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Tehnični pripomočki za invalidne osebe - Splošne zahteve in preskusne metode

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

Technische Hilfen für behinderte Menschen - Allgemeine Anforderungen und Prüfverfahren

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

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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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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of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by November 2012.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 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

3.6
clinical evaluation
means for confirming that an assistive product conforms to the requirements of EU Directive 93/42/EEC when used as intended by the manufacturer

Note 1 to entry: It may include a compilation of clinical data, any scientific literature and the results of any clinical investigations, taking into account any relevant harmonized standards.

3.7
clinical investigation
systematic study into human subjects, undertaken to verify the safety and performance of a specific medical device, under the manufacturer's intended conditions of use

3.8
disability
umbrella term for impairments, activity limitations and participation restrictions denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)

[SOURCE: ICF 2001, WHO]

3.9
hand held assistive products
equipment intended to be supported by the hand during normal use

3.10
impairments
problems in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2001, WHO]

3.11
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

Note 1 to entry: This information includes pre-sale information.

3.12
maximum rated load
greatest permissible load as specified by the manufacturer

Note 1 to entry: Includes user mass and the mass and loading of the accessories (mattresses, baskets, etc.).

3.13
medical electrical system
combination, as specified by its manufacturer, of items of equipment, at least one of which is a medical equipment to be inter-connected by functional connection or by use of a multiple socket-outlet

3.14
mobile assistive products
equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

3.15
normal use
operation. including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use

Note 1 to entry: Normal use is not to be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc..

3.16
operator
person handling the assistive product

Note 1 to entry: The operator can either be the user or the assistant.

3.17
person with a disability
person with one or more impairments, one or more activity limitations, one or more participation restrictions or a combination thereof

[SOURCE: ICF 2001, WHO]

3.18
portable assistive products
equipment intended to be moved from one location to another while being carried by one or more persons

3.19
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

3.20
technical documentation
manufacturer's data that shows that an assistive product conforms to the requirements of this standard and which may be used as part of the technical documentation required by EU Directive 93/42/EEC for conformity assessment procedures

3.21
user
person with a disability for whom the assistive product is intended

4 General requirements

4.1 Risk analysis

The safety of an assistive product shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in EN ISO 14971.

When using an assistive product in combination with a device that is not a medical device the device shall behave in a safe way regarding the MDD as a system.

NOTE 1 In the case of certain disabilities there may be a need for higher levels of safety for equipment used to offset the effects of that disability.

NOTE 2 Conformity with the requirements of this standard may be used to claim compliance with the requirements of EN ISO 14971 for those hazards and risks identified in this standard.

4.2 Intended performance and technical documentation

a) An assistive product shall have sufficient strength and durability to sustain all loads expected during its intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and scientific literature in addition to requirements in this standard, strength and/or durability calculations, appropriate test standards and their test results.

b) The intended performance including, if appropriate, strength, durability and tipping stability of an assistive product shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.

c) The technical documentation shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, conformity with appropriate test standards and their test results.

4.3 Clinical evaluation and investigation

A clinical evaluation shall be done for all assistive products.

If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN ISO 14155-1 and EN ISO 14155-2. A clinical evaluation shall always be done before performing a clinical investigation.

NOTE Guidance for the evaluation of clinical data is given in MEDDEV 2.7.1.

4.4 Assistive products that can be dismantled

If it is intended that an assistive product can be dismantled for storage or transportation, it shall not be possible to reassemble the assistive product in a manner that presents a hazard.

4.5 Fasteners

If it is intended that an assistive product can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling shall not be single use fasteners.

EXAMPLE Single use fasteners include wood screws and self-tapping screws.

4.6 Mass limits

The user mass limit and maximum rated load shall be declared by the manufacturer.

4.7 Immobilising means

If the movement of an assistive product or of any of its parts constitutes a risk for the user or a nearby person, there shall be immobilising means that provide control of the speed and/or prevent any undesired movement.

4.8 Design requirements in relation to persons with cognitive impairment

a) Persons with cognitive impairment shall be considered potential users of all assistive products.

b) Cognitive impairment aspects shall, as far as possible, be considered in the design, performance and use of all assistive products.

c) The result of such considerations shall be described in the producer´s technical documentation.

d) An assistive product may be used not only by whom it is primarily intended, but also by an assistant. Risk management shall include all involved persons.

NOTE Cognition is the understanding, integrating and processing of information. Cognition involves fundamental mental characteristics such as the capacity to learn, remember, understand, solve problems, plan, keep focused, etc. Cognitive impairment may reduce, more or less, the possibilites to learn how to operate a product, to understand warnings, etc. This increases the risk that persons with cognitive impairment will find themselves in hazardous situations. Cognitive impairment also involves a large and growing number of the population of Europe and other parts of the industrialized world.

For further guidance, see Annex C.

5 Materials

5.1 General

Manufacturers should, wherever possible, use materials that can be recycled for further use.

For guidance, see EN 60601-1-9.

5.2 Flammability

5.2.1 General

Manufacturers shall consider the environments and methods of use to which an assistive product or any materials that are usually used in combination with this assistive product, will be exposed and take appropriate steps to minimize any fire hazard.

The manufacturer shall include a warning in the instructions for use about safe combinations of flame resistant and non flame resistant materials.

NOTE 1 If flammable materials are used it needs to be indicated in the documentation.

Every effort should be made to use products which meet the flammability requirements as it is of particular importance to persons with a disability who may not be able to escape from a fire. The use of non-flame retardant materials should be reviewed regularly, as there is continuous development in this field.

Special attention shall be paid to assistive products where the main purpose is protection from fire.

NOTE 2 For guidance, see B.5.2.

5.2.2 Upholstered parts, mattresses, bed bases and bedding

Upholstered parts, mattresses and bed bases and bedding shall comply with the requirements of 5.2.2 a) or 5.2.2 b).

a) If the manufacturer claims that an assistive product is resistant to ignition by a cigarette or a small flame it shall comply with the appropriate requirements in 5.2.3, 5.2.4 or 5.2.5;

b) if the clinical requirements prevent the use of materials which comply with 5.2.2 a), the reasons shall be included in the technical documentation and the assistive product shall be supplied with the following:

   1) warning that it is not flame retardant, placed on the product if possible, and included in the instructions for use; and

   2) a description of the precautions required to offset the increased risk.

5.2.3 Upholstered parts

If the manufacturer claims that the upholstered parts are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-1 and EN 1021-2.

5.2.4 Mattresses and bed bases

If the manufacturer claims that mattresses and/or bed bases are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 597-1 and EN 597-2.