



SLOVENSKI STANDARD
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Pripomočki za stranišče, kopanje in prhanje - Zahteve in preskusne metode
(ISO/DIS 17966:2024)

Assistive products for toileting, bathing and showering - Requirements and test methods
(ISO/DIS 17966:2024)

Hilfsmittel zum Toilettengang, Baden und Duschen - Anforderungen und Prüfverfahren
(ISO/DIS 17966:2024)

Produits d'assistance pour les toilettes, le bain et la douche - Exigences et méthodes
d'essai (ISO/DIS 17966:2024)

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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).

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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*, respectively ISO/TC 173/WG 9, *Assistive products for personal hygiene*.

This document is foreseen to be adopted as an EN-ISO Standard by Technical Committee CEN/TC 293, *Assistive products and accessibility* falling under Standardization Request M/575 given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices. Therefore, the document uses dated references only.

This second edition of ISO 17966 replaces ISO 17966:2016, however, given the technical changes and added requirements in this document compared to ISO 17966:2016, a transition period of 24 months to comply with this document is recommended.

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.

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Introduction

This document specifies requirements and test methods that are relevant to assistive products for toileting, bathing and showering.

[Clause 4](#) to [Clause 22](#) and [Clause 26](#) to [Clause 28](#) contain general requirements for all types of products included in the Scope.

[Clause 23](#) to [Clause 25](#) contain specific requirements for mobile, fixed and portable products. These clauses indicate additional requirements to the general requirement clauses.

In order for a product to claim compliance with this document, all relevant clauses need to be fulfilled, depending on the type of product. For example, some products do not include electrical components; therefore, the clauses related to electrical components may not be relevant.

In addition to the requirements in this document, [Annex B](#) gives general recommendations.

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Assistive products for toileting, bathing and showering — Requirements and test methods

1 Scope

This document specifies requirements and associated test methods for assistive products for toileting, bathing and showering (from herein referred as 'assistive product' within the standard) and which are considered to be medical devices, intended by the manufacturer to alleviate or compensate for disability.

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

The standard specifies safety, functional and ergonomic requirements for both persons with disability and assistants that apply during normal use and foreseeable misuse and failure.

This document specifies requirements and test methods for assistive products within the following divisions of EN ISO 9999:2022.

There are no specific requirements and test methods for products marked with *. Only the relevant general requirements apply when these products are considered to be medical devices.

09 12 03 Commode chairs;

Chairs, with or without castors, with a collection receptacle used for toileting away from the bathroom

09 12 06 Toilets;*

Included are, e.g. raised or height adjustable toilets, toilets with built-in douche and air dryers.

09 12 09 Toilet seats;*

Devices attached to the toilet bowl or toilet chair for a person to sit on; they can provide stability and comfort

09 12 10 Toilet splash guards;*

Devices to keep bodily substances from splashing outside the toilet bowl

09 12 12 Raised toilet seats, free-standing

Raised toilet seats (separate) standing on floor, where the seat can easily be removed from the toilet bowl

Included are, e.g. over toilet frames.

09 12 15 Raised toilet seats, detachable;

Raised toilet seats (loose attachments) placed directly on the toilet bowl/toilet seat where the seat insert can easily be removed from the toilet bowl/toilet seat

09 12 18 Raised toilet seats fixed to toilet;

Devices permanently fixed on to a toilet bowl to increase the height of the seat and to facilitate sitting down upon, and standing up from, the toilet

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Included are, e.g. plinths.

- 09 12 21 Toilet seats with built-in raising mechanism to help standing up and sitting down;
Toilet seats that have a built-in lifting mechanism to assist a person to sit down on and get up from the toilet
- 09 12 24 Toilet arm supports and toilet back supports mounted on toilet;
Devices mounted on the toilet that provide support getting on or off the toilet
- 09 12 25 Toilet arm supports and toilet back supports, free standing;
- 09 12 36 Douches and air dryers for attachment to a toilet;*
Devices attached to a toilet to provide a water spray with or without air blowing afterwards to wash, and possibly dry, a person's bottom while sitting on the toilet
Included are, e.g. toilet seats with that function.
- 09 33 04 Bath boards;
Seats without back support placed on the rim across the bathtub
- 09 33 05 Bath seats;
Seats hung from the rim of or placed in the bathtub
Included are e.g., bath seats with or without backrest
- 09 33 07 Shower chairs with and without wheels;
Devices for supporting sitting during showering
Included are, e.g. shower stools.
- 09 33 08 Back supports for bath or shower;
Excluded are, e.g. back support cushions.
- 09 33 12 Bathing stretchers, shower tables and diaper-changing tables;
Stationary or portable tables, with or without castors, on which a person lies during bathing, showering or changing
NOTE 2: Mainstream diaper-changing tables for babies/toddlers are excluded. They are covered by prEN 12221:2023.
- 09 33 15 Wash basins;*
Stationary or portable basins for water used when washing parts of the body
- 09 33 18 Bidets;*
Stationary or portable basins primarily intended for washing genitals and bottom
- 09 33 36 Assistive products for drying oneself;*
Devices and materials for enabling a person to dry his/her own body
- 18 15 06 Height adjustable plinths and brackets;

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Height-adjustable surfaces or brackets on which furniture (e.g. wash basins) can be mounted

18 18 03 Handrails and support rails;

Bars, usually cylindrical, attached to a wall, floor or other stable structure that provide the means for a person to support or stabilize himself/herself using hands or arms while walking, e.g. up and down stairs or ramps or moving along corridors

18 18 06 Fixed grab bars and handgrips;

Devices, usually straight or angled bars, that are permanently attached to a wall, a wall and a floor, or a wall, ceiling and floor to provide support to a person while standing or changing position

18 18 10 Removable grab rails and handgrips;

Devices, usually straight or angled bars, that can be temporarily attached to walls, floors, ceilings or furniture using, e.g. clamps or suction pads and removed without tools providing support to a person while changing position

18 18 11 Hinged rails and arm supports;

Devices that provide support to a person when changing her/his position; they can be fixed to a wall or floor and can be folded up or sideways or lowered down to allow access or when they are not needed

This document does not apply for:

- safe mounting in building structures;
- fixed building installations e.g. water, electricity, drainage and sewerage, requirements in relation to excretion-disposal and -wrapping systems;
- bathtub hoists that are covered by EN ISO 10535:2021, namely
 - 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;
- 09 33 21 Bathtubs;
- stability and friction issues in relation to slippery surfaces due to soap;
- products that have been customised or custom-made for an individual user.

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.

EN 614-1:2006+A1:2009, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 1021-2:2014, *Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent*

EN 12527:1998, *Castors and wheels — Test methods and apparatus*

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EN 60601-1:2006, + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020)*

EN 60601-1-11:2015, + A1:2021, *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 60601-1-11:2015 + A1:2020)*

EN ISO 845:2009, *Cellular plastics and rubbers — Determination of apparent density (ISO 845:2006)*

EN ISO 2439:2009, *Flexible cellular polymeric materials — Determination of hardness (indentation technique) (ISO 2439:2008)*

EN ISO 3746:2010, *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 3746:2010)*

EN ISO 9227:2022, *Corrosion tests in artificial atmospheres — Salt spray tests (ISO 9227:2022)*

EN ISO 9999:2022, *Assistive products — Classification and terminology*

EN ISO 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

EN ISO 13849 (all parts), *Safety of machinery — Safety-related parts of control systems*

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

EN ISO 14971:2019, + A11:2021, *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

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

EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

EN ISO 22442-1:2020, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2020)*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60332-1-2:2015, *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 kW pre-mixed flame*

IEC 60529:2019, *Degrees of protection provided by enclosures (IP code); Amendment 2; Corrigendum 1*

IEC 60695-11-10:2013, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods; Corrigendum 1*

IEC 61508 (all parts), *Requirements and Guidance in the use of mathematical and logical techniques for establishing exact properties of software and its documentation*

ISO 7176-8:2014, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

ISO 7176-11:2012, *Wheelchairs — Part 11: Test dummies*

ISO 8191-2:1988, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*