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

SN/T 1672.8-2013

Replacing SN/T 1430.1-2004

**Rules for the inspection of import and export medical
equipment. Part 8: Ultrasonic diagnostic and physiotherapy
equipment**

(English Translation)

Issued on: January 1, 1970

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Issued by: General Administration of Customs

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Foreword

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

- 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;
- Part 7. medical endoscopes;
- Part 8. Ultrasound diagnostic and physiotherapy equipment.

This section SN/T 1672 Part 8.

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.

The partial replacement of SN/T 1430.1-2004 "the inspection of imported medical devices. ultrasonic medical diagnostic and therapeutic equipment." this section compared with the SN/T 1430.1-2004, in addition to editorial changes outside the main technical changes are as follows.

- Changing the name of the standard, the scope of application;
- Increased electromagnetic compatibility, environmental protection, energy efficiency and other requirements;
- Modify the test items, test content, test methods;

--- Provides a variety of inspection and supervision model and test methods.

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

This section drafted by. People's Republic of China Zhejiang Exit Inspection and Quarantine.

1 Scope

This section SN/T 1672 provisions sampling Importers ultrasonic medical diagnostic and treatment equipment, inspection and judgment.

This section applies to import and export inspection and export of ultrasonic medical diagnostic and treatment equipment.

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 GB 9706.7-2008 Medical electrical equipment - Part 2-5. Particular requirements for the safety of ultrasonic physiotherapy equipment GB 9706.9-2008 Medical electrical equipment - Part 2-37. Ultrasound diagnostic and monitoring equipment requirements for the safety GB 9706.15-2008 Medical electrical equipment - Part 1-1. General requirements for safety Collateral standard. medical electrical systems security Claim GB/T 16846-2008 acoustic output of medical diagnostic ultrasonic equipment disclosure requirements the basic provisions of SN/T 0002-2004 Electromechanical Import and Export Commodity Inspection procedures prepared YY0505 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.

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, the import and export commodities batch or batches pumping conformity assessment sampling, testing and inspection activity.

Compliance Verification mode modeofcomplianceinspection 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.