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Assistive products - Hoists for the transfer of persons - Requirements and test methods (ISO 10535:2021)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/22

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EUROPÄISCHE NORM

EN ISO 10535

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Supersedes EN ISO 10535:2006

English Version

Assistive products - Hoists for the transfer of persons - Requirements and test methods (ISO 10535:2021)

Produits d'assistance - Lève-personnes pour transférer des personnes - Exigences et méthodes d'essais (ISO 10535:2021)

Lifter zum Transfer von Menschen mit Behinderungen - Anforderungen und Prüfverfahren (ISO 10535:2021)

This European Standard was approved by CEN on 31 August 2021.

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European foreword

This document (EN ISO 10535:2021) has been prepared by Technical Committee ISO/TC 173 "Assistive products" in collaboration with Technical Committee CEN/TC 293 “Assistive products and accessibility” the secretariat of which is held by SIS.

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of an identical text or by endorsement, at the latest by May 2022, and conflicting national standards shall be withdrawn at the latest by May 2022.

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

This document supersedes EN ISO 10535:2006.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10535:2021 has been approved by CEN as EN ISO 10535:2021 without any modification.

INTERNATIONAL STANDARD

ISO 10535

Third edition
2021-10

Assistive products — Hoists for the transfer of persons — Requirements and test methods

Produits d'assistance — Lève-personnes pour transférer des personnes — Exigences et méthodes d'essais

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 10535:2006), which has been technically revised.

The main changes are as follows:

— aspects on hoists with robotic features has been included;

— guidelines regarding compatibility of hoists/body-support units have been included;

— the informative annex on Inspection has been further developed;

— lowering of minimum capacity of a mobile hoist from 120 kg to 100 kg;

— requirement of emergency lowering device for mobile hoist and standing/raising hoists has been included.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

This document specifies requirements and test methods that are relevant to hoists for the transfer of persons with disabilities. This document addresses further needs in terms of providing safety for both the person with a disability and the attendant, while taking into account the potential new development within robotic technology on hoist solutions.

INTERNATIONAL STANDARD **ISO 10535:2021(E)**

Assistive products — Hoists for the transfer of persons — Requirements and test methods

1 Scope

This document specifies requirements and test methods for hoists and body-support units intended for the transfer of persons with disabilities. The document applies to the following products classified in ISO 9999:—[1)].

— 12 36 03 Mobile hoists for transferring a person in sitting position with sling seats;

— 12 36 04 Mobile hoists for transferring a person in standing position;

— 12 36 06 Mobile hoists for transferring a person in sitting position with solid seats;

— 12 36 09 Mobile hoists for transferring a person in lying position;

— 12 36 12 Stationary hoists fixed to walls, floor or ceiling;

— 12 36 15 Stationary hoists fixed to, or mounted in or on, another product;

— 12 36 18 Stationary free-standing hoists;

— 12 36 21 Body-support units for hoists.

This document covers different types of mobile and stationary hoists. Some of the requirements and test methods are general and others are only valid for specific product types.

Annexes A, B and C provide general recommendations.

This document 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.

It does not include methods to qualify individual units prior to use.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

1) Under preparation. Stage at the time of publication: ISO/FDIS 9999:2021.

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

IEC 60204-1, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

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 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 13480-3:2017, *Metallic industrial piping — Part 3: Design and calculation*