SLOVENSKI STANDARD
SIST EN 12182:2000

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Tehniļ ni pripomoļ ki za invalidne osebe - Sploġne zahteve in preskusne metode

Technical aids for disabled persons - General requirements and test methods

Technische Hilfen für behinderte Menschen - Allgemeine Anforderungen und Prüfverfahren

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

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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 22 August 1999.

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.

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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.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.

3 Definitions

For the purposes of this standard the following definitions and abbreviations apply:

3.1 **Technical aid(s)**: Instrument, equipment (for disabled persons) 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.

NOTE 1: This is abbreviated to **aid(s)** in this text.

NOTE 2: This definition of technical aid is slightly different to the definition in EN ISO 9999:1998.

3.2 **Impairment**: Any loss or abnormality of psychological, physiological function or anatomical structure or function. [Identical with definition in EN ISO 9999:1998]

3.3 **Disability**: Restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being. [Identical with definition in EN ISO 9999:1998]

3.4 **Handicap**: Disadvantage for a given individual, resulting from an impairment or disability, that limits or prevents the fulfilment of a role that is normal (depending on age, sex and social and cultural factors) for that individual. [Identical with definition in EN ISO 9999:1998]

3.5 **Disabled person**: Person with one or more impairments, one or more disabilities, one or more handicaps or a combination of impairment, disability and/or handicap. [Identical with definition in EN ISO 9999:1998]

3.6 **Maximum rated load**: Greatest permissible load as specified by the manufacturer.

3.7 **User**: Person using the aid, either a disabled person and/or an attendant.

3.8 **Technical documentation**: Manufacturer's data that shows that an aid 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.

3.9 **Clinical evaluation:** Means for confirming that an aid conforms to the requirements of EU Directive 93/42/EEC when used as intended by the manufacturer. 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.

3.10 **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 [EN 540:1993, clause 3.3].

3.11 **Attendant:** Person who assists a disabled person.

NOTE: Examples of the ways in which attendants assist disabled persons are: Pushing wheelchairs, operating hoists, assisting with entering and leaving seats, beds and wheelchairs.

3.12 **Single fault condition:** Condition in which a single means for protection against a safety hazard in an aid is defective.

3.13 **Bedding:** Those 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.

4 General requirements

4.1 Risk analysis

The safety of an aid shall be assessed by identifying hazards and estimating the risks associated with them using the procedure specified in EN 1441:1997 supplemented by the requirements of 5.2, 5.4.2, 5.5, 6, 8.2.1, 9.4, 10, 22 and 24.

NOTE 1: The results of this assessment may be used to select from this standard the requirements which apply.

NOTE 2: 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 3: Conformity with the requirements of this standard may be used to claim compliance with the requirements of clause 4.5 of EN 1441:1997 for those hazards and risks identified in the following clauses.

4.2 Intended performance and technical documentation

a) An aid 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, strength and/or durability calculations, appropriate standards and test results.

b) The intended performance including, if appropriate, strength, durability and tipping stability of an aid 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, appropriate standards and test results.

4.3 Clinical evaluation

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 540:1993.

4.4 Aids that can be dismantled

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

4.5 Single use fasteners

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

NOTE: Single use fasteners include wood screws and self-tapping screws.

4.6 User mass limits

No normative requirements. Normative requirements may be considered for a future development of this standard.

NOTE: For guidance see 23 4) and Annex C, C.4.6

5 Materials

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

5.1 Flammability

Manufacturers shall consider the environments and methods of use to which an aid will be exposed and take appropriate steps to minimize any fire hazard.

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

NOTE 1: Every effort should be made to use products which meet the flammability requirements as it is of particular importance to disabled persons 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.

NOTE 2: For guidance see Annex C, C.5.1.

5.1.1 Upholstered parts, mattresses, bed bases and bedding

Upholstered parts, mattresses and bed bases and bedding shall comply with the requirements of 5.1.1 a) or 5.1.1 b).

a) if the manufacturer claims that an aid is resistant to smoker's materials it shall comply with the appropriate requirements in 5.1.2, 5.1.3 or 5.1.4;

b) if the clinical requirements prevent the use of materials which comply with 5.1.1a), the reasons shall be included in the technical documentation and the aid shall be supplied with the following:

1) a 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.

5.1.2 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 aid are tested in accordance with EN 1021-1 and EN 1021-2.

5.1.3 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.

5.1.4 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 .