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Produits d'assistance — Exigences générales 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.

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.

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 medical device labels, labelling and information to be supplied — General requirements*

ISO 20417, *Medical devices — Information to be provided 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, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
applied part
part of an *assistive product* (3.3) that in *normal use* (3.20) necessarily comes into physical contact with the *user* (3.32) to perform its function

3.2
assistant
person who is helping/supporting a *person with disability* (3.23) in using the *assistive product* (3.3)

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.

3.3
assistive product

instrument, equipment, or technical system intended by the *manufacturer* (3.15) to be used for the prevention, treatment, or alleviation of or compensation for *impairment* (3.13)

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

3.4
assistive product which supports or suspends users
assistive product (3.3) intended to *support* (3.4.1) or *suspend* (3.4.2) persons with *disability* (3.11) and/or an *assistant* (3.2) or *load* (3.16)

3.4.1
support
bear or hold up

3.4.2
suspend
hang by attachment to something above

3.5
autonomy
ability to perform intended tasks based on current state and sensing, without human intervention

Note 1 to entry: For a particular application, degree of autonomy can be evaluated according to the quality of decision making and independence from human. For example, metrics for degree of autonomy exist for medical electrical equipment in IEC/TR 60601-4-1.

[SOURCE: ISO/DIS 8373, 3.2]

3.6
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.

3.7
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)

3.8
clinical evaluation
means for confirming that an *assistive product* (3.3) conforms to the *intended use* (3.14) specified by the *manufacturer* (3.15)

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

3.9
clinical investigation
clinical trial
clinical study
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a *medical device* (3.18)

[SOURCE: ISO 14155:2020, 3.8, modified — Content of Note 1 to entry incorporated to the terms.]

3.10
detachable part
part designed to be unfastened or disconnected without damage to the part or the whole

[SOURCE: ISO 20342-1:2019, 3.10]

3.11
disability
umbrella term for *impairments* (3.13), 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]

3.12
hand-held device
hand-held assistive product
equipment or part of equipment intended to be supported by the hand during *normal use* (3.20)

3.13
impairment
problem in body function or structure

EXAMPLE A significant deviation or loss.

[SOURCE: ICF 2001, WHO]

3.14
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the *manufacturer* (3.15)

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

3.15
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.16
load
permissible weight

3.16.1
maximum user mass
greatest permissible mass of the person using the product, measured in kilograms (kg)

3.16.2
minimum user mass
lowest possible *user* (3.32) mass needed for activating or using an *assistive product* (3.3), measured in kilograms (kg)

3.16.3
maximum load
safe working load
maximum external mechanical *load* (3.16) (mass) on equipment or an equipment part that is permitted in *normal use* (3.20)

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.109, modified — Note 1 to entry added.]

Note 1 to entry: Depending on the type of assistive product, the maximum load can be either higher or lower than the user mass. In case of a product intended to carry both a user and an assistant and possibly accessories, the maximum load will be higher than the maximum user mass. In case of a product intended for the user to (just) lean on for support, the maximum user mass will be higher than the maximum load.

3.17
mechanism
system of parts working together

3.17.1
locking mechanism
mechanism (3.17) that ensure that the *assistive product* (3.3) will stay in an intended position

3.18
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.15) to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or *disability* (3.11);

— investigation, replacement, modification or support of the anatomy or of a physiological or pathological process or state,

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended

action by pharmacological, immunological or metabolic means, in or on the human body, but which might be assisted in its function by such means.

[SOURCE: ISO 13485:2016, 3.11, modified — Parts of the definition removed, Note 1 to entry modified, Note 2 to entry added.]

Note 1 to entry: Devices are different from drugs and their biological evaluation requires a different approach.

Note 2 to entry: Use of the term medical device includes dental devices.

3.19
mobile assistive product
equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

3.20
normal use
use of a product, process, or service in accordance with the specifications, instructions, and information provided by the *manufacturer* (3.15), not only intended for medical use, but also maintenance, service, transport, etc.

Note 1 to entry: Normal use is not to be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc. "Medical use" and "medical purpose" include the purpose of assistive products as described in 3.2.

[SOURCE: ISO 17966, 3.19, modified — Note 1 to entry added.]

3.21
operator
person handling the *assistive product* (3.3)

Note 1 to entry: The operator can either be the user or the assistant.

3.22
pendant control
hand-held device (3.12), which has a functional connection to the *assistive product* (3.3), controlling, e.g. articulations and/or movements

Note 1 to entry: Pendant controls can be wired or wireless, and can integrate other functions, (e.g. communications, radio/TV, etc.).

3.23
person with disability
person with one or more *impairments* (3.13), one or more activity limitations, one or more participation restrictions, or a combination thereof

[SOURCE: ICF 2001, WHO]

3.24
portable assistive product
equipment intended to be moved from one location to another while being carried by one or more persons

3.25
protection side rail
physical barrier, which can be a detachable accessory or integral to the overall construction of an *assistive product* (3.3) and is positioned to the side(s) of the assistive product, which will prevent the *user* (3.32) from getting out of the assistive product by itself. Can be movable, e.g., sliding sides, drop sides, folding sides.

[SOURCE: EN 50637:2017, 201.3.223]

3.26
risk management file
set of records and other documents that are produced by risk management

3.27
robot
programmed actuated *mechanism* (3.17) with a degree of *autonomy* (3.5) to perform locomotion, manipulation or positioning

Note 1 to entry: A robot includes the control system and interface of the control system.

[SOURCE: ISO/DIS 8373, 3.3, modified — Example removed.]

3.28
side rail
physical barrier, which can be a detachable accessory or integral to the overall construction of an *assistive product* (3.3) and is mounted to the side(s) of an assistive product

Note 1 to entry: When a side rail is closed/fully raised, it provides a physical barrier, which is intended to reduce the risk of the user accidentally slipping or rolling off the lying support surface.

[SOURCE: EN 50637:2017, 201.3.224, modified]

3.29
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

Note 1 to entry: In this document, a single fault also includes an error of the software.

3.30
technical documentation
manufacturer's (3.15) data that shows that an *assistive product* (3.3) conforms to specific requirements

3.31
usability
characteristic of the *operator* (3.21) interface that establishes effectiveness, efficiency, ease of operator learning and operator learnability and satisfaction

3.32
user
person with a *disability* (3.11) for whom the *assistive product* (3.3) is intended

4 General requirements

4.1 Risk analysis and management

The safety of an assistive product shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in ISO 14971 and, if relevant, ISO 12100. When an assistive product is intended by the manufacturer to be used in combination with a device that is not a medical device, the resulting combination of the assistive product and device shall behave in a safe way as a system.

An assistive product may only be used as specified by the manufacturer in the intended use.

Risk management shall include all involved persons.

NOTE In the case of certain disabilities there can be a need for higher levels of safety for equipment used to offset the effects of that disability.