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

SN/T 3062.4-2011

**Packaging materials for terminally sterilized medical devices for
import. Part 4: Requirements for materials and sterile barrier
systems of importing medical device sterilization packaging**

进口医疗器械灭菌包装 第4部分：材料和预成型无菌屏障系统要求

(English Translation)

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Foreword

SN/T 3062 "import medical equipment sterilization packaging" is divided into four parts.

- Part 1. forming, sealing and assembly processes to confirm the request;
- Part 2. Paper bags - Requirements and test methods;
- Part 3. sealable bags and coil combination requirements and test methods breathable material and plastic film composition;
- Part 4. Materials and preformed sterile barrier system requirements.

This section SN/T 3062 Part 4.

This section drafted in accordance with GB/T 1.1-2009 given rules.

This part is to modify the use of ISO 11607-1:2006 "Packaging for terminally sterilized medical devices - Part 1. materials, sterile barrier systems and packaging requirements of the system "(in English).

This part uses ISO 11607-1:2006 When the editorial changes, the main differences are as follows.

- Remove the ISO 11607-1:2006 in the preface, Annex A, Annex B and Annex ZA and references;
- The ISO 11607-1:2006, Annex C of this part as Appendix A;
- Of ISO 11607-1:2006 structure before and after the body was arranged, do not meet the inspection and quarantine work in the industry were content Deletion;
- Remove the ISO 11607-1:2006 requirements in Chapter IV;
- The ISO 11607-1:2006 Section 5.1 of Chapter 4 as a part of;
- The ISO 11607-1:2006 Section 6.3 of Chapter 5 as a part of;
- The ISO 11607-1:2006 Section 6.4 of Chapter 6 as a part of;

- The ISO 11607-1:2006 Section 5.2 in Chapter 7 as a part of;
- The ISO 11607-1:2006 Section 5.3 in Chapter 8 as a part of;
- The ISO 11607-1:2006 Section 5.4 of Chapter 9 as a part of;
- The ISO 11607-1:2006 Section 5.5 in Chapter 10 as a part of;
- Removed 11607-1 ISO .2006 in 6.1 and 6.2 of the content;
- Remove the ISO 11607-1:2006 Content Chapter 7.

This section proposed and managed by the National Certification and Accreditation Administration Committee.

1 Scope

SN/T 3062 provisions of this part of the imports of medical equipment sterilization packaging materials and sterile barrier system requirements and test methods preform.

This section applies to imports of medical equipment sterilization packaging materials and preformed sterile barrier system test.

This section does not include a requirement that the sterile barrier system on drug/device combination and the various stages of production and quality control assurance system.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 458 Paper and board - Determination of air permeability (ISO 5632-2. 1984, ISO 5636-3:1992, ISO 5636-5:2003, MOD) Processing ANSI/AAMIST65 used in health care facilities reusable surgical textiles

3 Terms and Definitions

The following terms and definitions apply to this document.

Introducing sterile asepticpresentation Using from microbial contamination conditions and procedures for the introduction and transfer of sterile products.

Bioburden

Product or sterile barrier system or in the number of viable microorganisms.

Closed closure

Close sterile barrier system without a method for forming a seal.

Example. a reusable container gasket or repeatedly folded to form a curved path can close a sterile barrier system.

Closed integrity closure integrity Closure property to ensure the prevention of microbial entry under specified conditions.

NOTE: See 3.8.

Validity expiry date

Date This date may be used in the product, expressed in years and months.

Tag labeling

Medical equipment or medical devices or packaging that comes with writing, printing, electronic or graphic symbols.