EESTI STANDARD EVS-EN 12182:2000

Tehnilised abivahendid puuetega inimestele. Üldnõuded ja katsemeetodid

Technical aids for disabled persons- General requirements and test methods

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 12182:2000 sisaldab Euroopa standardi EN 12182:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 18.02.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12182:2000 consists of the English text of the European standard EN 12182:1999. This document is endorsed on 18.02.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard specifies general requirements and test methods for technical aids for disabled persons.	**Scope:** This standard specifies general requirements and test methods for technical aids for disabled persons.

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Võtmesõnad:

EUROPEAN STANDARD
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English version

Technical aids for disabled persons

General requirements and test methods

Aides techniques pour personnes handicapées – Exigences générales et méthodes d'essai

Technische Hilfen für behinderte Menschen – Allgemeine Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 1999-08-22.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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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 March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

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 ZA, which is an integral part of this standard.

This standard provides one means to demonstrate that technical aids for disabled persons, 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.

Level 2 and 3 may be combined into one single document.

All European Standards produced or currently being developed by CEN/TC 293 are listed in Annex A.

This standard is a level 1 standard and contains requirements and recommendations which are generally applicable to technical aids for disabled persons. For certain types of aids, these requirements are to be supplemented, modified or replaced by the special requirements of a standard for a particular aid (level 2 or 3).

The level 2 standards apply to a more restricted set or family of technical aids such as walking aids. The level 3 standards apply to specific types of technical aids, e.g. elbow crutches and urine collection bags.

Where standards for particular aids or groups of aids exist (level 2 or 3), this general standard should not be used alone. 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 level.

European and International Standards for other technical aids for disabled persons are being or may be developed by other technical committees within CEN/CENELEC, ISO/IEC (e.g. hearing aids) and other organizations. For such aids, this level 1 standard is only applicable if explicitly cited as a normative reference in the particular standard, although it may be used for general guidance within the field of technical aids for disabled persons.

NOTE 1: Special care is required in applying this general standard to aids for which no particular standard exists to ensure that all aspects of safety are covered in the particular circumstances of the use of those aids. Guidance is given on aspects of the Essential Requirements of EU Directive 93/42/EEC to assist in this process.

NOTE 2: The use of technical aids may involve undesirable side effects and it is necessary to establish a balance between achieving the desired end result and the risk of such side effects. Hence, in exceptional circumstances, provision is made within this standard for clinical needs to override the requirements of this standard so long as adequate warnings are given.

NOTE 3: This standard calls for technical documentation to be prepared which may be used by manufacturers as part of the technical documentation required by EU Directive 93/42/EEC.

NOTE 4: Where this standard does not fully apply to particular aids, contracting parties should consider if appropriate parts of the 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 EU Directive 93/42/EEC.

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.

1 Scope

This European Standard specifies general requirements and test methods for technical aids for disabled persons which are intended by the manufacturer to be medical devices for the purposes of EU Directive 93/42/EEC concerning medical devices.

This standard does not apply to technical aids which achieve their intended purpose by administering pharmaceutical substances to the user.

Where other European Standards exist for particular types of technical aids then those standards apply. However, some of the requirements of this standard may still apply and may be specified in those other European standards

NOTE: Not all the items listed in EN ISO 9999:1998 are medical devices. Contracting parties may wish to consider if this standard, or parts of this standard can be used to specify aids which are not medical devices as defined in the EU Directive 93/42/EEC.

2 Normative references

This European Standard incorporates by dated or undated reference, provision 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 418	Safety of machinery. Emergency stop equipment, functional aspects - Principles for design
EN 540:1993	Clinical investigations of medical devices for human subjects
EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices - Validation and routine control of sterilization by irradiation.
EN 554	Sterilization of medical devices - Validation and routine control of steam sterilization by moist heat.
EN 556	Sterilization of Medical Devices - Sterility Assurance Level for Medical Devices labelled 'Sterile' - Requirements.

EN 563	Safety of machinery - Temperatures of touchable surfaces - Ergonomics data to establish temperature limit values for hot surfaces
EN 597-1	Furniture - Assessment of the ignitability of mattresses and bed bases - Part 1; Ignition source: smouldering cigarette.
EN 597-2	Furniture - Assessment of the ignitability of mattresses and bed bases - Part 2: Ignition source: Match flame equivalent.
EN 614-1	Safety of Machinery, Ergonomic design principles. Part 1: Terminology and general principles.
EN 868-1	Packaging materials for sterilisation of wrapped goods - Part I: General requirements and requirements for the validation of packaging for terminally sterilized devices.
EN 1021-1	Furniture - Assessment of the ignitability of upholstered furniture - Part 1: Ignition source: smouldering cigarette
EN 1021-2	Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source: Match flame equivalent
EN 1041	Information supplied by the manufacturer with medical devices
EN 1441:1997	Medical devices - Risk analysis
prEN 12442-1:1998	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 1: Analysis and management of risk
EN ISO 9999:1998	Technical aids for disabled persons - Classification
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests
EN ISO 12952-1	Textiles - Burning behaviour of bedding items - Part 1: Ignitability by a smouldering cigarette - General testing procedures.
EN ISO 12952-2	Textiles - Burning behaviour of bedding items - Part 2: Ignitability by a smouldering cigarette - specific testing procedures.

EN ISO 12952-3	Textiles - Burning behaviour of bedding items - Part 3: Ignitability by a small open flame - General testing procedures.
EN ISO 12952-4	Textiles - Burning behaviour of bedding items - Part 4: Ignitability by a small open flame - Specific testing procedures.
EN 60335-1	Safety of household and similar electrical appliances - Part 1: General requirements.
EN 60601-1:1987	Medical electrical equipment: Part 1: General requirements for safety.
EN 60601-1-2	Medical Electrical Equipment - Part 1: General requirements for safety - 2 collateral standard: Electromagnetic compatibility - Requirements and test methods.
EN 60601-1-4	Medical electrical equipment: Part 1: General requirements for safety. 4 Collateral standard: Programmable electrical medical systems
EN 61000-3-2	Electromagnetic compatibility (EMC) – Part 3: Limits - Section 2: Limits for harmonic current emissions.
EN 61000-3-3	Electromagnetic compatibility (EMC) – Part 3: Limits - Section 3: Limitation of voltage fluctuations and flicker in low voltage systems for equipment with current up to 16 A.
EN 61000-4-3	Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic field immunity

NOTE: Standards which are referred to in the text as informative material are listed in Annex B.