BRITISH STANDARD

BS EN ISO
15225:2000

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

The European Standard EN ISO 15225:2000 has the status of a British Standard

ICS 01.040.11; 01.040.35; 11.040.01; 35.240.80

# National foreword

This British Standard is the official English language version of EN ISO 15225:2000. It is identical with ISO 15225:1999.

The UK participation in its preparation was entrusted by Technical Committee CH/68, General terminology, symbols and information provided with medical devices, to Subcommittee CH/68/2, Identification, coding, nomenclature and regulatory data sets for medical devices, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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

**Cross-references**

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

**Summary of pages**

This document comprises a front cover, an inside front cover, the EN ISO title page, pages 2 to 26, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

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# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

# EN ISO 15225

February 2000

ICS 01.040.11; 11.040.01; 11.120.01

English version

## Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)

Nomenclature - Spécifications pour un système de nomenclature des dispositifs médicaux destiné à l'échange de données réglementaires (ISO 15225:2000)

Nomenklatur - Spezifikation für ein Nomenklatursystem für Medizinprodukte zum Zweck des regulativen Datenaustauschs (ISO 15225:2000)

This European Standard was approved by CEN on 15 November 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Central Secretariat: rue de Stassart, 36 B-1050 Brussels**



Ref. No. EN ISO 15225:2000 E

## Contents

**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.

For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are integral parts of this standard.

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 descritpion 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).

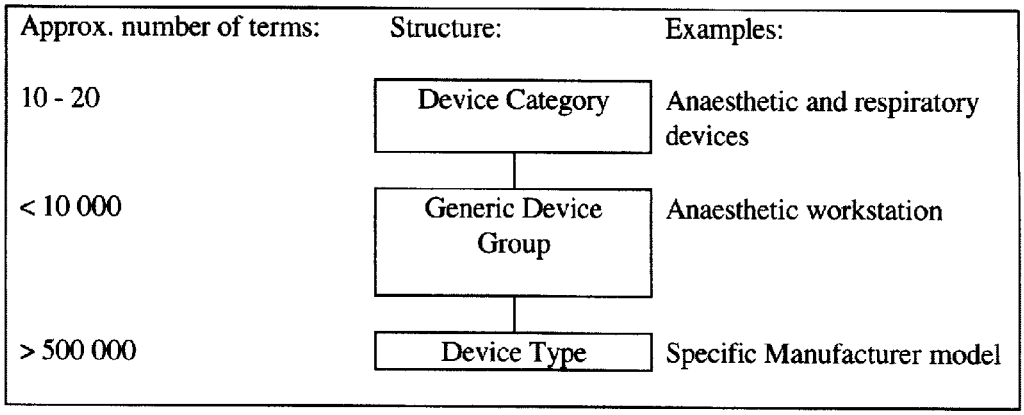


**Figure 1: General structure for the nomenclature.**

### 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;

f) for synonyms, code of the generic device group record holding the preferred term or template term; and

g) for templates, the template specifier.

NOTE: 5.2 specifies requirements for generic device groups and annex B gives examples of generic device groups.

### 4.4 Device Type

The device type contains individual medical devices including devices intended for clinical investigation (3.20) and custom-made devices (3.19) or set of medical devices including variants which may be produced. Device types contain sufficient characteristics in common for the manufacturer to establish a make and model. Device type has the smallest number of devices covered by each stored term (3.17).

For data organization device type includes the record holding the device type designation and its associated data such as its code and other attributes.

Names to be stored are drawn from the manufacturer's (3.22) documentation.

NOTE: 5.3 specifies requirements for device types.

## 5 Requirements

### 5.1 Device category

Device category shall be selected from the appropriate term(s) listed in annex A.

NOTE: At present the list is not exhaustive and a small number of Device Categories may need to be added.

### 5.2 Generic Device Group.

NOTE: See annex B for examples of the generation of Generic Device Groups terms.

### 5.2.1 *General*

NOTE: A generic device group can be a member of more than one device category.

The nomenclature shall be constructed using preferred terms (3.11), template terms and synonyms (3.15) as appropriate. All terms shall be given in the singular form. The reference version of the preferred terms and template terms in the Generic Device Group data file shall be in English.

### 5.2.2 *Abbreviations and acronyms*

Abbreviations and acronyms, other than symbols for units, used as a term, or as part of a term, shall be given in capitals.

Abbreviations used in preferred terms and template terms shall be expanded in the assigned definition. An abbreviation used as a synonym, or part thereof, shall be expanded within the term after the given abbreviation.

### 5.2.3 *Preferred terms*

A preferred term shall represent a set of Device types that perform similar or equivalent functions or have characteristics in common.

The preferred term shall be unambiguous and comprise the following:

a) base concept; followed by

b) if appropriate, one or more qualifiers separated from the base concept by a comma.

NOTE 1: More specific classification can be achieved by addition of further qualifiers.

The base concept shall be the primary listing basis.

Unambiguous qualifiers shall be used.

NOTE 2: Ambiguous qualifiers include phrases such as 'sundries', 'others', 'appliances', 'miscellaneous' and 'various'.

The preferred term 'unclassified' shall be available.

NOTE 3: This is to permit preliminary classification when no appropriate existing term is available.

Trade names shall not be used as preferred terms.

Preferred terms shall be assigned a definition of not more than 700 characters.

**5.2.4** ***Template terms***

A template term shall be used when more than two preferred terms are formed using the same base concept.

The template term shall be formed from the common base concept followed by the qualifier <specify>.

Template terms shall not be used as synonyms.

Template terms shall be assigned a definition of not more than 700 characters.

**5.2.5** ***Synonyms***

Synonyms, shall be linked to either:

a) the preferred term; or

b) the template term.

NOTE: Synonyms are an aid to locating the appropriate preferred term.

Synonyms shall not be linked to other synonyms.

**5.3 Device type**

The nomenclature shall be constructed using either:

a) the information included by the manufacturer in the declaration of conformity appropriate to the affixture of the CE mark; or

b) the information provided to the competent authority in respect of a custom-made device or a device intended for clinical investigation.

The device type designator shall comprise the following:

a) the name of the device as given in the information provided by the manufacturer; and

b) the name of the manufacturer or equivalent responsible person.

A device type shall not be a member of more than one device group.

Device types shall be designated under a generic device group in accordance with the primary intended use as specified by the manufacturer.

## 6 Data file dictionary

### 6.1 General

This part of the Standard 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. Each stage in the data structure is represented by a data file for which the requirements in 6.2 to 6.4 apply.

Further data fields may be added to all data files depending on the requirements of the end user of the database system in question. In systems having more than one natural language version of the terms in the same data file, the primary keys shall be qualified by a unique code for the different languages.

NOTE: This is to maintain their unambiguity.

The character set for transmissions shall be the Latin alphabet No. 1 as specified in ISO/IEC 8859 - 1:1998.

### 6.2 Device category data file.

The minimum number of fields shall be as specified in table 1.

**Table 1: Requirements for device category data file**

| Identifier: | Data category and format: | Comments: |
|---|---|---|
| code | numeric, 2 digits | Primary key |
| term | alphanumeric, 60 characters | Primary key |
| definition | alphanumeric, 18 x 70 characters | |

NOTE 1: The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

NOTE 2: Data for this data file are given in annex A (normative).

NOTE 3: When information is exchanged and records in the data files described in table 1 is part of this information then only the code of the relevant records need to be transmitted.

### 6.3 Generic device group data file

The data field code shall be assigned an incremental sequential cardinal number starting from the value 10000. After a new record is added to the data file, the code shall be incremented by one (1). A record with code set to zero (nil) and the term 'Unclassified', or its equivalent in other languages, shall always be present in the data file. The 'Unclassified' record shall have the data fields synonym code and template specifier set to zero (nil) (see table 2). The generic device group data file shall be as specified in table 2.

**Table 2: Requirements for generic device group data file**

| Identifier: | Data category and format: | Comments: |
|---|---|---|
| code | numeric, 5 digits | Primary key |
| term | alphanumeric, 60 characters | Primary key |
| synonym code | numeric, 5 digits | If not equal to zero (nil) then this device group is a synonym where the numeric value is the code of the preferred term or template |
| template specifier | numeric, 2 digits | If not equal to zero (nil) then this device group is a template. The numeric value represents how many characters from the term are to be used for looking up (listing) the matching preferred term base concept |
| definition | alphanumeric, max 10 x 70 characters | See 5.2 of this Standard |
| NOTE: Annex C gives example of device group records. | | |

NOTE 1: The rationale for having two primary keys is that the code will be used to facilitate automatic translation between natural language versions of the terms stored in this data file.

NOTE 2: There is no foreign key in this data file relating it to the Device category data file since there is a many-to-many relation between these two data files. The system designer should apply the method(s) available in the database tool to achieve this many-to-many relation, the most common method being a data file holding as foreign keys the codes of both the device category and generic device group records.

The code of the Generic Device groups records, where the synonym code or the template specifier is not zero (nil), shall not be used as a foreign key in related data files.

NOTE 3: These records may not be available in all natural language versions of the nomenclature system and in such cases no relation will exist (See annex C).

NOTE 4: Generic device group codes in the range 1-9999 cannot be used in data transmissions which comply with this 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 1-9999 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 Standard.

### 6.4 Device type data file

The minimum number of fields shall be as specified in table 3.

**Table 3: Requirements for device type data file**

| Identifier: | Data category and format: | Comments: |
|---|---|---|
| Generic device group code | numeric, 5 digits | Foreign key, represents the link to a generic device group record (preferred term in the nomenclature) |
| make | alphanumeric, 60 characters | Secondary key, can also act as a foreign key |
| model | alphanumeric, 60 characters | The make and model represents, when concatenated, the primary key |

When concatenated (see table 3) the contents of the data fields 'make' and 'model' shall be unique.

NOTE 1: The data field 'make' is used to identify the manufacturer on the device label. When appropriate the authorized representative may be identified. A shortened version such as an easily recognizable trade name or alpha-numeric trade mark may be used.

NOTE 2: The data field model should be the name used by the manufacturer to identify the particular type of device. In appropriate circumstances other informative formats such as brand, EAN (European Article Number) or HIBC (Health Industry Bar Code) may be used. This data field should not be confused with the serial number or lot number assigned to the individual device or lots of devices.

NOTE 3: The reasoning for having two data fields representing the primary key is that the model name used by one manufacturer (or even by the same manufacturer when he uses several makes to represent his name could possibly be used by other manufacturers) thus making it unsuitable for use as a primary key.

NOTE 4: The system designer may find it useful to assign a single (numeric) data field as a more manageable primary key in the database system for this data file.

**Annex A (normative)**

**Device categories description**

Code: 01 Term: Active implantable devices

This category includes devices relying on a source of power other than that directly generated by the human body or by gravity and intended to be totally or partially introduced, surgically or medically, into the human body, or by medical intervention into a natural orifice, and which is intended to remain there after the procedure.

NOTE 1: Examples of devices in this category are: pacemakers, implantable infusion pumps, cochlear implants and their accessories.

NOTE 2: See Active implantable medical device directive.

Code: 02 Term: Anaesthetic and respiratory devices

This category includes devices and accessories for supplying, conditioning, monitoring, dispensing and delivering respiratory, medical and anaesthetic gases and vapours for providing and/or controlling respiration and/or anaesthesia.

NOTE: Examples of devices in this category are: anaesthetic work stations, respiratory circuits, ventilators and their accessories.

Code: 03 Term: Dental devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment or alleviation of oral, maxillo-facial and dental disease.

NOTE: Examples of devices in this category are: dental hand instruments, impression materials, dental amalgam, dental tools and their accessories.

Code: 04 Term: Electro mechanical medical devices

This category includes devices where the operation depends upon a source of electrical energy (electromedical) or source of energy other than that directly generated by the patient's body or gravity and which uses this energy to produce its effect or action (mechanical).

NOTE: Examples of devices in this category are: EEG, infusion pumps, monitors for haemodialysis, monitors for ECG, spring driven and elastomeric pumps.

Code: 05 Term: Hospital hardware

This category includes devices which are not directly used in diagnosis or examinations, nor has direct influence on the clinical evaluation of the patient's condition, test results or further treatment.

NOTE: Examples of devices in this category are: sterilizers, patient transfer equipment, as well as disinfectants.

Code: 06 Term: In vitro diagnostic devices

This category includes devices which are used for in vitro examination of samples from the human body for the purpose of determining physiological or pathological conditions.

NOTE: Examples of devices in this category are: blood glucose monitors, bilirubinometers, microbial sensitivity systems and their accessories.

Code: 07 Term: Non-active implantable devices

This category includes devices other than active implantable devices which are implanted for longer than thirty days.

NOTE: Examples of devices in this category are: intrauterine devices, heart valves, bone prostheses and their accessories.

Code: 08 Term: Ophthalmic and optical devices

This category includes devices for use in diagnosis, prevention, monitoring, treatment, correction or alleviation of eye diseases and optical malfunctions.

NOTE: Examples of devices in this category are: tonometers, intraocular lenses, slit lamps and their accessories.

Code: 09 Term: Reusable instruments

This category includes devices which are used in surgery or elsewhere and are intended to be cleaned and sterilized for reuse.

NOTE: Examples of devices in this category are: retractors, haemostats, drills, saws and their accessories.

Code: 10 Term: Single use devices

This category includes devices which are intended to be used only once.

NOTE: Examples of devices in this category are: intravenous infusion sets, condoms and laparotomy sponges.

Code: 11 Term: Technical aids for disabled persons

This category includes devices specially produced or generally available which compensate for, relieve, prevent, or neutralize an impairment, disability or handicap.

NOTE: Examples of devices in this category are: crutches, artificial limbs, hearing aids, wheelchairs and their accessories.

Code: 12 Term: Diagnostic and therapitic radiation devices

This category includes devices which are diagnostic and/or therapeutic and use such modalities as X-rays, magnetic resonance imaging, ultrasound imaging, in vivo isotope imaging and linear accelerators.

NOTE: Examples of devices in this category are: X-ray equipment, computed tomography scanners and their accessories.

## Annex B (informative)

## Examples for generation of generic device group terms and synonyms

This informative annex provides examples for the purpose of generating Generic device group terms and the updating of the nomenclature.

### Structure of Generic Device Group terms

The preferred term should be of such a character that the nomenclature acquires a functional architecture, bearing in mind the users and use of the device. The qualifier, especially when common to many terms, may be based on the devices' properties or characteristics or field of use by using well established conventions when appropriate.

The general structure of the preferred term is the base concept (singular noun or noun phrase), followed by one or more qualifiers (adjectives or adjectival phrases), delimited or separated by a comma. The base concept is the broadest representation of the generic device group of medical devices that is further described by the qualifiers. The qualifiers, moving from left to right, should be ordered from broader (less specific) to narrower (more specific).

### Examples of Generic Device Group terms

A preferred term should be constructed in the following manner:

| Base concept | qualifier | qualifier |
|---|---|---|
| Noun or noun phrase | adjective or adjectival phrase | adjective or adjectival phrase |

NOTE: The terms used in the examples provided are for illustrative purposes.

Preferred terms, hierarchically structured:

| | | |
|---|---|---|
| Alarm, enuresis[1)] | not | Enuresis alarm |
| Circulatory assist unit, ventricular[2)] | not | Ventricular circulatory assist unit |

Preferred terms using a qualifier which reflects the 'property or characteristic' (principle/method) of the devices to be named by the term:

Suture, nylon
Suture, polyethylene
Suture, polyglyconate

[1)] Example beginning with a noun.
[2)] Example beginning with a noun phrase.

Preferred terms using a qualifier which reflects the 'field of use' of the devices to be named by the term:

Dialyser, apheresis
Dialyser, bicarbonate
Dialyser, blood serum/urine
Dialyser, haemodialysis

Where there are more than two preferred terms having the same base concept, a template should be introduced:

Audiometer, <specify>
Audiometer, Békésy
Audiometer, clinical
Audiometer, impedance
Audiometer, ... .

Synonyms:

| | | |
|---|---|---|
| Dinamap | linked to | Sphygmomanometer, electronic |
| Heart starter | linked to | Defibrillator. |
| Lucey lamp | linked to | Phototherapy unit |

Definition:

Any definition should be written in a manner that makes it comprehensible to all nomenclature users:

Audiometer, <specify>

A device that by using sound stimuli is used to examine hearing-related functions.

Audiometer, phase

A device that is used to determine the minimum perceivable phase difference between tones applied to a patient's left and right ear via a headset. It is used to diagnose nerve damage within the hearing system.

**Abbreviations**

Abbreviations used in, or as part of, a synonym or entry term:

TUMT (Trans-Urethral Microwave Thermo therapy) - see Thermo therapy unit.

CPAP unit - Continuous positive airway pressure unit

**Example of style**

The first letter of a Device Category term or a Generic device group term should be in upper case (capital letters). Thereafter all letters should be reproduced in lower case (small letters)

Capitalized first letter of the base concept:

Defibrillator.

Capitalized first letter of the base concept followed by a qualifier in small letters:

Microscope, general purpose.

## Annex C (informative)

## Examples of generic device group records

### C.1 Preferred term

| Code | Term | Synonym code | Template specifier | Definition |
|---|---|---|---|---|
| 12345 | Dialyser, serum/urine | 0 | 0 | |

The synonym code field and template specifier field are both 0 thus indicating that the term is a preferred term.

### C.2 Template term

| Code | Term | Synonym code | Template specifier | Definition |
|---|---|---|---|---|
| 12346 | Dialyser, <specify> | 0 | 10 | |

In this case the template specifier field is set to 10 to indicate the term is a template term and at the same time specify that the 10 first characters from the term field are used to look up the preferred terms that starts with the same 10 characters.

### C.3 Synonym term

| Code | Term | Synonym code | Template specifier | Definition |
|---|---|---|---|---|
| 12347 | Serum/urine dialyser, | 12345 | 0 | |

The synonym code field contains the code of the preferred term (or template term) to use.

## Annex ZA (informative)

## Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 93/42/EEC concerning medical devices

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 93/42/EEC.

**WARNING:** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Table ZA.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the requirements of the Directive concerned and associated EFTA regulations.

NOTE: Essential requirements are marked with an asterisk.

**Table ZA.1: Relationship between this standard and Directive 93/42/EEC**

| Clause of council directive 93/42/EEC | Relevant clause of this standard |
|---|---|
| Article 4, Clause 4 | 6.2, 6.3 |
| Article 8, Clause 1 | This standard |
| Article 8, Clause 3 | This standard |
| Article 10, Clause 1 | This standard |
| Article 10, Clause 2 | This standard |
| Article 10, Clause 3 | This standard |
| Article 11, Clause 6 | This standard |
| Article 13, Clause 1(b) | This standard |
| Article 13, Clause 2 | This standard |
| Article 14, Clause 1 | This standard |
| Article 14, Clause 3 | This standard |
| Article 9a), Clause 1 | This standard |
| Article 9b), Clause 2 | This standard |
| Annex I, Clause 13.3b)* | This standard |
| Annex I, Clause 13.6b)* | This standard |
| Annex I, Clause 13.6c)* | This standard |
| Annex II, Clause 3.1 | 5,6 This standard |
| Annex II, Clause 6.2 | This standard |
| Annex III, Clause 3 | 5.3, 6.3 |

| Clause of council directive 93/42/EEC | Relevant clause of this standard |
|---|---|
| Annex III, Clause 5 | 5.3, 6.3 |
| Annex III, Clause 7.1 | This standard |
| Annex IV, Clause 3 | This standard |
| Annex V, Clause 3.1 | 5.3, 6.3, This standard |
| Annex V, Clause 5.2 | This standard |
| Annex VI, Clause 3.1 | This standard |
| Annex VI, Clause 5.2 | This standard |
| Annex VII, Clause 3 | This standard |
| Annex VII, Clause 4 | This standard |
| Annex VIII, Clause 2.1 | This standard |
| Annex VIII, Clause 2.2 | This standard |
| Annex VIII, Clause 3.2 | This standard |

## Annex ZB (informative)

## Clauses of this European Standard addressing essential requirements or other provisions of Council Directive 90/385/EEC relating to active implantable medical devices

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 90/385/EEC.

**WARNING:** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Table ZB.1 lays out which clauses of this standard are likely to support the relevant requirements of Directive 90/385/EEC.

Compliance with these clauses of this standard provides one means of conforming with the requirements of the Directive concerned and associated EFTA regulations.

NOTE: Essential requirements are marked with an asterisk

**Table ZB.1 Relationship between this standard and Directive 90/385/EEC**

| Clauses of Council Directive 90/385/EEC | Relevant clauses of this standard |
|---|---|
| Article 4, Clause 4 | 6.2, 6.3 |
| Article 7, Clause 1 | This standard |
| Article 8, Clause 1 | This standard |
| Article 8, Clause 2 | This standard |
| Article 10, Clause 1 | This standard |
| Annex I, Clause 11* | This standard |
| Annex I, Clause 14* | This standard |
| Annex I, Clause 15* | This standard |
| Annex 2, Clause 3.1 | 5.6, This standard |
| Annex 2, Clause 6 | This standard |
| Annex 3, Clause 3 | 5 |
| Annex 3, Clause 5 | 5 |
| Annex 3, Clause 7 | This standard |
| Annex 4, Clause 3 | This standard |
| Annex 5, Clause 3 | 5, This standard |
| Annex 5, Clause 5 | This standard |
| Annex 6, Clause 2.1 | 5.3, 6.3, This standard |
| Annex 6, Clause 2.2 | 5.3, 6.3, This standard |
| Annex 6, Clause 3.2 | This standard |

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