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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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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]

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]

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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.

3.3
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.