

ICS 11.180  
CCS C45



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

**GB/T 24437-2023**

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**Division and evaluation of fitting institution grade for  
prostheses and orthoses**

假肢、矫形器配置机构的等级划分与评定

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## Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. This document replaces GB/T 24437-2009 "Classification of Prosthetic Orthotics Production and Assembly Mechanisms" and is consistent with GB/T 24437-2009. In addition to structural adjustments and editorial changes, the main technical changes are as follows:

- a) The number of divided levels has been changed, increasing the level division to 5 levels (see 4.1, Chapter 6, 4.1, Chapter 6 of the.2009 edition chapter);
  - b) Changed the "General Provisions" to "Classification and Use of Marks" (see Chapter 4, Chapter 4 of the.2009 edition), and added the validity of the grades Deadline, review, upgrade, downgrade, inability to apply for or cancel the grade (see 4.3~
  - c) Added "basic requirements" (see Chapter 5) and deleted the basic requirements in service quality requirements (see
- 5.2 of the.2009 version);

- d) Changed the specific requirements for business sites in AA level and above (see 6.2.1, 6.3.1, 6.4.1, 6.5.1, 2009 edition 6.2.1, 6.3.1, 6.4.1);
- e) The specific requirements for service facilities in each level have been changed (see 6.1.2, 6.2.2, 6.3.2, 6.4.2, 6.5.2, 2009 version 6.1.2, 6.2.2, 6.3.2, 6.4.2);
- f) The specific requirements for special equipment in each level have been changed (see 6.1.3, 6.2.3, 6.3.3, 6.4.3, 6.5.3, 2009 edition 6.1.3, 6.2.3, 6.3.3, 6.4.3);
- g) Changed "personnel qualification" in each level to "professional technical team" (see 6.1.4, 6.2.4, 6.3.4, 6.4.4, 6.5.4, 2009 edition 6.1.4, 6.2.4, 6.3.4, 6.4.4);
- h) Changed the specific requirements for technical capabilities in each level (see 6.1.5, 6.2.5, 6.3.5, 6.4.5, 6.5.5, Appendix A, 2009 Versions 6.1.5, 6.2.5, 6.3.5, 6.4.5);
- i) Added the index requirements for service quality in each level (see 6.1.6, 6.2.6, 6.3.6, 6.4.6, 6.5.6), deleted "service quality" Quantity" (see Chapter 5 of the 2009 edition);
- j) The specific requirements for operation and management at each level have been changed (see 6.1.7, 6.2.7, 6.3.7, 6.4.7, 6.5.7, 2009 version 6.1.6, 6.2.6, 6.3.6, 6.4.6);
- k) Added index requirements for innovation capabilities at AAA level and above (see 6.3.8, 6.4.8, 6.5.8);

## 1 Scope

GB/T 24437-2023 grades the facilities that fit prostheses and orthoses. A prosthetic limb or a spinal orthosis is not a product that can be bought and used: it has to be prescribed, cast or scanned, fabricated, fitted, aligned and adjusted over months, and the outcome depends far more on the skill of the practitioner and the equipment available than on the components themselves. A poorly fitted socket is not merely uncomfortable - it causes skin breakdown, gait compensation and secondary joint damage, and it is often abandoned entirely, which for a person who needed it is a serious loss. Facilities vary enormously, and a patient or a purchasing authority has no way to judge one. This document specifies the grading of prosthetic and orthotic fitting institutions and the use of the grade marks, the basic requirements, the requirements at each grade, and the assessment procedure by which a grade is awarded. It applies to the classification and evaluation of such institutions. Under ICS 11.180 and CCS C45, it is written for prosthetic and orthotic service providers, for the health and disability authorities that commission and accredit them, and for the patients and insurers choosing between them.

This document stipulates the grading and use of signs, basic requirements, grading requirements and grade assessment of prosthetic and orthotic configuration mechanisms. This document is applicable to the classification and evaluation of prosthetic and orthotic device configuration mechanisms (hereinafter referred to as "configuration mechanisms").

## 2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 10001.1 Graphic symbols for public information Part

## 3 Terms and definitions

The terms and definitions defined in GB/T 14191 (all parts), GB/T 16432, GB/T 35351 and the following apply to this document.

3.1 An institution that directly assembles prostheses or (and) orthotics for physically disabled people or people with physical impairments due to various reasons.

Note. Prosthetic limbs and orthotics configuration mechanisms include prosthetic limb configuration mechanisms, orthosis configuration mechanisms, and prosthetic limb and orthotic device configuration mechanisms. 3.2 3D printing3D printing Based on the three-dimensional model data, the print head, nozzle or other printing technology is used to manufacture parts or real objects through material accumulation. object craftsmanship.

Note. This term is often used as a synonym for additive manufacturing, also known as 3D printing. [Source: GB/T 35351-2017, 2.1.4, with modifications]

3.3 digitalization Transform a lot of complex and changeable information into measurable numbers and data, establish appropriate digital models, and introduce computers for integration

## 9 Accessible facilities symbols

GB/T 14191 (all parts) Prosthetics and orthotics terminology

GB/T 16432 Classification and terminology of rehabilitation assistive devices

GB/T 19001 Quality Management System Requirements

GB 22457 Prosthetic limb configuration services

GB/T 24431 Prosthetics and orthotics assembly facilities and equipment

GB/T 35351 Additive Manufacturing Terminology

GB 50763 Barrier-free design specifications