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Assistive products - General requirements and test methods (ISO 21856:2022)

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. 09/22

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EUROPÄISCHE NORM

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Supersedes EN ISO 16201:2006, EN 12182:2012

English Version

Assistive products - General requirements and test methods (ISO 21856:2022)

Produits d'assistance - Exigences générales et méthodes d'essai (ISO 21856:2022)

Hilfsmittel - Allgemeine Anforderungen und Prüfverfahren (ISO 21856:2022)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 21856:2022) 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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

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 16201:2006 and EN 12182:2012.

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.

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Endorsement notice

The text of ISO 21856:2022 has been approved by CEN as EN ISO 21856:2022 without any modification.

INTERNATIONAL STANDARD

ISO 21856

First edition
2022-07

Assistive products — General requirements and test methods

Produits d'assistance — Exigences générales et méthodes d'essai

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 first edition of ISO 21856 cancels and replaces ISO 16201:2006, which has been technically revised.

The main changes compared to the previous edition are as follows:

— scope changed to requirements and test methods for assistive products in general.

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

This document is developed due to a need to provide safety requirements and recommendations for assistive products that are not covered by another International Standard. Users of this document should check if there is a more relevant standard. Where requirements in this document are not covered in a standard for a particular type of assistive product, this document can be used as a supplement. This document can also serve as reference material when developing standards for a particular type of assistive product.

The general requirements and related test methods in this document are relevant to assistive products in different application environments such as hospitals, home care, and institutions. Some of the devices can apply in more than one application environment. This means that different requirements and test methods can apply to the same assistive product depending on the application environment.

Annex A gives general recommendations, Annex B gives environmental and consumer related guidance and Annex C provides guidelines for accessible information on assistive products.

This document is based on EN 12182:2012.

INTERNATIONAL STANDARD **ISO 21856:2022(E)**

Assistive products — General requirements and test methods

1 Scope

This document specifies general requirements and test methods for assistive products, considered to be medical devices, intended for use to alleviate or compensate for a disability.

This document does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

NOTE 1 Assistive products are considered to be medical devices in some jurisdictions but not in others.

NOTE 2 Requirements and test methods for particular types of assistive products are given in other International Standards, e.g. see Reference [33].

NOTE 3 Not all the items listed in ISO 9999 are medical devices. Contracting parties might wish to consider if this document or specific clauses or subclauses can be used for assistive products that are not medical devices.

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 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 12952-1, *Textiles — Assessment of the ignitability of bedding items — Part 1: Ignition source: smouldering cigarette*

ISO 12952-2, *Textiles — Assessment of the ignitability of bedding items — Part 2: Ignition source: match-flame equivalent*

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 15223-1, *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*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 24415-1, *Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips*

ISO 24415-2, *Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

IEC 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

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

IEC 60332-1-2, *Tests on electric and optical fibre cables under fire conditions - Part 1-2: Test for vertical flame propagation for a single insulated wire or cable - Procedure for 1 kWpre-mixed flame*

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, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

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 60695-11-10, *Fire hazard testing — Part 11-10: Test flames - 50 W horizontal and vertical flame test methods*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 60601-2-35, *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use*

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: match flame equivalent*

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

EN 716-2:2017, *Furniture — Children's cots and folding cots for domestic use —Part 2: Test methods*

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

UL 1581*(Ed. 4), Reference Standard for Electrical Wires, Cables, and Flexible Cords*