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

SN/T 0323.3-2007

Replacing SN/T 0964-2000

**Rules for the inspection of medical equipment for import and
export. Part 3: Plastics collapsible containers for human blood.
Blood components conventional containers**

进出口医疗器械检验规程 第3部分：人体血液及血液成分袋式塑料容器 传统型血
袋

(English Translation)

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Foreword

SN/T 0323 "Importers of medical equipment for the inspection," is divided into three parts.

- Part 1. one-time infusion (blood) control;
- Part 2. a one-time use of sterile syringes;
- Part 3. human blood and blood components bag plastic containers conventional blood bag.

This section SN/T Section 30323 of.

The partial replacement of SN/T 0964-2000 "Importers disposable plastic bags for the inspection." this section compared with the SN/T 0964-2000 The main changes are as follows.

- Technical requirements and test methods used in the ISO 3826-1:2003 international standard;
- Term corresponds with international standards;
- Modify the scope of regulations;
- Inspection of the product name was changed to conventional disposable plastic bags by the blood bag;
- In the chemical requirements to remove the "zinc", adding "metal, color, ammonium ions and alcohol effluent" inspection requirements;
- Removed in the biological requirements "mold, blood storage test, acute systemic toxicity," added "microbial impermeability, cytotoxic "Of testing and require the sterilization process control for each batch sterilization validation reports and batch quality records;
- In the physical requirements to remove the "seal blood bags, transfer bags airtight, eccentric resistance, temperature resistance, water vapor permeability, sticky labels Even firmness, "increased" thermal stability, resistance to leakage, revealing vapor, particulate pollution "inspection requirements;

--- Increased imports conformity assessment models;

--- Increase unpacking inspection test mode.

Appendix A of this section is an informative annex.

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

1 Scope

SN/T 0323 provisions of this part of the sampling, testing and qualification of import and export of traditional bags judgment.

This section applies to a closed, sterile row or even conventional blood bag (hereinafter referred to as "blood bags"), which can bring blood collection bags, blood transfusion jack, Lancets and transfer tube. According to requirements, anticoagulants and blood bags can be loaded (or) maintenance solution.

2 Normative references

The following documents contain provisions which, through reference SN/T 0323 this section, constitute provisions of this part. For dated reference documents Member, all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to reach under this section Parties to research agreement to use the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 2828.1 Sampling procedures for inspection - Part 1. by acceptance quality limit (AQL) retrieval batch inspection sampling plan (ISO 2859-1:1999, IDT) GB 14232.1-2004 human blood and blood components bag plastic containers - Part 1. Conventional blood bags (ISO 3826-1.

2003, IDT)

The basic provisions of SN/T 0002 Electromechanical Import and Export Commodity Inspection procedures prepared Symbol YY0466 medical equipment used with medical device labels, labeling and information provided People's Republic of China Pharmacopoeia (2005 edition)

3 Terms and Definitions

GB/T 2828.1, SN/T 0002 and established the following terms and definitions apply to SN/T 0323 of this section.

According to a predetermined cycle based on national technical specifications mandatory requirements, type testing, according to the scene to examine the provisions of the product

or batch Pumping batch sampling, determination and implementation of qualified supervision activities of the enterprise quality management system.

Mandatory requirements by national technical specifications, by checking the technical documentation and the necessary by-batch or batch sampling pump, for goods Compliance Judgment and evaluation activities.

When imported goods at the port of entry in accordance with relevant state regulations for goods related files, documents, technical data and goods mainly conducted Inspection activities.

For the implementation of sampling and collection of the same specifications, models, produced under the same conditions of production per unit of product, referred to as batch.