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IRISH STANDARD

I.S. EN ISO 10535:2006

ICS 11.180.10

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HOISTS FOR THE TRANSFER OF DISABLED PERSONS - REQUIREMENTS AND TEST METHODS (ISO 10535:2006)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:

16 February 2007

Price Code Q

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10535

December 2006

ICS 11.180.10

Supersedes EN ISO 10535:1998

English Version

Hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:2006)

Lève-personnes pour transférer des personnes handicapées - Exigences et méthodes d'essai (ISO 10535:2006)

Lifter für Behinderte - Anforderungen und Prüfverfahren (ISO 10535:2006)

This European Standard was approved by CEN on 18 October 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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 10535:2006: E

Foreword

This document (EN ISO 10535:2006) 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 June 2007, and conflicting national standards shall be withdrawn at the latest by June 2007.

This document supersedes EN ISO 10535:1998.

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)

Clauses of this EN addressing essential requirements or other provisions of EU Directives

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.

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 Standard and Directive 93/42/EEC

Clauses/sub-clauses of this European Standard	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/Notes
4 – 10	1	ISO 14971 (risk analysis part) is generally valid
4 – 10	2	
4.7, 10.6	3	
4.9, 4.10, 5.5, 6.5, 6.6, 10.8, 10.9	4	
4 – 10	5	Requirements for packaging not covered. Equivalent clauses of EN 12182:1997 apply. Information supplied by the manufacturer 4.13, 5.6, 6.7, 7.6, 8.4, 9.4, 10.16
4.1.1, 10.1.2	6	ISO 14971 (risk analysis part) is generally valid
4.3.1.4, 8.2, 8.4.2, 9.1, 9.4.2, 10.3.1.2,10.14	7.1	Flammability. Testing according to EN 1021-1:1993, EN 1021-2:1993
4.7.1.2, 4.7.2.2, 10.6	7.2	
	7.5, 7.6	Equivalent clauses of EN 12182:1997 apply.
4.13.3, 8.4.1, 9.4.2, 10.14, 10.15	8.1	
4.3.1.9, 4.3.1.21, 4.4, 4.5, 4.6, 7.2.1.1, 8.1, 8.4, 9.1, 9.4, 10.3.1.2, 10.3.1.4, 10.4, 10.5, 10.14, 10.15	9.1	

Table ZA.1 *(continued)*

Clauses/sub-clauses of this European Standard	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1, 4.1.2, 4.3.1.14, 4.3.1.23, 4.9, 5.5, 6.5, 9.2, 10.1.2, 10.1.3, 10.3.1.2, 10.3.1.4, 10.8, 10.15	9.2	ISO 14971 (risk analysis part) is generally valid. Ergonomics EN 614-1. Part 1
4.3.1.2, 10.3.1.2	9.3	Fire/explosion due to electrical fault (EN 60601-1)
4.13.3, 10.16.3	10.1	Limits of accuracy. 90/384/EEC Non-automatic Weighing Instruments.
4.3.1.2, 10.3.1.2	12.1	Reference to EN 60601-1
4.3.1.16, 10.3.1.2	12.2	
4.3.1.23, 10.3.1.4	12.5	
4.3.1.2, 10.3.1.2	12.6	
4.1.2, 4.3.1.5, 4.4 until 4.11, 5.2 until 5.6, 6.2 until 6.7, 7.2 until 7.6, 8.1 until 8.4, 9.3, 10.1.2, 10.3.1.2, 10.4 until 10.11	12.7.1	
4.1.3, 10.1.4	12.7.3	Test regarding sound level according to ISO 3746
4.11, 4.12, 10.11, 10.12	12.7.4	
	12.7.5	Equivalent clauses of EN 12182:1997 apply.
4.3.1.15, 4.13.1, 4.13.2, 10.3.1.2, 10.16.1, 10.16.2	12.9	EN 980 and EN 1041 'Information supplied by the manufacturer with medical devices' are generally valid. For electrical details, EN 60601-1 applies
4.13.1, 4.13.2, 8.4.1, 9.4.1, 10.16.1, 10.16.2	13.1, 13.2, 13.3, 13.4, 13.5	EN 980 and EN 1041 are generally valid.
4.13.3, 5.6, 6.7, 7.6, 8.4.2, 9.4.2, 10.16.3, Annex A	13.6	EN 980 and EN 1041 are generally valid. Annex A for guidance.

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