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TECHNICAL AIDS FOR DISABLED PERSONS - GENERAL REQUIREMENTS AND TEST METHODS

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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.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