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Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

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English Version

Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Fauteuils roulants électriques, scooters et leurs chargeurs -Exigences et méthodes d'essai Elektrorollstühle und -mobile und zugehörige Ladegeräte -Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 27 December 2013.

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.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 12184:2014) 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of an identical text or by endorsement, at the latest by September 2014 and conflicting national standards shall be withdrawn at the latest by March 2017.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This document supersedes EN 12184:2009, which is to be withdrawn (dow) three years after the date of availability (dav) of this edition. See CEN/TC 293 resolution 493.

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 Council 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 G 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 electrically powered wheelchairs, including electrically powered scooters with three or more wheels, with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 300 kg.

It also specifies requirements and test methods for battery chargers for wheelchairs and scooters.

This European Standard does not apply in total to:

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

NOTE Requirements for manually propelled wheelchairs are specified in EN 12183.

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 60335-1:2012, Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1:2010, modified)

EN 60529:1991, Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)

EN 60601-1:2006, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)

EN 62304:2006, Medical device software — Software life-cycle processes (IEC 62304:2006)

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 7176-2:2001, Wheelchairs — Part 2: Determination of dynamic stability of electric wheelchairs

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

ISO 7176-4:2008, Wheelchairs — Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

ISO 7176-6:2001, Wheelchairs — Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs

ISO 7176-8:1998, Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths

ISO 7176-9:2009, Wheelchairs — Part 9: Climatic tests for electric wheelchairs

ISO 7176-10:2008, Wheelchairs — Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs

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 7176-14:1997, Wheelchairs — Part 14: Power and control systems for electric wheelchairs — Requirements and test methods

NOTE ISO 7176-14:1997 is used only for requirements and test methods for battery chargers.

ISO 7176-14:2008, Wheelchairs — Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods

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 7176-21:2009, Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

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

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