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

SN/T 1430.1-2004

**Imported medical equipment for the inspection of ultrasonic
medical diagnostic and treatment equipment**

进口医疗器械检验规程 医用超声诊断和治疗设备

(English Translation)

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Foreword

This standard is proposed and managed by the National Certification and Accreditation Administration.

This standard was drafted. Zhejiang Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China.

1 Scope

This standard specifies the sampling, inspection and determination of the results of imported medical ultrasound diagnostic and therapeutic equipment.

This standard applies to the inspection of imported medical ultrasound diagnostic and therapeutic equipment.

2 Normative references

The terms in the following documents become the terms of this standard by reference to this standard. All dated references, followed by all Modifications (not including errata content) or revisions do not apply to this standard, however, parties to agreements based on this standard are encouraged to study is it possible to use the latest version of these files? For undated references, the latest edition applies to this standard.

GB/T 2828.1. Sampling and sampling procedures - Part 1 . Batch-to-batch sampling plan searched by the acceptance quality limit (AQL) GB 9706.1-1995 Medical electrical equipment - Part 1. General requirements for safety

3 Terms and definitions

The following terms and definitions apply to this standard.

The same batch of imported medical ultrasonic diagnostic and therapeutic equipment of the same specification and model under the same contract is called an inspection batch, referred to as the batch.

4.1 Inspection method

The settlement inspection is divided into unpacking inspection and machine performance and safety inspection, and each batch must be inspected.

4.2.1 Sampling conditions

The batch submitted for sampling shall be inspected by the manufacturer and a valid quality inspection report shall be provided.

4.2.2.1 Sampling plan and inspection level

The settlement inspection adopts GB/T 2828.1 normal inspection once sampling plan, and the inspection level is special inspection level S-1.

4.2.2.2 Receive quality limit AQL value

Consignment inspection non-conforming products are classified into Class A, Class B and Class C.

--- Class A non-conforming product. not allowed;

--- Class B non-conforming product. AQL=1.5;

---C non-conforming product. AQL=4.0.

4.2.3 Sampling method

Samples were randomly drawn from the batch.

4.3.1 Unpacking inspection

The unpacking inspection items are packaging, appearance, marking, random documents and specifications. The quality requirements, inspection methods and unqualified classification are shown in Table 1.

4.3.2 Machine performance and safety inspection

Machine performance and safety inspection items are protective grounding and functional grounding, continuous leakage current and patient auxiliary current, dielectric strength and performance