

Käsiajamiga ratastoolid. Nõuded ja katsemeetodid

Manual wheelchairs - Requirements and test methods

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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

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Foreword

This document (EN 12183:2014) has been prepared by Technical Committee CEN/TC 293 “Assistive products for persons with disability”, 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of an identical text or by endorsement, at the latest by September 2014 and conflicting national standards shall be withdrawn at the latest by March 2017.

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

This document supersedes EN 12183:2009, which is to be withdrawn (dow) three years after the date of availability of this edition. See CEN/TC 293 resolution 492.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

For relationship with the applicable EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Informative Annex E provides details of significant technical changes between this European Standard and the previous editions of 1999, 2006 and 2009.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This is the fourth edition of this European Standard. The first edition was published in 1999, the second in 2006 (withdrawn in 2007) and the third in 2009.

Where this European Standard does not apply to particular wheelchairs, contracting parties should consider whether appropriate parts of this European Standard can be used. Manufacturers might also wish to consider whether appropriate parts of this European Standard can be used to assess the performance of their products against the Essential Requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

This European Standard contains requirements for ergonomic design related to the ease of wheelchair operation.

1 Scope

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 250 kg.

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

This European Standard does not apply in total to:

- wheelchairs intended for special purposes, such as sports, showering or toileting,
- manual wheelchairs with handrim-activated power-assisted propulsion,
- custom-made wheelchairs,
- stand-up wheelchairs, and
- manual wheelchairs with add-on power kits used for propulsion.

NOTE Requirements for electrically powered wheelchairs are specified in EN 12184.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1021-2:2006, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 12182:2012, *Assistive products for persons with disability — General requirements and test methods*

EN 12184, *Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods*

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

ISO 7176-1:1999, *Wheelchairs — Part 1: Determination of static stability*

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

ISO 7176-8:1998, *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 7176-15:1996, *Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling*

ISO 7176-19:2008, *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2000, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007 (with the exception of the definition of wheelchair which is replaced by 3.2 below), EN 12182:2012 and the following apply.

3.1

loaded wheelchair

wheelchair loaded with a dummy as specified in 4.8

3.2

wheelchair

wheeled personal mobility device incorporating a body support system for a disabled occupant that is manually propelled by the occupant and/or an assistant whilst the occupant is seated

NOTE 1 Definition is adapted from the definition given in the Global Medical Devices Nomenclature (GMDN).

NOTE 2 A disabled occupant is a disabled person or a person not having the full capacity to walk unaided.

4 Test apparatus

4.1 Adjustable test plane, a flat, rigid plane having an adjustable slope, with a coefficient of friction as specified in ISO 7176-13:1989, of sufficient size to accommodate the wheelchair during the tests specified in 9.2, and such that the whole surface lies between two imaginary parallel planes 5 mm apart per 1 000 mm of extension in any direction and 50 mm apart per 6 000 mm of extension in any direction.

4.2 Horizontal test plane, a flat, rigid plane, with a coefficient of friction as defined in ISO 7176-13:1989, of sufficient size to accommodate the wheelchair under test, and such that the whole surface lies between two imaginary horizontal planes 5 mm apart per 1 000 mm of extension in any direction and 50 mm apart per 6 000 mm of extension in any direction.

4.3 Means to apply a force between 25 N and 200 N with an accuracy of $\pm 5\%$ and with a rate of application less than 5 N/s.

4.4 Means to measure force with an accuracy of $\pm 5\%$ in increments of 1 N in the range of 0 N to 200 N.

4.5 Means to measure distance in the range of 0 m to 5 m with an accuracy of ± 1 mm or $\pm 2\%$ whichever is the greater.

4.6 Means to measure angles to an accuracy of $\pm 0,1^\circ$.

4.7 Means to measure torque with an accuracy of $\pm 2\%$ in the range of 0,5 Nm to 10 Nm.

4.8 Test dummy, of appropriate mass, as specified in ISO 7176-11:2012.

4.9 Means to measure speed in the range 0,5 m/s to 1,5 m/s with an accuracy of $\pm 0,05$ m/s.

4.10 Means to move a brake lever smoothly for 60 000 cycles at a frequency of not more than 0,5 Hz.