Technical aids for disabled persons - Environmental control systems for daily living

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 16201:2006 sisaldab Euroopa standardi EN ISO 16201:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 24.11.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 16201:2006 consists of the English text of the European standard EN ISO 16201:2006. This document is endorsed on 24.11.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability.	**Scope:** This International Standard specifies functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability.

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Võtmesõnad:

EUROPEAN STANDARD

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English Version

Technical aids for disabled persons - Environmental control systems for daily living (ISO 16201:2006)

Aides techniques pour personnes avec un handicap - Systèmes de commande à distance pour la vie quotidienne (ISO 16201:2006)

Technische Hilfen für Behinderte - Umgebungs-Steuersysteme für das Alltagsleben (ISO 16201:2006)

This European Standard was approved by CEN on 19 August 2006.

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, 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 and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 16201:2006: E

Foreword

This document (EN ISO 16201:2006) has been prepared by Technical Committee CEN/TC 293 "Assistive products for persons with disability", the secretariat of which is held by SIS, in collaboration with Technical Committee ISO/TC 173 "Technical systems and aids for disabled or handicapped persons".

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 April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 and United Kingdom.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, *Medical Devices Directive*.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3, 4, 5.	
4.1	6	
4.2	9.1, 11.4, 13	
4.3	7.1	Only flammability and biocompatibility considered.
5.1	12.1	
5.2	12.9	
6	9.1, 9.2, 9.3, 11.3, 12.5, 12.6, 12.7.1, 12.7.4, 12.7.5	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 16201

First edition
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Technical aids for persons with disability — Environmental control systems for daily living

Aides techniques pour personnes handicapées — Systèmes de commande à distance pour la vie quotidienne

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16201 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products for persons with disability*, in collaboration with Technical Committee ISO/TC 173, *Assistive products for persons with disability*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

This International Standard provides one means to demonstrate that environmental control systems 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. 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 persons with disability. These are as follows, with level 1 being the highest:

a) Level 1: general requirements for technical aids;

b) Level 2: particular requirements for families of technical aids;

c) Level 3: specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (Level 2 or 3), 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 standard.

This is a combined Level 2, and Level 3 standard (lowest possible) for environmental control systems for persons with disability, which are also medical devices, as specified in the scope.

Technical aids for persons with disability — Environmental control systems for daily living

1 Scope

This International Standard specifies functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability.

NOTE Such systems are also known as electronic aids to daily living.

The aim of this International Standard is to provide safety requirements and recommendations for manufacturers of such environmental control systems.

Target devices are not covered by this International Standard. Technical requirements for items of equipment connected within the system are to be covered by their own specific standards, e.g. adjustable beds.

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.

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

EN 55011, *Industrial, scientific and medical (ISM) radio-frequency equipment — Radio disturbance characteristics — Limits and methods of measurement*

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

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

IEC 60601-1-1, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

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