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

*Produits d'assistance pour l'hygiène personnelle soutenant les  
utilisateurs — Exigences 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](http://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](http://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*.

## Introduction

This International Standard specifies requirements and test methods that are relevant to assistive products for personal hygiene that support users in home care, institutions and public places. Some of the devices can be used in more than one environment. This means that different requirements and test methods can be applied to the same product depending on the environment. [Clauses 1 to 21](#) and [Clause 25](#) contain general requirements for all types of products included in the Scope. [Clauses 22 to 24](#) contain specific requirements for mobile, fixed and static products. These clauses indicate additional requirements to the general clauses. In order for a product to claim compliance with this International Standard, 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 International Standard, [Annex B](#) gives general recommendations.



# Assistive products for personal hygiene that support users — Requirements and test methods

## 1 Scope

This International Standard specifies requirements and associated test methods for assistive products for personal hygiene (APPHs) that support users and which are intended by the manufacturer to alleviate or compensate for disability. The work environment and safety aspects for assistants are also included. It specifies safety and performance requirements that apply during normal use and foreseeable misuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and specifies limits on the forces needed for some operations.

This International Standard specifies requirements and test methods for assistive products within the following divisions of ISO 9999:2011:

09 12 03      Commode chairs;

NOTE      This covers mobile and static products.

09 12 06      Toilets with built in raising and height adjustable mechanism;

NOTE      This excludes toilets with built-in douche and air dryers.

09 12 09      Toilet seats;

09 12 12      Raised toilet seats mounted on frame;

09 12 15      Toilet seats inserts;

09 12 18      Raised toilet seats fixed to toilet;

09 12 21      Toilet seats with built-in raising mechanism to help standing up and sitting down;

09 12 24      Toilet arm supports and toilet back supports mounted on 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;

09 33 03      Bath/shower chairs (with and without wheels), bath boards, stools, back supports and seats;

09 33 12      Bathing stretchers, shower tables and diaper-changing tables;

18 15 06      Height adjustable plinths and brackets;

NOTE      Refers to height adjustable plinths and brackets when used as an assistive product for personal hygiene (APPH). Height adjustable mechanisms for other items such as basins may be included.

18 18 03      Handrails and support rails;

18 18 06      Fixed grab bars and handgrips;

18 18 10      Removable grab rails and handgrips;

NOTE      This excludes removable grab rails and handgrips which are static as defined in [3.27](#).

18 18 11      Hinged rails and arm supports;

This International Standard does not encompass requirements regarding:

- safe mounting in building structures;
- requirements regarding fixed building installations e.g. water and electricity;
- bathtub hoists that are covered by ISO 10535;
- 09 33 21 Bathtubs of ISO 9999:2011;
- 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 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.

CISPR 11, *Industrial, scientific and medical (ISM) radio-frequency equipment — Electromagnetic disturbance characteristics — Limits and methods of measurement*

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 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

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

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

ISO 9999:2011, *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 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

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

ISO 14155, *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 - Part 1: General requirements*

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

IEC 60335-1, *Household and similar electrical appliances – Safety – Part 1: General requirements*

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

IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*