SLOVENSKI STANDARD
SIST EN 12183:2000

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Invalidski voziļ ki na roļ ni pogon - Zahteve in preskusne metode

Manually propelled wheelchairs - Requirements and test methods

Rollstühle mit Muskelkraftantrieb - Anforderungen und Prüfverfahren

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

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English version

Manually propelled 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 18 February 1999.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", 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of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex Z, which is an integral part of this standard.

This standard provides one means to demonstrate that manually propelled wheelchairs, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42/EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

Level 1: General requirements for technical aids
Level 2: Particular requirements for families of technical aids
Level 3: Specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a combined level 2- and 3-standard (lowest possible) for manually propelled wheelchairs, which are also medical devices, as specified in the scope.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Where this standard does not apply to particular wheelchairs, contracting parties should consider if appropriate parts of this standard can be used. Manufacturers may also wish to consider if appropriate parts of this standard can be used to assess the performance of their products against the Essential Requirements of the Medical Devices Directive.

1 Scope

This European Standard specifies requirements and test methods for manually propelled wheelchairs intended for use by one person whose mass does not exceed 100 kg including the following classifications from EN ISO 9999:1998:

12 21 03	Manual attendant-controlled wheelchairs
12 21 06	Bimanual rear-wheel-driven wheelchairs
12 21 09	Bimanual front-wheel-driven wheelchairs
12 21 12	Bimanual lever-driven wheelchairs
12 21 15	Single side driven non-powered wheelchairs
12 21 15	Wheelchairs driven by one arm or one arm and one leg
12 21 18	Foot-driven wheelchairs

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, toiletting
- custom-made wheelchairs
- wheelchairs specially designed or with adaptations for specific disabled persons
- stand-up wheelchairs
- add-on power kits for manual wheelchairs.

NOTE: The application of this standard is limited to wheelchairs with a maximum occupant mass of 100 kg because this is the maximum mass of dummy available in ISO 7176-11. Further work is needed to investigate the effects of larger body masses.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1041	Information supplied by the manufacturer with medical devices
EN ISO 9999:1998	Technical aids for disabled persons – Classification (ISO 9999:1998)
prEN 12182:1999	Technical aids for disabled persons - General requirements and test methods
EN 12184:1999	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
ISO 6440	Wheelchairs - Nomenclature terms and definitions
ISO 7176-1	Wheelchairs - Part 1: Determination of static stability
ISO 7176-3	Wheelchairs - Part 3: Determination of efficiency of brakes
ISO 7176-8:1998	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-11	Wheelchairs - Part 11: Test dummies
ISO 7176-13	Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
ISO 7176-15	Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling
ISO 7176-16	Wheelchairs - Part 16: Resistance to ignition of upholstered parts - Requirements and test methods

3 Definitions

For the purposes of this standard the definitions in ISO 6440 and prEN 12182:1999 apply together with the following:

3.1 **Anti-tip device**: A device to prevent the wheelchair tipping over completely when reaching its limit of stability.

3.2 **Seat belt**: Strap to help maintain the occupant's position in the wheelchair during normal operation.

NOTE 1: This is a strap positioned over the occupant´s pelvis or waist.

NOTE 2: The seat belt is not necessarily intended for use as a safety restraint during transportation in vehicles.

3.3 **User manual**: Post sale information normally provided with the wheelchair to inform the user about the assembly, operation, maintenance, repair and warranty aspects of wheelchair ownership.

3.4 **Wheelchair(s)**: Abbreviation to represent the manually propelled wheelchair covered by the scope of this standard, to which the requirements and test methods are applied.

4 Test equipment

4.1 **Horizontal test plane**; comprising a flat, hard horizontal surface large enough to accommodate the wheelchair under test, such that the whole surface lies between two imaginary horizontal planes 5 mm apart. The surface of the plane shall have a coefficient of friction as defined in ISO 7176-13.

NOTE: The requirement for the horizontal test plane to lie between two imaginary horizontal planes is a measure of flatness of the horizontal test plane.

4.2 **Weights, dynamometer**, or similar means; to apply forces of between 1 N and 100 N with an accuracy of ± 2 %.

4.3 **Test dummies**; of appropriate sizes as specified in ISO 7176-11.

4.4 **Speedometer** or similar means of measuring the speed of the wheelchair to an accuracy of ± 10%.

4.5 **Test ramp**; a hard, smooth ramp at least 1,2 m broad, 2,5 m long and with a total inclination of 200 mm ± 10 mm such that the whole surface lies between two imaginary parallel planes 5 mm apart throughout the test when loaded with the test wheelchair (see figure 2). The surface of the plane shall have a coefficient of friction as defined in ISO 7176-13.

4.6 **Adjustable test plane**; a flat and hard test plane which can be set to sufficient size to enable the test indicated in 7.2.1 to be performed and with a surface of sufficient coefficient of friction to allow minimal wheel slippage during the performance of the test

NOTE: Further test equipment as described in the Normative references is needed.

5 General requirements

The wheelchair shall conform to the requirements of prEN 12182:1999 for:

- Risk analysis;
- Intended performance and technical documentation;
- Clinical evaluation;
- 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.

6 Design requirements

6.1 Footrests and legrests

6.1.1 Requirements for footrests and legrests

The wheelchairs shall be capable of being fitted with a means for preventing the user´s feet from sliding backwards.

If footrests and legrests can be adjusted or moved from one position to another they shall have provision to locate them securely in any operating position.

If the layout of footrests and legrests can be adjusted they shall have increment adjustments not exceeding 25 mm.

If the wheelchair is fitted with a separate footrest for each foot:

a) the gap between the footrests shall not exceed

35 mm for wheelchairs intended for adults
25 mm for wheelchairs intended for children

when tested as specified in 6.1.2;

or

b) the footrests shall be fitted with means for preventing the user´s feet from sliding into the gap.

6.1.2 Test method for footrests

Select a force appropriate to the intended user mass from Table 1. Apply the force to the centroid of each footrest normal to the plane of the unloaded footrest. Measure the minimum gap between the footrests in a transverse direction.

Table 1: Force to be applied to footplates

Max. intended user mass	Force on centroid of footplate
25 kg	25 N ± 5%
50 kg	50 N ± 5%
75 kg	75 N ± 5%
100 kg	100 N ± 5%

6.2 Requirement for pneumatic tyres

If the wheelchair is fitted with pneumatic tyres, they shall have identical valve connections.

6.3 Requirement for fitting a seat belt

The wheelchair shall have provision for a seat belt to be fitted.

6.4 Requirement for armrests and backrests

If armrests and backrests can be adjusted or moved from one position to another they shall have provision to locate them securely in any intended operating position.

6.5 Requirement for wheelchairs intended for use as seats in motor vehicles

If the manufacturer claims the wheelchair is intended for use as a seat in a motor vehicle, the manufacturer's information shall identify the wheelchair tiedown and occupant restraint systems (WTORS) that are suitable and the attachment points on the wheelchair.

NOTE: ISO/TC 173/SC1 develops standards for WTORS and wheelchairs intended for use in motor vehicles. Manufacturers should consider if the resulting standards can be applied to their products.

6.6 Brakes

6.6.1 Requirements for parking brakes

The wheelchair shall be fitted with a parking brake.

The parking brakes shall have provision for adjustment to compensate for any wear to any friction surfaces, tyres etc. that have worn to the point of replacement as recommended in the manufacturer´s documentation and for any wear occurring during the tests specified in 7.2.2 and 7.2.4.

6.6.2 Requirements for service brakes

If the wheelchair has a propulsion system that does not include provision to stop the wheelchair, a service brake shall be fitted.

NOTE 1: For example lever operated wheelchairs.

NOTE 2: Manual wheelchairs propelled by the occupant using a circular hand rim attached to the wheels and wheelchairs propelled by an attendant, are considered to have provision to stop the wheelchair, as the user or attendant can slow it down.

NOTE 3: Service brake is also called running brake.

6.7 Requirement for component weight

If the wheelchair is intended to be dismantled for ease of carrying

a) any component that has a mass greater than 10 kg shall be provided with suitable handling devices (e.g. handles);

or

b) the user manual shall indicate the points where the component part can be lifted safely and/or a method for handling during assembly.

6.8 Requirements for the fitting of anti-tip devices

If the minimum rearward static stability as measured by the method specified in ISO 7176-1 is less than 10°, there shall be provision for fitting anti-tip devices.

Anti-tip devices shall not move from their preset position when engaged by the loaded wheelchair.

7 Performance requirements

7.1 Requirements for wheelchair static, impact and fatigue strength

The wheelchair shall conform to the requirements of ISO 7176-8:1998.

> **NOTE:** Further requirements and tests beyond those specified in ISO 7176-8:1998 are considered to be necessary and may be considered for a future development of this standard.These include e.g. impact strength of anti-tip levers.

7.2 Parking brake performance and strength

7.2.1 Requirements for performance of parking brakes

When the parking brakes have been adjusted by the method specified by the manufacturer to give operating forces that do not exceed the following values when measured as in 7.2.3.

a) The force required to apply hand operated brakes shall not exceed 60 N.

b) The force required to apply foot push operated brakes shall not exceed 100 N.

c) The force required to apply foot pull operated brakes shall not exceed 60 N.

The wheelchair shall not slide, nor the wheels rotate when tested as in ISO 7176-3 facing up and down a slope of 7° from the horizontal.

If the wheelchair has adjustable stability or if the manufacturer declares that the wheelchair static stability is less than 7°, apply the minimum force necessary to the wheelchair so that all wheels remain in contact with the test plane during the test procedure.

7.2.2 Requirements for fatigue strength of parking brakes

When

- the wheelchair has been tested as specified in ISO 7176-8:1998;

- the parking brake has been operated 60 000 times as specified in 7.2.4;