



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 9999:2020**  
**01-september-2020**

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**Tehnični pripomočki - Razvrstitev in terminologija (ISO/DIS 9999:2020)**

Assistive products - Classification and terminology (ISO/DIS 9999:2020)

Hilfsmittel - Klassifikation und Terminologie (ISO/DIS 9999:2020)

Produits d'assistance - Classification et terminologie (ISO/DIS 9999:2020)

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## Assistive products — Classification and terminology

ICS: 11.180.01

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## ISO/DIS 9999:2020(E)

## 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*, Subcommittee SC 2, *Classification and terminology*.

This seventh edition cancels and replaces the sixth edition (ISO 9999:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Change of the titles of the classes to bring them in harmony with the terminology of the ICF.
- Major changes in class 09, class 12 and class 22.

A list of all parts in the ISO 9999 series can be found on the ISO website.

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).

## 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 (2016) 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 948 titles of which about 23 are new and 116 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. 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.

### **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.

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# Assistive products — 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 or by teachers;
- non-technical solutions, such as personal assistance, guide dogs or lip-reading;
- implanted devices;
- financial support.

## 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 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*

ISO 1087-2,<sup>1)</sup> *Terminology work — Vocabulary — Part 2: Computer applications*

ISO 7176-26, *Wheelchairs — Part 26: Vocabulary*

ISO 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 8549-2, *Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses*

ISO 8549-3, *Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to external orthoses*

ISO 8669-1, *Urine collection bags — Part 1: Vocabulary*

ISO 8670-1, *Ostomy collection bags — Part 1: Vocabulary*

ISO 9949-2, *Urine absorbing aids — Vocabulary — Part 2: Products*

ISO 9949-3, *Urine absorbing aids — Vocabulary — Part 3: Identification of product types*

ISO 10535, *Hoists for the transfer of disabled persons — Requirements and test methods*

1) Withdrawn.

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ISO 11199-1, *Walking aids manipulated by both arms — Requirements and test methods — Part 1: Walking frames*

ISO 11199-2, *Walking aids manipulated by both arms — Requirements and test methods — Part 2: Rollators*

ISO 11334-1, *Assistive products for walking manipulated by one arm — Requirements and test methods — Part 1: Elbow crutches*

ISO 11334-4, *Walking aids manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more legs*

ISO 22274:2013, *Systems to manage terminology, knowledge and content — Concept-related aspects for developing and internationalizing classification systems*

EN 12182, *Technical aids for disabled persons — General requirements and test methods*

**3 Terms and definitions**

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

**3.1****activity**

execution of a task or action by an individual

[SOURCE: ICF 2001, WHO]

**3.2****activity limitations**

difficulties an individual can have in executing activities

[SOURCE: ICF 2001, WHO]

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**3.3****assistive product**

product which optimizes a person's functioning and reduces disability

Note 1 to entry: Assistive products include devices, instruments, equipment, and software [ISO 9999:2016].

Note 2 to entry: Assistive products can be especially produced or generally available items [ISO 9999:2016].

**3.4****body functions**

physiological functions of body systems (including psychological functions)

[SOURCE: ICF 2001, WHO]

**3.5****classification**

process of assigning objects to classes according to criteria

[SOURCE: ISO 22274:2013]

**3.6****class**

description of a set of objects that share the same characteristics

[SOURCE: ISO 22274:2013]

**3.7****disability**

umbrella term for *impairments* (3.10), *activity limitations* (3.2) and *participation restrictions* (3.13) 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]

**3.8****environmental factors**

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

[SOURCE: ICF 2001, WHO]

**3.9****functioning**

umbrella term for *body functions* (3.4), *body structures*, activities and *participation* (3.13) 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]

**3.10****impairments**

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

[SOURCE: ICF 2001, WHO]

**3.11****person with disability**

person with one or more *impairments* (3.10), one or more *activity limitations* (3.2), one or more *participation restrictions* (3.13) or a combination thereof

**3.12****participation**

involvement in a life situation

[SOURCE: ICF 2001, WHO]

**3.13****participation restrictions**

problems an individual can experience in involvement in life situations

[SOURCE: ICF 2001, WHO]

**3.14****workplace**

any setting in which employment-related activities or vocational training are performed.

## 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 at the division level of the class according to its function.

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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 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.

**4.3.2** The digits for the codes were originally chosen with intervals of three. In subsequent revisions, the intervening digits have been used to introduce new classes, subclasses and divisions without significantly modifying the classification.

Codes that were originally used to classify items that have been removed from the classification are not used to classify new items that have been added to the classification. As a consequence, the order of the codes is no longer in all places in intervals of three and the divisions may not in all places follow a logic order.

**4.3.3** Classes 01, 02, and 90 to 99 and the associated subclasses and divisions are reserved for national applications.

The subclasses XX 01, XX 02, and XX 90 to XX 99 and the associated divisions are reserved for national applications.

The divisions XX XX 01, XX XX 02 and XX XX 90 to XX XX 99 are reserved for national applications.

Subclasses XX 88 and the divisions XX XX 88 are reserved for assistive products that are titled “Other (title of parent class or parent subclass)” for international applications.

In addition, further levels, e.g. 4th level, may be added to any part of the classification to serve national or local purposes

**4.3.4** A conversion table detailing the coding changes from the previous revision of the classification to this revision is given for information in [Annex C](#).

#### **4.4 Titles of classes, subclasses and divisions**

**4.4.1** The common language and framework of the ICF is used when appropriate, otherwise terminology in general use has been adopted; titles of classes are harmonized with the ICF.

**4.4.2** All titles in the classification are in the plural form.

**4.4.3** Titles at class level generally describe a broad area of function of the product, e.g. assistive products for domestic activities and participation in domestic life, assistive products for activities and participation relating to personal mobility and transportation and assistive products for work activities and participation in employment.

**4.4.4** Titles at subclass level describe a special function, e.g. “assistive products for reading”, within the broad area covered by the class, e.g. “assistive products for communication and information management”.

**4.4.5** Going down to the division level, the description gets more specific.

**4.4.6** Only in cases where an assistive product is intended for use by persons with a specific disability, age or gender should the title refer to that group.

#### **4.5 Rules used in classification**

**4.5.1** A class is equal to the sum of its subclasses and a subclass is equal to the sum of its divisions.

**4.5.2** In general, parts of assistive products, accessories to assistive products, individually adapted assistive products and individual adaptations in homes and other premises are classified in the same subclass or division of the assistive product with which they are associated.

**4.5.3** Parts, accessories and adaptations are separately classified when they are associated with a group of assistive products. In these cases, they are classified as close as possible to the group of assistive products with which they are associated, e.g. 12 07 accessories for assistive products for walking.

**4.5.4** The classification is organized in such a manner that all assistive products can be classified without being tested or measured.

**4.5.5** Classification of hypothetical assistive products is avoided.

**4.5.6** Classes are created in such a manner that they do not overlap in the described broad function of other classes. The subclasses are created in such a manner that they do not overlap in the specific function of other subclasses. The divisions are created in such a manner that they do not overlap with products in other divisions.

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## 5 Classification

## 5.1 One-level classification — Classes

- 04 Assistive products for measuring, stimulating or training physiological and psychological body functions
- 06 Orthoses and prostheses
- 09 Assistive products for self-care activities and participation in self-care
- 12 Assistive products for activities and participation relating to personal mobility and transportation
- 15 Assistive products for domestic activities and participation in domestic life
- 18 Furnishings, fixtures and other assistive products for supporting activities in indoor and outdoor human-made environments
- 22 Assistive products for communication and information management
- 24 Assistive products for controlling, carrying, moving and handling objects and devices
- 27 Assistive products for controlling, adapting or measuring elements of physical environments
- 28 Assistive products for work activities and participation in employment
- 30 Assistive products for recreation and leisure

## 5.2 Two-level classification — Classes and subclasses

- 04 Assistive products for measuring, stimulating or training physiological and psychological body functions
- 04 03 Assistive products for respiration
- 04 06 Assistive products for supporting and stimulating blood circulation
- 04 08 Assistive products for stimulating body control and conceptualization
- 04 09 Assistive products for light therapy
- 04 15 Assistive products for dialysis therapy
- 04 19 Assistive products for administering medicines
- 04 22 Sterilizing equipment
- 04 24 Physical, physiological and biochemical test equipment and materials
- 04 25 Cognitive test and evaluation materials
- 04 26 Assistive products to enhance cognitive function
- 04 27 Stimulators for treatment of muscles tissue and joints
- 04 28 Assistive products for stimulating senses
- 04 30 Assistive products for heat treatment or cold treatment

- 04 33 Assistive products intended to manage tissue integrity
- 04 45 Assistive products for spinal traction
- 04 48 Equipment for movement, strength, balance and cardio training
- 04 49 Wound care products
- 06 Orthoses and prostheses
- 06 03 Spinal and cranial orthoses
- 06 04 Abdominal orthoses
- 06 06 Upper limb orthoses
- 06 12 Lower limb orthoses
- 06 15 Functional neuromuscular stimulators and hybrid orthoses
- 06 18 Upper limb prostheses
- 06 24 Lower limb prostheses
- 06 30 Prostheses other than limb prostheses
- 09 Assistive products for self-care activities and participation in self-care
- 09 03 Clothes and shoes (standards.iteh.ai)
- 09 06 Body-worn assistive products for body protection
- 09 07 Assistive products for body stabilization  
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- 09 09 Assistive products for dressing and undressing
- 09 12 Assistive products for toileting
- 09 15 Assistive products for tracheostomy care
- 09 18 Assistive products for ostomy care
- 09 21 Products for skin protection and skin cleaning
- 09 24 Urine diverters
- 09 27 Assistive products for collecting urine and faeces
- 09 29 Assistive products for pain relief
- 09 30 Absorbing products to contain urine and faeces
- 09 31 Assistive products to prevent involuntary urine or faeces leakage
- 09 32 Assistive products for management of menstruation
- 09 33 Assistive products for washing, bathing and showering
- 09 36 Assistive products for manicure and pedicure
- 09 39 Assistive products for hair care