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I.S. EN 12183:2009

Manual wheelchairs - Requirements and test methods

I.S. EN 12183:2009

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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
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English Version

Manual wheelchairs - Requirements and test methods

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

Rollstühle mit Muskelkraftantrieb - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 27 August 2009.

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Foreword

This document (EN 12183:2009) 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of an identical text or by endorsement, at the latest March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 12183:2006.

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, as amended by Directive 2007/47/EC.

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

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This is the third edition of this European Standard which was originally issued in 1999. The second edition was published in 2006 but was withdrawn in 2007.

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 concerning medical devices 93/42/EEC of 14 June 1993, as amended by Directive 2007/47/EC.

This European Standard contains requirements for ergonomic design related to the ease of wheelchair operation. They are intended to be applicable to at least 80 % of adult users and are based upon:

- the body size of users within the range 5th percentile adult female to 95th percentile adult male,
- the abilities and restrictions of a 65-year-old 50th percentile female, and
- the wheelchair being equipped with operating devices which are not custom-made for individual users.

1 Scope

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 100 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;
- custom-made wheelchairs;
- stand-up wheelchairs; and
- add-on power kits for the propulsion of manual wheelchairs.

NOTE 1 The application of this standard is limited to wheelchairs with a maximum occupant mass of 100 kg because the maximum mass of dummy specified in ISO 7176-11:1992 is 100 kg. Annex A (informative) provides guidance for construction of dummies of mass 125 kg and 150 kg. At the time of publication, a new edition of ISO 7176-11 was under development, including test dummies with masses above 100 kg.

NOTE 2 Requirements for electrically powered wheelchairs are specified in EN 12184.

2 Normative references

The following referenced documents are indispensable for the application 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 1021-1:2006, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

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

EN 12182, *Technical aids for disabled persons — General requirements and test methods*

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

EN ISO 14971:2009, *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 7176-3:2003, *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 7176-11:1992, *Wheelchairs — Part 11: Test dummies*

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

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