DRAFT INTERNATIONAL STANDARD

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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

ICS: 11.040.01; 35.240.80

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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 third edition cancels and replaces the second edition, which has been technically revised.

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 following major changes have been made to the second edition:

— 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 analyze 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 is linked.

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 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 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)].

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

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

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

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.

3.4
collective term
term provides a multi-hierarchical structure to search for appropriate generic device group terms by using broad common features or characteristics

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

[SOURCE: ISO 1087-1:2000, 3.2.1]

3.6
definition
formal concise statement of the meaning of a term

3.7
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

3.8
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

3.9
device type
identification of a manufacturer's specific kind of products i.e., for similar usage or series of comparable models

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

3.10
file
named set of records stored or processed as a unit

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

3.12
generic device group
set of devices having the same or similar intended use and common technology, identified by a term

3.13
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.

3.14
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

3.15
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, definition 04.09.02]

3.16
multiple-linked synonym
alternative name(s) for a synonym term linked to more than one GMDN Term

[SOURCE: GMDN Agency]

3.17
name
verbal designation of an individual concept

[SOURCE: ISO 1087-1:2000, 3.4.2, modified — .]

3.18
nomenclature
terminology structured systematically according to pre-established naming rules

[SOURCE: ISO 1087-1:2000, 3.5.3]

3.21
product identifier
marker to indicate which terms can and cannot be used for product identification

[SOURCE: GMDN Agency]

3.24
synonym
alternative name for a term

EXAMPLE a proprietary or common name for a device

3.25
term
the basic data entity within the GMDN dataset

NOTE A term consists of a code, name and definition. It is the data representation of a generic device group.

[SOURCE: ISO 1087-1:2000, 3.4.3, modified — .]

3.26
Unique Device Identification
UDI
a unique number assigned to a device type

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.