## Elektri jõul töötavad ratastoolid, motorollerid ja nende laadijad. Nõuded ja katsemeetodid

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



#### **FESTI STANDARDI FESSÕNA**

teate avaldamisel EVS Teatajas.

### **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 12184:2009 sisaldab Euroopa standardi EN 12184:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase

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# EUROPEAN STANDARD

### EN 12184

## NORME EUROPÉENNE EUROPÄISCHE NORM

September 2009

ICS 11.180.10

Supersedes EN 12184:2006

### **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 August 2009.

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 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 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

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		age
Faraur	ord	
Introd	uction	
1	Scope	7
2	Normative references	7
3	Terms and definitions	
4	Test apparatus	
5	Type classes	
6	General requirements	
-	Design requirements	
/ 7.1	Design requirements	. 11
	Foot supports, lower leg supports and arm supports	. 11
7.2	Pneumatic tyres	. 11
7.3	Fitting an anterior pelvic support	
7.4	Wheelchairs for use as seats in motor vehicles	
7.5	Braking systems	
7.6	Freewheel device	
7.7	Component mass	
7.8	Battery enclosures and containers	. 12
7.9	Operations intended to be carried out by the occupant and/or assistant	. 13
7.10	Controls intended for operation by the occupant	. 13
7.11	Assistant control unit, push handles and handgrips	. 14
7.12	Charging connector	. 14
_	Performance requirements	
8		
8.1	General	
8.2	Foot supports, lower leg support assemblies and arm supports	. 14
8.2.1	Requirements	
8.2.2	Tests	
8.3	Static, impact and fatigue strength	. 15
8.3.1	Requirements	. 15
8.3.2	Test	. 15
8.4	Braking system	. 16
B. <b>4</b> .1	General requirements	. 16
8.4.2	Tests	
8.5	Operating forces	18
8.5.1	Requirements	
8.5.2	Test	
8.6	Assistant control unit, push handles and handgrips	
8.6.1	Requirements	
8.6.2	Test	
6.6.∠ 8.7	Charging connector	
-		
8.7.1	Requirements	
8.7.2	Test	. 20
8.8	Performance of driving characteristics	
8.8.1	General	
8.8.2	Ability to climb maximum safe slope	
8.8.3	Ground unevenness	
8.8.4	Maximum downhill speed	
995	Dynamic etability	21

8.8.6	Obstacle climbing	
8.8.7 8.8.8	Static stability	
8.8.9	Distance range	
8.9	Surface temperature	
8.10	Resistance to ignition	
8.10.1	Upholstered composite parts	24
8.10.2	Foam materials	
8.10.3	Other parts	
8.11 8.12	Climatic test	
8.12.1	Requirements	
8.12.2	Test method	
9 9.1	Electrical requirements	
9.1 9.2	Requirement for controller on/off switch	
9.2 9.3	Requirement for power indicator	
9.4	Requirements for circuit protection	
9.5	Requirements for battery chargers	
9.6	Charge level indicator	26
10	Requirements for information supplied by the manufacturer	26
10.1	General	
10.2	Pre-sale information	26
10.3	User information	
10.4	Service information	
10.5	Labels	
11	Test report	
12	Tables	
13	Figures	32
Annex	A (informative) Recommendations for test dummies of mass greater than 100 kg	
<b>A</b> .1	General	
A.2	Construction	
A.3 A.4	Accelerometer mounting  Design aims	
		37
Annex	B (informative) Recommendations for dimensions and manoeuvring space of electrically powered wheelchairs	45
B.1	Specific dimensions	
B.1.1	Dimensions when ready for use	45
B.1.2	Push handle height	
B.1.3	Ground clearance	
в. т.з В.2	Manoeuvring space	
B.2.1	Turning diameter	
B.2.2 B.3	Reversing widthSpeed settings	
	C (informative) Recommended design features	
Annex C.1	IntroductionIntroduction	
C.1 C.2	General recommendations	
C.2.1	Anti-tip devices	
C.2.1	Component mass	
	·	
C.2.3	Fittings and tools	
C.2.4	Tyres	47

C.2.5	Means to inflate tyres		•••••	47
C.2.6	Surface temperature			47
C.2.7	Occupant transfer into or out of the wheelchair			48
C.2.8	Resistance to contamination from urine incontinence	е		48
C.2.9	Indication for maximum safe slope			48
C.2.10	Mirrors			48
C.2.11	Head support			48
C.2.12 C.3	Accidental release of parking brakes and freewheel of Recommendations for performance characteristics			
C.3.1	Indication of electrical faults			49
C.3.2	Batteries and their containers			49
C.3.3	Lighting			49
C.3.4	Control mechanism feedback			49
C.3.5	Freewheel alarm			
C.3.6	Maximum speed			49
Annex	D (informative) Recommended seating design			50
_	E (informative) Manoeuvring forces			
Annex E.1	Recommendations			
E.1	Recommendations			5 <sup>,</sup>
E.1 E.1.1 E.1.2 E.2 Annex F.1 F.2	Push handle force	ted wheelchairs tions of EN 12184 and (2006) editions		5. 55. 55.
E.1 E.1.1 E.1.2 E.2 Annex F.1 F.2	Push handle force	ted wheelchairs tions of EN 12184 and (2006) editions Standard and the une 1993 concern	Essential ing medical	5′ 5′ 5′ 52′ 52′
E.1 E.1.1 E.1.2 E.2 Annex F.1 F.2	Push handle force	ted wheelchairs tions of EN 12184 and (2006) editions an Standard and the une 1993 concern	e Essential ing medical	51 51 52 52 53

### **Foreword**

This document (EN 12184:2009) 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 12184:2006.

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 occupants and are based upon:

- the body size of occupants 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
- ing de the wheelchair being equipped with operating devices which are not custom-made for individual occupants.

### 1 Scope

This European Standard specifies requirements and test methods for electrically powered wheelchairs with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 100 kg, which includes:

- manual wheelchairs with add-on power kits used for propulsion,
- electrically powered wheelchairs, and
- electrically powered scooters with three or more wheels.

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

This European Standard does not apply in total to:

- wheelchairs intended for special purposes, such as sports,
- custom-made wheelchairs,
- handrim activated power assisted wheelchairs and
- powered office chairs.

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 manually propelled wheelchairs are specified in EN 12183.

### 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 50272-3:2002, Safety requirements for secondary batteries and battery installations — Part 3: Traction batteries

EN 60335-1:2002, Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1:2001, 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 61000-3-2:2006, Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current  $\leq$  16 A per phase) (IEC 61000-3-2:2005)

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

ISO 7176-3:2003, 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 7176-9:2001, Wheelchairs — Part 9: Climatic test for electric wheelchairs

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

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 7176-14:1997, 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 7176-19:2001, Wheelchairs — Part 19: Wheeled mobility devices for use in motor vehicles

ISO 7176-21:2003, Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters

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