

ICS 11.180
CCS C45



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

GB/Z 40986-2021

**General technical conditions for assembly of upper extremity
prosthesis**

上肢假肢装配通用技术条件

Issued on: November 26, 2021

Implemented on: November 26, 2021

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

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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 of Standardization Documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying patents. This document was proposed by the Ministry of Civil Affairs of the People's Republic of China. This document is under the jurisdiction of the National Standardization Technical Committee for Rehabilitation and Special Equipment for the Disabled (SAC/TC148). This document was drafted by: Huaibei Feilong Disabled Prosthetics Co., Ltd., Anhui Quality and Standardization Research Institute, Ottobock (China) Engineering Co., Ltd. Industry Co., Ltd., National Research Center for Rehabilitation Aids, Shanghai Kesheng Prosthetics Co., Ltd., Danyang Prosthetic Factory Co., Ltd., Danyang Runben Rehabilitation Appliance Co., Ltd., Beijing Ruiha International Prosthetic Orthotics Trading Co., Ltd., Jinhua Deren Prosthetic Orthotics Rehabilitation Equipment Co., Ltd., Beijing Hui Ci Prosthetic Medical Supplies Development Co., Ltd., Information Research Institute of Huaibei City Quality and Technical Supervision Bureau. The main drafters of this document. Ma Haitao, Ding Changdong, Gao Tiecheng, Zhao Liwei, Luo Yongzhao, Yang Dongqing, Wu Jian, Wu Xihan, Jiang Luohui, Hou Ligang, Wu Qian and Zhang Guangfeng. General technical conditions for assembly of upper limb prostheses

1 Scope

GB/Z 40986-2021 is the Chinese national standard on general technical conditions for

assembly of upper extremity prosthesis, in the field of health care technology. The /Z suffix marks it as a guiding technical document: it does not prescribe requirements that can be certified against, but sets out the technique, the method or the state of the art that the standards bodies recommend following. It was issued on 26 November 2021 by the State Administration for Market Regulation; Standardization Administration of China. As a guiding technical document it carries no separate date of entry into force: it applies from publication. Classification: ICS 11.180, CCS C45. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the classification, assembly technical requirements, inspection methods, inspection rules, delivery, marking, packaging, transportation and store. This document applies to decorative upper limb prostheses, self-powered upper limb prostheses (cable controlled upper limb prostheses), electric upper limb prostheses, and hybrid upper limb prostheses. The finished product of the limb.

2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations Only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to This document.

GB/T 191 Packaging, storage and transportation pictorial signs

GB/T 1447 Test method for tensile properties of fiber reinforced plastics

GB/T 1449 Test method for bending performance of fiber reinforced plastics

GB/T 1451 Fiber-reinforced plastic simply supported beam impact toughness test method

GB/T 3768 Acoustic sound pressure method is used to determine the sound power level and sound energy level of noise sources using the simple envelope measurement surface above the reflecting surface. Easy method

GB/T 9174 General technical requirements for general cargo transportation packaging

GB/T 14191.1 Terminology of prosthetics and orthotics-Part

3 Terms and definitions

The following terms and definitions defined in GB/T 14191.1 apply to this document.

3.1 Decorative upper limb prosthesis cosmeticarm The main purpose of decoration is the upper limb prosthesis which pays attention to the appearance and shape of the limbs.

Note. Decorative upper limb prostheses are commonly known as cosmetic hands.

3.2 Body-powered upper limb prosthesis The movement of the upper limbs or torso is the manipulating power to control the upper limb prosthesis of special joints and hand devices.

Note. Self-powered upper limb prostheses are commonly known as cable-controlled upper limb prostheses.

3.3 Electric upper limb prosthesis electricarm The upper-limb prosthesis using micro-motors to drive the prosthetic joints and hand devices.