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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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GB/T 28922-2012

Technical aids for persons with disability -- Environmental control systems for daily living

Issued on: October 12, 2012 **Implemented on: February 1, 2013**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, Standardization Administration of the People's Republic of China

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Foreword

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

This standard uses the translation method identical with ISO 16201.2006 "aids for disabled persons everyday environment control system" (English

Version).

Correspondence between the consistency of the standards of international documents and normative references of the following documents.

--- GB 4208 housing protection (IP Code) (GB 4208-2008, IEC 60529.2001, IDT)

--- GB 4943 Safety of Information Technology Equipment (GB 4943-2001, IEC 60950-1.1999, IDT)

--- GB 7247.1 Safety of laser products - Part 1. Equipment Classification, Requirements and User's Guide (GB 7247.1-2001,

IEC 60825-1.1993, IDT)

--- GB 9706.1 Medical Electrical Equipment Part 1. General requirements for safety (GB 9706.1-2007, IEC 60601-1.

1988 A1.1991 A2.1995, IDT)

--- GB 9706.15 Medical electrical equipment - Part 1-1. General Requirements for Safety Collateral Standard. Safety requirements for medical electrical systems

(GB 9706.15-2008, IEC 60601-1-1.2000, IDT)

--- YY/T 0316 Medical Devices Risk Management for Medical Device Applications (YY/T 0316-2008, ISO 14971.2007,

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IDT)

The standard proposed by the People's Republic of China Ministry of Civil Affairs.

This standard by the national rehabilitation and special equipment Standardization Technical Committee on Persons with Disabilities (SAC/TC148) centralized.

This standard was drafted. national rehabilitation aids research center, Shanghai Rehabilitation Devices Association.

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Introduction

This standard gives the proof at the same time as the environmental control system of persons with disabilities in line with EU medical device guidelines 93/42EEC Appendix 1

Test Method for the basic requirements summarized. The standard test methods other than give guidance show compliance with the requirements.

Aids for disabled persons standard score below three levels, a maximum.

A. General requirements for assistive devices;

Class 2. Particular requirements for the series of assistive devices;

Three levels. the specific requirements of various types of assistive devices.

If for a particular class of assistive devices or aids existing standards (secondary or tertiary), a lower level to a higher standard priority, etc.

Class standards. Therefore, when all the requirements set forth specific aids, it is necessary to start from the lowest current standards.

This standard is the same time as the environmental control system with disabilities medical equipment secondary and tertiary (lowest level) portfolio standards, see the range.

Aids for disabled persons

Everyday environmental control system

1 Scope

The standard provides for mitigation, functional and technical requirements and test methods for disability compensation for environmental control systems.

NOTE. This system is also known as electronic aids for everyday use.

This standard is intended for environmental control systems and safety requirements given by the manufacturer recommendations.

This standard does not include the target device. Technical requirements for equipment connected to the system should follow their own specific criteria, such as adjustable beds.

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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.

ISO 14971 Medical Device Risk Management for Medical Device Applications (Medicaldevices-Applicationofriskmanage-

menttomedicaldevices)

IEC 60529 protection provided by enclosures (IP code) [Degreesofprotectionprovidedbyenclosures (IPCode)]

IEC 60601-1 Medical electrical equipment - Part 1. General requirements for safety (Medicalelectricalequipment-Part 1.

Generalrequirementsforbasicsafetyandessentialperformance)

IEC 60601-1-1 Medical electrical equipment - Part 1-1. General Requirements for Safety Collateral Standard. Safety requirements for medical electrical systems

(Medicalelectricalequipment-Part 1-1. Generalrequirementsforsafety-Colateralstandard. Safety

requirementsformedicalelectricalsystems)

IEC 60825-1 Safety of laser products - Part 1. Equipment Classification, Requirements and User's Guide (Safetyoflaserproducts-

Part 1. Equipmentclassification, requirementsanduser'sguide)

IEC 60950-1 Safety of Information Technology Equipment (Informationtechnologyequipment-Safety-Part 1. General

requirements)

EN55011 industrial, scientific and medical radio-frequency equipment - Radio disturbance characteristics limits and test methods (Industrial, scientific

and medical (ISM) radio-frequency equipment-Radio disturbancecharacteristics-Limitsand

methodsofmeasurement)

3 Terms and Definitions

As defined in IEC 60601-1 and the following terms and definitions apply to this document.

3.1

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Application part appliedpart

Environmental control system, to run its function in normal use, with the necessary contact portion of the body of persons with disabilities.

Example. If installed in the body of persons with disabilities (close) microphone.

3.2

The central unit centralunit

From the input and (or) the target device for receiving and processing information and outputs the signal unit to perform the correct function.

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