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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

SN/T 0323.1-2007

Replacing SN/T 0967-2000

Rules for the inspection of medical equipment for import and export. Part 1: Infusion and transfusion sets for single use

进出口医疗器械检验规程 第1部分：一次性使用输液(血)器

(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 10323 of.

The partial replacement of SN/T 0967-2000 "export disposable infusion, blood transfusion test procedures." this section compared with the SN/T 0967-2000 The main changes are as follows.

--- Increased imports of disposable infusion (blood) section;

--- Technical requirements and test methods used in ISO 8536-4:2004, ISO 1135-4:2004, ISO 594-1. 1986 and other international standard;

--- Term corresponds with international standards;

--- Modify the scope of regulations;

--- Increased the intake device, protective cover and injection member requirements;

--- Provide increased process control inspection lot sterilization validation reports and batch quality records;

--- Increased imports conformity assessment models;

--- Increase unpacking inspection test mode.

This section in Appendix A and Appendix B is an informative annex.

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

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1 Scope

SN/T 0323 provisions of this part of the import and export one-time infusion (blood) the sampling, testing and conformity determination.

This section applies to single-use, disposable type gravity infusion (hereinafter referred to as the "infusion") and one-time use of transfusion Hematocrit (hereinafter referred to as "blood transfusion").

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 8368-2005 disposable infusion gravity infusion of formula (ISO 8536-4:2004, MOD) GB 8369-2005 disposable blood transfusion (ISO 1135-4:2004, MOD) GB/T 14233.1 Infusion, transfusion, injection equipment - Part 1. Chemical analysis GB/T 14233.2 Infusion, transfusion, injection equipment test methods - Part 2. Biological test methods GB 18671-2002 disposable intravenous infusion needle 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

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 the mandatory requirements of national technical specifications 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

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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.

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