

CCS C 45



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

GB/T 41178-2021

**Prosthetics and orthotics - Soft orthoses - Uses, functions,
classification and description**

Issued on: December 31, 2021

Implemented on: December 31, 2021

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

foreword

Introduction

1 Scope

2 Normative references

3 Terms and Definitions

4 Purpose

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:

This document is equivalent to ISO 21063:2017 "Use, function, classification and description of soft orthoses for prostheses and orthoses":

Please note that some content of this document may be patented: The issuing agency of this document assumes no responsibility for identifying patents:

Introduction

There is currently no internationally recognized method for external applicators made of flexible materials that apply pressure to the body part they enclose:

law to describe it: In some areas, these devices are called "bandages":

This is the case for medical practitioners to prescribe such orthoses, manufacturers to describe their products, and to mention in patient treatment and efficacy reports:

And this kind of equipment caused trouble:

This document uses the term "soft orthosis" for this type of appliance:

Prosthetics and OrthoticsSoft Orthotics

Purpose, Function, Classification and Description

1 Scope

This document gives the purpose and function of soft orthoses and classifies and describes such orthoses and their components:

Materials or manufacturing processes are not described in this document:

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:

ISO 8549-1 Terminology for prosthetics and orthotics - Part 1: Basic terminology for external limb prostheses and external orthoses

(Prostheticsandorthotics-Vocabulary-Part 1:Generaltermsforexternallimbprothesesandexternalorthoses)

Note: GB/T 14191:1-2009 Terminology of prosthetics and orthotics - Part 1: Basic terms for external limb prostheses and external orthoses (ISO 8549-

1:1989, IDT)

ISO 8549-3 Prosthetics and Orthotics Terminology Part 3: Orthotic Terminology (Prosthetics and orthotics-Vo-

cabulary-Part 3:Termsrelatingtoexternalorthoses)

ISO 8551 Prosthetics and orthosesDescription of patients treated with orthoses, clinical treatment goals, functional requirements for orthoses

(Prostheticsandorthotics-Functionaldeficiencies-Descriptionofthepersonobetreatedwithan orthosis, clinical objective of treatment, and functional requirements of the orthosis)

ISO 13404 Prosthetics and orthotics Classification and description of orthoses and orthotic components (Prosthetics and orthotics-Cate-

gorizationanddescriptionofexternalorthosesandorthoticcomponents)

3 Terms and Definitions

Terms and definitions defined in ISO 8549-1, ISO 8549-3, ISO 8551 and ISO 13404 and the following terms and definitions apply to this document:

3:1

softorthoses

An orthosis made by applying pressure circumferentially from a soft surface material: If

desired, it can be wrapped by using pads and/or inserts

Apply localized pressure to the surface of the wrapped body part:

NOTE: They may contain orthotic joints and/or other components used to control joint movement and/or alignment: Does not include tape, stockings, and burns

pressure clothing:

4 Purpose

Soft orthoses can achieve the following clinical purposes:

- a) stimulate motor sensory feedback;