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Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

Nomenclature — Spécifications pour un système de nomenclature des dispositifs médicaux destiné à l'échange de données réglementaires

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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 3.

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

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15225 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 210, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this standard, read "...this European Standard..." to mean "...this International Standard...".

Annex A forms a normative part of this International Standard. Annexes B and C are for information only.

For the purposes of this International Standard, the CEN annexes regarding fulfilment of European Council Directives have been removed.

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Foreword

The text of EN ISO 15225:2000 has been prepared by Technical Committee CEN/TC 257 “Symbols and information provided with medical devices and nomenclature for regulatory data exchange”, the secretariat of which is held by SFS**,** in collaboration with Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices”.

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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

This standard has been prepared by CEN/TC 257. It is the endorsement of ISO 15225 with the necessary common modifications. It is intended to complement the specific requirements of the EU Directives on medical devices relating to the information exchanged between parties communicating in conformity with requirements of the Directives.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard gives rules and guidelines for the construction of a nomenclature system for medical devices in order to enable Competent Authorities, Notified Bodies and manufacturers to meet the requirements of Council Directives on medical devices. It is also intended to assist in the implementation of community sectoral legislation and to facilitate co-operation and exchange of information within the European Community and at international level. It is intended that this assistance and facilitation could be extended to other relevant parties such as Regulatory Bodies and Health Care Providers.

This European Standard also gives the requirements for a minimum data set and relating to this data system its structure. These requirements are provided for system designers setting up databases utilizing the nomenclature system described herein. It is intended that the information covered by this standard should be available in the public domain.

The requirements contained in this standard are applicable to the development and updating of a European Nomenclature for medical devices.

This European Standard provides rules and guidelines for nomenclature design, which will ensure that nomenclatures built upon this standard will be simple to use, rational, applicable by all grades and professions of users and suitable for both computerized systems and printed matter.

In order to avoid the proliferation of nomenclature systems, even though each may be in conformity with this standard, it is desirable that a control body be set up to administer and maintain the European Nomenclature system. This standard has been prepared with the needs of such a body in mind and to provide ease of management at reasonable cost.

It is anticipated that the European Gatekeeper will liaise with other bodies responsible for maintaining nomenclatures in other regulatory environments, with a view to appropriate international harmonization.

1 Scope

This European Standard specifies requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate co-operation and exchange of regulatory data on an international level between interested parties such as: Regulatory Authorities, Manufacturers, Suppliers, Health Care Providers, and End Users.

NOTE 1: This European Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases utilizing the nomenclature system described herein.

The requirements contained in this standard are applicable to the development and maintenance of a European nomenclature for medical device identification.

NOTE 2: This European Standard will not include the nomenclature itself. The nomenclature will be supplied as a separate document.

NOTE 3: It is intended to complement the specific requirements of the EC Directives on medical devices in the context of specifying means by which common identification can be achieved between bodies required to exchange data in conformity with the requirements of the Directives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possiblity of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1087 : 1990	Terminology - Vocabulary
ISO/IEC 8859-1 : 1998	Information processing - 8-bit single-byte coded graphic character sets
ISO/IEC 2382-1 : 1993	Information technology - Vocabulary - Part 1: Fundamental terms
ISO 2382-4 : 1987	Information processing systems - Vocabulary - Part 4: Organization of data
ISO/IEC 2382-17 : 1996	Information technology - Vocabulary - Part 17: Databases

NOTE: Other documents which may be useful for the understanding of this standard are listed in the Bibliography.

3 Definitions

For the purposes of this standard, the following definitions apply:

> NOTE: Many terms are used in this document which have their basis in regulatory statutes. Examples of these words are “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature will be used. There is no attempt to define these terms in this document because of potential conflicts with the legal definitions of the respective jurisdiction. This standard has been crafted so as to transcend and avoid substantive conflict of different definitions of these terms.

3.1 character: A member of a set of elements used for the organization, control or representation of data [ISO/IEC 8859-1:1998]**.**

3.2 concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087:1990].

3.3 device category: No definition available.

> NOTE: 4.2 contains a description of the term “device category”.

3.4 device type: No definition available.

> NOTE: 4.4 contains a description of the term ‘device type’.

3.5 file: A named set of records stored or processed as a unit [ISO/IEC 2382-1:1993].

3.6 foreign key: In a relation, one or a group of attributes that corresponds to a primary key in another relation [ISO/IEC 2382-17:1996].

3.7 generic device group: No definition available.

> NOTE: 4.3 contains a description of the term ‘generic device group’

3.8 identifier: One or more characters used to identify or name a data element and possibly to indicate certain properties of that data element [ISO 2382-4:1987].

3.9 name: Designation of an object by an linguistic expression [ISO 1087:1990].

3.10 nomenclature: System of terms which is elaborated according to pre-established naming rules [ISO 1087:1990].

3.11 preferred term: Term recommended by an authoritative body [ISO 1087:1990].

3.12 primary key: A key that unambiguously identifies one record [ISO/IEC 2382-17:1996].

3.13 relational structure: A structure of data that are arranged as relations [ISO/IEC 2382-17:1996].

3.14 secondary key: A key that is not a primary key, but for which an index is maintained and that may identify more than one record [ISO/IEC 2382-17:1996].

3.15 synonyms: Different terms that refer to the same entity [ISO/IEC 2382-17:1996].

3.16 template term: Base concept which occurs in more than two preferred terms.

3.17 term: Designation of a defined concept in a special language by a linguistic expression [ISO 1087:1990].

3.18 control body: Organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the global medical device nomenclature.

3.19 custom made device: Any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for sole use of a particular patient.

NOTE: See Council Directive 93/42/EEC concerning medical devices.

3.20 device intended for clinical investigation: Any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of annex X [of Council Directive 93/42/EEC] in an adequate human clinical environment.

NOTE: See Council Directive 93/42/EEC concerning medical devices.

3.21 gate keeper: Organization which maintains and issues the global medical device nomenclature accountable to the control body.

3.22 manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

NOTE: See Council Directive 93/42/EEC concerning medical devices.

3.23 medical device; device: Any instrument, apparatus, appliance, material or othe article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE: See Council Directive 93/42/EEC concerning medical devices.

4 Principle of structure

4.1 General

The nomenclature is structured in three stages as shown in figure 1. 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 (3.13) in the following order:

a) device category (see 4.2);

b) generic device group (see 4.3); and

c) device type (see 4.4).

NOTE: Attention is drawn to the difference between ‘product category’, as used in the EU Directives on medical devices, and ‘device category’ as used in this standard. The former represents a small group of closely related devices. The latter represents a broader based grouping (see 4.2).

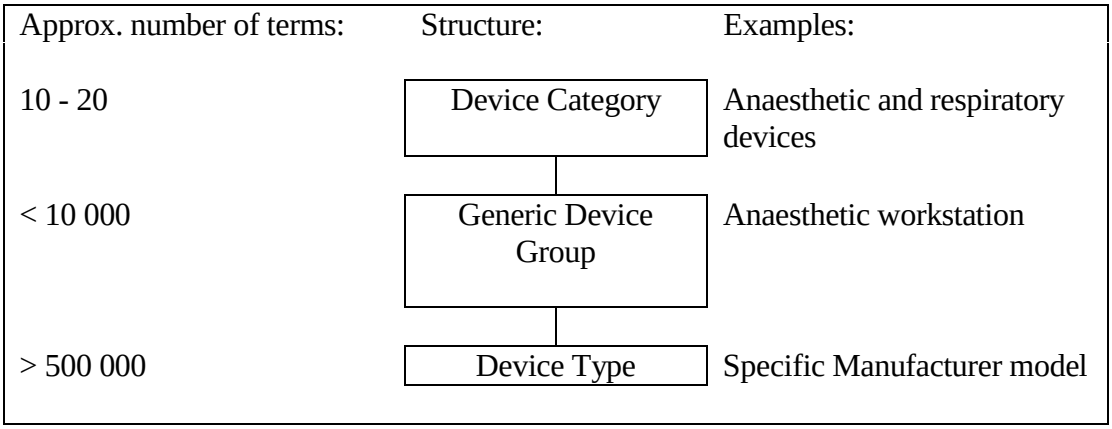

Figure 1: General structure for the nomenclature.

4.2 Device Category

Individual categories have broad usage definitions that represent disparate devices having common areas of intended use or common technology. Device Category has the largest number of devices covered by each stored term (3.17).

For data organization device category includes the record holding a device category term (3.17) and associated data such as its code and other attributes.

NOTE: 5.1 specifies requirements for device categories.

4.3 Generic Device Group

The 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 (for example: 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 (3.17). The device group term (3.17) can include the following:

a) preferred term (3.11);

b) template term (3.16 and 5.2.4); and

c) synonym (3.15);

and associated data as follows:

d) code;

e) definition;