in GB/T 19633.1-2024,

5.1.10 and 5.1.11 shall be followed (e.g. assembly, disassembly, maintenance, repair, storage).

8 Sterile fluid-path packaging

Assembly of sterile fluid-path components and closures shall meet the requirements of Chapter 5 and Chapter 6.

Appendix A

(informative)

Process development

Process development, while not a formal part of process validation, should be considered as an integral part of forming and sealing. Process development or process design requires an assessment to identify and evaluate.

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