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

SN/T 3696-2013

**Risk assessment guideline for inspection of imported
mechanical and electrical products to be remanufactured
(English Translation)**

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Foreword

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

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

This standard was drafted. People's Republic of China SZCIQ, People's Republic of China Jiangsu Entry-Exit Inspection and Quarantine Bureau, People's Republic of China Guangdong Entry Inspection and Quarantine Bureau.

1 Scope

This standard specifies the determination and use of mechanical and electrical products import remanufacturing inspection-related hazards, estimate and evaluate the associated risks, control these risk, control (measures) to monitor the effectiveness of the

program. This standard does not specify acceptable risk levels.

This standard applies to imports of electromechanical products remanufacturing uses a risk assessment test.

Requirements of this standard apply to imports of mechanical and electrical remanufacturing all stages of product testing purposes.

NOTE: In drafting this standard is assumed by a person suitably qualified and experienced use this guide.

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 20000.4 Guide for standardization - Part 4. Safety aspects Standard GB/T 23694 risk management terminology SN/T 2447.2-2010 inspection General requirements for the import and export of electromechanical products - Part 2. Risk Assessment ISO 14971 Medical Device Risk Management for Medical Device Applications

3 Terms and Definitions

GB/T 23694 and ISO 14971 define the following terms and definitions apply to this document. For ease of use, the following repeating Lists the GB/T 23694 and definitions of certain terms of.

Risk risk

Import inspection activities in remanufacturing use mechanical and electrical products, the impact of product safety, health, environmental protection, anti-fraud and other events and probability A combination of its consequences. At the same time should be considered relevant laws and regulations, social concern, economic viability and environmental factors.

Note 1: Adapted from GB/T 23694-2009, the definition of 3.1.1.

Note 2: This definition does not specify the events and consequences of correspondence.

Risk management for risk analysis, evaluation, control, monitoring and review procedures and practices to system operation.

Note: Adapted from ISO 14971, definitions 2.22. This definition adds support for analysis and evaluation after the review process.

Risk analysis the re-use products manufactured during the inspection of risk identification, process descriptions and estimates.

Note: Adapted from GB/T 23694-2009, the definition of 3.3.2.