National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 16201:2006

ICS 11.180.01

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TECHNICAL AIDS FOR DISABLED PERSONS - ENVIRONMENTAL CONTROL SYSTEMS FOR DAILY LIVING (ISO 16201:2006)

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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

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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of an identical text or by endorsement, at the latest by April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.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.