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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

SN/T 1672.6-2013

Rules for the inspection of import and export medical equipment. Part 6: Magnetic resonance imaging equipment for medical diagnosis

进出口医用设备检验规程 第X部分：医疗诊断用磁共振设备

(English Translation)

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

Issued by: General Administration of Customs

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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 6.

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 provides import and export of medical diagnosis using magnetic resonance equipment inspection requirements.

This section applies to the import and export of medical diagnostic magnetic resonance apparatus with the import and export of sampling, testing and judgment.

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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 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 YY0319-2008 Medical electrical equipment - Part 2-33. Medical diagnostic equipment requirements for the safety of magnetic resonance 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, YY0319-2008 and SN/T 0002-2004 and defined the following terms and definitions apply to this file.

Medical diagnostic magnetic resonance apparatus magneticresonanceimagingequipmentformedicaldiagnosis in medical diagnostics, used in magnetic resonance imaging of the human body for medical electrical equipment.

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 modeofcomplanceassessment 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.

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