Manuaalsed ratastoolid. Nõuded ja katsemeetodid

Manual wheelchairs - Requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12183:2009 sisaldab Euroopa standardi EN 12183:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 12183:2009 consists of the English text of the European standard EN 12183:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 30.09.2009.	Date of Availability of the European standard text 30.09.2009.
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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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Contents

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of an identical text or by endorsement, at the latest March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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*

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

ISO 7176-19:2001, *Wheelchairs — Part 19: Wheeled mobility devices for use in motor vehicles*

ISO 7176-22:2000, *Wheelchairs — Part 22: Set-up procedures*

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

ISO 10542-5:2004, *Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 5: Systems for specific wheelchairs*

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 3.3 below), EN 12182 and the following apply.

3.1
loaded wheelchair
wheelchair loaded with a dummy as specified in 4.8

3.2
maximum safe slope
maximum slope specified by the manufacturer on which the wheelchair meets all the requirements of static stability, braking performance and slope climbing, traversing and descending

3.3
wheelchair
wheeled personal mobility device incorporating a seating 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 7.4, 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 25 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 25 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 ± 5 % and with a rate of application less than 5 N/s.

4.4 Means to measure force with an accuracy of ± 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 ± 2 % whichever is the greater.

4.6 Means to measure angles to an accuracy of ± 0,1°.