



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

GB/T 45265-2025

**General technical requirements for the additive manufacturing
of lower limb prostheses**

下肢假肢增材制造通用技术要求

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is issued by the Ministry of Civil Affairs of the People's Republic of China. This document was prepared by the National Technical Committee for Standardization of Rehabilitation and Special Equipment for the Disabled (SAC/TC148) and the National Technical Committee for Standardization of Additive Manufacturing. It is jointly managed by the Technical Committee (SAC/TC562). This document was drafted by: Guangzhou Kangyibo Prosthetics and Orthotics Technology Co., Ltd., China Rehabilitation Assistive Devices Association, Shenzhen Sunshine Optoelectronics Technology Co., Ltd., Foshan Gongqiao Medical Equipment Co., Ltd., Xiamen Gaoqi Prosthetics Co., Ltd., Henan Xiangyu Medical Equipment Co., Ltd. Co., Ltd., China Machinery Research Institute of Standards and

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1 Scope

GB/T 45265-2025 sets the general technical requirements for making lower limb prostheses by additive manufacturing. A prosthetic socket is the one part of a limb that must be unique to its wearer, which is why 3D printing took hold here before almost anywhere else in medical devices; what it lacked was a standard, because a printed socket fails differently from a laminated one, along the build layers and from process defects invisible from outside. The document sets the requirements on the materials and on their biocompatibility, on the digital workflow from scan to model to build file, on the process parameters and their control and on the build orientation, on the post-processing and finishing, on the static and cyclic strength of the finished component and on the test loads it is verified against, on the identification and traceability of each printed part back to its build, and on the marking and the accompanying information. For a prosthetics workshop, an AM service provider or a regulator in China, this is the framework such a device is made and accepted under.

This document specifies the technical requirements for additive manufacturing of lower limb prostheses and describes the corresponding test methods. This document is applicable to the production of prosthetic sockets at different amputation planes of lower limbs using

additive manufacturing.

Note. Includes the receiving cavity of hip disarticulation prosthesis, thigh prosthesis, knee disarticulation prosthesis, calf prosthesis and Syme prosthesis.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 13461 Modular lower leg prosthesis

GB/T 14191.2 Prosthetics and orthotics terminology Part

3 Terms and definitions

The terms and definitions defined in GB/T 14191.2, GB/T 16432 and GB/T 35351 and the following apply to this document.

3.1 Lower limb stump data collection The process of using data collection tools to obtain the shape data of the lower limb residual limb.

3.2 Digital design of stump socket The process of designing a digital model of the prosthetic socket through computer-aided design based on the collected data.

3.3 Additive manufacturing A process of manufacturing parts or objects by stacking materials based on 3D model data.

3.4 Additive manufacturing of stump socket Digital design of prosthetic socket is carried out based on residual limb data collection, using polymer, metal and other special materials for additive manufacturing. Additive manufacturing technology, the process of obtaining a prosthetic socket.

3.5 lower limb prostheses assembledwithadditivemanufactured stump The additive manufacturing socket is assembled and aligned with the common parts of the lower limb prosthesis. After confirming the fit, it is delivered for customized use.