SLOVENSKI STANDARD
SIST EN ISO 9999:2022

01-september-2022

Nadomešča:
SIST EN ISO 9999:2017

Tehnični pripomočki - Razvrstitev in terminologija (ISO 9999:2022)

Assistive products - Classification and terminology (ISO 9999:2022)

Hilfsmittel - Klassifikation und Terminologie (ISO 9999:2022)

Produits d’assistance - Classification et terminologie (ISO 9999:2022)

Ta slovenski standard je istoveten z: **EN ISO 9999:2022**

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.180.01	Pripomočki za onesposobljene in hendikepirane osebe na splošno	Aids for disabled and handicapped persons in general

SIST EN ISO 9999:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9999

June 2022

ICS 11.180.01

Supersedes EN ISO 9999:2016

English Version

Assistive products - Classification and terminology (ISO 9999:2022)

Produits d'assistance - Classification et terminologie (ISO 9999:2022)

Hilfsmittel - Klassifikation und Terminologie (ISO 9999:2022)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 9999:2022) 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of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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 9999:2016.

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.

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Endorsement notice

The text of ISO 9999:2022 has been approved by CEN as EN ISO 9999:2022 without any modification.

INTERNATIONAL STANDARD

ISO 9999

Seventh edition
2022-05

Assistive products — Classification and terminology

Produits d'assistance — Classification et terminologie

Reference number
ISO 9999:2022(E)

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Published in Switzerland

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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*, Subcommittee SC 2, *Classification and terminology,* 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 seventh edition cancels and replaces the sixth edition (ISO 9999:2016), which has been technically revised. The main changes are as follows:

— deletion of class 05 was;

— major changes in class 09, class 12 and class 22.

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

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 (ISO 9999:2016) and this document (ISO 9999:2022) and an alphabetical index are provided in order to facilitate the use of and to improve the accessibility of the classification.

This document has 948 titles of which about 23 are new and 116 are changed, including minor editorial 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 document has been revised to align it with the terminology of the International Classification of Functioning, Disability and Health (ICF, WHO, 2018).

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 document was stimulated.

This document makes use of the terminology of the ICF, which 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. Assistive products in this list are viewed as part of the environmental factors. The ICF is one of the core classifications of the WHO-FIC (see Annex A).

An alphabetical index of terms in Annex D is provided for information to facilitate access to the classification. Terms used in inclusion statements are incorporated in the index.

NOTE Some of the assistive products can be classified as medical devices.

Assistive products — Classification and terminology

1 Scope

This document specifies a classification and terminology of assistive products, especially produced or generally available, for persons to optimize functioning and reduce disability.

Assistive products used by a person to optimize functioning and reduce 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 document:

— items used for the installation of assistive products;

— solutions obtained by combinations of assistive products that are individually classified in this document;

— medicines;

— assistive products and instruments used exclusively by healthcare professionals or by teachers;

— non-technical solutions, such as personal assistance, guide dogs or lip-reading;

— implanted devices;

— financial support.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology 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
activity
execution of a task or action by an individual

[SOURCE: ICF 2018, WHO]

3.2
activity limitation
difficulties an individual can have in executing *activities* (3.1)

[SOURCE: ICF 2018, WHO]

3.3
assistive product
product that optimizes a person's functioning and reduces disability

Note 1 to entry: See Annex B.

Note 2 to entry: Assistive products include devices, instruments, equipment, and software.

Note 3 to entry: Assistive products can be especially produced or generally available items.

3.4
body function
physiological functions of body systems (including psychological functions)

[SOURCE: ICF 2018, WHO]

3.5
body structure
anatomical parts of the body such as organs, limbs and their components

[SOURCE: ICF 2018, WHO]

3.6
disability
umbrella term for *impairments* (3.9), *activity limitations* (3.2) and *participation restrictions* (3.12) 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 2018, WHO]

3.7
environmental factor
physical, social and attitudinal environment in which people live and conduct their lives

[SOURCE: ICF 2018, WHO]

3.8
functioning
umbrella term for *body functions* (3.4), *body structures*, *activities* (3.1) and *participation* (3.11) 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 2018, WHO]

3.9
impairment
problems in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2018, WHO]

3.10
person with disability
person with one or more i*mpairments* (3.9), one or more *activity limitations* (3.2), one or more *participation restrictions* (3.12) or a combination thereof

3.11
participation
involvement in a life situation

[SOURCE: ICF 2018, WHO]

3.12
participation restriction
problems an individual can experience in involvement in life situations

[SOURCE: ICF 2018, WHO]

3.13
workplace
setting in which employment-related activities or vocational training are performed

3.14
robot
programmed actuated mechanism with a degree of autonomy to perform locomotion, manipulation or positioning

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

4 Elements and rules used in classification

4.1 Principle

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

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 according to its function.

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

4.2 Construction

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.

4.3 Codes

4.3.1 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 document, 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).