Irish Standard
I.S. EN ISO 11199-2:2021

Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators (ISO 11199-2:2021)

I.S. EN ISO 11199-2:2021

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 11199-2:2021 is the adopted Irish version of the European Document EN ISO 11199-2:2021, Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators (ISO 11199-2:2021)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11199-2

July 2021

ICS 11.180.10

Supersedes EN ISO 11199-2:2005

English Version

Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators (ISO 11199-2:2021)

Produits d'assistance à la marche manipulés avec les deux bras - Exigences et méthodes d'essai - Partie 2: Déambulateurs (ISO 11199-2:2021)

Technische Hilfen zum Gehen für beidarmige Handhabung - Anforderungen und Prüfverfahren - Teil 2: Rollatoren (ISO 11199-2:2021)

This European Standard was approved by CEN on 12 June 2021.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 11199-2:2021) has been prepared by Technical Committee ISO/TC 173 "Assistive products" in collaboration with Technical Committee CEN/TC 293 “Assistive products and accessibility” the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11199-2:2005.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11199-2:2021 has been approved by CEN as EN ISO 11199-2:2021 without any modification.

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INTERNATIONAL STANDARD

ISO 11199-2

Third edition
2021-07

Assistive products for walking manipulated by both arms — Requirements and test methods —

Part 2: Rollators

Produits d'assistance à la marche manipulés avec les deux bras — Exigences et méthodes d'essai —

Partie 2: Déambulateurs

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, Assistive products, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, Assistive products and accessibility, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11199-2:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

— 3.1 was changed to be in accordance with ISO 9999;

— subclause 16.3 on strength of backrest was added;

— Clause 6 on general requirements for assistive products was added.

A list of all parts in the ISO 11199 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A rollator can be used when a person needs assistance when walking. The rollator can provide stability when walking and standing and reduce the risk of falling. Rollators are designed to support the user inside a frame to carry the user's weight. Rollators can be equipped with a resting seat, backrest and/or shopping bag. Rollators are not intended to be moved with the user on the seat like a wheelchair. The seat is provided as a resting seat with brakes engaged.

Assistive products for walking manipulated by both arms — Requirements and test methods —

Part 2: Rollators

1 Scope

This document specifies requirements and test methods of rollators being used as assistive products for walking with wheels, manipulated by both arms, without accessories, unless specified in the particular test procedure. This document also gives requirements relating to safety, ergonomics, performance and information supplied by the manufacturer including marking and labelling.

The requirements and tests are based on every-day use of rollators as assistive products for walking for a maximum user mass as specified by the manufacturer. This document includes rollators specified for a user mass of no less than 35 kg.

This document is not applicable to rollators with horizontal forearm supports, classified as walking tables, for which ISO 11199-3 is applicable.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8191-2, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

EN 614-1+A1, *Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp