



# SLOVENSKI STANDARD SIST EN 12183:2010

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Manual wheelchairs - Requirements and test methods

Manual wheelchairs - Requirements and test methods

Rollstühle mit Muskelkraftantrieb - Anforderungen und Prüfverfahren

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

|  | Page |
|--|------|
| Foreword.....  | 4    |
| Introduction .....   | 5    |
| 1 Scope .....  | 6    |
| 2 Normative references .....   | 6    |
| 3 Terms and definitions .....  | 7    |
| 4 Test apparatus .....   | 7    |
| 5 General requirements.....  | 8    |
| 6 Design requirements .....  | 9    |
| 6.1 Foot supports, lower leg supports and arm supports .....                             | 9    |
| 6.2 Pneumatic tyres .....  | 9    |
| 6.3 Fitting an anterior pelvic support.....  | 9    |
| 6.4 Wheelchairs for use as seats in motor vehicles.....                                  | 9    |
| 6.5 Braking systems .....  | 9    |
| 6.6 Component mass .....   | 9    |
| 6.7 Operations intended to be carried out by the occupant and/or assistant.....          | 9    |
| 6.8 Operator controls.....   | 10   |
| 6.9 Push handles and handgrips.....  | 10   |
| 7 Performance requirements .....   | 11   |
| 7.1 General.....   | 11   |
| 7.2 Foot supports, lower leg support assemblies and arm supports .....                   | 11   |
| 7.3 Static, impact and fatigue strength.....   | 12   |
| 7.4 Braking system .....   | 12   |
| 7.5 Fatigue strength of manually operated parking brakes.....                            | 14   |
| 7.6 Operating force .....  | 15   |
| 7.7 Push handles and handgrips.....  | 15   |
| 7.8 Static stability.....  | 16   |
| 7.9 Surface temperature .....  | 16   |
| 7.10 Resistance to ignition .....  | 16   |
| 7.11 Seating adjustments for tilt and recline systems.....                               | 17   |
| 7.12 Castor stem .....   | 17   |
| 7.13 Electrically powered ancillary equipment .....                                      | 17   |
| 7.14 Pushing force .....   | 18   |
| 8 Requirements for information supplied by the manufacturer .....                        | 18   |
| 8.1 General.....   | 18   |
| 8.2 Pre-sale information .....   | 19   |
| 8.3 User information .....   | 19   |
| 8.4 Service information .....  | 20   |
| 8.5 Labelling .....  | 20   |
| 9 Test report .....  | 21   |
| 10 Tables.....   | 21   |
| 11 Figures .....   | 22   |
| Annex A (informative) Recommendations for test dummies of mass greater than 100 kg ..... | 26   |
| A.1 General.....   | 26   |
| A.2 Construction.....  | 26   |

|   |   |    |
|---|---|----|
| A.3   | Accelerometer mounting .....  | 26 |
| A.4   | Design aims .....   | 27 |
| Annex B (informative) Recommendations for dimensions and manoeuvring space .....  |   | 35 |
| B.1   | Specific dimensions .....   | 35 |
| B.1.1   | Dimensions when ready for use and when folded and/or dismantled .....       | 35 |
| B.1.2   | Push handle height .....  | 35 |
| B.1.3   | Ground clearance .....  | 35 |
| B.2   | Manoeuvring space .....   | 35 |
| B.2.1   | Turning diameter .....  | 35 |
| B.2.2   | Reversing width .....   | 35 |
| Annex C (informative) Recommended design features .....   |   | 37 |
| C.1   | Introduction .....  | 37 |
| C.2   | General recommendations .....   | 37 |
| C.2.1   | Fittings and tools .....  | 37 |
| C.2.2   | Tyres .....   | 37 |
| C.2.3   | Means to inflate tyres .....  | 37 |
| C.2.4   | Surface temperature .....   | 37 |
| C.2.5   | Occupant transfer into or out of the wheelchair .....                       | 37 |
| C.2.6   | Resistance to contamination from urine incontinence .....                   | 38 |
| C.2.7   | Head support .....  | 38 |
| C.2.8   | Accidental release of parking brakes .....                                  | 38 |
| C.2.9   | Tipping device .....  | 38 |
| C.2.10  | Anti-tip devices .....  | 38 |
| Annex D (informative) Recommended seating design .....  |   | 39 |
| Annex E (informative) Manoeuvring forces .....  |   | 40 |
| E.1   | Recommendations .....   | 40 |
| E.1.1   | Push handle force .....   | 40 |
| E.1.2   | Handrim force .....   | 40 |
| Annex F (informative) Technical changes from previous editions of EN 12183 .....  |   | 41 |
| F.1   | Technical changes between the first (1999) and second (2006) editions ..... | 41 |
| F.2   | Technical changes from the second (2006) edition .....                      | 42 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ..... |   | 43 |
| Bibliography .....  |   | 47 |

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**EN 12183:2009 (E)****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.

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**EN 12183:2009 (E)****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**

[SIST EN 12183:2010](https://standards.iteh.ai/catalog/standards/sist/58a6bb6b-af7b-450d-9084-85d3c0e580c1/sist-en-12183-2010)

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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

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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  $\pm 5\%$  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  $\pm 1$  mm or  $\pm 2\%$  whichever is the greater.

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

**EN 12183:2009 (E)**

**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 size, as specified in ISO 7176-11:1992.

NOTE Annex A gives guidance on construction of dummies with masses larger than those specified in ISO 7176-11:1992.

**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.

**4.11 Means to measure elapsed time** in the range 0 to 30 s with an accuracy of  $\pm 1$  s.

## 5 General requirements

The wheelchair shall conform to the requirements specified in EN 12182 for the following:

- intended performance and technical documentation;
- aids that can be dismantled;
- single use fasteners;
- biocompatibility and toxicity;
- contaminants and residues;
- infection and microbiological contamination;
- overflow, spillage, leakage and ingress of liquids;
- safety of moving parts;
- prevention of traps for parts of human body;
- folding and adjusting mechanisms;
- surfaces, corners and edges;
- clinical evaluation;
- ergonomics.

A risk analysis shall also be carried out in accordance with EN ISO 14971:2009.

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## 6 Design requirements

### 6.1 Foot supports, lower leg supports and arm supports

The wheelchair shall be fitted with foot supports that have a means of positioning the occupant's feet at the required height, that prevent the occupant's feet from sliding backwards and that meet the performance requirements specified in 7.2.

Where fitted, lower leg supports and arm supports shall meet the performance requirements specified in 7.2.

### 6.2 Pneumatic tyres

If the wheelchair is fitted with pneumatic tyres, they shall have the same type of valve connection on all tyres.

The tyres or the rims shall be marked with the maximum pressure in kPa or bar.

### 6.3 Fitting an anterior pelvic support

The wheelchair shall have provision for an anterior pelvic support to be fitted. The manufacturer of the wheelchair shall have available as an option an anterior pelvic support which can be used with that provision.

### 6.4 Wheelchairs for use as seats in motor vehicles

If the manufacturer specifies that the intended use of the wheelchair includes use by an adult as a seat in a motor vehicle, the wheelchair shall conform to the performance requirements of ISO 7176-19:2001.

If the manufacturer specifies that the intended use of the wheelchair includes use as a seat in a motor vehicle by a child of mass greater than 22 kg, the wheelchair shall conform to the performance requirements of ISO 7176-19:2001 with the exception of the horizontal excursion limits and the selection of the Anthropomorphic Test Device (ATD). The horizontal excursion limits specified in Table 1 of ISO 10542-5:2004 and the ATD selection specified in Table A.1 of ISO 10542-5:2004 shall apply.

### 6.5 Braking systems

The wheelchair shall be fitted with a braking system that meets the performance requirements specified in 7.4.

If one or more brake levers are fitted to a wheelchair in the form used on bicycles and mopeds, the hand-grip width of such brake levers, measured 15 mm from the end of the brake lever, shall not be greater than 75 mm before a force is applied. See Figure 1.

### 6.6 Component mass

If the wheelchair is intended to be dismantled for storage or transportation, any component that requires moving or handling that has a mass greater than 10 kg shall be provided with suitable handling devices (e.g. handles). The manufacturer shall provide information indicating the points where such components can be lifted and describing how they shall be handled during disassembly, lifting, carrying, and assembly to reduce risks to the person or persons moving or handling them.

### 6.7 Operations intended to be carried out by the occupant and/or assistant

Wheelchairs shall be designed to facilitate ease of operation by the occupant and/or assistant as specified in the manufacturer's instructions and meet the performance requirements of 7.2.1, 7.6.1, 7.7.1, 7.11.1 and 7.14.1. In addition, brake levers shall meet the applicable requirements of 7.4.1.

Examples include:

**EN 12183:2009 (E)**

- operation of adjustable seating;
- use of detachable components, including removable arm supports, lower leg supports etc., to facilitate safe transfers into and out of the wheelchair;
- use of folding mechanisms, including folding frames etc., to facilitate storage and transportation of unoccupied wheelchairs;
- carrying out maintenance, including use of tools etc.;
- use of braking systems;
- use of push handles; and
- use of electrical ancillary equipment.

**6.8 Operator controls****6.8.1 Controls intended for operation by the occupant**

Controls intended to be operated by the occupant while seated shall be within the user reach as shown in Figure 2.

The following controls, if fitted, are included:

- brakes intended to be operated by the occupant;
- seating adjustments;
- detachable components, including removable arm supports, lower leg supports etc., to facilitate safe transfers into and out of the wheelchair;
- means of propulsion; and
- electrical ancillary equipment.

**6.8.2 Controls intended for operation by an assistant**

Controls intended to be operated by an assistant shall be within the region specified in Figure 3.

Examples include:

- brakes intended to be operated by an assistant,
- seating adjustments,
- detachable components, including removable arm supports, lower leg supports etc., to facilitate safe transfers into and out of the wheelchair,
- push handles, and
- electrical ancillary equipment.

**6.9 Push handles and handgrips**

When fitted, push handles and handgrips shall meet the performance requirements specified in 7.7.

## 7 Performance requirements

### 7.1 General

Unless otherwise specified in this clause, the wheelchair shall be prepared as specified in ISO 7176-22:2000 for each test.

### 7.2 Foot supports, lower leg support assemblies and arm supports

#### 7.2.1 Requirements

Any swing away, movable or removable foot support, lower leg support assembly or arm support fitted on the wheelchair shall

- a) incorporate a means to locate it securely in any intended operating position,
- b) be adjustable in increments not exceeding 25 mm,
- c) be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended usage and within the reach space shown in Figure 2, and
- d) be operable without the use of tools.

When tested as specified in 7.2.2.2, separate foot supports shall have a gap between them that

- does not exceed 35 mm if the wheelchair is intended to be occupied by an adult,
- does not exceed 25 mm if the wheelchair is intended to be occupied by a child, or
- that is fitted with a means to prevent the occupant's feet from sliding into the gap.

#### 7.2.2 Tests

##### 7.2.2.1 Test for general performance

- a) Fit foot supports, lower leg support assemblies and arm supports in the operating position(s) specified in the manufacturer's instructions.
- b) Adjust the foot supports, lower leg support assemblies and arm supports as specified in the manufacturers' instructions.
- c) Record whether the foot supports, lower leg support assemblies and arm supports met the requirements.

##### 7.2.2.2 Test for foot support gap

- a) Simultaneously apply a force  $F_0^{+5}$  N to the centroid of each foot support, normal to the plane of the unloaded foot support. In cases where the foot support has no identifiable plane, apply the force within 5° of vertical. The force  $F$  is calculated from the following equation:

$$F = 0,125 \times m \times g$$

where

$F$  is the force applied to each foot support, expressed in newtons;