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

SN/T 3062.2-2011

**Packaging materials for terminally sterilized medical devices for
import. Part 2: Paper bags. Requirements and test methods**

进口医疗器械灭菌包装 第2部分：纸袋-要求和试验方法
(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 2.

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

The partial modification using BSEN868-4:2009 "sterile medical device packaging materials - Part 4. Paper bags - Requirements and determination method".

This portion BSEN868-4. compared to 2009, made the following changes.

- Modify the standard structure, format, chapter is structured;
- Modify the normative references;
- Deleted Appendix A "to this European standard and the previous version of the major technological changes more";
- BSEN868-4:2009 in Appendix B and Appendix C of this standard as Appendix A and Appendix B.

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

1 Scope

SN/T 3062 This section specifies the requirements and test methods for paper bags imported medical devices, and its purpose is to protect the final sterilization Sterile medical equipment requirements.

This Part of the paper used for imports of medical equipment sterilization packaging applies only to unique applications.

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.

Packaging materials and systems - Part 3 EN868-3 medical sterilization items. Sterilization of medical devices and systems for the production of packaging materials Paper bag with paper (see detailed provisions EN868-4) and production of pouches and reels of paper requirements and test methods (see EN868-5 detailed provisions) Constant rate extension method. Part 2 ISO 1924-2 Determination of tensile properties of paper and board ISO 6588-2:2005 Determination of pH paper, paperboard and pulp water extraction Characterization data exchange format information and times ISO 8601 Data and Information Exchange ISO 9197 Determination of paper, paperboard and pulp water-soluble chlorides ISO 9198 Determination of paper, paperboard and pulp water soluble sulphates ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1. General requirements ISO 11607-1:2006 final packaging sterilized medical devices - Part 1. materials, sterile barrier systems and packaging systems requirements

3 Terms and Definitions

ISO 11607-1:2006 definition of terms and definitions apply to this document.

4.1 General

See ISO 11607-1:2006 requirements. Forming process validation requirements, sealing, assembly process, see ISO 11607-2.

NOTE: ISO 11607-1:2006 5.1.4 refers to the production and processing conditions influence (for electrostatic conductivity, bioburden) for its products.

4.2.1 General

4.2.1.1

paper should be unified according to EN868-3 specified by the manufacturer.

4.2.1.2

The following terms shall be described in a paper bag design.

- a) the back. paper bags have a longitudinal seam side;
- b) front. no bags longitudinal seam side;