



# SLOVENSKI STANDARD SIST EN ISO 10535:2007

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Nadomešča:  
SIST EN ISO 10535:2000

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**Dvigala za prestavljanje invalidnih oseb - Zahteve in preskusne metode (ISO 10535:2006)**

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

Lifter zum Transport von behinderten Menschen - Anforderungen und Prüfverfahren (ISO 10535:2006)

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

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**Ta slovenski standard je istoveten z: EN ISO 10535:2006**

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**ICS:**

11.180.10	Pripomočki in prilagoditve za gibanje	Aids and adaptation for moving
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**SIST EN ISO 10535:2007**

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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.

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COMITÉ EUROPÉEN DE NORMALISATION  
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**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.

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## 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.

# INTERNATIONAL STANDARD

**ISO**  
**10535**

Second edition  
2006-12-15

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## Hoists for the transfer of disabled persons — Requirements and test methods

*Lève-personnes pour transférer des personnes handicapées —  
Exigences et méthodes d'essai*

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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 10535 was prepared by Technical Committee CEN/TC 293, *Assistive products for persons with disability*, of the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 6, *Hoists for transfer of persons*, in conformance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10535:1998), which has been technically revised.

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## Introduction

It appears from studies that the nursing and caring profession involves many physically burdening factors in the caring for and nursing of disabled persons. A hoist offers a safe means of supportive lifting and moving, either assisted or independently.

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# Hoists for the transfer of disabled persons — Requirements and test methods

## 1 Scope

This International Standard specifies requirements and test methods only for hoists and body-support units intended for the transfer of disabled persons as classified in ISO 9999:2002:

- 12 36 03 Mobile hoists with sling seats
- 12 36 04 Standing mobile hoists
- 12 36 06 Mobile hoists with solid seats
- 12 36 09 Hoist trolleys
- 12 36 12 Stationary hoists fixed to the wall/walls, floor and/or ceiling
- 12 36 15 Stationary hoists fixed to, mounted in or on another product
- 12 36 18 Stationary free-standing hoists
- 12 36 21 Body-support units for hoists

This International Standard does not apply to devices that transport persons between two levels (floors) of a building.

It does not include methods for the determination of ageing or corrosion of such hoists and units.

The requirements of this International Standard are formulated with regard to the needs of both the disabled persons being hoisted and the attendant using the hoist.

## 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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3758, *Textiles — Care labelling code using symbols*

ISO 9999:2002, *Technical aids for persons with disabilities — Classification and terminology*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 14253-1, *Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for proving conformance or non-conformance with specifications*

**ISO 10535:2006(E)**

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

EN 614-1, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 853, *Rubber hoses and hose assemblies — Wire braid reinforced hydraulic type — Specification*

EN 854, *Rubber hoses and hose assemblies — Textile reinforced hydraulic type — Specification*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1021-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: Smouldering cigarette*

EN 1021-2, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source: Match flame equivalent*

EN 12182:1999, *Technical aids for disabled persons — General requirements and test methods*

EN 13480-3:2002, *Metallic industrial piping — Part 3: Design and calculation*

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

IEC 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2005, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current  $\leq 16$  A per phase)*

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IEC 61000-3-3 am1, *Electromagnetic compatibility (EMC) — Part 3: Limits — Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current  $\leq 16$  A*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency electromagnetic field immunity test*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

##### **adverse condition**

condition in which failure is most likely to occur

#### 3.2

##### **attendant**

person who operates the hoist if not the lifted person

#### 3.3

##### **backrest**

part of the body-support unit that supports the back of the person being lifted, transferred or moved along with the associated attachment structure

EXAMPLE A body-support unit can be a sling, seat or stretcher.

**3.4****backwards**

180° to the forwards direction of travel

**3.5****bathtub hoist**

piece of equipment that is specifically designed to be used in or adjacent to a bathtub and with which a disabled person is lifted, transferred or moved

**3.6****body-support unit**

part of the hoist that supports the person being lifted, transferred or moved along with its associated attachment structure

EXAMPLE A body-support unit can be a sling, seat or stretcher.

**3.7****ceiling hoist**

overhead mounted hoist system fixed to the ceiling or wall(s), including the tracking system

**3.8****central suspension point****CSP**

reference point on the hoist to be used for measurements

NOTE This point may be a connecting point.

**3.9****connecting point(s)**

part(s) to which the body-support unit attaches

**3.10****control devices**

part or parts of the hoist which operate the lifting and lowering mechanisms of the CSP as well as other functions

EXAMPLE A function can be the leg opening of the mobile base.

**3.11****end limiting device**

device that stops any movement at a predetermined end position

**3.12****flexible device**

component along with any associated joining components that functions as a lifting device

EXAMPLE A flexible device can be a chain, tape or rope.

**3.13****footrest**

part of the body-support unit that supports the feet

**3.14****forwards**

intended direction of travel, as indicated by the manufacturer in the instructions for use

**3.15****free-standing stationary hoist**

equipment for transferring by lifting and moving a disabled person in an area limited by the system with the hoist free-standing on the floor