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

GB/Z 41083-2021

Classification and general technology of lower limb orthoses

下肢矫形器的分类及通用技术条件

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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" drafted: Please note that some content of this document may be patented: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the Ministry of Civil Affairs of the People's Republic of China: This document is under the jurisdiction of the National Technical Committee on Standardization of Rehabilitation and Special Equipment for Persons with Disabilities (SAC/TC148): This document is drafted by: China Association of Rehabilitation Assistive Devices, Beijing Zhongzhan Kanghao Orthotics Center, Beijing Vocational College of Social Management, Beijing Huici Prosthetic Medical Products Co., Ltd., Hebei Province Disabled Assistive Devices Resource Center, Guangxi Zhuang Autonomous Region Disabled Welfare Fund Association, Guangxi Zhuang Autonomous Region Disabled Assistive Devices Center, Yunnan Disabled Rehabilitation Center, Henan Disabled Assistive Devices Center, Hebei An Chen Medical Equipment Co., Ltd., Children's Hospital Affiliated to Chongqing Medical University: The main drafters of this document: Zhang Xiaoyu, Zhan Yongan, Zhang Tong, Xu Jing, Hou Ligang, Xia Feiqi, Wei Jincheng, Xu Jijun, Zhou Jianxun, Liu Fang, Cheng Pengqiang, Zhan Chao, Li Ming, Qin Jiaqiang, Luo Cong, Liu Xing: Classification and general technical conditions of lower extremity orthoses

1 Scope

GB/Z 41083-2021 is the Chinese national standard on classification and general technology of lower limb orthoses, 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 31 December 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 and type, requirements, inspection methods, inspection rules, signs and labels, instructions for use, packaging, transportation, etc: of lower extremity orthoses transport and storage: This document applies to the design, manufacture, inspection and use of lower extremity orthoses:

2 Normative references

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

GB/T 191 Graphical signs of packaging, storage and transportation

GB/T 10000 Chinese adult human body size GB/T 14191:

1 Terminology of Prosthetics and Orthotics Part 1: Basic Terminology of External Limb Prosthetics and External Orthotics

GB/T 16432 Classification and Terminology of Rehabilitation Assistive Devices

GB 18401 National Basic Safety Technical Specification for Textile Products

GB/T 30659 Requirements and test methods for prosthetics and orthoses

3 Terms and Definitions

The terms and definitions defined in GB/T 14191:1, GB/T 16432 and the following apply to this document: 3:

1 Terminology for classifying lower limb orthosis sites of action 3:1:1 foot orthoses An orthosis that surrounds all or part of the foot: 3:1:

2 Ankle-footorthoses Orthotics around the ankle joint and all or part of the foot: 3:1:3 knee orthoses Orthotics around the knee joint: 3:1:

4 Knee-ankle-footorthoses Orthotics for knees, ankles and feet: 3:1:5 calf orthoses legorthoses Orthotics around the lower leg:

Note: the orthosis for fracture treatment: