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Manual wheelchairs - Requirements and test methods



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

Manual wheelchairs - Requirements and test methods

Fauteuils roulants à propulsion manuelle - Exigences et méthodes d'essai

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 17 July 2022.

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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.

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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 12183:2022) has been prepared by 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of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by May 2024.

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 12183:2014.

Annex G provides details of the significant technical changes between this document and EN 12183:2014.

Requirements and test methods for electrically powered wheelchairs are specified in EN 12184.

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

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Türkiye and the United Kingdom.

Introduction

This is the fifth edition of this European Standard. The previous editions were published in 1999, 2006, 2009 and 2014.

Where this document does not apply to particular wheelchairs, contracting parties should consider whether appropriate parts of this document can be used. Manufacturers can also consider whether appropriate parts of this document can be used to assess the performance of their products against the general safety and performance requirements of Regulation (EU) 2017/745 [18] of 5 April 2017 on medical devices.

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1 Scope

This document specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not less than 25 kg and not greater than 250 kg, including

- stand-up manual wheelchairs, and
- manual wheelchairs whose intended use includes showering and/or toileting.

This document does not apply to custom-made manual wheelchairs, manual wheelchairs intended for use in sports, or manual wheelchairs intended only for showering and/or toileting.

This document also specifies requirements and test methods for manual wheelchairs with electrically powered ancillary equipment.

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.

EN 614-1:2006+A1:2009, *Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles*

EN 1021-2:2014, *Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source match flame equivalent*

EN 12184:2022, *Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods*

EN ISO 14971:2019¹, *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 10993-1:2020, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 13732-1:2008, *Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006)*

EN ISO 14155:2020, *Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)*

EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

EN ISO 22442-1:2020, *Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)*

ISO 7176-1:2014, *Wheelchairs — Part 1: Determination of static stability*

ISO 7176-3:2012, *Wheelchairs — Part 3: Determination of effectiveness of brakes*

¹ EN ISO 14971:2019 is amended by EN ISO 14971:2019/A11:2021.

ISO 7176-8:2014, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

ISO 7176-11:2012, *Wheelchairs — Part 11: Test dummies*

ISO 7176-13:1989, *Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces*

ISO 7176-19:2008², *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2014, *Wheelchairs — Part 22: Set-up procedures*

ISO 7176-26:2007, *Wheelchairs — Part 26: Vocabulary*

ISO 8191-2:1988, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*

ISO 16840-10:2021, *Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method*

ISO 17966:2016, *Assistive products for personal hygiene that support users — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007 and the following apply.

NOTE The definitions of wheelchair and manual wheelchair in ISO 7176-26:2007 are replaced by 3.2 below.

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>

— IEC Electropedia: available at <https://www.electropedia.org/>

3.1

loaded wheelchair

wheelchair loaded with a test dummy

Note 1 to entry: Instructions for selecting and fitting a test dummy are given in Clause 6.

3.2

wheelchair

manual wheelchair

wheeled mobility device, intended to transport a seated occupant who has impaired mobility, that is manually propelled by the occupant and/or an assistant

3.3

pre-sale information

publicly available information provided by the manufacturer about the wheelchair

Note 1 to entry: A specification sheet is part of the pre-sale information.

² ISO 7176-19:2008 is amended by ISO 7176-19:2008/AMD 1:2015.