

Abistavad tooted puuetega inimestele. Üldnõuded ja katsemeetodid

Assistive products for persons with disability - General requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 12182:2012 sisaldab Euroopa standardi EN 12182:2012 ingliskeelset teksti.	This Estonian standard EVS-EN 12182:2012 consists of the English text of the European standard EN 12182:2012.
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English Version

**Assistive products for persons with disability - General
requirements and test methods**

Produits d'assistance pour personnes en situation de
handicap - Exigences générales et méthodes d'essai

Technische Hilfen für behinderte Menschen - Allgemeine
Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 9 March 2012.

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Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 12182:2012) has been prepared by Technical Committee CEN/TC 293 "Assistive products for persons with a 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of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by November 2012.

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 12182:1999.

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 EU Directive(s).

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

This standard provides one means to demonstrate that assistive products for persons with a disability, which are also medical devices, conform to the essential requirements outlined in general terms in Annex I 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 assistive products for persons with a disability. These are as follows, with Level 1 being the highest:

- Level 1: General requirements for assistive products;
- Level 2: Particular requirements for families of assistive products;
- Level 3: Specific requirements for types of assistive products.

Levels 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 assistive products for persons with a disability. For certain types of assistive products, these requirements are to be supplemented, modified or replaced by the special requirements of a standard for a particular assistive product (Level 2 or 3).

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

Where standards for particular assistive products or groups of assistive products 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 assistive product, it is necessary to start with standards of the lowest available level.

European and International Standards for other assistive products for persons with a disability are being or may be developed by other technical committees within CEN/CENELEC, ISO/IEC (e.g. assistive products for hearing) and other organisations. For such assistive products, 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 assistive products for persons with a disability.

NOTE 1 Special care is required in applying this general standard to assistive products for which no particular standard exists to ensure that all aspects of safety are covered in the particular circumstances of the use of those assistive products. 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 assistive products 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 assistive products, contracting parties should consider if appropriate parts of the standard can be used.

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, Croatia, 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, Turkey and the United Kingdom.

1 Scope

This European Standard specifies general requirements and test methods for assistive products for persons with a disability, which are medical devices according to the definition laid down in the EU Directive 93/42/EEC.

This European Standard does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

Where other European Standards exist for particular types of assistive products then those standards apply. However, some of the requirements of this standard may still apply and may be considered in addition to those in other European standards.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source: Smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered 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 980, *Symbols for use in the labelling of medical 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 of medical devices*

EN ISO 25424, *Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424)*

EN 60065, *Audio, video and similar electronic apparatus — Safety requirements (IEC 60065)*

EN 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1)*

EN 60529, *Degrees of protection provided by enclosures (IP Code) (IEC 60529)*

EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007, modified)*

EN 60695-11-10, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods (IEC 60695-11-10)*

EN 60730-1, *Automatic electrical controls for household and similar use — Part 1: General requirements (IEC 60730-1)*

EN 60950-1, *Information technology equipment — Safety — Part 1: General requirements (IEC 60950-1)*

EN 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2)*

EN 61000-3-3, *Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection (IEC 61000-3-3)*

EN 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3)*

EN 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test (IEC 61000-4-8)*

EN 62304, *Medical device software — Software life-cycle processes (IEC 62304)*

EN 80601-2-35, *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35)*

EN ISO 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746)*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1)*

EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1)*

EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2)*

EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1)*

EN ISO 12952-1, *Textiles - Assessment of the ignitability of bedding items - Part 1: Ignition source: smouldering cigarette (ISO 12952-1)*

EN ISO 12952-2, *Textiles - Assessment of the ignitability of bedding items - Part 2: Ignition source: match-flame equivalent (ISO 12952-2)*

EN ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces (ISO 13732-1)*

EN ISO 13850, *Safety of machinery — Emergency stop — Principles for design (ISO 13850)*

EN ISO 14155, *Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971)*

EN ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1)*

EN ISO 24415-1, *Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips (ISO 24415-1)*

ISO 24415-2, *Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches*

CISPR 11, *Industrial, scientific and medical equipment — Radio-frequency disturbance characteristics — Limits and methods of measurement*

NOTE Standards which are referred to in the text as informative material are listed in the Bibliography.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

assistant

person who is helping a person with a disability in using the assistive product

Note 1 to entry: Examples of the ways assistants help persons with a disability are; pushing wheelchairs, operating hoists, assisting with entering and leaving seats, beds and wheelchairs.

3.2

assistive product(s)

instrument, equipment or technical system intended by the manufacturer to be used for the prevention, treatment or alleviation of, or compensation for injury, impairment, a disability or handicap of a person with a disability

Note 1 to entry: The definition is not identical to the definition in EN ISO 9999 because EN 12182 is restricted to medical devices.

3.3

bedding

items normally placed on a mattress

Note 1 to entry: Bedding includes; mattress covers, underlays, incontinence sheets and pads, sheets, blankets, electric blankets, quilts (duvets) and their covers, pillows and bolsters, pillow cases.

3.4

class I

referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution so that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

3.5

class II

referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions