SLOVENSKI STANDARD
oSIST prEN ISO 21856:2020

01-maj-2020

Tehnični pripomočki - Splošne zahteve in preskusne metode (ISO/DIS 21856:2020)

Assistive products - General requirements and test methods (ISO/DIS 21856:2020)

Hilfsmittel - Allgemeine Anforderungen und Prüfverfahren (ISO/DIS 21856:2020)

Produits d'assistance - Exigences générales et méthodes d'essai (ISO/DIS 21856:2020)

Ta slovenski standard je istoveten z: **prEN ISO 21856**

ICS:

11.180.01	Pripomočki za onesposobljene in hendikepirane osebe na splošno	Aids for disabled and handicapped persons in general

oSIST prEN ISO 21856:2020 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 21856

ISO/TC **173**

Secretariat: **SIS**

Voting begins on:
2020-03-26

Voting terminates on:
2020-06-18

Assistive products — General requirements and test methods

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

ICS: 11.180.01

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 21856:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information. The committee responsible for this document is ISO/TC 173, Assistive products for persons with disability.

ISO 21856 was prepared by ISO/TC 173, Assistive Products for persons with disability which is in line with EN 12182 Assistive Products for persons with disability - General Requirements and Test methods.

This document supersedes ISO 16201 (E).

Introduction

This International Standard specifies general requirements and test methods that are relevant to assistive products for persons with disability. This Standard does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

This document specifies general requirements and related test methods that 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. To conform with this document, all relevant clauses need to be fulfilled, depending on the type of assistive product. For example, some assistive products do not include electrical components; therefore, the clauses related to electrical components might not be relevant.

In addition to the requirements in this International Standard, Annex A provides cognitive impairment information, Annex B gives general recommendations, Annex C gives environmental and consumer related guidance and Annex D provides guidelines for accessible information on assistive products.

Assistive products — General requirements and test methods

1 Scope

This International Standard specifies general requirements and test methods for assistive products intended for use to alleviate or compensate for a disability.

The aim of this International Standard is to provide safety requirements and recommendations for manufacturers of such assistive products.

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

Where other International Standards exist for particular types of assistive products then those standards apply.

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

NOTE 2 Not all the items listed in ISO 9999 are medical devices. Contracting parties may wish to consider if this standard or parts of the standard can be used for assistive products which are not medical devices.

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 2631-1, *Mechanical vibration and shock — Evaluation of human exposure to whole-body vibration — Part 1: General requirements*

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 5349-1, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements*

ISO 5349-2, *Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace*

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

ISO 9227, *Corrosion tests in artificial atmospheres — Salt spray tests*

ISO 9999, *Assistive products for persons with disability — Classification and terminology*

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 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*

ISO 13849, *Safety of machinery — Safety-related parts of control systems*

ISO 13850, *Safety of machinery — Emergency stop function — Principles for design*

ISO 14155, *+ A1 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 medical device labels, labelling and information to be supplied - General requirements*

ISO 17049, *Accessible design — Application of braille on signage, equipment and appliances*

ISO 17966, *Assistive products for personal hygiene that support users — Requirements and test methods*

ISO 19028, *Accessible design — Information contents, figuration and display methods of tactile guide maps*

ISO 20342-1, *Assistive products for tissue integrity when lying down — Part 1: General requirements*

ISO/DIS 20417, *Medical devices - Information to be provided by the manufacturer*

ISO/DIS 21801-1, *General guidelines on cognitive accessibility*

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*

ISO 24505, *Ergonomics - Accessible design - Method for creating colour combinations taking account of age-related changes in human colour vision*

ISO 24509, *Ergonomics — Accessible design — A method for estimating minimum legible font size for people at any age*

ISO/IEC 40500, *Information technology — W3C Web Content Accessibility Guidelines (WCAG) 2.0*

ISO/IEC Guide 71, *Guide for addressing accessibility in standards*

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

IEC 60332-1-2, *+ A1, 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, *+AMD2: Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1+AMD1, *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 60601-1-11, *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 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

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

IEC 62304, *Medical device software - Software life cycle processes*

IEC 62311, *Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)*

IEC/TR 80002-1, *Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software*

IEC 80601-2-35, *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*

IEC 82079-1, *Preparation of instructions for use - Structuring, content and presentation - Part 1: General principles and detailed requirements*

IEC 82304-1, *Health software — Part 1: General requirements for product safety*

ANSI UL 2900-1, *Standard for Safety, Standard for Software Cybersecurity Network- Connectable Products, Part 1: General Requirements*

ANSI UL 2900-2-1, *Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems*

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 Ignition source smouldering cigarette*

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

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

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

EN 894-3+A1, *Safety of machinery - Ergonomics requirements for the design of displays and control actuators : Control actuators*

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

EN/ISO 20417, *Medical Devices -- Requirements for general information to be provided by the manufacturer*

EN 12182, *Assistive products for persons with disability. General requirements and test methods*

EN 50637, *Medical electrical equipment. Particular requirements for the basic safety and essential performance of medical beds for children*

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

NOTE Standards which are referred to in the text as informative material are listed in the Bibliography.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For the safety and test methods of electrical medical equipment, the terms and definitions given in IEC 60601-1 apply.

3.1
assistant
Person who is helping/supporting a person with disability in using the assistive product

Note 1 to entry: Examples of the ways assistants help persons with disability are pushing wheelchairs; operating hoists; and assisting with entering and leaving seats, beds and wheelchairs.

Note 2 to entry: An assistant can be a health care professional or a non-professional - for example, a relative.

3.2
assistive product(s)
instrument, equipment, or technical system intended by the manufacturer to be used for the prevention, treatment, or alleviation of or compensation for impairment

Note 1 to entry: The definition is not identical to the definition in ISO 9999 because ISO 21856 is restricted to medical devices.

3.3
assistive products which support or suspend users
intended to support or suspend persons with disability and/or an assistant or load

3.3.1
support
to bear or hold up (a load, mass, structure, part, etc.)

3.3.2
suspend
to hang by attachment to something above

3.4
bedding
items normally placed on a mattress

Note 1 to entry: Bedding includes mattress covers, underlays, incontinence sheets and pads, sheets, blankets, electric blankets, quilts (duvets) and their covers, pillows and bolsters, and pillow cases.

3.5
body mass index (BMI)
simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults and defined as the weight in kilograms divided by the square of the height in meters (kg/m^2)

3.6
clinical evaluation
means for confirming that an assistive product conforms to the intended use specified by the manufacturer

Note 1 to entry: A clinical evaluation may include a compilation of clinical data, any scientific literature and the results of any clinical investigations, taking into account any relevant standards.

3.7
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device

Note 1 to entry: Clinical trial or clinical study is synonymous with clinical investigation.

[SOURCE: ISO 14155, *3.6*]

3.8
detachable part
a part designed to be unfastened or disconnected without damage to the part or the whole (from ISO **338** 20342-1 draft)

3.9
disability
umbrella term for impairments, activity limitations, and participation restrictions, denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)

[SOURCE: ICF 2001, WHO]

3.10
hand-held device/assistive products
equipment or part of equipment intended to be supported by the hand during normal use

3.11
impairments
problems in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2001, WHO]

3.12
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

Note 1 to entry: This information includes pre-sale information.

3.13
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of adevice before it is placed on the market under his own name, regardless of whether these operationsare carried out by that person himself or on his behalf by a third party

3.14
Loads
Permissible weight

3.14.1
Maximum user mass
greatest permissible weight of the person using the product.