Chinastandards.org

ICS 11.040.01
CCS C37

SN

INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

SN/T 1672.1-2013

Rules for the inspection of import and export medical equipment. Part 1: General requirements

进出口医用设备检验规程 第1部分：通用要求

(English Translation)

Issued on: March 1, 2013 **Implemented on: September 16, 2013**

Issued by: General Administration of Customs

Preview: page 1 of 3 shown, 6 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/sn-t-1672-1-2013

Chinastandards.org

Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and Definitions

Foreword

SN/T 1672 "Importers of medical equipment for the inspection," is divided into six parts.

--- Part 1. General requirements;

--- Part 2. whole body spiral CT scanner;

--- Part 3. Transcranial Doppler blood analyzer;

Part -- Chapter 4. B-type ultrasonic diagnostic equipment;

--- Part 5. diagnostic X-ray machine;

--- Part 6. magnetic resonance equipment for medical diagnosis.

This section SN/T 1672 Part 1.

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

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents.

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

1 Scope

SN/T 1672 This section specifies the general requirements for inspection of import and export of medical equipment.

This section applies to a sample import and export of medical electrical equipment, inspection and judgment.

Preview: page 2 of 3 shown, 6 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/sn-t-1672-1-2013

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 2828.1 Sampling procedures for inspection - Part 1. by acceptance quality limit (AQL) retrieval batch inspection sampling plan GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety the basic provisions of SN/T 0002-2004 Electromechanical Import and Export Commodity Inspection procedures prepared YY0505-2005 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and tests

3 Terms and Definitions

GB 9706.1-2007 and SN/T 0002-2004 and defined the following terms and definitions apply to this document.

Medical equipment and a specialized power supply network has more than one connection to the patient under medical supervision for diagnosis, treatment or care with patients or electrical contact with the body, and (or) obtained from the patient or the patient transferred energy, and (or) detects these transmitted or made energy electric Gas equipment. Accessories also include those designated by the manufacturer, the equipment can be used normally required.

Inspection Lot for the implementation of sampling and collection of the same specifications, models, under the same conditions of production per unit of product produced is called the inspection lot, referred to as batch.

Type Test mode modeoftypetest According to a predetermined cycle based on the mandatory requirements of national technical specifications type testing, according to on-site inspection requirements for product pumping batch inspection Inspection, supervision and implementation of the conformity assessment activities of the enterprise quality management system.

Sampling mode modeofsamplinginspection According to the mandatory requirements of national technical specifications, batch import and export commodities or pumping batch sampling, testing and inspection of conformity assessment activities.

Compliance Verification mode modeofcomplanceqssessment According to the mandatory requirements of national technical specifications, inspection and testing documents Document is consistent with the goods, if necessary, carry out random inspection, and Conformity assessment activities supervision.

Preview: page 3 of 3 shown, 6 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/sn-t-1672-1-2013