

ICS 11.040.40

CCS C 35



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

GB/T 30659-2014

**External limb prostheses and external orthoses --
Requirements and test methods**

假肢和矫形器 要求和试验方法

(English Translation)

Issued on: December 31, 2014

Implemented on: July 1, 2015

Issued by: Standardization Administration of China

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References

Foreword

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

This standard uses the translation method identical with ISO 22523:2006 "prosthetics and orthotics requirements and test methods." Correspondence between the consistency of the standards of international documents and normative references of the following documents.

--- GB 4706.8-2008 household and similar electrical appliances - Safety blankets, pads and similar flexible heating appliances special Requirements (IEC 60335-2-17:2006, IDT);

--- GB/T 14191.1-2009 Prosthetics and orthotics academic language - Part 1. external limb prostheses and external orthoses Basic terms (ISO 8549-1. 1989, IDT);

--- GB/T 15721.1-2009 Prosthetics and orthotics - Limb deficiencies - Part 1. congenital limb deficiencies described party Method (ISO 8548-1. 1989, IDT);

--- GB/T 15721.2-2009 Prosthetics and orthotics - Limb deficiencies - Part 2. Method of

describing lower limb amputation stumps (ISO 8548-2:1993, IDT);

Method of describing upper limb amputation stumps. --- GB/T 15721.3-2009 Prosthetics and orthotics - Limb Part 3 missing (ISO 8548-3:1993, IDT);

--- GB/T 17255.1-2009 Prosthetics and orthotics - Classification and description of prosthetic components - Part 1. Classification of prosthetic components (ISO 13405-1:1996, IDT);

--- GB/T 17255.2-2009 Prosthetics and orthotics - Classification of prosthetic components and description Part 2. lower limb prosthetic components Description (ISO 13405-2:1996, IDT);

--- GB/T 17255.3-2009 Prosthetics and orthotics - Classification of prosthetic components and description Part 3. upper limb prosthetic components Description (ISO 13405-3:1996, IDT);

--- GB/T 17626.3-2006 Electromagnetic compatibility - Testing and measurement techniques RFEMS test (IEC 61000-4-3:2002, IDT);

--- GB/T 19543-2004 prosthetic hip structure inspection (ISO 15032:2000, IDT);

--- YY0505-2012 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and Test (IEC 60601-1-2:2004, IDT).

This standard made the following editorial changes.

--- 4.4.4 in the second column item number repetitions of the letters "a)" to "b)", "b)" to "c)", "c)" to "d)";

--- D.6.4 Note the number "Note 5" to "Note 4." 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 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.

Introduction

This standard gives as medical equipment prosthetics and orthotics compliance with EU Directive 93/42 appendix/EEC 1 describes medical Basic treatment equipment required authentication method.

This standard also gives radio equipment with 3.8 defined prosthetics and orthotics

compliance with EU Directive 99/5/EC of the radio set Equipment and basic requirements for telecommunications terminal equipment authentication method.

The standard authentication method meet other requirements of the Directive is not given.

Aids standard score below three, 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 there are existing standards (two or three) for a particular class of auxiliary aids or devices, the lower-level standards take precedence over the more Grade standards. Therefore, when all the requirements set forth specific assistive devices, it is necessary to reference the existing minimum grade standards.

This standard is secondary and tertiary (lowest level) combination of standard prosthetics and orthotics, see the range.

This standard, in addition to the existing reference test standards, test methods for several types of prosthetics and orthotics also see Appendices A to D. respectively this standard relations with the EU Directive, see Appendix E.

NOTE: Although this standard EN12181 standard level of the auxiliary appliance "aids - General requirements and test methods" are not mentioned, but it is recommended that the reference to standard.

Prosthetics and orthotics requirements and test methods

1 Scope

This standard gives requirements and test methods of prosthetics and orthotics ISO 9999 classified as follows.

0603-0615 orthosis

0618-0627 prostheses this standard covers strength, materials, usage restrictions, risk and normal conditions of use and the related components and component assembly information.

Due to special corrective seat does not belong to ISO 9999 and is a non-classified orthotics normal wearing article, this standard does not include special corrective seat.

Note 1: This standard will be included in future the new orthopedic shoes (0633 classification).

Note 2: The ISO 13485 and ISO 13488 quality system set forth or referred to are suitable.