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Classification and terminology of assistive products

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Introduction

There are many products that can help people with disabilities enhance their quality of life. Hearing aids, wheelchairs, braille equipment, communication devices, software, urine collection systems, oxygen apparatus, and mobile hoists all help people with disability to function better in their daily life and to participate in the society.

Subdivisions of assistive products can be found in several classifications and nomenclatures. Important ones at the international level are ISO 9999 *(Assistive products for persons with disability – Classification and terminology)*, GMDN *(Global Medical Device Nomenclature)* and SNOMED CT *(Systematized Nomenclature of Medicine – Clinical Terms)*.

This article focuses on ISO 9999 *'Assistive products for persons with disability – Classification and terminology'*. ISO 9999 is an international classification of assistive products in which all products that can be used by persons with disabilities are included. The goal of ISO 9999 is to promote communication internationally about the use of assistive products by people with disability including elderly people.

In this article, several aspects of ISO 9999, such as its history, scope and content, are described. To place ISO 9999 in the general context of the classification of assistive products, this article starts with a short description of the others systems mentioned above: the GMDN and SNOMED CT.

GMDN

The Global Medical Device Nomenclature (GMDN) is a comprehensive system of internationally recognized coded descriptors in the format of preferred terms with definitions used to generically identify and characterize types of medical devices and related health care products. GMDN includes products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. The concept of a 'medical device' is much broader than that of an 'assistive product', and consequently the scope of GMDN is much broader than the scope of ISO 9999.

Many of the assistive products included in ISO 9999 may be recognized on the market as medical devices and handled as such in accordance with applicable legislation and

regulations. Other assistive products (e.g., home and environmental adaptations, general communication devices and some products relating to mobility) are not directly connected to the body or only indirectly influence body function. A product is 'assistive' if it contributes to the functioning of a person with disability. It may also improve the health of the user, in which case it may be classified as a medical device as well as an assistive product. For medical devices, dedicated legislation, with which the product has to comply, exists at the international and national level. For assistive products, no specific legislation exists and the assistive products are freely available on the consumer market. In case a product is classified as both a medical device and an assistive product, the legislation regulating medical devices applies fully.

The main purpose of the GMDN is to provide a single naming system for medical devices that will support patient safety for national and international regulatory authorities, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and other affiliated parties. GMDN codes indicate the generic descriptor by which a medical device can be identified; referring to GMDN's globally accepted generic medical device nomenclature. This means other devices having substantially similar generic features but originating from another source can be identified. The system allows data exchange between regular authorities and others, exchange of post-market vigilance information and inventory purposes.

The GMDN is managed by the GMDN Agency, a non-profit organization. For more information on the GMDN see the website: http://www.gmdnagency.org.

SNOMED CT

SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) aimed to be a worldwide comprehensive, multilingual clinical healthcare terminology. SNOMED CT was originally created by the College of American Pathologists by combining SNOMED RT (related terms) and the UK National Health Service's Clinical Terms Version 3 (formerly known as Read Codes), a computer-based nomenclature and classification. The International Health Terminology Standards Development Organization (IHTSDO) is the organization entrusted with SNOMED CT. IHTSDO is a non-profit association that seeks to improve the health of humankind by fostering the development and use of suitable standardized clinical terminologies, notably SNOMED CT, in order to support safe, accurate, and effective exchange of clinical and related health information. The focus is on enabling the implementation of semantically accurate health records that are interoperable.

SNOMED CT provides the core general terminology for the electronic health record and contains more than 311,000 active concepts with unique meanings and formal logic-based definitions organized into hierarchies. When implemented in software applications, SNOMED CT can be used to represent clinically relevant information as an integral part of producing electronic health records. The hierarchies (like clinical finding / disorder, procedure / intervention, observable entity and social context) have multiple levels of granularity. Assistive products are part of the 'physical objects' hierarchy. The subdivision of assistive products in SNOMED CT is not identical to the one presented in ISO 9999.

More information on SNOMED CT can be found on the website of IHTSDO: http://www.ihtsdo.org.

ISO 9999

ISO 9999 is a product of ISO, the International Organization for Standardization (www.iso.org). ISO consists of technical committees (TC) and subcommittees (SC). Each subcommittee can have different working groups (WG). ISO 9999 is placed under TC173 *Assistive products for persons with disability*, SC2 *Classification and terminology*, WG11 *Classification and terminology for the revision of ISO 9999*. The secretariat is hosted by NEN, the Netherlands Standardization Institute. WG11 is composed of experts from China, Japan, Republic of Korea, United States of America and several European countries (Finland, France, Germany, the Netherlands, Portugal and Sweden).

Short history of ISO 9999

In 1983, ISO/TC173/SC2 convened a meeting to establish an international classification system for technical aids for people with disability. The Nordic classification system, which was had been adopted in some of the Scandinavian countries in 1981 as a common classification system on technical aids for handicapped people (de Kleijn-de Vrankrijker and Valk 2003), served as the starting point for the new international classification. ISO initiated this international effort because there was a need for uniform terminology in the area of assistive products. With the increasing volume of international trade in assistive products, a classification was necessary to facilitate location and selection of technical aids and to provide a consistent basis for product information, prescription guidelines, legal documents, information systems, catalogues, administration of stocks and for surveys and the production of statistics (de Kleijn-de Vrankrijker 2002). The target audiences for the classification included consumers, governmental authorities, professionals, prescribers, and social security funds.

In 1992 ISO published the first edition of ISO 9999, 'Technical aids for disabled persons – Classification' (ISO 9999: 1992) with an integral approval by CEN (European Committee for Standardization) of the new international standard as EN 29999: 1994 (de Kleijn-de Vrankrijker and Valk 2003).

To adapt to the continuous innovation and expansion of the assistive product market, the classification has been revised three times since its first edition. The most recent version is the fourth edition published in 2007, '*Assistive products for persons with disability – Classification and terminology'*. The next version, the fifth edition (fourth revision), will be published in 2011. The DIS (Draft International Standard) version of the fifth edition was published in February 2010. In this article we will refer to the 2007 version of ISO 9999.

Definition of assistive product in ISO 9999

According to the 2007 version of ISO 9999, "an assistive product is any product (including devices, equipment, instruments, technology and software) especially produced or generally available, for preventing, compensating, monitoring, relieving or neutralizing impairments, activity limitations and participation restrictions".

This definition was revised in the DIS version of the fifth edition of ISO 9999:

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

- for participation;

- to protect, support, train, measure or substitute for body functions / structures and activities; or
- to prevent impairments, activity limitations or participation restrictions."

Scope of ISO 9999

Assistive products used by a person with disability, but which require the assistance of another person for their operation, are included in the classification. ISO 9999 excludes several products and services from the definition of an assistive product. These include the following:

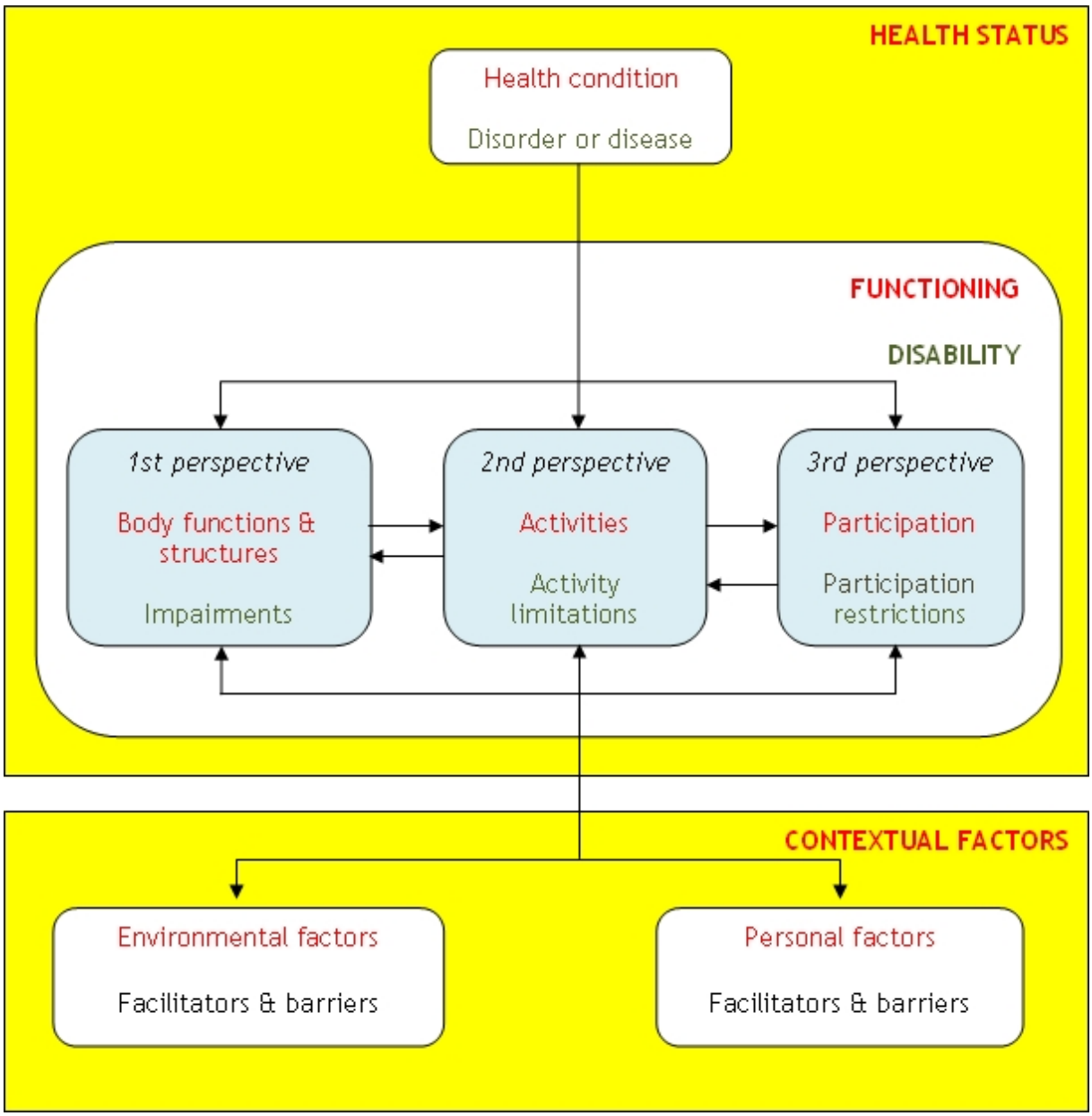
- items used for the installation of assistive products;
- solutions obtained by combinations of assistive products which are individually classified in the classification;
- medicines;
- assistive products and instruments used exclusively by healthcare professionals;
- non-technical solutions and services, such as personal assistance, guide dogs or lip-reading;
- implanted devices; and
- financial support

Relation of ISO 9999 with 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). WHO-FIC is comprised of high quality classifications for relevant sectors of the health system, such as the ICD-10 (International Statistical Classification of Diseases and related health problems) and the ICF (International Classification of Functioning, Disability and Health) (Madden et al, 2007). The association of ISO 9999 with WHO-FIC provides the classification with expanded credibility on the international stage.

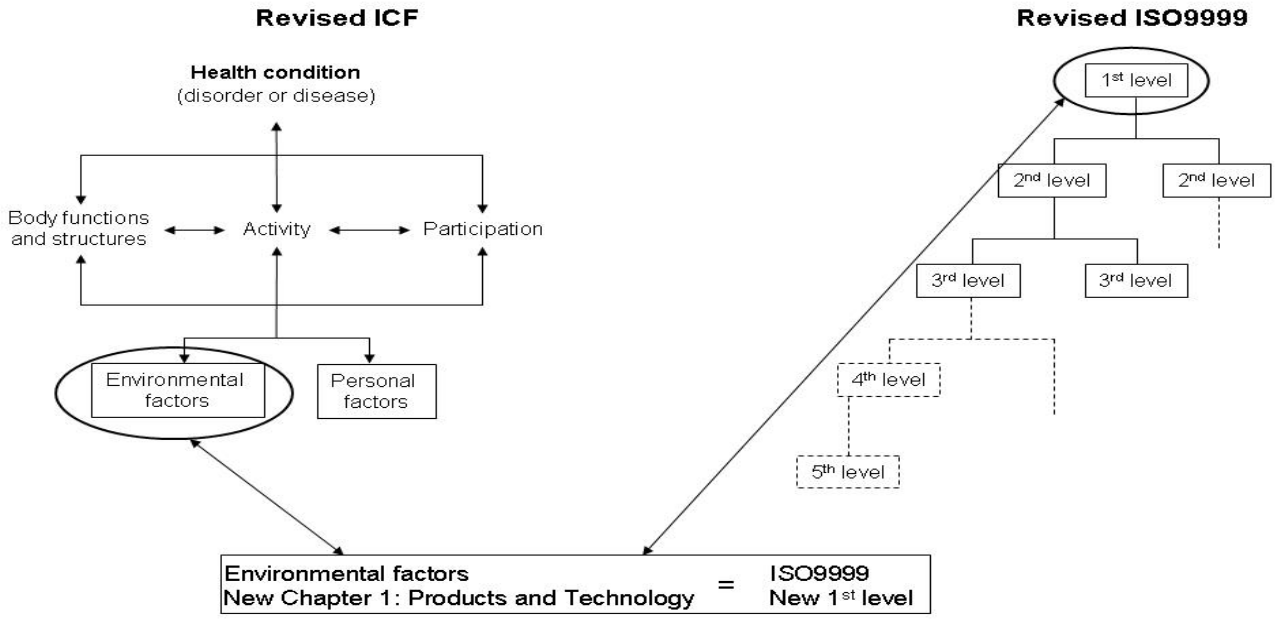
ISO 9999 makes use of the terminology of the ICF. The ICF is a classification of health and health-related components (WHO, 2001). These components are classified from body, individual and societal perspectives. On the body level there are two classifications: a classification of body functions and a classification of body structures. For activities and participation there is a common classification. Since an individual's functioning and disability occurs in context, ICF also includes a list of environmental factors to define that context. Although personal factors are also relevant for functioning, there is not yet an international consensus about the items to be included in a list of personal factors. In Figure 1 the ICF scheme is presented.

Figure 1: ICF Scheme (WHO, 2001); both with the neutral as well as the 'negative' terms



Chapter 1 'Products and technology' of the list of environmental factors of the ICF contains assistive products. Although the definition of assistive products is derived from ISO 9999, the subdivision of chapter 1 is not identical to the first level classes of ISO 9999 (see Figure 2). A proposal by ISO/TC173/SC2/WG11 to harmonize both subdivisions is in development.

Figure 2: Relation between the list of environmental factors of the ICF and 1st level classes of ISO 9999



More information on the ICF can be found on the WHO website: http://www.who.int/classifications/icf/en (application, training material, ICF and ICF-CY on line (multiple languages)). A working document indicating the relation between ISO 9999 and ICF can be found on the website of the Dutch WHO Collaborating Centre for the Family of International Classifications: http://www.rivm.nl/who-fic/ISO-9999eng.htm.

Relation of ISO 9999 with other standards

Where relevant product standards exist, their terminology is used in ISO 9999. These standards are included in the classification's bibliography, and are listed in Annex 1.

Structure of the ISO 9999

Assistive products (including software) are classified according to their main function, such as mobility or employment. The classification consists of three hierarchical levels and the codes each consist 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. When a class is named individually, it is indicated by only the first pair of digits (e.g., Class 12 instead of Class 12 00 00) and subclasses are indicated by two pairs of digits (e.g., Subclass 12 03 instead of Subclass 12 03 00). The numeric codes determine the positions of each class, subclass, or division in the classification. See table 1 for an overview of the classes and some examples of subclasses and divisions.

Table 1: The classes of ISO 9999 and some examples of subclasses and divisions

Classes (one-level classification) of ISO 9999

04	Assistive products for personal medical treatment
05	Assistive products for training in skills
06	Orthoses and prostheses
09	Assistive products for personal care and protection
12	Assistive products for personal mobility
15	Assistive products for housekeeping
18	Furnishings and adaptations to homes and other premises
22	Assistive products for communication and information
24	Assistive products for handling objects and devices
27	Assistive products for environmental improvement, tools and machines
30	Assistive products for recreation

Subclasses (two level) of class 12 Assistive products for personal mobility

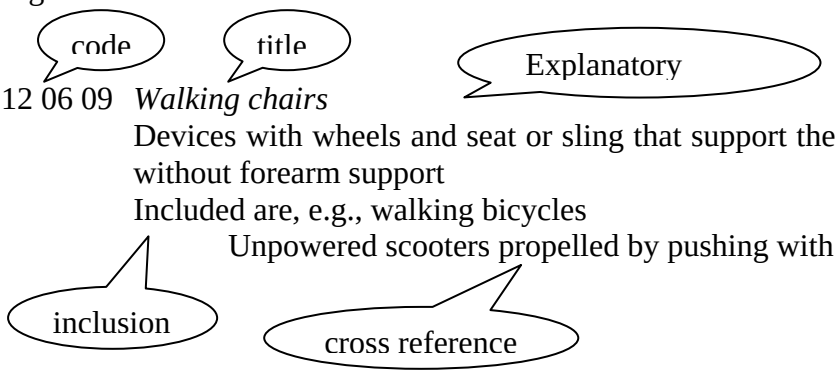
12 03	Assistive products for walking, manipulated by one arm
12 06	Assistive products for walking, manipulated by both arms
12 07	Accessories for assistive products for walking
12 10	Cars
12 12	Car adaptations
12 16	Mopeds and motorcycles
12 18	Cycles
12 22	Human driven wheelchairs
12 23	Powered wheelchairs
12 24	Wheelchair accessories
12 27	Vehicles
12 31	Assistive products for transfer and turning
12 36	Assistive products for lifting
12 39	Assistive products for orientation

Divisions (three level) of subclass 12 31 Assistive products for transfer and turning

12 31 03	Sliding boards and sliding mats and turning sheets
12 31 06	Turntables
12 31 09	Free-standing rails for self-lifting
12 31 12	Grip ladders
12 31 15	Lifting belts and harnesses
12 31 18	Carrying chairs, harnesses and baskets
12 31 21	Transfer platforms

Like other classifications, ISO 9999 provides codes, titles, explanatory notes, inclusions, exclusions and cross-references for each level of the classification.

E.g.



Besides the explanatory text and the classification itself, a table of conversion between the previous (2002) edition and the 2007 edition and an alphabetical index are provided in order to facilitate the use of and to improve the accessibility of the classification.

Use of the ISO 9999

The ISO 9999 is used in several national databases of assistive products, including like AbleData (USA), Rehadat (Germany), HANDY-WIJZER (the Netherlands) and Vilatech (the Netherlands), and in financial systems from (local) government a/or health insurance. There are some attempts to add additional codes to the ISO 9999 to make it possible to describe characteristics of the assistive products in more detail (such as Cliq).

AbleData

AbleData provides free objective information on assistive technology and rehabilitation equipment available from domestic and international sources to consumers, organizations, professionals, and caregivers within the United States (http://www.abledata.com).

AbleData is sponsored by the National Institute on Disability and Rehabilitation Research (NIDRR), part of the Office of Special Education and Rehabilitative Services (OSERS) of the U.S. Department of Education.

AbleData's most significant resource is the AbleData database of assistive technology, which contains objective information on more than 37,000 assistive products (over 23,000 of which

are currently available). For each product, a detailed description of the product's functions and features, price information (when available), and contact information for the product's manufacturer and/or distributors are provided. AbleData's product information is updated daily, and its staff add over 1,200 new products each year. Listing products on AbleData is free for assistive technology companies. The AbleData website receives over 260,000 visitors and over 900,000 page views each month.

AbleData has maintained an independent classification system for over 20 years; however, it recently began to link that system to ISO 9999 so that AbleData's users will be able to locate product information using ISO 9999.

Rehadat

Rehadat 'Information system on vocational rehabilitation' is an information system supporting the vocational integration of disabled persons that has been commissioned by the German Federal Ministry of Labour and Social Affairs and was established by the Cologne Institute for Economic Research (http://www.rehadat.de/rehadat/eng/).

The database structure is based on ISO 9999 and can be searched in German or English. The descriptions of the products are available in English (translated manually or by translation software). Documenting more than 20,000 products, the database contains most of the technical aids for disabled persons that are available in Germany. The range of technical aids includes aids for housekeeping, orthoses and prostheses, and adapted machines and tools. Rehadat includes entries detailing each product's manufacturer, distributor and price, and it provides technical descriptions and information on the reimbursement of costs by health insurance organisations. Contact details for manufacturers or distributors include the e-mail and Web addresses of the companies as links that can be accessed directly from the database. Graphics and pictures supplement many documents.

HANDY-WIJZER

HANDY-WIJZER is a freely accessible website on assistive products from the Dutch company HANDY-BRAINS. It uses the Dutch language and is visited by users of assistive products as well as professionals mainly in the Netherlands and Belgium. The system is supported by financial contributions from participating companies that put commercially oriented information on their products and services on the website. The product information includes functional and technical characteristics, dimensions, compliance with international standards, available options and product variants, and pictures.

The products are classified by HANDY-BRAINS following ISO 9999 with national additions (see Cliq) in order to specify in depth the intended use of the assistive product. Additionally, HANDY-BRAINS adds - in general and on the product level - information on law and legislation, policy and future-oriented topics, and developments in the wide field of assistive products. HANDY-BRAINS also performs quality control and checks the internal consistency of product information originating from different sources. The information may be retrieved using ISO 9999 or through free text search on key terms that include the intended use and specific user of the assistive product.

The site is updated every three months with new products and other information and has early 2010 about 40.000 new visitors per month which have a look at up to 200.000 pages. For more information, go to http://www.handy-wijzer.nl or http://www.handy-wijzer.be (only in Dutch).

Vilatech

Vilatech 'hulpmiddelenwijzer' is a Dutch database with independent information on assistive products for people with disability or chronic disease and elderly people. In three steps, people get an overview of the assistive products that might be useful for them. After selecting one or more products, more detailed information can be found, including a description of the functionality of the product(s), technical details, reimbursement systems from (local) government and/or health insurance, manufacturers and price. People can search the database by defining 'activity', 'environment in which the product will be used' and 'solution' or by using free text words. The subdivision of products is based on ISO 9999. For more information, visit http://www.vilatechdatabank.nl or http://www.vindeenhulpmiddel.nl (only in Dutch).

Cliq

Cliq (Classification with IQ) is derived from ISO 9999, providing more detailed categories than the original classification. It was developed in the Netherlands. To the original six-digit codes (3 pairs of two digits) of ISO 9999, a maximum of six extra digits (three pairs of two digits) are added. With these additional digits, the 'product related intended use' of the products can be described. 'Product related intended use' is a legal term that indicates what the user can and may expect of the assistive product. It encompasses the following characteristics:

- functionality: activities (indirectly participation) for which the assistive product can be used (such as standing and work) and functions and structures supported by the product (such as respiration and a joint's range of motion)
- technical characteristics
- user friendliness
- external and cosmetic features (like color)
- other characteristics.

It is important to match the wishes of the user with respect to the assistive product (human related intended use) (coded in ICF terms) to the characteristics of the products (product related intended use) (in Cliq codes).

Future

As indicated, the fifth version of ISO 9999 will be published in 2011. Plans for the sixth version (to be published in 2015) include harmonization of the classification with ICF and the addition of a fourth level.

Invitation

Proposals for changes or additions to the ISO 9999, to revise existing classes/subclasses/divisions or propose new ones, in accordance with the rules of the classification, may be submitted to a national member body of ISO with an accompanying explanation of the proposal.

More information on ISO 9999

More information can be found on the ISO website: http://www.iso.org. In the online bookstore, the ISO 9999 can be ordered in English and French. For other languages, the national standardization organization of the respective country can be consulted. For example,

the Dutch version is available at the Netherlands Standardization Institute (NEN) (http://www.nen.nl).

Annex: Standards used in ISO 9999

- ISO 1087-1, Terminology work — Vocabulary — Part 1: Theory and application
- ISO 1087-2, Terminology work — Vocabulary — Part 2: Computer applications
- ISO 6440, Wheelchairs — Nomenclature, terms and definitions
- 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
- 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, Walking aids 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
- ICF, WHO, Geneva, 2001, International Classification of Functioning, Disability and Health
- EN 12182:1999, Technical aids for disabled persons — General requirements and test methods

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