American National Standard

ANSI/AAMI/ISO 15225:2010

Medical devices — Quality management — Medical device nomenclature data structure

Association for the Advancement of Medical Instrumentation

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI/ISO 15225:2010
(Revision of ANSI/AAMI/ISO 15225:2000/(R)2006
and ANSI/AAMI/ISO 15225:2000/A1:2004/(R)2006)

Medical devices — Quality management — Medical device nomenclature data structure

Approved 8 March 2010 by
Association for the Advancement of Medical Instrumentation

Approved 20 April 2010 by
American National Standards Institute, Inc.

Abstract: Provides rules and guidelines for a medical device nomenclature data structure in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties such as regulatory authorities, manufacturers, suppliers, health care providers and end users.

Keywords: medical device nomenclature

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003/(R)2010	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical

International designation	U.S. designation	Equivalency
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO 15225 as a revision of ANSI/AAMI/ISO 15225:2000/(R)2006 and ANSI/AAMI/ISO 15225:2000/A1:2004/(R)2006 was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Symbols and Nomenclature Working Group (U.S. Sub-TAG for ISO/TC 210/WG 3), chaired by Leighton Hansel of Abbott Laboratories and Charles Sidebottom of Medtronic, Inc. played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee** had the following members:

Cochairs
Carol L. Herman, FDA/CDRH
Charles B. Sidebottom, PE, Medtronic Inc.

Members
Leighton W. Hansel, Abbott Laboratories
Carol L. Herman, FDA/CDRH
Ed R. Kimmelman, BME, JD, (Independent Expert)
David Osborn, Philips Healthcare
Harvey Rudolph, PhD, Underwriters Laboratories Inc.
Charles B. Sidebottom, PE, Medtronic Inc.
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Candice Betz, Becton Dickinson & Company
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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 15225:2010

As indicated in the foreword to the main body of this document (page ix), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

International standard ISO 15225:2010 was developed by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices to provide rules and guidelines for a medical device nomenclature data structure in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties such as regulatory authorities, manufacturers, suppliers, health care providers, and end users.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation on behalf of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of quality management and corresponding general aspects for medical devices. Upon review of ISO 15225, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI Symbols and Nomenclature Working Group decided to adopt it verbatim, as a revision of ANSI/AAMI/ISO 15225:2000/(R)2006 and its 2004 amendment.

This edition of ISO 15225 has been technically revised from the previous edition and includes definitions for base concept, collective term, device category, device type, generic device group, GMDN, GMDN agency, multiple-linked synonym, product specifier and template specifier. Annex A contains three new codes and updated descriptions based on examples of new technologies. Annex D has been added which contains examples of collective terms.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr. Suite 301, Arlington, VA 22203-1633.

NOTE—Beginning with the ISO foreword on page ix, this American National Standard is identical to ISO 15225:2010.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15225 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 15225:2000), which has been technically revised. It also incorporates the Amendment ISO 15225:2000/Amd.1:2004.

Introduction

This International Standard is intended to assist competent authorities, conformity assessment bodies, healthcare providers and manufacturers in the submission and exchange of information. It is intended that the information covered by this International Standard be available in the public domain.

This second edition of this International Standard is based on experience gained from utilization of the first edition. The following major changes have been made to the first edition:

— definitions have been added in Clause 3 for base concept, collective term, device category, device type, generic device group, Global Medical Device Nomenclature (GMDN), GMDN agency, multiple-linked synonym, product specifier and template specifier;

— Codes 13, 14 and 15 have been added in Annex A, and the descriptions have been updated with examples of new technologies;

— Annex D has been added containing examples of collective terms.

The requirements contained in this International Standard are applicable to the development and updating of an international nomenclature and have been prepared specifically for construction of the Global Medical Device Nomenclature (GMDN).

Medical devices — Quality management — Medical device nomenclature data structure

1 Scope

This International Standard provides rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.

This International Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein.

The requirements contained in this International Standard are applicable to the development and maintenance of an international nomenclature for medical device identification.

This International Standard does not include the nomenclature itself, which is provided as a data file.

2 Normative references

The following referenced documents are indispensable for the application 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/IEC 8859-1:1998, *Information technology — 8-bit single-byte coded graphic character sets — Part 1: Latin alphabet No. 1*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply[1)].

3.1
base concept
broadest representation of the generic device group, and the primary listing basis of the GMDN

[GMDN Agency]

1) In this International Standard, many terms are used which have their basis in regulatory statutes, e.g. “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature are used.

3.2
character
member of a set of elements used for the organization, control or representation of data

[ISO/IEC 8859-1:1998, definition 4.3]

3.3
code
system of alpha, alphanumeric or numeric characters and rules by which information is represented, communicated, or both

3.4
collective term
term used to describe broad common features or characteristics within which a number of generic device group terms are recognized, for regulatory or other purposes

NOTE Generic devices can be linked to one or more collective terms to indicate, for example, the following:

— common areas of intended use;

— the application of common technology;

— the use of specific hazardous or difficult materials;

— the application of a particular medical speciality;

— the need for application of specific manufacturing processes;

— the presence of other common attributes with which to identify certain devices;

— the common descriptor of a broad device concept (i.e. a template term).

3.5
concept
unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000, definition 3.2.1]

3.6
definition
formal concise statement of the meaning of a preferred term or template term

3.7
device category
broadest grouping within the nomenclature

3.8
device intended for clinical investigation
device intended for use in a designed and planned systematic study in or on human subjects to verify the safety, performance, or both

3.9
device intended for performance evaluation
device intended by the manufacturer to be subject to performance evaluation studies in laboratories for medical analyses or other appropriate environments outside the manufacturer's premises

3.10
device type
identification of a manufacturer's specific product

NOTE The manufacturer's specific product is the make and model.

3.11
file
named set of records stored or processed as a unit

[ISO/IEC 2382-1:1993, definition 01.08.06]

3.12
foreign key
⟨relation⟩ one or a group of attributes that corresponds to a primary key in another relation

[ISO/IEC 2382-17:1999, definition 17.04.15]

3.13
generic device group
set of devices having the same or similar intended use, common technology, or both

3.14
Global Medical Device Nomenclature
GMDN
nomenclature based on the structure of this International Standard, which provides information in the form of a code to indicate the generic descriptor within which a device type can be identified

NOTE By reference to this globally accepted, generic medical device nomenclature, other particular devices which have substantially similar generic features but which come from another source can be identified, for reasons of data exchange between competent authorities and others, for the exchange of post-market vigilance information and for inventory purposes.

3.15
GMDN agency
organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the GMDN, and is responsible for the development, control and distribution of the GMDN

3.16
identifier
⟨organization of data⟩ one or more characters used to identify or name a data element and possibly to indicate certain properties of that data element

[ISO/IEC 2382-4:1999, definition 04.09.02]

3.17
multiple-linked synonym
alternative name(s) for a synonym term linked to more than one preferred or template term

[GMDN Agency]

3.18
name
verbal designation of an individual concept

NOTE Adapted from ISO 1087-1:2000, definition 3.4.2.

3.19
nomenclature
terminology structured systematically according to pre-established naming rules

[ISO 1087-1:2000, definition 3.5.3]

3.20
preferred term
name established to describe a device, or devices, having the same or similar intended use or commonality of technology

3.21
primary key
a key that identifies one record

[ISO/IEC 2382-17:1999, definition 17.03.11]

3.22
product specifier
marker to indicate which terms can and cannot be used for product identification

[GMDN Agency]

3.23
relational structure
data structure in which the data are arranged as relations

[ISO/IEC 2382-17:1999, definition 17.04.03]

3.24
secondary key
a key that is not a primary key, but for which an index is maintained and that may denote more than one record

[ISO/IEC 2382-17:1999, definition 17.03.12]

3.25
synonym
alternative name for a preferred or template term

3.26
template specifier
data field which is set to indicate that the term is a template term and, at the same time, which specifies that the first characters from the term field are used to look up the preferred terms that start with the same characters

3.27
template term
term used to create a simple hierarchy for preferred terms

3.28
term
verbal designation of a general concept in a specific subject field

NOTE Adapted from ISO 1087-1:2000, definition 3.4.3.

4 Principle of structure

4.1 General

The nomenclature is structured in four stages. These stages differ in the breadth of the sets of devices represented by the terms defined within each stage. All medical devices can be classified within each stage. The stages have a relational structure in the following order:

a) device category (see 4.2);

b) collective term (see 4.3);

c) generic device group (see 4.4);

d) device type (see 4.5).

4.2 Device category

Individual categories have broad usage definitions representing disparate devices that have common areas of intended use or common technology. Device category has the largest number of devices covered by each term.

For data organization, device category includes the record holding a device category term and associated data, such as its code and other attributes.

4.3 Collective term

Collective terms are terms used in the nomenclature for:

a) grouping together preferred terms with common characteristics, e.g. common technology, materials, medical specialties, manufacturing processes;

NOTE Collective terms can replace or support template terms.

b) illustrating the scope of certificates issued by certification bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system;

c) identifying the range of skills and general technological abilities for which a notified body has been approved, and is so appointed by the relevant regulatory authority;

d) exchanging of information between regulatory authorities when general information on individual manufacturers capabilities is notified for inclusion within data-exchange systems.

Collective terms are linked directly to preferred terms.

4.4 Generic device group

A generic device group contains sets of devices having the same or similar intended uses or commonality of technology. Sets of devices are grouped together for the purpose of device vigilance reporting, or other purposes where sets of essentially similar devices from different sources need to be collected. Potentially, any device attribute (e.g. implant/non-implant, sterile/non-sterile) can be used as a means of arranging associated data.

For data organization, the generic device group includes the record holding a device group term. The device group term can include the following:

a) preferred term (see 5.2.3);

b) template term (see 5.2.4);

c) synonym (see 5.2.5);

d) multiple-linked synonym (see 5.2.6).

It can also include associated data, as follows:

— code;

— definition;

— for synonyms or multiple-linked synonyms, code of the generic device group record holding the preferred term or template term;

— for templates, the template specifier.

4.5 Device type

A device type contains individual medical devices including devices intended for clinical investigation, devices intended for performance evaluation and custom-made devices or sets of medical devices including variants which may be produced. Device types contain sufficient characteristics in common for the manufacturer to establish a make and model.

For data organization, device type includes the record holding the device type designation and its associated data, such as its code and other attributes.

Names to be stored are drawn from the manufacturer's documentation.

4.6 Nomenclature structure example

Table 1 is an example of the nomenclature structure.

Table 1 — Example of GMDN structure linked to an alignment rod

Device categories:	03 Dental devices 09 Reusable devices
Links to - -	
Collective terms:	
	CT465 Cranial surgery
	CT146 Dentistry
	CT317 Infant/pediatric
	CT321 Long-term surgical invasive
	CT326 Manually powered/operated
	CT177 Metals
	CT328 Natural orifice
	CT166 Oral surgical fixation/distraction and ancillary
	CT152 Pediatrics
	CT982 Reusable
	CT335 Single purpose
	CT334 Single-patient use
	CT337 Sterilizable
	CT233 Surgery
Links to - -	
Generic device group:	GMDN code:47677 Term: Craniofacial alignment rod Definition: A surgical instrument typically used in pairs to facilitate correct cranial orientation of craniofacial implants (e.g., fixation plates being attached to jaw bones) and other devices (e.g. craniofacial distractors) during their application in craniofacial surgery. It is typically designed as a long, thin, rigid rod made of high-grade stainless steel or titanium alloy with connectors at either end for attachment to the devices being aligned; it may have a knurled mid section (to provide better grip) onto which other instruments can be locked to assist the orientation procedure. This is a reusable device.
Links to - -	
Device type:	Make: Acme Model: 298FK3Z Trade name: Alignment rod

5 Requirements

5.1 Device category

Device categories are managed by the GMDN agency and are part of the data file.

The list is not exhaustive, other device categories may be added (see Annex A).

5.2 Generic device group

5.2.1 General

Generic device groups are managed by the GMDN agency and are part of the data file.

For the generation of generic device group terms, see Annex B.

A generic device group can be a member of more than one device category.

The nomenclature shall consist of preferred terms, template terms, synonyms and multiple-linked synonyms. All terms should be given in the singular form.

5.2.2 Abbreviations and acronyms

Abbreviations and acronyms can be used to create generic device group names.

Any abbreviation being adopted should use widely recognized terminology.

5.2.3 Preferred term

A preferred term represents a device type or a set of device types that perform similar or equivalent functions or have technical characteristics in common.

A preferred term is the only term that can be used for product identification.

A preferred term shall be unambiguous and comprise the following:

a) base concept;

b) (if appropriate) one or more qualifiers following the base concept, and which are separated from the base concept by a comma;

c) a comma and one space to delimit each qualifier.

EXAMPLE Brachytherapy system applicator, remote afterloading, bladder.

More specific classification can be achieved by addition of further qualifiers.

The base concept shall be the primary listing basis.

Unambiguous qualifiers shall be used.

Ambiguous qualifiers include phrases such as “sundries”, “others”, “appliances”, “miscellaneous” and “various”.

Trade names shall not be used as preferred terms.

Preferred terms shall be assigned a definition of not more than 700 characters.

5.2.4 Template terms

A template term is used when more than two preferred terms are formed using the same base concept.

The template term shall be formed from the common base concept followed by the qualifier <specify>.

A template term functions only as a navigational term within the nomenclature. Its permanency cannot be guaranteed due to preferred term development.

Template terms cannot be used for product identification.

Template terms shall not be used as synonyms.

Template terms shall be assigned a definition of not more than 700 characters.

5.2.5 Synonyms

Synonyms shall be linked to only one preferred term or to one template term, whichever is appropriate.

Synonyms are an aid to locating the appropriate preferred term.

Synonym terms cannot be used for product identification.

Synonyms shall not be linked to other synonyms.

5.2.6 Multiple-linked synonyms

A multiple-linked synonym is a term that is typically of a higher order, and can therefore be linked to more than one preferred term, or template term, or preferred term and template term.

EXAMPLE 1 Higher order terms

EDMA term: **Thyroid Function Hormones**

GMDN related terms: **Triiodothyronine uptake kit**

Thyroxine kit

Triiodothyronine kit

Free triiodothyronine kit

Free thyroxine kit.

EXAMPLE 2 Combination product terms

UMDNS term: **Reagents, Staphylococcus/Streptococcus Detection**

GMDN related terms: **Staphylococcus kit**

Streptococcus antibody kit

Streptococcus antigen kit.

A multiple-linked synonym shall have the same construction format and status as a synonym term.

Multiple-linked synonym terms may not be used for the purpose of product identification.

5.3 Device type

Device types are used to identify a manufacturer's specific product (i.e. make and model) and are managed by, or on behalf of, the device manufacturer.

A device type shall not be linked to more than one preferred term.

Device types shall be designated under the code of a preferred term, in accordance with the primary intended uses specified by the manufacturer.

5.4 Collective term

Collective terms shall group several preferred terms with common features (see 4.3). Collective terms are managed by the GMDN Agency and are part of the data file.

See Annex D.

6 Data file dictionary

6.1 General

This clause is provided for information system designers implementing the nomenclature within a database. It provides the minimum requirements for the data fields needed to hold the nomenclature system. Each stage in the data structure is represented by a data file for which the requirements of 6.2 to 6.5 apply.

Further data fields may be added to all data files depending on the requirements of the end user of the database system in question.

The character set for transmissions shall be the Latin alphabet No. 1 as specified in ISO/IEC 8859-1.

6.2 Device category data file

The minimum number of fields shall be as specified in Table 2.

The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

See Annex A for examples.

When information is exchanged and records in the data files described in Table 2 are part of this information, then only the code of the relevant records needs to be transmitted.

Table 2 — Requirements for device category data file

Identifier	Data category and format	Comments
Code	Numeric, two digits	Primary key
Term	Alphanumeric, 60 characters	Primary key
Definition	Alphanumeric, 1,260 characters	—

6.3 Generic device group data file

The data field code shall be assigned an incremental sequential cardinal number starting from the value 10,000. After a new record is added to the data file, the code shall be incremented by one (1).

The generic device group data file shall be as specified in Table 3.

Table 3 — Requirements for generic device group data file

Identifier	Data category and format	Comments
Code	Numeric, five digits	Primary key
Term	Alphanumeric, 120 characters	Primary key
Synonym code	Numeric, five digits	If not equal to zero (nil) then this device group is a synonym where the numeric value is the code of the preferred term or template.
Template specifier	Numeric, two digits	If not equal to zero (nil) then this device group is a template. The numeric value represents how many characters from the term are to be used for looking up (listing) the matching preferred term base concept.
Definition	Alphanumeric, max 700 characters	See also 5.2.
Product specifier	Alpha, 30 characters	The text “product identifier” or “not for product identification” is linked to all terms to make it clear to the nomenclature user which terms are allowed for product identification and which are not.
NOTE Annex C gives examples of device group records.		

The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

There is no foreign key in this data file relating it to the device category data file, since there is a many-to-many relation between these two data files. The system designer should apply the method(s) available in the database tool in order to achieve this many-to-many relation, the most common method being a data file holding as foreign keys the codes of both the device category and generic device group records.

The code of the generic device group’s records, where the synonym code or the template specifier is not zero (nil), shall not be used as a foreign key in related data files.

These records may not be available in all natural language versions of the nomenclature system and in such cases no relation will exist (see Annex C).

Generic device group codes in the range 1 to 9,999 cannot be used in data transmissions that comply with this International Standard. This demands that an official list of generic device groups will never contain records having these code values. Generic device group codes in the range 1 to 9,999 are exclusively reserved for assignment by the end user. These codes are made available for the convenience of end users to store terms outside the scope of this International Standard.

6.4 Device type data file

The minimum number of fields shall be as specified in Table 4.

Table 4 — Requirements for device type data file

Identifier	Data category and format	Comments
Generic device group code	Numeric, five digits	Foreign key, represents the link to a generic device group record (preferred term in the nomenclature)
Make	Alphanumeric, 60 characters	Secondary key, can also act as a foreign key
Model	Alphanumeric, 60 characters	The make and model represents, when concatenated, the primary key

When concatenated (see Table 4) the contents of the data fields “make” and “model” shall be unique.

The data field “make” is used to identify the manufacturer on the device label. When appropriate, the authorized representative may be identified. A shortened version, such as an easily recognizable trade name or alpha-numeric trade mark, may be used.

The data field model should be the name used by the manufacturer to identify the particular type of device. In appropriate circumstances, other informative formats, such as brand or bar code data, may be used. This data field should not be confused with the serial number or lot number assigned to the individual device or lots of devices.

The reasoning for having two data fields representing the primary key is that the model name used by one manufacturer (or even by the same manufacturer when he uses several makes to represent his name) could possibly be used by other manufacturers, thus making it unsuitable for use as a primary key.

The system designer may find it useful to assign a single (numeric) data field as a more manageable primary key in the database system for this data file.

Each device type record should be supported by a unique code for data transmission.

If it is considered of value to include device risk class data, this should be limited to links at the device type. Risk classification at the generic device group level is not considered in this International Standard.

6.5 Collective term data file

The minimum number of identifiers shall be as specified in Table 5.

Table 5 — Requirements for collective term data file

Identifier	Data category and format (maximum)	Comments
Code	Alphanumeric, six characters	Primary key
Term	Alphanumeric, 150 characters	Primary key
Definition	Alpha, 300 characters	—

The collective term code consists of two alpha characters, followed by up to four numeric characters.

EXAMPLE CT1234.

Annex A
(informative)

Device categories

This annex provides descriptions and examples of device categories.

— **Code: 01**

Term: Active implantable devices

Devices that operate with an integral power source (i.e. independent of energy from the human body or gravity), that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain temporarily or permanently.

EXAMPLE 1 Cochlear implants, implantable defibrillators, implantable infusion pumps, implantable stimulators, pacemakers, and their accessories.

— **Code: 02**

Term: Anesthetic and respiratory devices

Devices used to supply, condition, monitor, dispense or deliver respiratory or anesthetic gases, vapors or other substances, in order to provide or control respiration or anesthesia.

EXAMPLE 2 Airways, anesthesia systems, breathing circuits, humidifiers, tracheal tubes, ventilators, and their accessories.

— **Code: 03**

Term: Dental devices

Devices used to diagnose, prevent, monitor, treat or alleviate oral, maxillo-facial and dental disease/disorders.

EXAMPLE 3 Dental amalgam, dental cements, dental hand instruments, dental implants, dental materials, dental tools/laboratory devices, and their accessories.

— **Code: 04**

Term: Electro mechanical medical devices

Devices that operate on electrical energy (electromedical) or through some integrated physical mechanism or machinery (mechanical).

EXAMPLE 4 Specialized beds, defibrillators, dialysis systems, electrocardiographs (ECG), electroencephalographs (EEG), endoscopes, infusion pumps, lasers, operation/examination tables/lights, suction systems, and their accessories.

— **Code: 05**

Term: Hospital hardware

Devices that typically do not directly or actively participate in the diagnosis or treatment of patients, but that support or facilitate such activities.

EXAMPLE 5 Air cleaners, baths, detergents, disinfectants, floor coverings/mats, incinerators, patient beds, patient transfer equipment, sterilizers, and their accessories.

— **Code: 06**

Term: *In vitro* diagnostic devices

Devices used to examine clinical samples taken from the human body to evaluate physiological or pathological conditions.

EXAMPLE 6 Analyzers, blood glucose monitoring devices, *in vitro* diagnostic (IVD) test kits/calibrators/controls, dedicated laboratory equipment, microbial sensitivity systems, and their accessories.

— **Code: 07**

Term: Non-active implantable devices

Devices without an integral power source that are totally or partially introduced, surgically or medically, into the human body or body-orifice, where they are intended to remain for longer than 30 days.

EXAMPLE 7 Cardiovascular clips, embolization implants, orthopedic fixation systems, intrauterine devices, heart valves, bone prostheses, and their accessories.

— **Code: 08**

Term: Ophthalmic and optical devices

Devices used to diagnose, prevent, monitor, treat, correct or alleviate diseases or disorders related to the eye.

EXAMPLE 8 Contact lenses, keratomes, intraocular lenses, slit lamps, ophthalmic test instruments, phacoemulsification systems, tonometers, and their accessories.

— **Code: 09**

Term: Reusable devices

Devices that can be used for more than one application period, often involving cleaning or sterilization between the periods.

EXAMPLE 9 Drills, elastic bandages, hemostats, medicine administration kits, saws, scar management garments, reusable surgical instruments (chisels, scissors, retractors, scalpels), and their accessories.

— **Code: 10**

Term: Single-use devices

Device that is intended for one use, or on a single patient during a single procedure.

EXAMPLE 10 Adhesive tapes, bandages, blood collection devices, catheters, condoms, dressings, electrodes, kits/sets (biopsy, intravenous infusion), needles, single-use surgical instruments/products (cannulae, scalpels, absorbents), and their accessories.

— **Code: 11**

Term: Assistive products for persons with disability

Devices specially produced or adapted which compensate for, relieve, prevent or neutralize an impairment, disability or handicap.

EXAMPLE 11 Artificial limbs, audiometers, crutches, hearing aids, lifts, orientation aids, rehabilitation devices, wheelchairs, and their accessories.

— **Code: 12**

Term: Diagnostic and therapeutic radiation devices

Devices that use radiation energy, including *in vivo* isotopes, excited particle energy, magnetic resonance imaging, nuclear energy, ultrasound and x-ray, for the purpose of providing diagnostic imaging or therapeutic radiation treatment.

EXAMPLE 12 Accelerator systems, bone absorptiometric systems, accelerator systems, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, positron emission tomography (PET) system, X-ray systems, and their accessories.

NOTE Radiant warming devices are excluded.

— **Code: 13**

Term: Complementary therapy devices

Devices that use traditional or alternative methods to diagnose or treat illness. These devices may be used alone or to complement allopathic medicine; their use is commonly related to the body's innate energy system.

EXAMPLE 13 Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups.

— **Code: 14**

Term: Biological derived devices

Devices incorporating human or animal tissues, or tissue derived products.

EXAMPLE 14 Heart valves, tissue growth products.

— **Code: 15**

Term: Healthcare facility products and adaptations

Building-related products and furnishings for the function and utilization of healthcare facilities, or for home healthcare, which are not involved in patient diagnosis or disease-related treatment.

EXAMPLE 15 Electrical outlets, safety systems (e.g. electrical fail-safe systems, personnel assistance warning systems), fixed generators, sanitation products (e.g. special toilets and baths for routine hygiene), permanent floor/wall coverings, goods transportation systems, adapted and standard furniture, and their accessories.

Annex B
(informative)

Examples for generation of generic device group terms and synonyms

B.1 General

This annex provides examples for the purpose of generating generic device group terms and updating the nomenclature.

The terms used in the examples provided are for illustrative purposes.

B.2 Structure of generic device group terms

The preferred term should be of such a character that the nomenclature acquires a functional architecture, bearing in mind the users and use of the device. The qualifier, especially when common to many terms, may be based on the properties, characteristics or field of use of the devices, by using well-established conventions when appropriate.

The general structure of the preferred term is the base concept (singular noun or noun phrase), followed by one or more qualifiers (adjectives or adjectival phrases), delimited or separated by a comma. The base concept is the broadest representation of the generic device group of medical devices that is further described by the qualifiers. The qualifiers, moving from left to right, should be ordered from broader (less specific) to narrower (more specific).

B.3 Examples of generic device group terms

B.3.1 A preferred term should be constructed in the following manner:

Base concept	qualifier	qualifier
Noun or noun phrase	adjective or adjectival phrase	adjective or adjectival phrase

B.3.2 The following are examples of preferred terms structured by base concept followed by qualifier.

EXAMPLE 1 Suture, nylon.

EXAMPLE 2 Suture, polyethylene.

EXAMPLE 3 Suture, polyglyconate.

B.3.3 The following are examples of preferred terms using a qualifier which reflects the “field of use” of the devices to be named by the term.

EXAMPLE 1 Hemofiltration system.

EXAMPLE 2 Peritoneal dialysis system.

EXAMPLE 3 Hemodialysis system.

EXAMPLE 4 Hemodialysis system air bubble/foam guard.

EXAMPLE 5 Hemodialysis system bicarbonate mixer.

B.3.4 Where there are more than two preferred terms with the same base concept, a template may be introduced.

EXAMPLE 1 Audiometer, <specify>.

EXAMPLE 2 Audiometer, auditory evoked response.

EXAMPLE 3 Audiometer, automatic-recording.

EXAMPLE 4 Audiometer, computer-controlled.

B.3.5 The following are examples of synonyms:

EXAMPLE 1	Dinamap	“linked to”	Sphygmomanometer, electronic, <specify>
EXAMPLE 2	AED (automatic external defibrillator)	“linked to”	Defibrillator, automatic
EXAMPLE 3	Ambu bag	“linked to”	Resuscitator, pulmonary, <specify>

B.3.6 Any definition should be written in a manner that makes it comprehensible to all nomenclature users.

EXAMPLE 1 Audiometer, <specify>

An electroacoustic device designed for the measurement of hearing, most commonly for measuring the hearing threshold level. It uses controlled levels of test tones and signals to conduct diagnostic hearing evaluations and assist in the diagnosis of possible otological disorders.

EXAMPLE 2 Audiometer, automatic, computer-controlled

An electroacoustic device designed to measure the hearing threshold of a patient by presenting tones of increasing or decreasing intensity through headphones to establish the level at which the patient first becomes aware of the sounds. A computer or microprocessor in the device automatically produces tones that sweep the audiometric scale and controls tone intensity and frequency. The device also records the patient's responses and may display calculated hearing thresholds. This device may have the capacity to present a fixed frequency or a steadily changing frequency. It may also provide both continuous and pulsed tone outputs.

B.4 Abbreviations

The following are examples of abbreviations used in, or as part of, a synonym:

EXAMPLE 1 AARK (automated anaesthesia record keeper).

EXAMPLE 2 CPAP unit (continuous positive airway pressure unit).

B.5 Example of style

B.5.1 The first letter of a device category term or a generic device group term should be in upper case (capital letters). Thereafter, all letters should be reproduced in lower case (small letters).

EXAMPLE 1 Capitalized first letter of the base concept: Defibrillator

EXAMPLE 2 Capitalized first letter of the base concept followed by a qualifier in small letters: Microscope, general-purpose

B.5.2 Capital letters may be used in the generic device group term or synonym term names, when appropriate.

EXAMPLE 1 Inventor's name: Von Frey hairs

EXAMPLE 2 Chemical substances: Anti-B2-glycoseprotein I antibody calibrator

EXAMPLE 3 Device name: X-ray tube support, C-arm

B.6 Punctuation

The character set to be used for the nomenclature is defined in 6.1.

The following punctuation has been adopted for use in the nomenclature as legal character elements used in the construction of term names or in the definitions:

— comma (,) used as a delineator or comma;

— hyphen (-) used to create compound words;

— forward slash (/) means “and”, or alternatively “or”, or both;

— apostrophe (') used in some chemistry names or as an apostrophe;

— plus character (+) used in some chemistry names.

Annex C
(informative)

Examples of generic device group records

C.1 General

This annex provides examples of generic device group records.

C.2 Preferred term

Code	Term	Synonym code	Template specifier	Definition	Product specifier
12345	Dialyzer, serum/urine	0	0		

The synonym code field and template specifier field are both 0, thus indicating that the term is a preferred term.

C.3 Template term

Code	Term	Synonym code	Template specifier	Definition	Product specifier
12346	Dialyzer, <specify>	0	10		

In this case, the template specifier field is set to 10 to indicate that the term is a template term and, at the same time, to specify that the first 10 characters from the term field are used to look up the preferred terms that start with the same 10 characters.

C.4 Synonym term

Code	Term	Synonym code	Template specifier	Definition	Product specifier
12347	Serum/urine dialyzer	12345	0		

The synonym code field contains the code of the preferred term (or template term) to use.

Annex D
(informative)

Examples of collective terms

This annex provides examples of collective terms.

— **Code: CT101**

Term: Hearing aids/Hearing restoration devices

Sound-amplifying and hearing restoration devices worn by, or implanted (e.g. cochlear implants) into the user and that are intended to compensate for impaired hearing and that typically operate through air- or bone conduction methods (see also CT118).

— **Code: CT102**

Term: Beds for medical purposes and ancillary devices

Devices containing a mattress and/or support platform used for sleeping/resting of an occupant during a period of diagnosis, monitoring, prevention, treatment, or alleviation of disease, or compensation for an injury or handicap.

— **Code: CT103**

Term: Assistive mobility aids for disabled

Assistive devices used to provide a person with a disability the ability to move, or be moved, from one position to another, with or without assistance from an attending person.

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