SLOVENSKI STANDARD
oSIST prEN 12182:2009

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Tehniļ ni pripomoļ ki za invalidne osebe - Sploġne 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 draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 293.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (prEN 12182:2009) has been prepared by Technical Committee CEN/TC 293 “Assistive products for persons with disability”, the secretariat of which is held by SIS.

This document is currently submitted to the CEN Enquiry.

This document will supersede 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 EC Directive(s).

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

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 <>, and conflicting standards shall be withdrawn at the latest by <>.

This standard provides one means to demonstrate that assistive products for persons with disability, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42/EEC, as amended by Directive 2007/47/EC. It is not intended to provide a means to show conformity with the requirements of any other directive.

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

There are three levels of European Standards dealing with assistive products for persons with 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.

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 assistive products for persons with 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 disability are being or may be developed by other technical committees within CEN/CENELEC, ISO/IEC (e.g. assistive products for hearing) and other organizations. 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 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, as amended by Directive 2007/47/EC 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, as amended by 2007/47/EC.

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.

1 Scope

This European Standard specifies general requirements and test methods for assistive products for persons with disabilities, which are intended by the manufacturer to be medical devices for the purposes of EU Directive 93/42/EEC, as amended by 2007/47/EC.

This 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 those 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, as amended by 2007/47/EC.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 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 716-2, *Furniture – Children's cots and folding cots for domestic use – Part 2: Test methods*

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 ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

EN ISO 9999, *Assistive products for persons with disability – Classification and terminology*

EN ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing*

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*

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*

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

EN ISO 12952-1, *Textiles – Burning behaviour of bedding items – Part 1: General test methods for the ignitability by a smouldering cigarette*

EN ISO 12952-2, *Textiles – Burning behaviour of bedding items – Part 2: Specific test methods for the ignitability by a smouldering cigarette*

EN ISO 12952-3, *Textiles – Burning behaviour of bedding items – Part 3: General test methods for the ignitability by a small open flame*

EN ISO 12952-4, *Textiles – Burning behaviour of bedding items – Part 4: Specific test methods for the ignitability by a small open flame*

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

EN ISO 13850, *Safety of machinery – Emergency stop – Principles for design*

EN ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects – Part 1: General requirements*

EN ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans*

EN ISO 14971, *Medical devices – Application of risk management to medical devices*

EN 15424, *Sterilization of medical devices – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices*

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

FprEN ISO 24415-1–[1)], *Tips for assistive products for walking – Requirements and test methods – Part 1: Friction of tips*

ISO DIS 24415-2–[2)], *Durability of tips for crutches*

EN 60065, *Audio, video and similar electronic apparatus – Safety requirements*

EN 60335-1, *Household and similar electrical appliances – Safety – Part 1: General requirements*

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

EN 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

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1) To be published.

2) To be published.

EN 60601-2-35, *Medical electrical equipment - Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use*

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

EN 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

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

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*

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

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

EN 62304, *Medical device software -- Software life-cycle processes*

IEC 60730-1, *Automatic electrical controls for household and similar use – Part 1: General requirements*

CISPR 11, *Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement*

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

3 Terms and definitions

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

3.1
assistant
person who is helping a person with disability in using the assistive product

NOTE Examples of the ways in which assistants helps persons with disabilities 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, disability or handicap of a person with disability

NOTE The definition is not identical with the definition in EN ISO 9999 because EN 12182 is restricted to medical devices.

3.3
bedding
items normally placed on a mattress

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

3.5
class II
term 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 as amended by 2007/47/EC when used as intended by the manufacturer.

NOTE 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
any systematic study in 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)

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

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

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

NOTE 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 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 maintenance, service, transport, etc. as well.

3.16
operator
person handling the assistive product

NOTE The operator can either be the user or the assistant.

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

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 as amended by 2007/47/EC for conformity assessment procedures

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

4 General requirements

4.1 Risk management

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

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.

NOTE 3 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.

4.2 Intended performance and technical documentation

a) An assistive product shall have sufficient strength and durability to sustain all loads expected during 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 14155-1:2003 and EN ISO 14155-2:2003. A clinical evaluation shall always be done before performing a clinical investigation. Evaluation of clinical data should be done using 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 asisitive product or of any of its parts costitutes a risk for the user or a nearby person, there shall be immobilising means that provide control of the speed and/or prevent any un-desired movement.

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, Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious for guidance.

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 user instruction about safe combinations of flame resistant and non flame resistant materials.

If an assistive product is not flame resistant, the manufacturer's information shall describe the precautions necessary to ensure the safety of the user and/or assistant and the assistive product shall be labelled to show that it is not flame resistant.

Every effort should be made to use products which meet the flammability requirements as it is of particular importance to persons with disabilities 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 were the main purpose is protection from fire.

NOTE For guidance see Annex B, 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 smoker´s materials 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 user instructions;

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 smoker´s materials, 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 smoker´s materials, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 597-1 and EN 597-2.

5.2.5 Bedding

If the manufacturer claims that bedding is resistant to ignition by cigarette, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN ISO 12952-1 and EN ISO 12952-2.

If the manufacturer claims that bedding is resistant to ignition by small flames, such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN ISO 12952-3 and EN ISO 12952-4.

5.2.6 Moulded parts

If the manufacturer claims that a moulded part is resistant to ignition by cigarettes, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 60695-11-10 FV-1 or better. If the product is of a type that the user normally (by himself) cannot escape from or detect as a dangerous situation it shall be FV-0.

If the manufacturer claims that moulded parts is resistant to ignition by small flames , such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 60695-11-10.

5.3 Biocompatibility and toxicity

Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1 and shall fulfil the following requirements.

The assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the product.

The assistive products must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

The result of the assessment shall be incorporated in the risk management (see 4.1).

The product shall not contain or release any carcinogenic, mutagenic or reprotoxic chemicals (CMR chemicals) in amounts exceeding 0.1 % by weight of the whole product.

The product shall not contain or release any substance which is listed in Annex XIII of Reach, in amounts exceeding 0.1 % by weight of the whole product.

Textile parts of the product shall not contain formaldehyde in quantities higher than 75 ppm.

Textile parts of the product shall not contain pesticide residue in quantities higher than 0.5 ppm measured as a sum of all pesticides as given in Annex D, D.5.

The amount of extractable heavy metals in textile parts shall not exceed the following limits: Sb, 30.0 ppm; As, 0.5 ppm; Pb, 0.8 ppm; Cd, 0.1 ppm; Cr, 2.0 ppm; Co, 4.0 ppm; Cu, 50.0 ppm; Ni, 1.0 ppm; Hg, 0.03 ppm; and Sn, 4.0 ppm.

Textile parts of the product shall not contain phthalates in quantities higher than 0.1 ppm.

Chlorinated benzenes and toluenes shall not be present in textile parts in quantities higher than 1.0 ppm.

Orthophenylphenol (OPP) shall not be present in textile parts in quantities higher than 100 ppm.

Textile parts shall not contain flame retardants that are assigned risk phrases R50, R51, R52 or R53 in amounts exceeding 0.1 % by weight.

Textile parts shall not contain finishes that are assigned risk phrases R50, R51, R52 or R53 in amounts exceeding 0.1 % by weight.

Textile parts shall not contain or release colorants which are classified to be carcinogenic and listed in Annex D, D.5.

The product shall not contain or release substances which are assigned any of the following Risk-phrases (or combinations thereof): R24, R27, R38, R42 and R43.

Textile parts shall not contain or release colorants which are classified to be allergenic and listed in Annex D, D.5.

The colour fastness to acidic and alkaline perspiration of textile parts falls within the range of 3 to 4.

Plastic parts of the product shall not contain phthalates in quantities higher than 0.1 ppm. Excluded from this criterion are products for which the use of phthalates is necessary on technical grounds.

The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in plastic components shall not exceed 100 ppm.

Halogenated polymers and additions of organic halogenated compounds as flame retardants shall not be permissible in plastics. Exempted are Fluor organic additives (< 0.5 weight percent), fluoroplastics, plastic parts weighing less than 25 grams and large-sized plastic parts which are reused. The small plastic parts (< 25 g) and large-sized plastic parts may not contain PBBs, PBDEs or chlorinated paraffin's.

Metal parts must not be coated with cadmium, chromium, nickel and their compounds. In exceptional cases, metal surfaces may be treated with chromium or nickel where this is necessary on the grounds of heavy physical wear or in the case of parts that require particularly tight connections. This exemption does not include parts that are intended to come into frequent contact with skin and the treated parts must be recyclable.

NOTE 1 The product should not contain any PBT and vPvB substances (based on the criteria listed in Annex XII of REACH) and shall not contain any PBT and vPvB substances listed in Annex XIII of REACH, in amounts exceeding 0.1 % by weight.

NOTE 2 For additional guidance and test methods see Annex D.

5.4 Contaminants and residues

5.4.1 General

The requirements given in 5.4.2 do not apply to the body fluids which may be collected in an assistive product (e.g. stomacare products) but only to those substances which are an integral part of an assistive product or are needed for its function (e.g. oil and grease).

5.4.2 Substances which may leak from an assistive product in intended use and in fault conditions

Substances which may leak from the assistive product shall either:

a) be assessed for biocompatibility in accordance with the guidance given in EN ISO 10993-1. The assessment shall take into account the intended use and contact by those involved in user care, transport and storage;

or

b) be provided with protection that minimizes the possibility of such substance becoming a biological hazard.

NOTE 1 Substances that can leak include lubricants and hydraulic fluids.

NOTE 2 An example of a method of protection from a hazardous substance is where batteries are placed in a container made from acid resistant material.