

BS EN ISO 15225:2016



BSI Standards Publication

Medical devices — Quality management — Medical device nomenclature data structure

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National foreword

This British Standard is the UK implementation of EN ISO 15225:2016. It supersedes BS EN ISO 15225:2010 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/210/3, General terminology and symbols for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Medical devices - Quality management - Medical device nomenclature data structure (ISO 15225:2016)

Dispositifs médicaux - Management de la qualité -
Structure des données de nomenclature des dispositifs
médicaux(ISO 15225:2016)

Medizinprodukte - Qualitätsmanagement -
Datenstruktur für die Nomenklatur von
Medizinprodukten (ISO 15225:2016)

This European Standard was approved by CEN on 9 June 2016.

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**CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels**

European foreword

This document (EN ISO 15225:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.

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

This document supersedes EN ISO 15225:2010.

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Endorsement notice

The text of ISO 15225:2016 has been approved by CEN as EN ISO 15225:2016 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of this International Standard based on experience gained from utilization of the second edition cancels and replaces the second edition (ISO 15225:2010), which has been technically revised. The following major changes have been made:

- Template terms have been removed as the hierarchy within the GMDN is now managed with the use of 'collective terms'.
- 'Device category' has been removed as this provides no benefit for navigation and its value has now been superseded by the use of 'collective terms'.
- The prefix 'preferred' has been removed from term in the document and the word 'term' now denotes the primary identifier for generic device groups of medical devices.
- 'Collective terms' can now be used by medical device regulators and other users to select larger groups of medical devices and analyse larger sets of data. 'Terms' however remain the only way to identify generic device groups of medical devices.
- 'Device type' data specification has been removed as it is outside the scope of the GMDN dataset, but remains a concept to which GMDN data are linked.

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 third edition of this International Standard is based on experience gained from utilization of the second edition.

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 specifies 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, healthcare 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 separate data file.

2 Normative references

The following documents, in whole or in part, are normatively referenced in the document and are indispensable for its application. 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 apply¹⁾.

3.1 character

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

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

3.2 code

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

3.3 collective term

term provides a multi-hierarchical structure to search for appropriate generic device group terms by using broad common features or characteristics

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 is used.

3.4

concept

unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1, modified — Note 1 to entry has been deleted.]

3.5

definition

formal concise statement of the meaning of a term

3.6

device intended for clinical investigation

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

3.7

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

3.8

device type

identification of a manufacturer's specific kind of products, i.e., for similar usage or series of comparable models

Note 1 to entry: This data element is not included in the GMDN nomenclature, but is coded in various ways outside of the nomenclature and linked to terms.

3.9

file

named set of records stored or processed as a unit

[SOURCE: ISO/IEC 2382:2015, 2121414]

3.10

generic device group

set of devices having the same or similar intended use and common technology, identified by a term

3.11

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 1 to entry: 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.

3.12

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

**3.13
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

[SOURCE: ISO/IEC 2382-4:1999²⁾, 04.09.02, modified – Note has been deleted.]

**3.14
multiple-linked synonym**

alternative name(s) for a synonym term linked to more than one GMDN Term

**3.15
name**

verbal designation of an individual concept

[SOURCE: ISO 1087-1:2000, 3.4.2, modified — The preferred term in ISO 1087-1:2000 (appellation) is not used in this International Standard.]

**3.16
nomenclature**

terminology structured systematically according to pre-established naming rules

[SOURCE: ISO 1087-1:2000, 3.5.3, modified — Note 1 to entry has been deleted.]

**3.17
product identifier**

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

**3.18
synonym**

alternative name for a term

EXAMPLE A proprietary or common name for a device.

**3.19
term**

basic data entity within the GMDN dataset

Note 1 to entry: A term consists of a code, name and definition. It is the data representation of a generic device group.

4 Principle of structure

4.1 General

The nomenclature shall consist of terms, collective terms, synonyms and multiple-linked synonyms. All elements have codes and names, and terms additionally have definitions. All terms should be given in the singular form.

The nomenclature is structured as a 'flat' listing of terms, linked to many levels within a multi-hierarchical system of collective terms. The level at which a term is linked to a collective term determines the breadth of the sets of devices grouped by the collective term. All medical devices can be classified within each level.

All elements are managed by the GMDN agency.

For an example of an exported format of the data file for terms, see [Annex B](#).

2) This standard is withdrawn and has been replaced by ISO/IEC 2382.

4.2 Term

4.2.1 Description

A term describes a generic device group of medical devices, i.e. a set of devices having the same or similar intended use(s) and commonality of technology. Sets of devices are grouped together (as a generic device group) 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. A term is the only method used for product identification.

A term shall be unambiguous and unique and comprise the following elements:

4.2.2 Term name

The term name shall be a short unique descriptor which unambiguously describes the device group. It shall be in the form of a single or compound noun, possibly with familiar adjectives, that is as close to natural language as is practically possible. One or more qualifiers considered to be important distinguishing features, e.g. single-use/reusable, sterile/non-sterile, can be added and preceded by a comma.

EXAMPLE General-purpose surgical drape, single-use, sterile.

Ambiguous phrases such as “sundries”, “others”, “appliances”, “miscellaneous” and “various” should not be used.

Trade names shall not be used in term names.

4.2.3 Term definition

Terms shall be assigned a definition of not more than 700 characters in the English Language version which defines the scope of the term name, i.e. the devices that are included in the generic device group. It should include statements about the intended clinical application, the technology used and important attributes. Definitions shall be worded in such a way that users will understand and be familiar with the content, so that it is clear whether a particular device type is covered by the term.

4.2.4 Term code

A five-character numeric code shall be assigned systematically to each term, to be used as the digital identifier. The identifier will be unique and be attached to the same entity for the full life cycle of the term.

4.2.5 Links to relevant collective term(s) (see [4.3](#))

Within the database, relationships shall be established between the term and all the collective terms that are relevant, and that can be used to group devices at a higher level than the term. The relationship between terms and collective terms may necessarily be many-to-many. See [4.3](#).

4.2.6 Links to synonym(s)

See [4.5](#).

4.2.7 Links to multiple-linked synonym(s)

See [4.6](#).

4.3 Collective term

Collective terms may be terms used in the nomenclature for the following:

- a) grouping together terms with common characteristics, e.g. clinical application, common technology, materials, medical specialities, manufacturing processes;
- b) determining the range of skills and general technological abilities required for the assessment of a device.

Collective terms shall link directly to terms. Collective terms shall also be linked to each other to form a multi-hierarchical structure.

Collective terms may group several terms with common features.

A collective term can be used to select a larger group of medical devices and also to analyse larger sets of data.

The collective terms are arranged in a multi-hierarchy with individual parent-child cascades having a variable number of levels. The multi-hierarchical structure of collective terms supports the grouping of larger sets of terms.

There are a number of top-level nodes (see [Annex D](#)) which represent important grouping attributes/properties/function.

Terms are linked to a collective term at any level in a cascade and will be automatically linked to all the parents of that collective term. Terms can be linked to many collective terms in different parts of the tree structure. Collective terms shall not be used for the purpose of product identification.

4.4 Nomenclature structure example

[Table 1](#) is an example of the nomenclature structure.

4.5 Synonyms

A synonym may be an alternative name to a term name that may be familiar to users of the nomenclature. It shall be linked to only one term and can be used as an aid to locating the appropriate term. It shall not be used for product identification.

NOTE Synonyms were created and used in the early phase of development of the GMDN and their future use is likely to be less significant.

4.6 Multiple-linked synonyms

A multiple-linked synonym is a synonym that is linked to more than one term. It shall have the same construction format and status as a synonym term.

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

NOTE Multiple-linked synonyms were created and used in the early phase of development of the GMDN and their future use is likely to be less significant.

Table 1 — Example of GMDN term for a femoral prosthesis device group

Term code	33175
Term name	Metallic femoral head prosthesis
Term definition	A sterile implantable artificial substitute for a diseased or injured femoral head that has an outer surface made of metal (e.g. titanium alloy). It is designed to be attached to the trunnion of a prosthetic femoral stem/shaft or a head/stem adaptor, and to articulate with an acetabulum prosthesis as part of a total hip arthroplasty (THA) or with a bipolar component as part of a partial hip arthroplasty. The device ranges in form from partially to fully spherical (ball-shaped) and is available in various sizes
Collective terms:	
	CT1006 Orthopaedic devices
	CT125 Implantable joint prostheses and associated devices
	CT837 Implantable hip prostheses
	CT1245 Femoral head prosthesis
	CT244 Prostheses and associated devices
	CT1370 Prostheses
	CT446 Implantable prostheses
	CT334 Single-patient use
	CT336 Sterile
	CT983 Surgical invasive
	CT321 Long-term surgical invasive
	CT156 Orthopaedics
	CT979 Inorganic materials
Device type:	<i>Make: Acme</i> <i>Model: 298FK3Z</i> <i>Trade name: Insert Femoral Head LH</i>

4.7 Abbreviations and acronyms

Abbreviations and acronyms may be used in term names or definitions in certain circumstances when their use aids reading and understanding the nomenclature.

Any abbreviation being adopted should use widely recognized terminology.

5 Data file dictionary

5.1 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.

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

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

5.2 Term 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 term data file shall be as specified in [Table 2](#).

Table 2 — Requirements for term data file

Identifier	Data category and format	Comments
Code	Numeric, five digits	Unique index
Term name	Alpha, max 120 characters	—
Term definition	Alpha, max 700 characters	See also 4.2.3
Term status	Alpha, 10 characters	"Active" or "Obsolete" is linked to all terms to make it clear to the nomenclature user which terms are active and which are obsolete.
NOTE Annex B gives examples of term records.		

Term codes in the range 1 to 9999 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 9999 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.

5.3 Collective term data file

The minimum number of identifiers shall be as specified in [Table 3](#).

Table 3 — Requirements for collective term data file

Identifier	Data category and format	Comments
Code	Numeric, max four characters	Unique index
Term name	Alpha, max 150 characters	—
Term definition	Alpha, max 300 characters	—

Annex A **(informative)**

Examples for generation of generic device group terms and synonyms

A.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.

A.2 Examples of term names

Metallic acetabulum prosthesis

General-purpose bowl, reusable

A.3 Examples of term definitions

A sterile implantable principal component of a total hip prosthesis (acetabular component) designed to replace or repair the acetabulum. The component is of a one-piece construction and is made entirely of metal [e.g. stainless steel, titanium (Ti)]; it may include fixation devices (e.g. screws) for attachment to the body.

A portable bowl or basin designed to be used for a variety of medical purposes such as containing fluids, carrying or holding instruments prior to or during a procedure, and collecting body waste or other matter. The design and shape can vary from round, oblong, deep or quite shallow. This is a reusable device.

A.4 Abbreviations

The following are examples of abbreviations:

EXAMPLE 1 AARK (automated anaesthesia record keeper)

EXAMPLE 2 CPAP unit (continuous positive airway pressure unit)

A.5 Example of style

A.5.1 The first letter of a term name 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 term name: External defibrillator electrode pad.

EXAMPLE 2 Capitalized first letter of the term name followed by a qualifier in small letters: External defibrillator electrode, adult, single-use.

A.5.2 Capital letters may be used in term names and definitions, when appropriate.

EXAMPLE 1 Inventor's name: von Frey hairs aesthesiometer.

EXAMPLE 2 Chemical substances: 1,3-Beta-D-glucan IVD, kit, enzyme immunoassay (EIA).

Annex B (informative)

Example of term record

This Annex provides an example of a term record. This example of an output file is in XML format.

```
<term>
  <termCode>34637</termCode>
  <termCat>Non-IVD</termCat>
  <termName>Headreflector</termName>
  <termDefinition>A head-worn device consisting of a circular concave
mirror (reflector) attached to a headband designed to reflect light to a
site of examination/minor intervention (e.g. the nose, throat, or body
surface) on a patient. The examiner wears the device on his/her head,
places the reflector in front of one eye, and views the site through a
small hole in the centre of the reflector. This is a reusable
device.</termDefinition>
  <termStatus>Active</termStatus>
  <alternatives/>
  <modifiedDate>2012-11-20</modifiedDate>
  <createdDate>2004-05-17</createdDate>
</term>
```

Annex C (informative)

Examples of collective terms

CT101	Hearing	Devices intended to aid, restore, or test a patient's hearing, and other associated devices.
CT102	Beds and associated devices	Structures typically comprised of a mattress and support platform designed to sustain a patient's recumbent body while sleeping/resting during a period of diagnosis, monitoring, prevention, or treatment of disease, or compensation for an injury or handicap, and associated devices.
CT103	Personal mobility assistive products	Devices designed to provide a person with a disability the ability to move, or be moved, from one position or place to another, with or without assistance from an attending person.

Annex D (informative)

Examples of top-level collective term nodes

- *Clinical Specialities*
- *Device Applications*
- *Device Attribute Assortment*
- *Device Invasiveness*
- *Device Materials*
- *Device Power/Operation*
- *Device Sterility*
- *Device use Frequency*
- *High-level Device Groups*

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- [2] ISO 1942, *Dentistry — Vocabulary*
- [3] ISO/IEC 2382:2015, *Information technology — Vocabulary*
- [4] ISO 25964-1:2011, *Information and documentation — Thesauri and interoperability with other vocabularies — Part 1: Thesauri for information retrieval*
- [5] ISO 25964-2:2013, *Information and documentation — Thesauri and interoperability with other vocabularies — Part 2: Interoperability with other vocabularies*
- [6] ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*
- [7] ISO 9999, *Assistive products for persons with disability — Classification and terminology*
- [8] ISO 10241-1, *Terminological entries in standards — Part 1: General requirements and examples of presentation*
- [9] IEC 60601 (all parts), *Medical electrical equipment*
- [10] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
- [11] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- [12] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- [13] ENV 12611, *Medical informatics — Categorial structure of systems of concepts — Medical devices*
- [14] GMDN AGENCY. Control body for the Global Medical Device Nomenclature available at: <http://www.gmdnagency.org>

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