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Medical devices — Quality management — Medical device nomenclature data structure

Dispositifs médicaux — Management de la qualité — Structure des données de nomenclature des dispositifs médicaux

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation 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 apply[1)].

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 2382-4:1999[2)], 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.