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

GB/T 44666-2024

Finger orthoses

指矫形器

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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 is under the jurisdiction of the National Technical Committee for Standardization of Rehabilitation and Special Equipment for Persons with Disabilities (SAC/TC148). This document was drafted by: National Rehabilitation Equipment Research Center, Beijing Social Management Vocational College (Ministry of Civil Affairs Training Center), Anyang Beiruisi Medical Equipment Co., Ltd., Beijing Jingbo Modern Prosthetics and Orthotics Technology Co., Ltd., Ottobock (China) Industrial Co., Ltd., China Rehabilitation Assistive Devices Association, Beijing Green Rainbow Prosthetics and Orthotics Technology Co., Ltd. The main drafters of this document are: Guo Lin, Ma Fengling, Tao Jing, Liu Junling, Wang Yun, Yang Dehui, Ma Lifang, Yang Rong, Xiong Baolin, Li Xiaotang, Jin Fengchen, Li Hong, Pang Qun, Xue Jing. Finger Orthosis

1 Scope

GB/T 44666-2024 is the Chinese standard for finger orthoses: the static and dynamic splints used after a tendon repair, a fracture, a burn or a stroke to hold a finger in position, to prevent contracture or to apply a controlled corrective force. They are small, cheap

devices whose effect on the outcome of a hand injury is out of proportion to their cost, and they were not previously covered by a national standard. The document sets the classification of finger orthoses by function and by the joint they act on, the requirements on the materials and their biocompatibility and on the skin contact, the requirements on the design and construction including the adjustability, the fit and the pressure distribution, the requirements on the corrective force where one is applied and on its maintenance over time, the mechanical requirements covering strength, fatigue and the retention of shape, the requirements on cleaning and on reuse, the marking and the information supplied with the device, together with the test methods and the inspection rules. For an orthotics manufacturer, a hand therapy service or a procurement body in China, this is the acceptance text.

This document provides the classification and model of finger orthoses, and specifies the requirements, inspection rules, marking labels, instructions for use, Packaging, transportation and storage, and describe the corresponding test methods. This document applies to the design, manufacture and inspection of finger orthoses.

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 191 Pictorial markings for packaging, storage and transportation GB/T 9056 Metal Ruler

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

GB/T 10000 Chinese adult body dimensions

GB/T 14191.1 Prosthetics and orthotics terminology Part

3 Terms and definitions

The terms and definitions defined in GB/T 14191.1, GB/T 16432 and GB/T 34410 and the following apply to this document.

3.1 An orthosis that surrounds all or part of a finger. [Source: GB/T 34410-2017, 3.3]

3.2 A finger orthosis that changes the position and shape of the fingers during use.

3.3 A finger orthosis that does not change the position and shape of the finger during use.

3.4 A finger orthosis whose main function is to keep the fingers correctly aligned, fix and protect the fingers, and prevent finger injuries or diseases.

5 In vitro cytotoxicity test

GB/T 16886.10-2017 Biological evaluation of medical devices Part

10 Irritation and skin sensitization tests GB/T 23315 Velcro

GB/T 34410 Classification and general technical requirements for upper limb orthoses

QB/T 1519 Fiber measuring tape

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