



NSAI
Standards

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:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN ISO 11199-2:2021

Published:

2021-07-21

This document was published under the authority of the NSAI and comes into effect on:

2021-08-09

ICS number:

11.180.10

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

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)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

EN ISO 11199-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

EN ISO 11199-2:2021 (E)

Contents	Page
European foreword.....	3

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.

This page is intentionally left blank

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



Reference number
ISO 11199-2:2021(E)

© ISO 2021

ISO 11199-2:2021(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Apparatus	7
5 Test conditions	8
6 General requirements and test methods	9
6.1 Risk analysis	9
6.2 Rollators that can be dismantled	9
6.3 Fasteners	9
6.4 User mass/load limit	9
6.5 Structure requirements	9
6.6 Brakes	10
6.6.1 General requirements	10
6.6.2 Brake effectiveness	10
6.6.3 Durability of brakes	11
6.7 Handgrip	11
7 Materials	11
7.1 General	11
7.2 Flammability	12
7.2.1 General	12
7.2.2 Upholstered parts	12
7.3 Biocompatibility and toxicity	12
7.4 Infection and microbiological contamination	12
7.4.1 General	12
7.4.2 Cleaning and disinfection	12
7.5 Resistance to corrosion	12
8 Ingress of liquids	13
9 Temperatures of parts that come in contact with human skin	13
10 Safety of moving parts	13
10.1 Squeezing	13
10.2 Mechanical wear	14
11 Prevention of traps for parts of the human body	14
11.1 Holes and clearances	14
11.2 V-shape openings	15
12 Folding, adjusting and locking mechanisms	15
12.1 General	15
12.2 Folding mechanisms	15
12.3 Locking mechanisms	15
13 Carrying handles	15
13.1 General	15
13.2 Requirements	16
13.3 Test method	16
14 Surfaces, corners and edges	16
15 Static stability	17
15.1 Requirements for static stability	17
15.2 Test method for static stability	17

ISO 11199-2:2021(E)

15.2.1	Forward-direction static stability test.....	17
15.2.2	Rearward-direction static stability test.....	18
15.2.3	Sideway-direction static stability test.....	19
15.2.4	Accessory equipment static stability test.....	20
16	Static strength.....	20
16.1	Static strength of resting seat.....	20
16.1.1	General.....	20
16.1.2	Requirements for static strength of resting seat.....	20
16.1.3	Test method for static strength of resting seat.....	20
16.2	Static strength of the rollator.....	21
16.2.1	General.....	21
16.2.2	Requirements for static strength of the rollator.....	21
16.2.3	Test method for static strength of the rollator.....	21
16.3	Strength of backrest.....	22
16.3.1	General.....	22
16.3.2	Requirement for strength of backrest.....	22
16.3.3	Test method for strength of backrest.....	22
17	Durability test.....	22
17.1	Requirement for durability.....	23
17.2	Test method for durability.....	23
18	Ergonomic principles.....	24
19	Packaging.....	24
20	Information supplied by the manufacturer.....	25
20.1	General.....	25
20.2	Information marked on the product.....	25
20.3	Instruction manual.....	25
20.4	Test report.....	26
Annex A (informative) Consideration items for hazards when designing the products.....		28
Annex B (informative) General recommendations.....		30
Bibliography.....		32

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

ISO 11199-2:2021(E)

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>

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-