

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

SN/T 0323.2-2007

Replacing SN/T 0323-1994

**Rules for the inspection of medical equipment for import and
export. Part 2: Sterile hypodermic syringes for single use**

进出口医疗器械检验规程 第2部分：一次性无菌注射器

(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 20323 of.

The partial replacement of SN/T 0323-1994 "Importers time use of sterile syringes for the inspection." this section compared with the SN/T 0323-1994 The main changes are as follows.

--- Technical requirements and test methods to modify the use of ISO 7886-1:1993 international standard;

--- Term corresponds with international standards;

--- Modify the scope of application of procedures;

--- Increased coat, hands spacing requirements of the piston;

--- Increased its needle 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, Appendix B Appendix informative.

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

1 Scope

SN/T 0323 provisions of this part of the import and export disposable sampling, testing and conformity determination sterile syringe.

This section applies to the body as a subcutaneous, intramuscular, intravenous injection of the drug solution and other one-time use, for pumping liquid or liquid injection after Now use sterile syringe injection manually (hereinafter referred to as "syringe").

This section does not apply to disposable insulin syringes, glass syringe with needle permanent syringes, with power-driven syringe pumps , A manufacturer of prefilled syringes, as well as with the liquid supporting the syringe.

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/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 15810-2001 disposable sterile syringes (eqv ISO 7886-1:1993) GB 15811-2001 disposable sterile needles (eqv ISO 7864:1993) 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 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.