

SLOVENSKI STANDARD

SIST EN 1985:2000

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Walking aids - General requirements and test methods

Gehhilfen - Allgemeine Anforderungen und Prüfmethoden

Aides a la marche - Prescriptions générales et méthodes d'essai

Ta slovenski standard je istoveten z: EN 1985:1998

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ICS:

11.180.10 Ú!ā [{ [\āā Á!āæ [āāç^Áæ Aids and adaptation for
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ICS 11.180

Descriptors: medical equipment, disabled persons aids, disabled persons, elbow crutches, walking rehabilitation carriages, design, equipment specifications, safety, accident prevention, hazards, protection against mechanical hazards, thermal protection, tests, information

English version

Walking aids - General requirements and test methods

Aides à la marche - Prescriptions générales et méthodes
d'essai

Gehhilfen - Allgemeine Anforderungen und Prüfmethoden

This European Standard was approved by CEN on 8 November 1998.

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.

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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 May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

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.

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 a means to demonstrate that walking aids, 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.

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This is a level 2-standard for walking aids, as specified in the scope. Lower level standards may specify the requirements of the higher level standards or may modify them. Where standards for particular types of walking aids exist (level 3-standards), this standard should not be used alone. The level 1-standard may be applicable.

All European Standards produced or currently being developed by CEN/TC 293 and which concern the family of walking aids are listed in Annex A.

1 Scope

This standard specifies requirements and test methods for Walking Aids manipulated by one arm (Walking Aids used singly or in pairs, each manipulated by one of the arms, possibly in combination with the upper body) and Walking Aids manipulated by both arms (Walking Aids used singly, manipulated by both arms, possibly in combination with the upper body), as covered by the subclasses 1203 and 1206 in EN ISO 9999:1998.

This Standard does not apply to walking aids specially designed or with adaptations for specific disabled persons.

Note: Appropriate parts of this standard may be applied to the above products and other walking aids outside this scope.

2 Normative references

This European Standard incorporates by dated or undated references, 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 1441	Medical devices - Risk analysis
EN ISO 9999:1998	Technical aids for disabled persons - Classification
prEN 12182:1997	Technical aids for disabled persons - General requirements and test methods

3 Definitions

For the purpose of this standard the following definitions apply:

- 3.1 Walking aid:** A device which, together with one or both legs, is designed to give support to the user for walking.
- 3.2 User weight:** The body mass of the person the walking aid is designed to accommodate.

4 Risk analysis

EN 1441 applies.

5 Requirements regarding design and construction

5.1 A walking aid shall conform to clause 11 and 12 of prEN 12182:1997 in respect of safety of moving parts and prevention of traps for the human body.

5.2 Materials used in the manufacture of a walking aid shall conform to clause 5.2 of prEN 12182:1997.

5.3 The materials used in a walking aid shall not mark, scratch or discolour the surroundings or the walking surface.

5.4 All parts of a walking aid and its auxiliary parts shall be designed so as to be accessible for cleaning. Any cavities in which liquid could accumulate shall be self-draining. Compliance shall be verified by inspection.

5.5 For ergonomical principles, clause 22 of prEN 12182:1997 shall apply.

6 Requirements regarding construction and environmental properties

6.1 Ancillaries supplied by the manufacturer or supplier for use in combination with a walking aid and the possible mechanisms for fixing them to a walking aid, shall be according to the same safety requirements and quality as for the walking aid.

6.2 Unless a specific part of the function of a walking aid, all accessible edges, corners and surfaces shall conform to clause 17 of prEN 12182:1997.

6.3 A walking aid shall be designed so as to be manoeuvrable for indoor or outdoor use or a combination of the two. Where applicable, the following requirements apply:

Indoor use on a level surface

- the front wheel diameter shall be greater or equal to 75 mm (to aid manoeuvrability on carpets);

- a walking aid shall be equipped with parking brakes operating on two wheels. Rubber tips are deemed to be such parking brakes;

- the maximum width of a walking aid shall be smaller or equal to 650 mm for use in private homes;

Outdoor use

- the front wheel diameter shall be greater or equal to 180 mm;

- the wheel width shall be greater or equal to 28 mm;

- a walking aid shall be equipped with brakes operating on two wheels. The user shall be able to manipulate the brakes when walking. Rubber tips are deemed to be such brakes;

- a walking aid shall be equipped with parking brakes operating on two wheels. Rubber tips are deemed to be such parking brakes.

7 Protection against mechanical and thermal risks

7.1 A walking aid shall function as intended by the manufacturer and there shall be no material failure of any part of the walking aid subjected to the static loading, fatigue, stability and temperature tests either as specified in the relevant level 3-standard, or to comparable performance criteria for those walking aids where no level 3-standard has been specified. The manufacturer shall provide evidence validating such performance criteria.

Note: Recommendations are given in B5.1.

Values for some of the loadings specified in the specific level 3-standards are related to a user weight of 100 kg, and will be adjusted according to the user weight specified by the manufacturer for each individual walking aid.

7.2 A walking aid shall be clearly and indelibly marked with the maximum limits of its adjustment ranges.

Compliance shall be verified by inspection.

7.3 Folding and adjusting mechanisms shall be securely locked when a walking aid is in the working position.

Compliance shall be verified by inspection.

8 Information supplied by the manufacturer

8.1 The requirements given in clause 23 of prEN 12182:1997 apply, together with 8.2 - 8.5 below.

8.2 Information on whether or not the walking aid is designed for indoor or outdoor use, according to 6.3.

8.3 Information regarding assembly, adjustment of all kinds, folding and unfolding of a walking aid shall accompany each product or be clearly marked on it.

8.4 A walking aid shall be clearly and indelibly marked with the maximum permissible user weight.

8.5 A walking aid shall be clearly and indelibly marked with the maximum limits of its adjustment ranges (see 7.2).

Annex A (Informative) -

European Standards concerning walking aids, produced or currently being developed by CEN/TC 293

Level 1:	prEN 12182	Technical aids for disabled persons - General requirements and test methods
Level 2:	EN 1985	Walking aids - General requirements and test methods (this document)
Level 3:	EN ISO 11334-1:1997	Elbow Crutches - Requirements and test methods
	prEN ISO 11199-1	Walking Frames - Requirements and test methods
	prEN ISO 11199-2	Rollators - Requirements and test methods
	prEN ISO 11334-4	Walking sticks with three or more legs - Requirements and test methods

Note: The above listed level 3-documents are International Standards as well. The use or the status as International Standards is not affected by the European 3-level system.

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