INTERNATIONAL STANDARD

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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*