

SLOVENSKI STANDARD SIST EN ISO 9999:2017

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Nadomešča: SIST EN ISO 9999:2011

Tehnični pripomočki za invalidne osebe - Razvrstitev in terminologija (ISO 9999:2016)

Assistive products for persons with disability - Classification and terminology (ISO 9999:2016)

Hilfsmittel für Menschen mit Behinderungen-Klassifikation und Terminologie (ISO 9999:2016) (standards.iteh.ai)

Produits d'assistance pour personne<u>stent situation de h</u>andicap - Classification et terminologie (ISO 9999:2016)ds.iteh.ai/catalog/standards/sist/7fb7b60f-17c1-4cdf-8d1d-8f22b28ea38a/sist-en-iso-9999-2017

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Health care technology (Vocabularies) Aids for disabled and handicapped persons in general

SIST EN ISO 9999:2017

en



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Supersedes EN ISO 9999:2011

English Version

Assistive products for persons with disability -Classification and terminology (ISO 9999:2016)

Produits d'assistance pour personnes en situation de handicap - Classification et terminologie (ISO 9999:2016)

Hilfsmittel für Menschen mit Behinderungen -Klassifikation und Terminologie (ISO 9999:2016)

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 9999:2016) has been prepared by Technical Committee ISO/TC 173 "Assistive products for persons with disability" in collaboration with Technical Committee CEN/TC 293 "Assistive products for persons with disability" 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of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by May 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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INTERNATIONAL STANDARD

ISO 9999

Sixth edition 2016-10-15

Assistive products for persons with disability — Classification and terminology

Produits d'assistance pour personnes en situation de handicap — Classification et terminologie

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 173, Assistive products for persons with disability, Subcommittee SC 2, Classification and terminology. SIST EN ISO 9999:2017

This sixth edition cancels and **replaces** the fifth edition (ISO799999:2011), which has been technically revised. 8f22b28ea38a/sist-en-iso-9999-2017

Introduction

Assistive products (including software) are classified according to their function. The classification consists of three hierarchical levels and the codes each consist of three pairs of digits. Like other classifications, for each level, codes, titles, explanatory notes, inclusions, exclusions and cross-references are given. Besides the explanatory text and the classification itself, a table of conversion between the previous edition (2011) and this edition and an alphabetical index are provided in order to facilitate the use of and to improve the accessibility of the classification.

This edition has 945 titles of which about 44 are new and 456 are changed, including minor editorial and grammatical revisions.

All assistive products in this classification are primarily intended for use outside of health care settings; however, some of the products can be used in facilities such as rehabilitation centres to teach clients how to use these products. It should be noted that the titles of some subclasses and divisions in class 28 refer to the "workplace". This term does not refer to a specific setting or geographical location; instead, it refers to any setting in which employment-related activities or vocational training are performed.

The definition of "assistive product" used by this International Standard has been revised to align it with the terminology of the International Classification of Functioning, Disability and Health (ICF).

Relation to the WHO Family of International Classifications

In 2003, ISO 9999 was accepted as a related member of the WHO Family of International Classifications (WHO-FIC). The WHO-FIC comprises high-quality classifications for relevant sectors of the health system. With this inclusion, the use of this International Standard was stimulated.

This International Standard makes use of the terminology of the International Classification of Functioning, Disability and Health (ICF, WHO, 2001). ICF is a classification of health and health-related domains. These domains are classified from body individual and societal perspectives by means of two lists: a list of body functions and structure and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, ICF also includes a list of environmental factors. The ICF is one of the core classifications of the WHO-FIC (see Annex A).

A major change in this edition is a change of the titles of the classes to bring them in harmony with the terminology of the ICF.

Proposal for changes

Proposals for changes or additions to this International Standard, both in respect of existing and proposed new classes/subclasses/divisions, which take into account the given rules for classification, may be submitted to a national member body of ISO with an accompanying explanation for the proposal. See http://www.iso.org for addresses of national member bodies.

NOTE 1 Some of the assistive products for persons with disability can be classified as medical devices.

NOTE 2 National member bodies are encouraged to improve the accessibility of the classification by the addition of national language synonyms to the nationally implemented standard.



Assistive products for persons with disability — Classification and terminology

1 Scope

This International Standard establishes a classification and terminology of assistive products, especially produced or generally available, for persons with disability.

Assistive products used by a person with disability, but which require the assistance of another person for their operation, are included in the classification.

The following items are specifically excluded from this International Standard:

- items used for the installation of assistive products;
- solutions obtained by combinations of assistive products that are individually classified in this International Standard;
- medicines;
- assistive products and instruments used exclusively by healthcare professionals;
- non-technical solutions, such as personal assistance, guide dogs or lip-reading;
 - (standards.iteh.ai)
- implanted devices;

 financial support.
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2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

activity

execution of a task or action by an individual

[SOURCE: ICF 2001, WHO]

2.2

activity limitations

difficulties an individual can have in executing activities

[SOURCE: ICF 2001, WHO]

2.3

assistive product

any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for *persons with disability* (2.12)

- for participation (2.13),
- to protect, support, train, measure or substitute for *body functions* (2.4)/structures and activities, or
- to prevent impairments (2.11), activity limitations (2.2) or participation restrictions (2.14)

Note 1 to entry: The definition of assistive product is in discussion at the GATE, the Global cooperation on Assistive Health Technology (a WHO initiative), and the information is given in <u>Annex B</u>.

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2.4

body functions

physiological functions of body systems (including psychological functions)

[SOURCE: ICF 2001, WHO]

2.5

body structures

anatomical parts of the body such as organs, limbs and their components

[SOURCE: ICF 2001, WHO]

2.6

classification

system of concepts or a structured set of concepts established according to the relations between them, each concept being determined by a systematic code and its positions in the system of concepts

2.7

class

collection of similar articles, divided according to definite and chosen rules

2.8

disability

umbrella term for *impairments* (2.11), *activity limitations* (2.2) and *participation restrictions* (2.14) 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]

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2.9 environmental factors

environmental factors <u>SIST EN ISO 9999:2017</u> physical, social and attitudinal environment/in/which people/live/and conduct/their-lives

[SOURCE: ICF 2001, WHO]

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2.10

functioning

umbrella term for *body functions* (2.4), *body structures* (2.5), activities and *participation* (2.13) denoting the positive 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]

2.11

impairments

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

[SOURCE: ICF 2001, WHO]

2.12

person with disability

person with one or more *impairments* (2.11), one or more *activity limitations* (2.2), one or more *participation restrictions* (2.14) or a combination thereof

2.13

participation involvement in a life situation

[SOURCE: ICF 2001, WHO]

2.14 participation restrictions

problems an individual can experience in involvement in life situations

[SOURCE: ICF 2001, WHO]

2.15

workplace

defined area or areas in which the work activities are carried out

[SOURCE: EN 1540:1998]

3 Principle

The classification is based on the function of the products being classified.

In particular, it should be noted that assistive products, which are used exclusively for training in skills, are included in class 05. Assistive products that have a principal function other than training, but which can also be used for training, are included in the class covering their primary function.

Software is classified at the division level of the class relating to its function.

Multifunctional products are also classified based on the primary function. References may be added related to secondary functions of the item.

Teh STANDARD PREVIEW Elements and rules used in classification 4 (standards.iteh.ai)

4.1 Construction

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The classification consists of three hierarchical levels, classes, subclasses and divisions.

Each class, subclass or division consists of a code, a title and, if necessary, an explanatory note and reference to other parts of the classification.

Explanatory notes are used to clarify the content of the class, subclass or division. Inclusions and exclusions are used to provide examples.

References are used for two purposes:

- to separate classes, subclasses or divisions from one another;
- for information, e.g. references between related products.

In general, references are made to the lowest possible level.

4.2 Codes

4.2.1 The code consists of three pairs of digits.

The first pair of digits indicates a class, the second pair of digits a subclass and the third pair of digits a division.

For practical reasons, in this International Standard, the classes are indicated by one pair of digits only (deleting two pairs of zeros) and subclasses are indicated by two pairs of digits (deleting one pair of zeros).

The code determines the position of the class, the subclass or the division, respectively, in the classification.