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BSI Standards Publication

## Assistive products — General requirements and test methods

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## National foreword

This British Standard is the UK implementation of EN ISO 21856:2022. It is identical to ISO 21856:2022. It supersedes BS EN 12182:2012 and BS EN ISO 16201:2006, which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/173, Assistive products for persons with disability.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

This European Standard was approved by CEN on 29 July 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

### Endorsement notice

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

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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 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](http://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](http://www.iso.org/members.html).



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## 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.

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# 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*