G·M·D·N

Global Medical Device Nomenclature

User Guide - Version 2002

This User Guide is approved by the GMDN MA Policy Group and is applicable to the GMDN versions:

- GMDN Beta 3.1
- GMDN 2002.1

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1. Introduction

Recent work by the standards organizations CEN and ISO have resulted in a standard for building a nomenclature for medical devices. This standard is published as EN ISO 15225 *Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange*. Following this a project was set up by CEN with financial support from the European Commission. The aim of the project being to create a comprehensive nomenclature for all medical devices suitable for use by all interested parties globally. On the 1st of November 2001 the Global Medical Device Nomenclature (GMDN) was published as *CEN Report CR 14230* and as *ISO.TS 20225.*

The nomenclature is officially named by its governing technical committee to be:
GMDN (Global Medical Device Nomenclature)

1.1. Background

Many nomenclatures for medical devices and healthcare products exist on a worldwide basis having been created with different approaches, structures, and for different purposes. In spite of this little has been achieved regarding the possibility of unambiguously classifying medical devices. These different nomenclatures, though often workable in their own right, have had no impact on improving the overall situation of providing a common platform whereby medical devices can be unambiguously identified and related data safely exchanged.

For the manufacturer, having to deal with the different national and international requirements regarding classification can be a nightmare scenario. Many of the larger manufacturers simply use their own in-house product identification scheme and, whilst this approach may work extremely well for them, it is likely to be incompatible with and unusable for others. The medium and small size manufacturers experience even greater difficulties, but simply try to carry on as best they can. The running and application of different nomenclatures worldwide is extremely time-consuming and expensive; this without improving the data quality to the level required by modern data communication.

With the advent of the European Union (EU) Directives for Medical Devices, a new era was initiated where both national and international bodies, are given the opportunity to co-operate and harmonise efforts to achieve something that they all need. Within all regulations concerned with medical devices there are a number of obligations placed on the manufacturer. In addition, the authorities are faced with the task of regulating manufacturers and their devices, and there are people involved in trade with these devices, e.g. suppliers, before the devices themselves are finally brought into use. Finally, of course, there is the myriad of users who, when the devices initially arrive, struggle with the quite hopeless task of trying to correctly classify the devices. This means that there are a number of players, all of whom have quite different responsibilities, but all with the common interest of ensuring the availability of sound medical devices. To assist this important process

there is a need for a common method for describing and identifying these medical devices in an unambiguous manner. Consequently, as medical devices are manufactured, distributed, and brought into use worldwide, it has been necessary to develop the GMDN as the new global nomenclature for medical devices.

1.2. Scope

The GMDN is a nomenclature, the purpose of which is to enable Competent Authorities (CA), Notified Bodies (NB) and manufacturers to meet the requirements of Council Directives on medical devices. The GMDN is also intended to assist in the implementation of community sectorial legislation and to facilitate co-operation and exchange of information within the European Community and at an international level. Through international participation of ISO the GMDN is vested to become a comprehensive nomenclature for all medical devices suitable for use by all interested parties globally. The Global Harmonization Task Force (GHTF) has been continually updated on the GMDN activities, the intention being that they will endorse the GMDN and its use in their recommendations.

Although the nomenclature was initially created to provide a method for classification of medical devices, their accessories, systems, and procedure packs, it also includes many technical aids, hospital and home care products, which may or may not be medical devices. It has been anticipated that the GMDN will, because of its status in Europe and potential impact at a global level, be used by many professions within the healthcare services. Therefore products which are border line to true medical devices are also included.

The GMDN is a data file that, by nature of its content, requires continual updating and revision. To achieve this the GMDN Maintenance Agency (GMDN MA) has been established in accordance with the rules of procedure that have been approved by CEN.

1.3. Acknowledgements

To attain global acceptance, the planners of the GMDN had to take account of a number of considerations. Through the co-operation of ISO full participation of major stakeholders outside of Europe, who played a vital role in the GMDN development, was brought about. These were the Food and Drug Administration (FDA) of the USA, the Japanese Federation of Medical Device Associations (JFMDA) – Japanese manufacturers, and the ECRI organization. Also, recognising that the ECRI UMDNS nomenclature had a prominent position in many organizations dealing with nomenclature, it was evident that it would be highly beneficial should this nomenclature be given a default preference when creating the GMDN. This meant that whenever a new term made for the GMDN was derived from an original UMDNS term (1997 and 1998 editions), the UMDNS code was retained to become the new GMDN code.

Likewise for the FDA, all of their existing terms were entered into the GMDN and linked, in most cases, as synonym terms to a new GMDN preferred term. This is

intended to help the FDA customers to identify the original FDA terms and trace them to the new GMDN terms.

The submission of the European Diagnostic Manufacturers Association (EDMA) product classification of 1996 also played an invaluable role in merging this knowledge into the GMDN.

The quality of the GMDN product and the inherent future development capability has to be accredited to the excellent product knowledge and expertise provided by the participating experts. Not forgetting that, behind all great achievements, there is the ground crew, the management, the secretaries, and the data people, all of who made it possible.

Great credit must be given to the organizations, and the participating individuals for their resilience in providing resources, technical input, and high-level technical knowledge.

1.4. Copyright

The product described in this guide is not intended for use as a critical component in life support devices or any system in which failure could be expected to result in personal injury.

The product described in this guide is subject to continuous development and improvement. All information of a technical nature and particulars of the product and its use (including the information and particulars in this guide) are given by the GMDN MAPG in good faith. However, the GMDN MAPG cannot accept any liability for any loss or damage arising from the use of any information or particulars in this guide.

1.5. Disclaimer:

The GMDN Maintenance Agency (GMDN MA) is at all times working to create a best possible nomenclature that defines medical devices/related healthcare products at a generic level for the purpose of product classification. This will provide a globally acceptable method so that related information can be utilized for a number of purposes. It is the responsibility of the GMDN user to ensure that the correct applicable term is used when classifying products, nor does the inclusion of a device definition in the GMDN exempt the responsible person from any product approval requirements called for by legislation. Nor does the GMDN attempt to predefine

when a generic device group is a medical device or not, this is entirely dependant on the regulating legislation. In no circumstances will the GMDN MA be held liable for any direct, indirect, consequential or incidental damage, including loss of profits, business interruption, loss of data, incurred by the user through deficiencies, the inability to use the GMDN, or wrong information presented in the GMDN, regardless of presentation medium. It is the obligation of the user to ensure notification of dubious or incorrect classification presentation to the GMDN MA in the case of dissent between the user and the GMDN.

1.6. Comments

If you have any comments on this guide, please complete FORM A at the back of the guide and send it to:

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2. The GMDN project

The project brought together a team of experts from industry and regulatory bodies to create a single global medical device nomenclature. This involved the implementing of the new European and International Standard *EN ISO 15225 Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange,* which defines the format and structure of terms for medical devices both for written communication and electronic databases.

To facilitate in the rapid production of the GMDN 6 chosen existing nomenclatures were adopted. These covered a wide range of terms defining medical devices and healthcare products and constituted approximately 13,500 terms.

The 6 chosen nomenclatures were:

- **CNMD** Classification Names for Medical Devices and in Vitro Diagnostic Products. Developed by Food and Drug Administration (FDA). Is the USA official nomenclature.
- **EDMA** European Diagnostic Manufacturers Association in vitro diagnostic product classification. Used in Europe.
- **ISO** 9999 Technical Aids for Disabled Persons Classification. International use.
- **JFMDA** Japanese Medical Device Nomenclature. Used in Japan and south East Asia.
- **NKKN** *Norsk Klassifisering Koding & Nomenklatur,* Norwegian Nomenclature. Used in Norway and some use in Europe.
- **UMDNS** Universal Medical Device Nomenclature System. Developed by ECRI. Is in use in the USA, some countries in Europe and some countries worldwide.

During the project phase trace-ability between the new and old nomenclature terms was maintained, providing a link for users changing to the new nomenclature. This link allowed users to use and interpret data collected over time without having to establish a new set of records. This mapping data is the property of the organization responsible for the respective nomenclatures.

2.1. Why this Nomenclature?

Within all regulations concerned with medical devices there are first of all a number of obligations placed on the manufacturer. There are the authorities faced with the task of regulating manufacturers and their devices, and there are people involved in trade with these devices, e.g. suppliers, before the devices themselves are finally brought into use. And, of course, there are the users. This means that we have a number of players with quite different responsibilities but all with the common interest of ensuring the availability of sound medical devices. To assist this important process there is a need for a common method for describing and identifying the device in question in an unambiguous manner.

Prior to the GMDN, many nomenclature systems existed that have been built upon different structures, and that have been used locally or nationally for different purposes. These different systems, though often workable in their own right, have had no impact on improving the overall situation of providing a common platform whereby medical devices can be correctly identified and related data safely exchanged. The advent of the European directives have initiated a new era where national, and indeed international bodies, are given the opportunity to co-operate and harmonize efforts to achieve something that they all need. Furthermore, the running and applying of different nomenclatures worldwide is extremely time consuming and expensive without improving the data quality to the level required by modern data communication.

2.2. The users

Potential users of the GMDN will be:

- Regulatory Competent authorities for registration and vigilance
- Notified Bodies and Conformity Assessment entities
- Accredited test houses
- Manufacturers
- Health authorities
- Purchasers of the Buyers Departments in Hospital (BDH)
- Suppliers/Trading/E-commerce
- Clinical engineers/Technicians
- Clinical personnel
- Researchers

The way in which some of these organisations and individuals will use the nomenclature will be:

■ Regulatory Competent authorities

The Competent Authority will, in most countries, simply be identical with the Health Authorities. Their job will be to (1) establish a surveillance system for incidents/accidents related to medical devices, and (2) ensure that remedial or corrective actions are carried out in accordance with the governing directives/legislation. These are complex and important tasks, and success will be totally dependent upon a smooth running data exchange system.

With a comprehensive nomenclature, authorities receiving the pre-marketing registration of devices will have a much greater opportunity to build up a database useable for their coming tasks. In order to make registration an activity useful for the future, and not simply another useless burden, a proper generic description of the device, together with its make and model, is essential. The nomenclature must be comprehensive and cover all the devices put on the market or considered a device at a global level, and provide a definition suitable for a correct classification of the device in question.

■ Notified Bodies and Conformity Assessment Bodies

The new situation brought about by the EU, its expansion to include Eastern Europe, as well as MRAs (Mutual Recognition Agreements) with other trading partners, introduces free movement of medical devices across borders. A conformity assessment carried out according to rules in one place will provide the proof that the product complies with all necessary and relevant standards. Notified Bodies and other Conformity Assessment entities will monitor and assist these proceedings.

Their tasks are:

- Identification of types.
- Keeping records of certification and refused types.
- Keeping records of audited (certified) manufacturers.
- Supervision of QA system of audited manufacturers.
- Certification of types (regular rechecking of safety and performance).

■ Manufacturers

Whatever regulations exist, the manufacturer will have to go through some kind of procedure before the device is allowed on the market. This will normally be a conformity assessment according to agreed criteria, for high-risk devices by a third party, or as an approval in more traditional regulations. In most cases this will lead up to a registration of the device with some authorities. It is obvious that a standardized, well formulated generic description of the device, together with an appropriate term name, - *i.e. what people involved in that particular discipline would recognize as a sensible term ordered in a nomenclature hierarchy* - will facilitate communication. There will then be little dispute about what the manufacturer claims he has produced. For those involved in the assessment process, access to reference literature and to standards would be improved and certificates issued will be less ambiguous. This process is in contrast to the methods applied previous to the GMDN, where the user, hospitals or the authorities, were individually making qualified classification attempts of the products they were selectively interested in.

This, of course, resulted in the proliferation of mass ambiguity. A classification done at the start of the process will be the only accepted device data.

■ **Hospitals/institutions**

A standardized classification system will be beneficial to many of the professions engaged with medical devices. These professions include logistics, maintenance, quality control, planning, and clinical - *e.g. doctors, nurses and pharmacists.*

■ Clinical Engineering Departments (CED)

Some of the many tasks performed by the CED include the upkeep of an inventory for medical devices, proposing replacement requirements and maintaining the hospital's equipment. To summarize the needs of the Clinical Engineering Department, their tasks are to be able to:

- identify type (make and model)
- fit the local identification number
- keep a record of guarantee period
- keep a record of compulsory/voluntary rechecking and recalibrations
- keep a record of training
- receive incidents/accidents and take the necessary measures
- keep a record of:
- technical state of medical device
- ad hoc (prompt) services
- collaborate with the departments of the Institution
- keep a record of the accessories and materials necessary to operate the medical device
- identify certifying Notified Body
- co-operate with CED of other institutions

■ Purchasing Department/Administration (Logistics)

The Purchasing Department normally controls the procurement of medical devices to the hospital. This applies both to the consumables such as single use sterile products, and to capital goods like Computer Tomographs. A common classification system will simplify the process of tender, both nationally and throughout the Common Market, alleviating the mechanisms for free flow of products. To summarize the needs of the Administration, their tasks are:

- Administrative management of medical devices
- Planning purchases
- Keeping and maintaining the inventory of medical devices
- Providing information for top management on:
    - available stock
    - nominal value of the stock
    - real value of the stock
- Connection to manufacturers and dealers of medical devices
- Purchase of necessary medical devices

■ Suppliers and Trade

For trading purposes, and in particular with tendering procedures, the generic definition given in the GMDN will be useful. Together with a possible specification, or with defined attributes, necessary data for the device itself is provided. With electronic trading these advantages should be obvious for involved persons on both sides of the table. The new GMDN will again provide a basic common platform, which is necessary if electronic trading is to become a reality and not just local experiments.

Conclusion

All parties involved with medical devices - *manufacturers, regulators, conformity assessment bodies, traders, owners or users* - will all have a common interest in an unambiguous classification (i.e. definition and term) for each device. The obvious person to assign a device to its class is the manufacturer. By using the GMDN all players will have at hand a globally recognized tool which provides better results for all.

3. Definitions

This chapter defines specific words and concepts used by the GMDN.

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

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

device category
A term for the broadest grouping of devices having common areas of intended use or other common characteristics.

NOTE: Twelve categories, based upon European trade associations have been identified. These are already being used to assist the implementation of the European vigilance system and must be adhered to.

device type
A name, (the manufacturer's make and model designation), given to a device or set of devices by the manufacturer for the purpose of identifying this/these device(s).

This name is used to identify related information such as the record holding the device type designation and its associated data such as its code and other attributes.

Device type has the smallest number of devices covered by each stored name.

NOTE: A device type is the information (the name or designation), provided by the manufacturer, that uniquely identifies a specifically produced type of medical device. This unique qualifier is made up of the *make* and *model*.

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

generic device group:
A term representing a set of devices having the same or similar intended use or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics such as brand or trade names. A generic device group comprises a set of devices identified by their device type that are grouped together for the purpose of reporting or data retrieval.

NOTE: Product classification is to be performed using a preferred term only.

name
Designation of an object by an linguistic expression (ISO 1087:1990).

nomenclature:
System of terms that is elaborated according to pre-established naming rules (ISO 1087:1990).

preferred term
Name recommended by that authoritative body to represent an entity (Adapted from: ISO 1087:1990).

relational structure
A structure of data arranged according to relationships made between data elements (Adapted from: ISO/IEC 2382-17:1996).

synonym term
A common use or familiar name used to reference an entity (Adapted from: ISO/IEC 2382-17:1996).

template term:
A name created when the same base concept occurs in more than two generic device group terms (preferred terms) for the sole purpose of presenting these in a sub-ordinated hierarchy.

EXAMPLE:

The function of the template term Audiometer, <specify>:
Audiometer, <specify>
Audiometer, auditory evoked response
Audiometer, automatic-recording
Audiometer, computer-controlled

term
Designation of a defined concept in a special language by a linguistic expression (ISO 1087:1990).

custom made device
Any device specifically made in accordance with a duly qualified medical practitioner's written prescription that 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.

manufacturer
The natural or legal person with responsibility for the design, manufacture, packing 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.

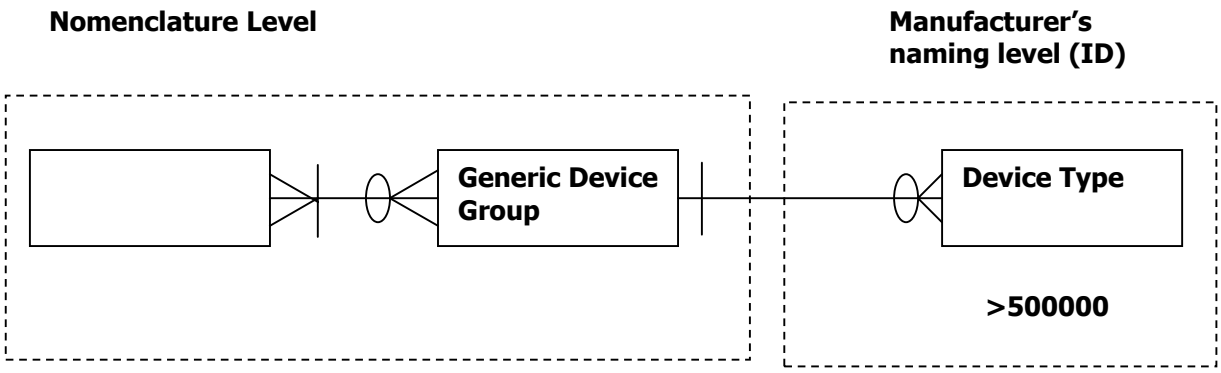
NOTE: See Council Directive 93/42/EEC concerning medical devices.

4. Structure

4. 1 The nomenclature structure

4. 1. 1. The general data structure

Figure 1 General structure for the nomenclature



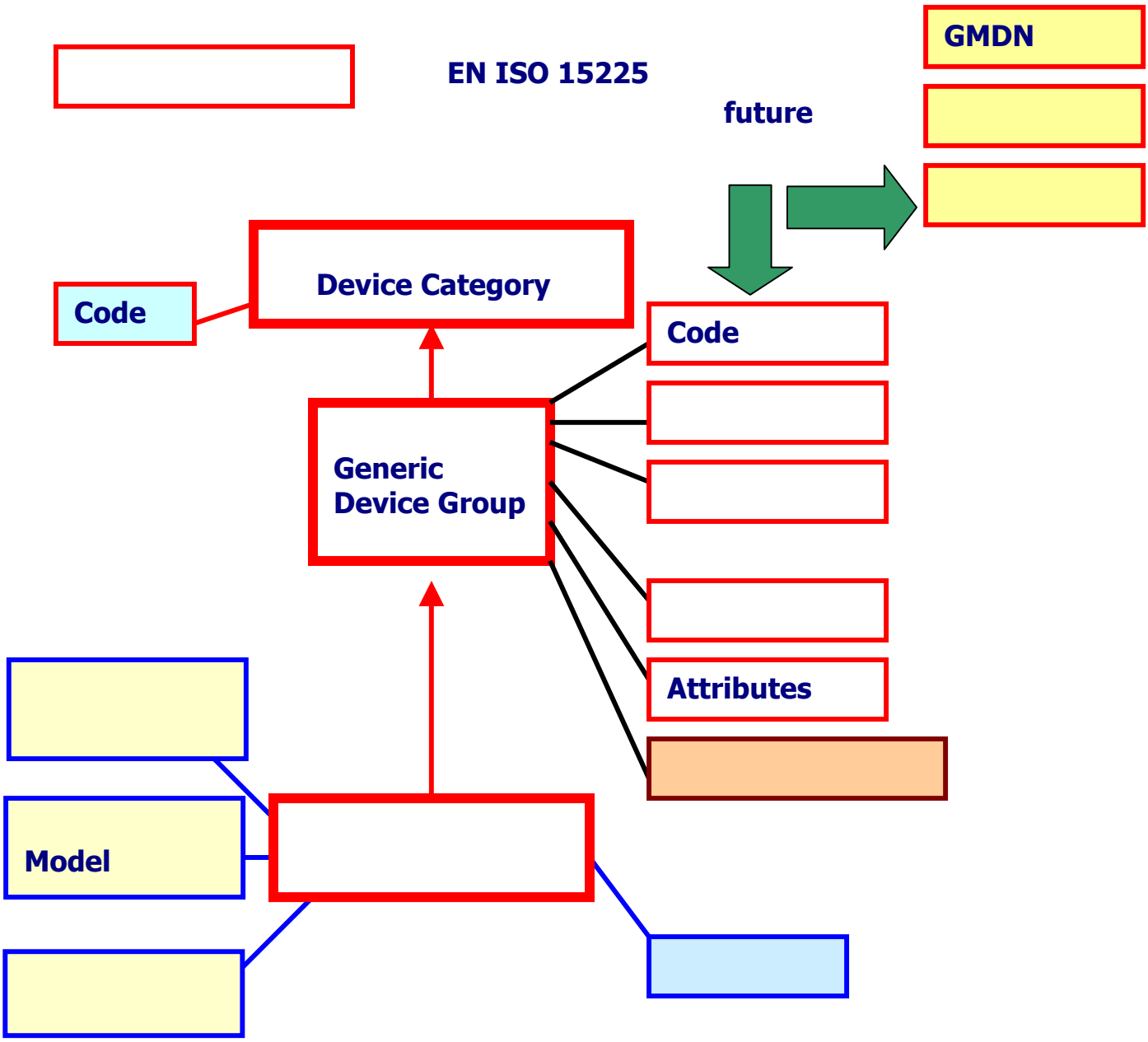
The general structure of the GMDN is regulated by the requirements provided in the standard ISO 15225 or EN ISO 15225 and the Proposed Draft Amendment to EN ISO 15225 (document; Draft amendment ISO 15225:2000/DAM 1).

Figure 1 shows the basic three level data structure, which is the backbone of the system. Each level carries independent information that divides medical devices into more refined groups. The three levels are data relational, e.g. a Generic Device Group can be linked to one or many Device Categories. Likewise one Generic Device Group can be linked to zero or many Device Types.

The GMDN stops at the device type level, which is the level considered specific enough to identify the model, and provide the grounds for the EC declaration of conformity. The identification of types of devices (device type level), e.g. by make and model, is outside the scope of the GMDN nomenclature.

4.1.2. Attributes

The concept of the GMDN also includes the inclusion of attributes. This means that other areas of information can be linked to the general data structure to fulfil the particular requirements of that user. Such attributes can be e.g. e-commerce information providing the necessary granulation of product detail, links to standard references, expanded generic device group definitions, etc.



4. 2. Device category

The device category is the broadest breakdown of the medical device product market. The device category currently contains 12 product areas based upon clinical speciality/use, technology, or common characteristics. These categories are fully implemented in the EU and EEA and are used by governments for the accumulation of statistical information.

The established device categories are:

Code	Term
01	Active implantable devices
02	Anaesthetic and respiratory devices
03	Dental devices
04	Electro mechanical medical devices
05	Hospital hardware
06	In vitro diagnostic devices (IVD)
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable instruments
10	Single use devices
11	Technical aids for disabled persons
12	Diagnostic and therapeutic radiation devices

It is anticipated that, through technology development, it will be necessary to add new categories of devices to this list. The device categories and their descriptions are defined in the standard EN ISO 15225, Annex A. *See 6.8 Instructions for filling in the GMDN proposal form.*

IMPORTANT: One generic device group can be linked to more than one device category.

NOTE: This process is described in *5.2.4 Category Selection method*

4. 3. Generic device group

The generic device group is the nomenclature level and comprises three kinds of terms. These are:

- Preferred terms
- Template terms
- Synonym terms

EXAMPLE:

Adhesive, <specify>	template term
Adhesive, aerosol, drape	preferred term
Drape, adhesive, aerosol	synonym term

4.3.1. Preferred terms

Preferred terms are all the names available for the purpose of classification of medical devices. It is a term representing a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics such as brand or trade names.

A generic device group (represented by a preferred term) comprises a set of devices, which are identified by their device type and grouped together for the purpose of reporting or data retrieval.

IMPORTANT: Only preferred terms can be used for GMDN classification

EXAMPLE:

Term: Bed, air fluidised
Definition: A bed designed for the treatment of severely and extensively burned patients. It may also be used in cases of decubitus ulcers of where the patient has little remaining body fat and the displacement of the body weight is vital for treatment. It employs the circulation of filtered and temperature regulated air being forced through large quantities of ceramic spherules (small round ceramic beads), which become almost liquid (fluidized) in this state, providing the patient with complete uplift over the whole body surface. The combined effect of this process provides other extremely beneficial results.
Code: 35921
Category: 04

4.3.2. Template terms

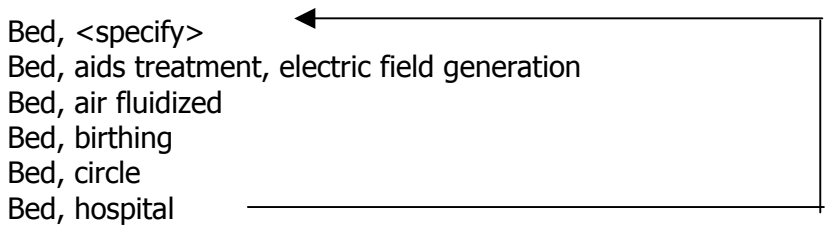
Template terms are broad names that are used to collectively group similar preferred terms - *a kind of heading*.

NOTE: This is a navigational tool only and must **NOT** be used for classification purposes.

It is a term used when the same base concept occurs on more than two preferred generic device group terms for the sole purpose of presenting these in a sub-ordinated hierarchy.

RULE: Where there is more than two preferred terms having the same base concept, a template term shall be introduced.

EXAMPLE:



This idea behind the introduction of a template term is to assist the user by presenting the narrowest list of choices.

In order to create a user-friendly nomenclature, a liberal use of synonyms (entry terms) has been introduced into the nomenclature. It would be ideal if every synonym automatically leads directly to the preferred term it represents. This would create a highly automated computerized nomenclature. However, because a synonym can sometimes lead the user to mentally visualize options, and because human evaluation is required, the system has been designed so that synonyms providing choices lead to the appropriate template term. Here the user should be confronted with a narrowed down *pick list* of terms from where he or she can select the appropriate preferred term.

The template term is constructed in the same manner as a preferred term but has a more general definition. It is formed from the common base concept and always ends with the qualifier, <specify>.

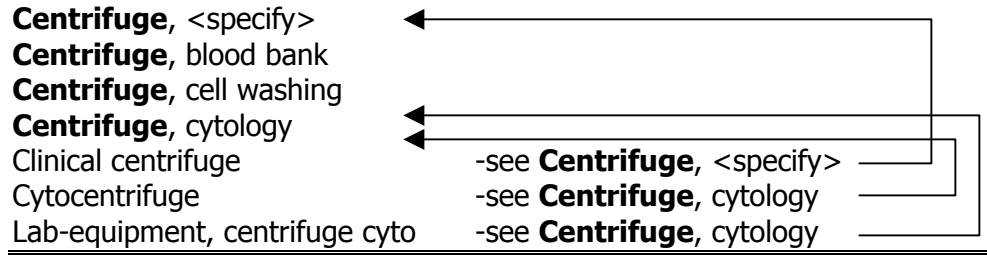
4. 3. 3. Synonym terms

Synonym terms are navigational terms (entry terms) used in the nomenclature. A synonym term is a common use or familiar name. It is an alternative term for a preferred or template term that is linked to the preferred or template term to direct persons who use the synonym to the preferred or template term.

EXAMPLE:

Fluidized bed is a synonym term directly linked to the preferred term: **Bed, air, fluidized**

Term interactions:
Using the centrifuge as an example



The broad synonym term *Clinical centrifuge* directs the user to the template term *Centrifuge, <specify>* where several choices are listed and a human evaluation is required as to which of the three subordinated preferred terms, (*Centrifuge, blood bank/ Centrifuge, cell washing/ Centrifuge, cytology*) is applicable for classification. The synonym terms *Cytocentrifuge and Lab-equipment, centrifuge cyto* are direct hits to the preferred term *Centrifuge, cytology.*

EXAMPLE of real time data relationships

Code	Term name	Synonym code
10778	Centrifuge, <specify>	
15115	Centrifuge, blood bank	
35901	Centrifuge, cell washing	
35881	Centrifuge, cytology	
30869	Clinical centrifuge	10778
32933	Cytocentrifuge	35881
37214	Lab-equipment, centrifuge cyto	35881

NOTE: See also EN ISO 15225 Annex C

4. 3. 4. Example of style

In the standard EN ISO 15225 under Annex B, and section 5.2. Generic Device Group, there are requirements and examples for the method used to create terms. During the GMDN project phase certain guidelines evolved and these were adopted to enhance the overall nomenclature layout. These amendments are given in the Proposed Draft Amendment to EN ISO 15225 (document; Draft amendment ISO 15225:2000/DAM 1). *See also 6.1 Rules and Conventions for Nomenclature Development .*

In order for the user to fully understand the GMDN those sections relating to the presentation style of the terms are given below.

■ **Uppercase/lowercase**
The first letter of a device category term or a generic device group term is in upper case (capital letters). Thereafter all letters are reproduced in lower case (small letters).

Capitalized first letter of the base concept

EXAMPLE:
Defibrillator

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

EXAMPLE:
Microscope, general-purpose

Capital letters may be used in the generic device group term, when appropriate

EXAMPLE:	
Inventor's name	Von Frey hairs
Chemical substances	Anti-B2-glycoseprotein I antibody calibrator
Device name	X-ray tube support, C-arm

■ Punctuation

The following punctuation has been adopted for use in the GMDN as legal character elements used in generic device group names or in the definitions.

Comma	(,)	used as a delineator or comma
Hyphen	(-)	used to create compound words
Forward slash	(/)	means ***and*** alternatively ***or***, or **both**
Apostrophe	(')	used in some chemistry names or as an apostrophe
Plus character	(+)	used in some chemistry names

4.4 Device Type

The device type level is not part of the GMDN nomenclature. It is, however, an essential part of the GMDN general data structure and it is important for the GMDN user to understand this level and its purpose.
The device type information is the concern of the product manufacturer and is the level considered specific enough to provide unique product identification for the purpose of declaration of conformity, product registration and product traceability.

EXAMPLE:

Make	**Model**
Heraeus Sepatech	3635
Heraeus Sepatech	5003490
Kubota	8100
Kubota	KS-5200C
Sigma	203
Sigma	3E-1
Sigma	4 K 10

When concatenated *(joined or linked together)*, the contents of the data fields *make* and *model* shall be unique. This will represent the device type data.

EXAMPLE:

Heraeus Sepatech 3635
Kubota 8100
Sigma 203

NOTE: This is defined in ISO 15225 section 6.4 Device type data file.

All of these device types produced by three different manufacturers have sufficient characteristics in common allowing them to be grouped under one common generic device group using the preferred term.

EXAMPLE:

Centrifuge, general-purpose laboratory
GMDN code 36465

A device that is a general-purpose laboratory centrifuge used to separate the components of suspensions by the application of centrifugal force. It typically consists of an electrically powered drive unit with a vertical shaft and horizontal rotor attached to the upper end. This device is intended to centrifuge patient samples, e.g. body fluid, either alone or after addition of reagents or other additives before measuring analytes. It is typically a low speed (up to 6000 rpm) or medium speed (up to 12000 rpm) machine.

4.5. Coding

All terms in the GMDN are assigned a unique code. This code is an incremental, sequential cardinal number comprising five digits starting from 10000. The codes can be deemed nonsensical because they do not feature any inherent hierarchical structure. Whilst, through the lifetime of the GMDN, the term name and definition may be subject to revision because of technological changes, the code will always remain the same, and therefore act as the unique identifier.

■ **codes in the range of 1-9999** are not represented in the GMDN since these are exclusively reserved for assignment by the end user and may be used as desired in the user's local application.

■ **codes in the range of 10000-30000** are represented in the GMDN and have been reserved to represent the original code given to an ECRI UMDNS term that has been adopted for use in the GMDN. This will provide the GMDN user with automatic mapping from the ECRI UMDNS terms that could be adopted to the GMDN, to assist in transition.

EXAMPLE:

Original ECRI term	**code**	**GMDN term**	**code**
Adhesives	10034	Adhesive,<specify>	10034
Adhesives, aerosol	10035	Adhesive, aerosol, general purpose	10035
Adhesives, liquid	10036	Adhesive, liquid	10036

■ **codes in the range of >30000** represent all other terms used in the GMDN whether these terms have been imported from existing source nomenclatures or have been created as brand new terms.

EXAMPLE:

Original EDMA term	**code**	**GMDN term**	**code**
cr Albumin (CC)	11 02 01 01 00	Albumin kit	30155
Original FDA term	**code**	**GMDN term**	**code**
Alarm, blood-pressure	CVDSJ	Alarm, blood-pressure	31691
Brand new term		**GMDN term**	**code**
Ambulance, terrain		Ambulance, terrain	41475

The GMDN code, being the unique identifier of the classification and all related information, should be ideally be applied to the product and/or packing of the product in question.

4.6. Preferred term structure

The preferred term is the only term that can be used for classification of products. It is recognizable by the 3 elements it is made up of. These being the 5 digit unique code, the term name, and the unique definition.

NOTE: The template term, which must **NOT** be used for classification, also consists of these 3 elements. It is, however, easily recognizable by the last qualifier in the term name shown as: <specify>.

EXAMPLE:

Restraint, <specify>
Resuscitator, pulmonary, <specify>

IMPORTANT: Any term ending with <specify> must not be used for classification.

The preferred and template terms are structured in a flat hierarchical layout comprising a base concept (the first level of the term name) and when appropriate, one or more qualifiers. The base concept represents the broadest concept level. The addition of each qualifier adds greater specificity to the term.

EXAMPLE:

Base concept
Resuscitator

Base concept, **qualifier**
Resuscitator, pulmonary

Base concept, qualifier, qualifier, **qualifier**
Resuscitator, pulmonary, manual, single use

NOTE: A comma and one space delimit each qualifier (each level of specificity).

4.6.1. Base concept construction

Base concepts are created whenever generic device group terms share the same or similar intended use or commonality of technology.

EXAMPLE:

Alarm
Laser

Base concepts should be constructed so that they incorporate only a homogenous group of medical devices.

EXAMPLE:

Applicator
Clamp
Retractor
Scissors
etc.

Very broad concepts that incorporate heterogeneous medical devices, e.g. *surgical instrument*, are not appropriate for use as base concepts. To aggregate devices under broad concepts the term definitions should be utilized. In such cases, a common descriptor, e.g. *surgical instrument* shall be provided in the first sentence of the definition for each appropriate term, providing a common word search facility. See document *(Section 6.1.): Rules and Conventions for Medical Device Nomenclature Development*.

4.6.2. Term specificity

The GMDN is a generic nomenclature and is not developed to the most specific qualifier possible, unless this is required to meet regulatory needs.

NOTE: Generic means: characteristics of or relating to a class; general, not specific or special. Having no brand name: not protected by a registered trade mark.

The addition of more qualifiers to a term increases the degree of specificity and moving from left to right, should be ordered from broader (less specific) to narrower (more specific). Qualifiers will also function in a word search facility for collective grouping of similar products across the entire nomenclature.

EXAMPLE:

Reusable
Single use
Software
Accessory
Custom made

5. Application

The GMDN is a nomenclature primarily designed for the purpose of classifying medical devices and related healthcare products (*see 1 Scope).* It covers medical devices and products as defined in the European directives which are, devices, systems, procedure packs (kits), accessories, and in vitro diagnostics (IVD's).

This nomenclature is a very large data file that, by the nature of its size and design, will function best when imported into a suitable data programme application. It has been designed so that a paper format can be produced, should the user wish to do this, e.g. print out a segment by category.

5.1 Installation

The GMDN electronic data file has been created according to the specification given in the standard EN ISO 15225. It will therefore function as intended, e.g. automatic switch from a selected synonym term to the target term (either a preferred term or a template term) when installed into a data application configured to this standard. This standard defines the minimum requirements for the data fields that are needed to hold the nomenclature and the relationships between the data levels and code links.

NOTE: During the GMDN project phase, it was anticipated that the field length requirement of alphanumeric 60 characters for the generic device group data file, given in the standard, would be insufficient.

IMPORTANT: This field length has been increased to be 120 characters and this adjustment **must be** catered for when setting up a database or importing the GMDN electronic file.
The governing CEN and ISO technical committees have approved this change to the standard. *See document; Draft amendment ISO 15225:2000/DAM 1*.

The GMDN electronic file can be imported into existing software applications, e.g. spreadsheets.

5.1.1. File format

The GMDN will be released as an electronic data file as: version 2002.1. The data is presented as ASCII files as specified in ISO/IEC 8859-1:1998. These being, a tilde-delimited file, and an XML file.
The data string will contain the information as presented in the standard EN ISO 15225 section 6 Data file dictionary and exemplified in Annex C. These data elements are:

1. **CODE**:
A unique five-digit number used to identify each term. These codes are unintelligent, that is they provide no information on term meaning or nomenclature structure.

2. **TERM**:
A chosen name representing a defined concept, typically a medical device. In the GMDN there are of three kind of terms:

- **Preferred** Term – an established name used to classify a medical device group.
- **Synonym** Term – common use or familiar name used to reference a device.
- **Template** Term – a name used to group similar preferred terms into a simple hierarchy. Identified by the qualifier <specify> at the end of the term.

Template terms exist only where three or more preferred terms begin with the same description (base concept).

3. **SYNONYM CODE**:
A number that indicates the status of a term as a synonym term. If the number is **0** then the term is not a synonym term. If the number is a five-digit code then the term is a synonym term, and the number is the code of the preferred or template term to which it is linked.

4. **TEMPLATE SPECIFIER**:
A number that indicates the status of a term as a template term. If the number is **0** then the term is not a template term. If the number is other than **0** then the term is a template term, and the numerical figure represents the number of characters in the term that should be used to reference subordinate preferred terms (e.g., if the number is 10 then the first 10 characters of the template term are identical to the first 10 characters if its subordinate preferred terms). **If both the synonym code and the template specifier are 0 then the term is a preferred term.**

5. **DEFINITION**:
A brief generic description of the scope of the term. The definition usually includes the intended use of the device and may include cross-references. Only preferred and template terms are defined.

6. **CATEGORY**:
A number that represents a general medical device family to which the term has been assigned. All terms have a primary category; some also have secondary and tertiary categories. The numbers correspond to the category code.

EXAMPLE

TILDE-DELIMITED FILE

Each separate data element is delimited by using the ISO character: number **126** name: **tilde** character: **~**
Reference Latin alphabet No. 1 as specified in ISO/IEC 8859-1:1998.
Each line of the file contains eight tilde characters and is ended by CrLf (Carriage return/Line feed); this represents one row from the database table.

Code~Term~Synonym code~Template specifier~Definition~Category~Category ~Category~

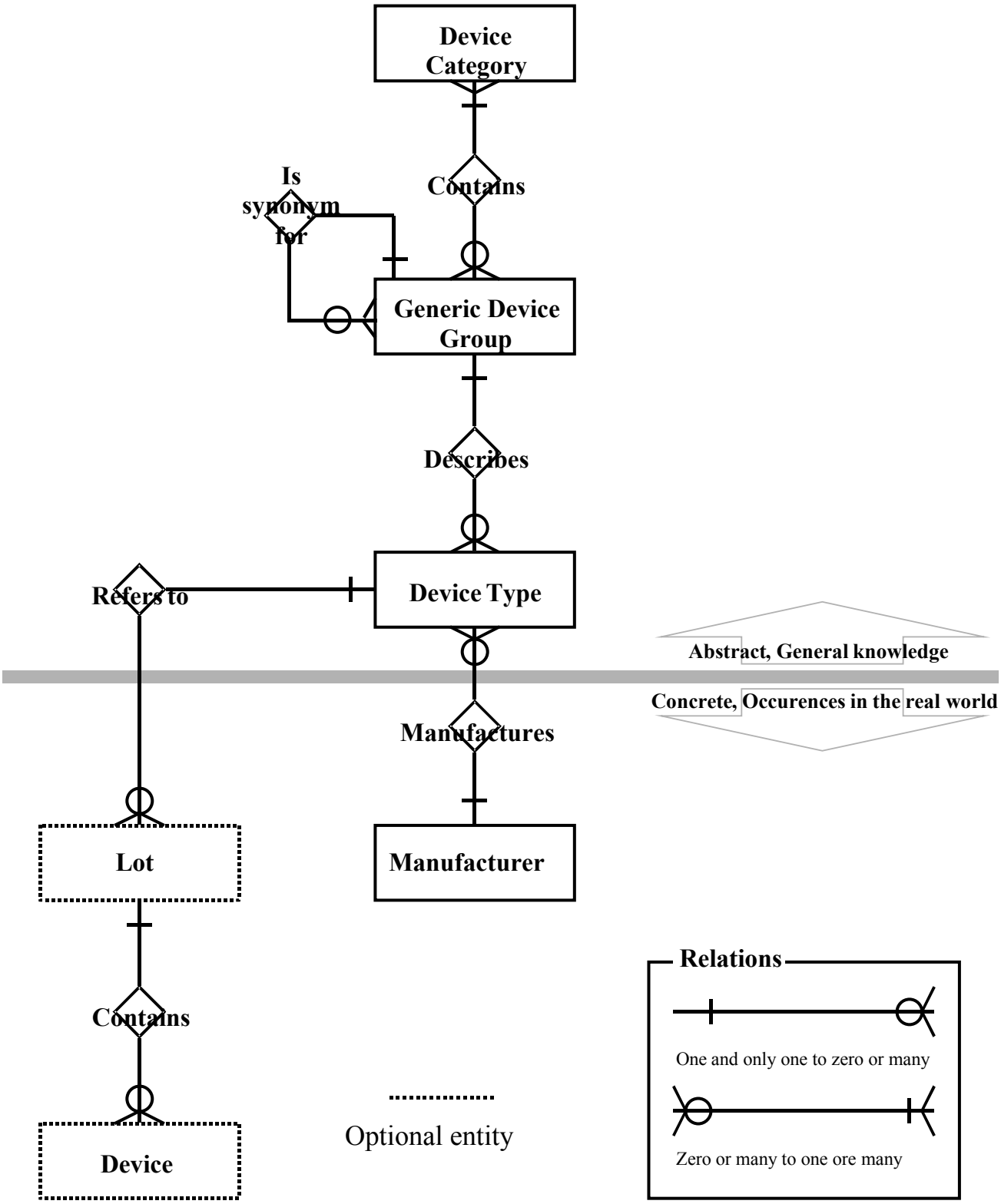
38956~1-nitroso-2-naphthol (fluorometric), free tyrosine~31358~0~~6~~~
30367~17-hydroxyketosterone kit~0~0~Immunochemistry reagents, fertility/pregnancy hormones/proteins, 17-hydroxy-ketosterone kit. A kit is one or more items provided as a single unit for use in combination to achieve the intended use of the device.~6~~~
30324~17-hydroxyprogesterone kit~0~0~Immunochemistry reagents, fertility function hormones/proteins, 17 OH progesterone kit. A kit is one or more items provided as a single unit for use in combination to achieve the intended use of the device.~6~~~

XLM FILE

An XML file is a broader type of file that can be used to represent a multitude of data not only restricted to database tables. It features a system for "tagging" the contents of a file with their correct semantic meanings. These tags can have attributes and can contain other tags, making it easy to represent a hierarchical structure. In addition the XML format includes a Document Type Definition (DTD) which is used to set strict rules for the ordering of the tags and their contents. This enables the file to be self-explanatory and enables parsers (programs that read the file, e.g. Microsoft Access) to perform checks to see if the XML file contains any errors (deviations from the DTD).

```
<?xml version="1.0" encoding="ISO-8859-1" ?>
- <gmdn version="2002.1">
- <group>
  <GMDNCode value="38956" />
    <termName value="1-nitroso-2-naphthol (fluorometric), free tyrosine" />
  <synonymCode value="31358" />
  <templateSpecifier value="0" />
  <definition value="" />
- <categories>
  <category value="6" />
  </categories>
  </group>
- <group>
  <GMDNCode value="30367" />
  <termName value="17-hydroxyketosterone kit" />
  <synonymCode value="0" />
  <templateSpecifier value="0" />
   <definition value="Immunochemistry reagents, fertility/pregnancy hormones/proteins, 17-hydroxy-ketosterone kit. A kit is one or more items provided as a single unit for use in combination to achieve the intended use of the device." />
- <categories>
  <category value="6" />
  </categories>
  </group>
```

Figure 2: Relational structure of the data model



5. 2. Classification

5. 2. 1. Who should classify?

It is not an easy task to assign a medical device or related health care product its correct classification, i.e. its predefined definition and linked term. Even among people trained by the same instructor there will be different views and hence a different classification. The only secure way to have a device classified is by, or through, its manufacturer who will know its intended purpose and the way it is intended to operate and perform, as well as the technology involved. This operation will make certain everybody later involved, be it in assessment, registration, trade, purchase or incident reporting, knows its proper classification (the code, term, and definition).

IMPORTANT: The job of claiming the class for a product is the responsibility of the product's manufacturer since, by using the nomenclatures definition, the manufacturer appoints the claim of intended purpose and mode of action.

However, it will probably be the case that the manufacturer will require assistance to find the correct applicable term.

5.2.2. How to classify

The classification of a medical device or related health care products is a process of human judgement. This process will be best achieved by using the electronic version of the GMDN in an appropriate data programme, e.g. having a good word search facility. The intended use of the device shall be used to select the term that provides the most specific classification.

IMPORTANT: Only preferred terms can be used for GMDN classification. Only one preferred term is to be used for each product (device type) to be classified.

It is then necessary to locate the appropriate preferred term and assure that this term and the definition is compatible to the product in question. Because the category code is also a classification requirement it will be necessary to check that at least one of the linked categories made available are applicable. A product can be classified to one or more categories. *See section 5.2.4 Category selection method*.

The GMDN is set up so that there are a number of ways in which listing of terms can be viewed in order to locate and select a compatible term.

a) **Alphabetical search**

The terms are listed alphabetically and users can scroll up and down the list until the term or similar groups of terms are found.

EXAMPLE:

Terms
1-nitroso-2-naphthol (fluorometric), free tyrosine
17-hydroxyketosterone kit
a1-acid glycoprotein
Abacus
B lymphocyte marker kit
Baby care kit

b) **Navigational search**

The GMDN is supported by many synonym terms that may direct the user directly to the term being sought, or to a group of similar terms subordinated under a template term.

EXAMPLE

Using ***clinical centrifuge*** as a search word

Centrifuge, <specify>	
Centrifuge, blood bank	
Centrifuge, cell washing	
Centrifuge, cytology	
Clinical centrifuge	-see **Centrifuge**, <specify>
Cytocentrifuge	-see **Centrifuge**, cytology
Lab-equipment, centrifuge cyto	-see **Centrifuge**, cytology

The broad synonym term ***Clinical centrifuge*** directs the user to the template term ***Centrifuge****, <specify>* where several choices are listed and a human evaluation is required as to which of the three subordinated preferred terms, (*Centrifuge, blood bank/Centrifuge, cell washing/Centrifuge, cytology*) is most appropriate for classification.

c) **Category selection search**

By knowing what the intended purpose of the product is, one should have knowledge of what category the product belongs to. A product made, e.g. for dental use will be found in Category 3. By selecting terms in Category 3 only, the listing of terms will be considerably narrowed.

EXAMPLE

Terms	Category
Abrasive strip, dental	03
Absorbent, saliva	03
Adhesive, denture	03
Bite registration device	03
etc.	

d) **Word search**

Searching by a chosen word can have two targets. This can be done by
(1) searching either directly at the term name level, hitting a targeted qualifier, (*See 6.4. Search words by qualifier*).

EXAMPLE - **By qualifier**

accessory
custom-made
home use
kit
software
etc.

A search on ***custom-made*** gives:

Terms	**Category**
Cushion, *custom-made*	11, 05 and 04
Dental veneer, *custom-made*	03 and 10
Fixation device, internal, *custom-made*	07
Orthosis, footwear, orthopaedic, shoe, *custom-made*	11
Prosthesis, internal, joint, *custom-made*	07
Root canal post, *custom-made*	03
etc.	

OR

(2) by searching on a descriptor (*a semantic link*) that has been purposely fitted into the definition.

EXAMPLE - **By descriptor**

blood
disposable
immunochemistry
rigid
surgical instrument
etc.

A search on ***immunochemistry*** gives:

Term: Drug control Category: 06

Definition: Immunochemistry reagents, controls/standards/calibrators
immunochemistry, control for therapeutic drug monitoring and/or determination of drugs of abuse. A control is a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of the device.

Term: Monoethylglycinexylidide kit Category: **06**

Definition: Immunochemistry reagents, specific organ function assays, liver function (Immunochemistry), kit for MEGX. A kit is one or more items provided as a single unit for use in combination to achieve the intended use of the device.

Depending upon the set up of the data application into which the GMDN is installed, a search using either a qualifier or a descriptor can produce a listing where the search word can be found both in the term name and/or the definition.

EXAMPLE

A search on ***blood*** gives:

Term	**Category**
Analyser, ***blood*** gas, transcutaneous	06 **and** 02
Flowmeter, *blood*, magnetic resonance	04 **and** 12
Sphygmomanometer, electronic, automatic	04
Stethoscope, ultrasonic	04
etc.	

Term: Analyser, ***blood*** gas, transcutaneous
Definition: An automatic or semi-automatic instrument used to measure the partial pressure of oxygen (po2) or carbon dioxide (pCo2) in ***blood*** …
Category: 06 and 02

Term: Flowmeter, ***blood***, magnetic resonance
Definition: A device that provides a quantitative method for determining the adequacy of ***blood*** …
Category: 04 and 12

Term: Sphygmomanometer, electronic, automatic
Definition: An electronically steered device used for the indirect (noninvasive) measurement of the ***blood*** …
Category: 04

Term: Stethoscope, ultrasonic
Definition: A device used with a hand-held ultrasound scanner for audible detection of ***blood*** …
Category: 04

These methods will create listing of terms that do not necessarily have any similarity, other than that of containing the word searched for. They can easily come from different device categories.

e) **Term selection**

When selecting an appropriate preferred term, whether this is done by a direct hit or through a selection list (automatically presented or generated by word search), it is important to make sure that you select the term that is most specific to the intended use of the product being classified.

EXAMPLE:

The device to be classified is an Electrosurgical unit which, in some parts of the world are popularly known as a Diathermy. These are devices used to cut tissue by using applied electric current. In the alphabetical listing, these will be found under the template term Electrosurgical unit, <specify>. Here we can also find generic device group terms under the template term Diathermy unit, <specify>. If one reads the definition defined as:

Diathermy unit, <specify>
A therapeutic device that applies to specific areas of the body energy, e.g. electromagnetic, or high frequency microwave energy which is intended to generate heat within body tissues for the treatment of selected medical conditions, e.g. relief of pain, muscle spasms or joint contractures, but is not for the treatment of malignancies. The tissues are warmed but not damaged as in surgical diathermy; therefore this is not an electrosurgical unit (ESU). See also: Interferential treatment unit.
Code: 41540

One can see that this relates to a device other than an electrosurgical unit. So this is not the term to use.

Should one choose to do a word search on **Diathermy** the following list will show up.

EXAMPLE

Diathermy unit analyzer, shortwave
Diathermy unit, <specify>
Diathermy unit, microwave
Diathermy unit, shortwave
Diathermy unit, surgical
Gel, electrode
Phantom, therapeutic hyperthermia, test object

The synonym term (*see 4.3.3. Synonym terms*): *Diathermy unit, surgical* leads directly to the preferred term: Electrosurgical unit, general-purpose. We are lead back to the listing of preferred terms under the template term: Electrosurgical unit, <specify>. This list includes the different generic device groups (preferred terms).

EXAMPLE

Electrosurgical unit, <specify>
Electrosurgical unit, argon, enhanced
Electrosurgical unit, cautery, line powered
Electrosurgical unit, endotherapy
Electrosurgical unit, gas delivery, argon
Electrosurgical unit, general-purpose
Electrosurgical unit, mechanical vibration
Electrosurgical unit, ophthalmic

For classification of the product you are required to select the most specific preferred term appropriate for your device. Is the device an Electrosurgical unit? Is it used for general-purpose surgery or does it have a more dedicated intended purpose, e.g. for endotherapy use only, for ophthalmic use only, etc.?

EXAMPLE:

Four manufacturers, e.g. Erbe, Martin, Mira and Olympus produce Electrosurgical units. Two of the products are similar, whilst those of Mira and Olympus have differing intended purposes.

GMDN classification would be:

■ Erbe 10122-041 and Martin ME 400
- category code: 04
- generic device group code: 30005
- generic device group name: Electrosurgical unit, general-purpose
- device definition: use GMDN definition (and, if required, submit suggestion for improvement. *See section 6.7*. *Form B*)

■ Mira MD1000
- category code: 08 and 04
- generic device group code: 41645
- generic device group name: Electrosurgical unit, ophthalmic
- device definition: use GMDN definition (and, if required, submit suggestion for improvement. See section 6.7. Form B)

■ Olympus PSD-20
- category code: 04
- generic device group code: 33602
- generic device group name: Electrosurgical unit, endotherapy
- device definition: use GMDN definition (and, if required, submit suggestion for improvement. *See section 6.7. Form B)*

The last example demonstrates the difference reflected by intended purpose. The Erbe and the Martin devices are clearly for general-purpose use, whilst the Mira device is a dedicated design for use in ophthalmic surgery only and could not be used for general-purpose surgery. The Olympus device could, however, be used for general-purpose surgery, but it has been specially designed for use together with endoscopic equipment. It may e.g. have a built-in light source, special attachments for connecting dedicated endoscopes, and is therefore classified to this degree of product specificity.

5. 2. 3. Classification of devices

The method for classifications used in the GMDN includes the following steps:

(1) **Select** most specific applicable preferred term.
(2) **Check** that the definition is adequate. If not, submit a suggestion for improvement (see Form B)
(3) **Check** that the device category, or, at least, one of the categories already indicated and linked to the selected preferred term is applicable. If not, submit a proposal for an additional category (*see Form B*).
(4) **Register** the product with the following details:
Category code(s) (2 digits)
Generic device group code (5 digits)

NOTE: A product may have an intended use that is applicable to more than one category and must be classified to show the categories it can belong to.

NOTE: The codes for the category and the generic device group are the information carriers. Anyone receiving these codes and having access to the GMDN will be able to retrieve the full information string, e.g. the selected category name(s) and definition(s), the generic device group name (the selected preferred term), and its definition (generic device group definition).

5. 2. 4. Category selection method

■ Introduction

This method has been devised to assist in the selection of one or more categories. A product being classified shall be done so by selecting an appropriate compatible generic device group (a preferred term). This in turn shall be linked to, at least, one device category; it can be linked to multiple categories when this is found appropriate.

EXAMPLE

Code:	13215
term:	Infusion pump, general-purpose
categories:	2, 4, 11

This device could theoretically function in an anaesthesiology setting, a general-purpose hospital/institution setting, or as an aid for a disabled person. The product's intended purpose does, of course, totally depend upon the manufacturer's device type design.

■ Method

Generic device group terms, should be assigned to the most specific category based on the intended use of the device.

The selection list below is the categories ordered from most specific (top) to least specific (bottom). By moving from the top and downwards of the arranged list of categories the product should be assigned to the first category in which it fits. This process can be repeated should a product be potentially suitable for secondary or tertiary categories.

Device categories ordered by degree of specificity:

	Code	**Term**
a)	06	In vitro diagnostic devices (IVD)
b)	03	Dental devices
c)	08	Ophthalmic and optical devices
d)	02	Anaesthetic and respiratory devices
e)	12	Diagnostic and therapeutic radiation devices
f)	11	Technical aids for disabled persons
g)	01	Active implantable devices
h)	07	Non-active implantable devices
i)	04	Electromechanical medical devices
j)	10	Single use devices
k)	09	Reusable instruments
l)	05	Hospital hardware

5.2.5. No GMDN term available

If you can not find an appropriate compatible generic device group (preferred term) for the classification of your product you will need to notify the GMDN Maintenance Agency. You are requested to fill in the GMDN proposal Form (Form B in this manual) and, together with informative product documentation, submit this to the address given at the bottom of the form. Your proposal will be evaluated by the expert panel for that particular product. As soon as a result has been concluded you will receive notification on the outcome, which will also inform you of the classification.

The term ***Unclassified, code 38442*** has been made available in the GMDN to use when no existing GMDN term is found to be appropriate for classification by the user. This term may be used by Notified Bodies or manufacturers as a temporary measure during the process of certification of the product, prior to release on the market. When applying this term the manufacturer is obligated to contact the GMDN MA with the intention of finding an applicable preferred term. The manufacturer is obligated to supply the necessary information as described above.

5.2.6. Classification hints & tips

This section has been developed in order to provide some advisory hints and tips that should prove helpful.

The GMDN was basically designed to cover medical devices as defined in the EU directives.

- Active implantable Medical Devices
  (Council Directive 90/385/EEC of 20 June 1990)

- Medical Devices
  (Council Directive 93/42/EEC of 14 June 1993)

- In-Vitro-Diagnostica
  (Directive 98/79/EEC of the European Parliament and Council of 27 October 1998)

Therefore the GMDN caters for:

- Medical devices
- Procedure packs
- Systems
- Accessories

However, it also includes technical aids for disabled persons and other hospital and home care products, which may or may nor be medical devices.

■ Accessories

Accessories within the GMDN are defined as devices that are considered to be important enough for classification. It does not attempt to incorporate parts. Accessories are best located by searching on the qualifier *accessory*. A wide search using *accessory* will produce a large listing of terms that may or may not be true accessories*. See the 6.3 Glossary of terms.*

NOTE: Other terms could be considered to be accessories. E.g. **Holder, patient, arm** could be considered to be an accessory to an operation table or an examination table.

The user must therefore look at alternative classification possibilities before making a final decision.

■ Multifunction

A typical problem when classifying devices that have more than one function is knowing how to approach this. Many devices, especially those taking measurements, or delivering treatment to or from the patient, are able to do several tasks simultaneously.
The search word *multifunction* is currently not widely utilized in the GMDN and will therefore not provide a usable listing of all such devices. Multifunction is also synonymous with other qualifiers such as multichannel and general-purpose. It will be best to search on the base concept of the device, (intended use).

EXAMPLE

Infusion pump, multichannel
Patient monitor, <specify>
Pulmonary function analyser, <specify>

This will especially apply to devices that have been manufactured for one main intended purpose but which include other *side-features*. Let us say that a device has been designed with its main function being an electronically driven sphygmomanometer that can also measure pulse oximetry and calculate and display heart rate. This device although being able to display more than one measurement, is not constructed with a true multifunctional role and should be classified according to the main intended function.

EXAMPLE

Sphygmomanometer, electronic, automatic
Sphygmomanometer, electronic, manual

■ Procedure packs

Procedure packs are represented by terms including the qualifier or word ***Kit*** or ***Set***. *See 6.3 Glossary of terms* for the definition.

■ Software

Computer systems become a medical device when it is placed on the market with the intention that it be used with a medical device, or itself to fulfil one or more purposes of a medical device as defined in the EU directives.

Software used on general-purpose computer, as well as general software, used in a medical environment may function as a medical device, depending on the intended use.

Software can be embedded (an inherent component of the medical device or medical system) or it can be stand-alone software, e.g. replacement software that changes the intended purpose of the parent device.

Terms covering software found in the GMDN are all defining dedicated software. This means that a particular generic software term has a dedicated device or group of devices that it is intended to be used in.

Terms for software are located by searching on the qualifier ***software*** at the term name level.

■ Systems

Systems are best located by searching on the qualifier ***system*** in the term name. *See 6.3 Glossary of terms* for the definition.

The word system is widely used and will often refer to *methods*, *mechanisms*, etc. Therefore a search using ***system*** at the definition level will give a listing of terms that are not systems.

6. Appendices

6. 1. Rules and Conventions for Nomenclature Development

Based on the Global Medical Device Nomenclature Project

I. **Basic Components**

Names for medical devices, i.e., medical device terms, should be created at the level of the generic device group. The generic device group is a set of devices having the same or similar intended use, or common technology, allowing general classification of the devices.

The names for medical devices should be organized as the following types of terms:

- Preferred terms
- Template terms
- Synonym terms

(a) **Preferred Terms**

The preferred term is the optimal name selected to represent a generic device group; it consists of:

(1) A base concept, which is the first and principal component of the term, e.g. ***Catheter***
this may be followed by:
(2) One or more qualifiers, if appropriate, used to increase the degree of specificity of the term. Qualifiers should be separated from base concepts and other qualifiers with a comma, e.g., ***Catheter, biliary, manometric***
(3) An associated definition
(4) A unique numerical code

NOTE: The base concept can be a single noun as in ***Catheter***
or a compound noun as in ***Catheter guide wire***

The base concept must represent a **medical device object** and not:

- pure procedure/method – e.g. *Dialysis* or *Radioimmunoassay*

or

- analyte e.g. *Glucose*

The qualifiers, moving from left to right, should be ordered from broader (less specific) to narrower (more specific). The base concept and all qualifiers should be in a singular form, e.g., ***Bottle*** not ***Bottles***, and the first letter of the base concept is the only letter of a term that should be capitalized (except for proper names and other appropriate capitalization).

Where appropriate, the preferred term should be structured so that the nomenclature acquires a functional architecture.

EXAMPLE

Catheter, angioplasty, atherectomy
Catheter, angioplasty, atherectomy, ablative
Catheter, angioplasty, balloon dilatation
Catheter, angioplasty, balloon dilatation, coronary perfusing

Trade names, inventor names, and transitory terms shall not be used as preferred terms.

NOTE: Qualifiers giving specifics like size, volume, capacity or colour will normally not be accepted as these can make the Generic Device Group to narrow and they could easily become discriminating by sometimes accepting only a few, or only one, type (Make & Model).

(b) **Template Terms**

The template term is a name used to group similar preferred terms and to develop a hierarchy in the nomenclature. The template term should be created and added to the nomenclature when the same base concept occurs in three or more preferred terms. The template term should be formed from the common base concept followed by a comma and then the qualifier <**specify**>. Depending on its hierarchical level, a template term may have additional qualifiers between the base concept and the <**specify**>.

Use of the template term is demonstrated in the following example.

EXAMPLE:

Catheter, <specify>	**7 Catheter** preferred terms
Catheter, **angioplasty**, <specify>	**3 Catheter**, **angioplasty** preferred terms
Catheter, angioplasty, atherectomy	
Catheter, angioplasty, atherectomy, ablative	
Catheter, angioplasty, balloon dilatation	
Catheter, **cardiac**, <specify>	**4 Catheter, cardiac** preferred terms
Catheter, cardiac, ablation	
Catheter, **cardiac**, **balloon**, <specify>	**3 Catheter, cardiac, balloon** preferred terms
Catheter, cardiac, balloon, intra-aortic	
Catheter, cardiac, balloon, oxygenation monitoring	
Catheter, cardiac, balloon, pacing electrode	

The grammatical rules that apply to preferred terms should also be applied to template terms. Each template term should have an associated definition that is broad enough to encompass all of the terms for devices that fall under its hierarchical domain. Template terms are also associated with a unique numerical code.

c) **Synonym Terms**

The synonym term is a common use or familiar name used in the nomenclature. It is an alternative term for a preferred term or a template term that is linked to the preferred or template term to direct persons who use the synonym term to the preferred or template term. Synonym terms commonly include hospital jargon terms for medical devices.

The following are examples of linked synonyms.

EXAMPLE

Anesthesia arm
linked to the template term
Facility boom, <specify>

ACT-meter
linked to the preferred term
Analyser, coagulation

Dinamap
linked to the preferred term
Sphygmomanometer, electronic

Heart starter
linked to the template term
Defibrillator, <specify>

Ambu bag
linked to the preferred term
Resuscitator, pulmonary, manual

Each synonym term should be linked to only one preferred or template term. In the case where a synonym could potentially be linked to more than one preferred term, the link should be made to the template term to which the preferred terms are subordinate, if applicable. The grammatical rules that apply to preferred terms should also be applied to synonym terms. Synonym terms should not be given definitions, but are associated with a unique numerical code.

d) **Definitions**

The definitions for preferred terms and template terms should be concise and written in a manner that makes them comprehensible to all users. If technical language is used then it should be explained in parentheses.

EXAMPLE

…The device determines hematocrit **(**volume percent of red blood cells**)** in a sample of blood.

The definitions for template terms should be general enough to incorporate all subordinate preferred terms, while the definitions for preferred terms should be specific enough to allow clear differentiation between preferred terms.

As much as possible, definitions should:

- express the intended uses of the device
- express the target area of intended use
- describe how the device is used through technical principal or working method
- describe materials and/or components involved
- describe the form/shape/physical state of the device

These points are demonstrated in the following definition of the preferred term *Catheter, angioplasty, balloon dilatation, coronary perfusing*

EXAMPLE

A thin, flexible plastic tube that is inserted into a narrowed artery of the heart to dilate the vessel by controlled inflation of a balloon attached to the tube. The tube contains holes on both sides of the balloon that permit blood to flow around and beyond the balloon when it is distended so that the coronary arteries will continue to receive blood during the procedure.

e) **Abbreviations**

The use of abbreviations in preferred and template terms should be avoided. Even well known abbreviations (e.g., HIV) should be spelled out when used in preferred or template terms.

Abbreviated names for medical devices can be used as synonym terms. In addition, abbreviations can be used in the definitions of preferred and template terms if they are accompanied by explanations as in the following example.

EXAMPLE

TUMT (Trans-Urethral Micro-wave Thermo therapy)
CPAP (Continuous Positive Airway Pressure)
ENDOCAM (ENDOscopy CAMera)

f) **Field Length**

Generic device group terms should be constructed so that they are explicit; the attempt should be made to limit their field length to a maximum of 120 alphanumeric characters. Likewise, concisely written definitions shall not exceed a maximum field length of 700 alphanumeric characters.

II. Term Specificity

It is important to set parameters for how broad and how narrow generic device group names should be constructed. An established level of specificity will provide stability for the nomenclature.

Normally all devices having the same intended purpose, i.e. suitable for the same job, based on the same technology and operated in more or less the same manner should fall within the same Generic Device Group.

a) Base Concept Specificity

Base concepts should be constructed so that they incorporate only a homogenous group of medical devices.

EXAMPLE
Catheter
Bed
Prosthesis
Table

Very broad concepts that incorporate a heterogenous set of medical devices are not appropriate for use as base concepts. Examples of **inappropriate** base concepts include:

- Accessory
- Agent
- Anesthesia equipment
- Kit
- Laboratory equipment
- Material
- Ophthalmic instrument
- Oxygen therapy equipment
- Patient transport equipment
- Surgical instrument
- System
- Test

It would be appropriate to construct base concepts using some of these broad terms in compound nouns to increase the specificity of the concept, as shown in the following example.

EXAMPLE

Corneal smoothing agent
Anesthesia kit
Wound care kit
Blood urea nitrogen kit
X-ray system
Hyperthermia system
Prostate specific antigen rapid test

To aggregate devices under broad concepts the term definitions should be utilized. The broad term could be included as a descriptor, ***surgical instrument***, for example, in all the definitions of appropriate device terms.

Terms for accessory/component devices should describe the accessory/component in the base concept and the parent device should be listed as a qualifier.

EXAMPLE

- Software, **thermography** system

NOT

- **Thermography** system, software

In all cases, the device on which the term has principal focus should be included in the base concept.

B) Qualifier Specificity

Unambiguous qualifiers should be used to name medical devices; words such as:

- sundries
- others
- appliances
- miscellaneous
- various

should **not** be used to form a generic device group term. Conversely, a generic term nomenclature should not contain terms that are developed to the most specific qualifier possible, unless this is required to meet regulatory needs. In general, up to three or four qualifiers should be sufficient to develop most terms to an appropriate level of specificity. Essentially, qualifiers should be used to characterize device concepts so that they can be distinguished from one another.

The selection of qualifiers can be based on the:

- functional aspect of devices
- clinical indication/application of devices
- general technology of devices
- general design of devices

There are special circumstance qualifiers:

- The qualifiers **single**-**use** and **reusable** are applicable to many devices. These qualifiers should only be used in terms for devices that come in both single-use and reusable forms:

- If **single**-**use** is incorporated as a qualifier in the term of such a device then a term incorporating **reusable** as a qualifier should be created, or the reverse

- If a device is ONLY **single**-**use** or ONLY **reusable** then the qualifier should not be used in the device name, but it can be used in the term definition

- **custom**-**made** should only be used if it is necessary from a post-market vigilance perspective.

REFERENCES

1. prENV 12611: Medical Informatics – categorical structure of systems of concepts – medical devices.

2. ISO/FDIS 15225: International standard for nomenclature – specification for a medical device nomenclature system for the purpose of regulatory exchange.

3. EN ISO 15225: European standard for nomenclature – specification for a medical device nomenclature system for the purpose of regulatory data exchange (ISO 15225:2000)

6.2. Abbreviations

Abbreviation	Word or phrase
ACE	angiotensin converting enzyme
ACT	activated clotting time
ADC	analogue-to-digital converter
AEP	auditory evoked potentials
AIDS	acquired immune deficiency syndrome
ANA	antinuclear antibody
APC	activated protein C
APGAR	name of inventor – Virginia Apgar who devised the Apgar score, often transpired as: Appearance (colour), Pulse (heartbeat), Grimace (reflex), Activity (muscle tone), and Respiration /breathing. Medical students memorize these signs by using the mnemonic of Apgar's name: **A**ppearance, **P**ulse, **G**rimace, **A**ctivity, **R**espiration
APL	adjustable pressure limiting (valve)
ASK	antistreptokinase
AST	aspartate aminotransferase
ATP	adenosine triphosphate
BIS	bispectral Index
BPH	benign prostatic hypertrophy
BSER*	brain stem evoked response
BTA	bladder tissue antigen
CAD/CAM	computer-aided design/computer-aided manufacturing
CAPD	continuous ambulatory peritoneal dialysis
CAR	Cancer Associated Retinopathy
CCD	charge-coupled device
CD	compact disc
CD-ROM	compact disc read-only memory
CF	complement fixation

Abbreviation	Word or phrase
CMV	1. controlled mechanical ventilation 2. cytomegalovirus
CPM	continuous passive motility
CPR	cardiopulmonary resuscitation
CPU	central processing unit
CRT	cathode-ray tube
CSF	1. colony stimulating factor 2. cerebrospinal fluid
CTG	cardiotocograph
DAT	digital audio tape
DCM	dehydrated culture media
DEXA	dual-energy x-ray absorptiometry
DHEA	dehydroepiandrosterone
DISS	diameter-indexed safety system connector
DMS	digital mammography system
DNA	deoxyribonucleic acid
DSA	digital subtraction angiography
DSI *	Digital spot imaging
EBV	Epstein-Barr virus
ECG	1. electrocardiogram - The record made by an electrocardiograph. Also called cardiogram. 2. electrocardiograph - a device for recording the waveforms of voltages developed in the chest and lower parts of the human body in synchronism with action of the heart.
EDI	electronic data interchange
EEG	1. electroencephalogram - The record made by an electroencephalograph. 2. electroencephalograph a device for recording the waveforms of voltages developed in the brain using electrodes applied to the scalp.
EIS	electrical impedance scanner

Abbreviation	Word or phrase
ELISA	enzyme-linked immunoabsorbent assay
EMG	1. electromyogram - The record made by an electromyograph 2. electromyography - a device for measuring and recording voltages generated by muscles in the body
ENA	extractable nuclear antigen
ENG	1. electronystagmogram - The record made by an electronystagmograph 2. electronystagmograph - a device for the detection of the involuntary movement of the eye. It is especially used for the examination of the balance organs (equilibrium) in the inner ear
ENT	ear, nose, and throat – This is displayed as: ear/nose/throat in the GMDN terms
ERA*	evoked response audiometry
ERG	1. electroretinogram - The record made by an electroretinograph 2. electroretinograph - a device for the registering the electrical potentials evoked in the retina and ocular fundus in response to a visual stimulus
ESDP	endoscopic subfascial dissection of the perforating veins
ESR	1. electron spin resonance 2. erythrocyte sedimentation rate
ESU	electrosurgical unit
ESWL	extracorporeal shock wave lithotripsy
ETO	not an official abbreviation. It appears to be an accepted branch abbreviation for Ethelyne oxide
EWNP	exsufflation with negative pressure
FFT	fast Fourier transform
FITC	fluorescein isothiocyanate
FSH	follicle stimulating hormone
FTA	ABS-fluorescent treponemal antibody absorption (test)
GM	Geiger-Muller
GMDN	Global Medical Device Nomenclature

Abbreviation	Word or phrase
HAV	hepatitis A virus
HCG	human chorionic gonadotrophin
HDL	high density lipoprotein
HEPA	high-efficiency particulate air
HGV	hepatitis G virus
HHRFS *	hand-held radionuclide fluoroscopy system
HIS	not an abbreviation. It is a group of electrical fibres in the heart that are responsible for transmitting the electrical impulses that generate a normal cardiac contraction.
HIS	hospital information system
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HMW	high molecular weight
hPLAP *	human placental alkaline phosphatase
HPLC *	high-performance liquid chromatography
HTLV	human T-cell lymphocytotropic virus; human T-cell lymphoma/leukemia virus
ICP	intracranial pressure
ICU	intensive care unit
IM	1. internal medicine 2. intramuscularly
IMV	intermittent mandatory ventilation
IR	infrared
ISE	ion-selective electrode
IUD	intrauterine device
KVO *	keep vein open
LAF	laminar air flow
LASER	light amplification by stimulated emission of radiation
LDH	lactate dehydrogenase

Abbreviation	Word or phrase
LDL	low-density lipoprotein
LED	light-emitting diode
LMW	low molecular weight
lox	liquid oxygen
LSD	lysergic acid diethylamide
LV	left ventricular
MA	Maintenance Agency – The responsible organization for the running of the GMDN
MCA *	mucin-like carcinoma-associated antigen
MEMS	1. medical equipment management system 2. medication event monitoring system
MR	magnetic resonance
MRI	magnetic resonance imaging
NIST	non-interchangeable screw-threaded connector
OB/GYN	obstetrical and gynaecologigical
OR	operating room/operational research
OTC	over the counter (non-prescription drug)
PAP	Papanicolaou test
PCA	1. passive cutaneous anaphylaxis 2. patient controlled analgesia
PDU *	Power Distribution Unit
PEF	peak expiratory flow
PET	positron emission tomography
PMMA	polymethylmethacrylate
ppm	parts per million
PTCA	percutaneous transluminal coronary angioplasty
PTFE	polytetrafluoroethylene
PUVA	Psoralen + UVA (Oral administration of) psoralen (and subsequent exposure to) ultraviolet light of A wavelength (uv-a)

Abbreviation	Word or phrase
QA *	Quality Assurance
QST	quantitative sensory testing
RCF	relative centrifugal force
RF	radio frequency
RIS	radiology information system
RNP	ribonucleoprotein
RPD	removable partial denture
rpm	revolution per minute
RQ	respiratory quotient
RTTPS *	Radiation therapy treatment planning system
sa node	sinoatrial node
SAD	seasonal affective disorder
SGOT	serum glutamic-oxaloacetic transaminase (aspartate aminotransferase)
SIDS*	sudden infant death syndrome
SIMV	1. synchronised intermittent mandatory ventilation 2. spontaneous intermittent mandatory ventilation
SM	smooth muscle
SPECT	single photon emission computed tomography
TBG	thyroid binding globulin
TCI	target controlled infusion
TDM	therapeutic drug monitoring
TEM	1. transanal endoscopic microsurgery 2. transmission electron microscopy
TENS	transcutaneous electrical nerve stimulation
TLD	thermoluminescent dosimetry
UHMWPE	ultra-high molecular weight polyethylene
UPS	uninterruptable power supply
UV	ultraviolet

Abbreviation	Word or phrase
VDU	visual display unit
VER*	visual evoked response
WRO	water reversed osmosis
YAG	yttrium aluminium garnet

NOTE: Abbreviations marked with an asterisk (*****) have not been corroborated and the presentation of the word or phrase may be incorrect.

6.3. Glossary of terms

Introduction

This chapter provides a glossary of terms, which within the context of the GMDN, are defined as the specific meaning provided with the term or abbreviation.

Term	Definition
ACCESSORY	A device will be considered as an accessory when it can only fulfil a purpose when functioning together with a *parent* medical device, or the *parent* device can not fulfil all its potential functions as intended by the manufacturer without the accessory. An accessory, when applied, will typically enhance the function of the parent device. **NOTE**: Accessory is the chosen form when used as part of the term construction.
ADAPTOR	A device for making equipment compatible **NOTE**: This spelling of adaptor shall be used in the GMDN when referring to these devices.
ADOLESCENT	A person above the age of puberty that has not yet attained full growth (usually about 13-24 years of age).
ADULT	A mature, grown-up human.
ALARM	A device designed to produce audible, visible and, or tactile signals when certain events occur or prefixed limits of a variable parameter are exceeded. **NOTE**: Alarms are typically used to alert one to sudden changes in patient status (e.g. respiratory or cardiac arrest) and, or technical failures of critical care medical devices, e.g. ventilators. Other examples of alarms include those devices designed to alert one to a patient falling out of bed. Devices designed to alert one to sudden loss of power, or unexpected shutdown.
AMBULATORY	Of or adapted for walking. Medical devices designed to be carried upon the patient's person, usually because the device is actively functioning in an ongoing treatment.

ANALYSER	Devices designed primarily to separate or break any whole (e.g. sample) into its parts, for the purposes of determining their nature, proportion, function or relationship. **NOTE**: Analysers are typically used for in vitro analysis in the clinical laboratory setting and, or at the point-of-care. Other types are used in direct physiologic or technical parameter analysis.
APPARATUS	The equipment needed for a particular purpose or function. **NOTE**: This word is not used in any preferred terms and is purposely avoided used in the GMDN though in some instances it is utilised.
APPLIANCE	A device or piece of equipment used for a specific task.
CALIBRATOR	A calibrator is any substance, material or article intended by its manufacturer to be used to establish the measurement relationships of a device.
CATEGORY	The individual broad usage definitions that represent disparate devices having common areas of intended use or common technology. The GMDN is divided at its broadest level into 12 categories.
CHILD	A young human being below the age of puberty. **NOTE**: Paediatric shall be used in the GMDN when referring to sick children.
COMPONENT	A part of a device that is composed of two or more parts.
CONSOLE	A panel or unit accommodating a set of switches, controls, etc. Any operating control mounted together to form an array of controls where the operator can stand and steer/control the parent device to some degree.
CONTROL	A control is a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of the device.
CONTROL UNIT	All steering devices with connections to the parent device and which can steer, direct, or change its operational parameters. This can be done by automatic, semi-automatic or manually operated commands.

DEVICE GROUP	A shortened version of *Generic device group* typically used in the term definitions to save allocated space.
DEVICE TYPE	This is the level of the GMDN structure containing types of medical devices. A device type is recognised by information provided by the manufacturer, this being the Make and Model information.
EQUIPMENT	The necessary article for the purpose. A general word with no special application.
FIRMWARE	For computers: computer programs contained permanently in a hardware device, as a *Read-only memory*
FIXED	This means the device is physically fixed, e.g. screwed, bolted, etc. in a permanent position or location and cannot be moved unless dismantled.
FLEXIBLE	Medical devices designed to be bent (to a reasonably high degree) without breaking. Easily lead, manageable with the intention of assisting positioning, manoeuvrability.
GENERAL PURPOSE	A medical device designed for general use. It includes features common to the individuals of the Generic Device Group, and is not for specialised purposes.
GENERIC DEVICE GROUP	The generic device group is the level of the GMDN that contains sets of devices having similar intended uses or commonality of technology. A generic device group is a so-called *preferred term* by which a manufactured product may be classified. A shortened version of this is *Device group*.
HAND-HELD	A device, system or object that is designed to be held in the hand whilst it is being used.
HARDWARE	For computers: the physical mechanical and electronic components of a computer.
HOME USE	A medical device specifically designed for use in the home and to be managed, partly or wholly, by the patient.
INFANT	A child during the earliest period of its life up to 24 months of age (this meaning also baby, new-born).

INSTRUMENT	A tool, implement, or a measuring device. This includes surgical tools - both mechanical and electrical, and devices providing measurements/readings, e.g. Test instrument, for measuring, testing - electrical or mechanical.
KIT	A **kit** is one or more items provided as a single unit for use in combination to achieve the intended use of the device. A **procedure pack** is a number of items packaged together and placed on the market or put into use by one manufacturer or responsible person to be used in a specified medical procedure or procedures. - If all items in the pack have the CE marking affixed and are used as intended, the procedure pack does not bear a CE marking. - If some of the items do not bear a CE marking, or are not being used for their intended purpose, the whole pack is treated as a medical device. In either case the pack will require a Generic Device Group name including the qualifier *kit* or *set* with appropriate descriptive semantic linking to include *has constituent*(s) and *has specification* <*sterility type*>.
LONG-TERM	An event occurring in or relating to a long period of time.
MOBILE	Designed to be easily moved from one place to another, usually on wheels. May have a powered drive to the wheels. **NOTE**: See also Portable, Transportable, Ambulatory.
MODULE	A standardized unit made to readily fit into a parent device. It will typically have a *plug-in* design for easy exchange between compatible devices. It will usually have one or more functions that interface with the parent device, the patient, or other devices.
MONITOR	A device primarily designed for the display of information (data, signals, etc.) from other devices that have made the registration. This can be, e.g. regarding physiologic, morphologic or technical data.
MULTIFUNCTION	Having or fulfilling several functions.

NEONATE	An infant during the first four weeks of postnatal life. This period is usually accepted to be the first 28 days of life.
OPERATOR	A person operating a device, or a person acting in a specified way. The operator is the person who has been provided with qualified instructions as how to use a specific medical device. **NOTE**: This person can be a professional worker, e.g. doctors, nurses, engineers, or the patient him/herself.
PAEDIATRIC	Relating to the care and medical treatment of children, belonging to or concerned with paediatrics.
PARENT DEVICE	A medical device acting as the *parent*, being the device and where other devices connected to it are its *children*.
PATIENT	Person receiving or registered to receive medical treatment.
PATIENT MONITOR	A device which performs the measurement, registration, signal and data processing, and display of patient related data. It typically includes measuring instruments, electronic data processors, recording and display features. Monitors are typically used to display ongoing physiologic data for the critically ill patient, i.e. vital signs and/or technical data from devices.
PORTABLE	Easily movable, convenient for carrying. This also includes devices that can be easily dismantled, transported to another location and easily reassembled. *See also Transportable*.
PROCEDURE PACK	See: KIT or SET
RECORDER	A device designed to produce and store a representation of information, usually in the form of time varying signals. **NOTE**: Recorders typically store information in a chart, tape, magnetic/optical disc or electronic media.
REFERENCE DEVICE/ MATERIAL	A reference is a material or substance one or more of whose property values are sufficiently homogeneous and well-established to be used for the calibration of an apparatus, the assessment of a measurement procedure, or for assigning values to materials.

RIGID	Not flexible, cannot be bent.
SELF-TESTING DEVICE	A self-testing device is any device intended by the manufacturer to be able to be used by lay persons in a home environment.
SEMI-RIGID	Partly, to some degree bendable.
SET	See: KIT
SOFTWARE	For computers: the programs and other operating information used by a computer.
STATIONARY	A device designed to be located in one place for extended periods. It may have wheels, but these are only for the convenience of movability within a confined area.
SYSTEM	A system is a number of items connected together and placed on market or put into use by one manufacturer or responsible person for a specific intended purpose. - If all the items and their connections have the CE marking affixed and are used as intended, their mutual compatibility having been verified, the system does not bear a CE marking. - If some of the items or connections do not bear a CE marking, or are not intended for the specified purpose, the complete system is treated as a medical device. In either case, the system will require a Generic Device Group name using the base concept *system* with appropriate descriptive semantic linking such as; *performs*, *has-target*, *has constituent*(*s*), etc.
TEST INSTRUMENT	A device primarily designed to measure, register and display readings whereby a calibration of the technical parameters of the device being tested may be adjusted. **NOTE**: Test instruments are typically used for the periodical and post-repair evaluation and/or calibration of the electric, mechanical, and other physical parameters of medical devices. They may simulate a physiologic characteristic (e.g. phantoms) or organ/tissue function (e.g. bioelectric signals). Test instruments are also used to determine the safety of a particular medical device.

TEST STRIP	A test strip is a strip intended by the manufacturer to be used either manually or in combination with an instrument to achieve its intended purpose. It may be a self-testing or a point of care device, e.g. colorimetric glucose test strip, glucose biosensor strip, urine dipstick.
TRANSPORTABLE	A device specially designed for constant transportation, easily movable. Can have been designed to be carried by hand, whether or not it has to be partly dismantled for this purpose, e.g. A portable x-ray apparatus, or transported as a fixture in a vehicle. This device will typically be designed to withstand constant transportation, e.g. a more robust, protective construction. *See also Portable*.
UNIT	An individual thing, or group, regarded as single or complete. A device with a specified function forming part of a complex mechanism.
UNIVERSAL	Being able to do all the general applications for that particular field of medical devices or clinical speciality.
USER	*The user* - A person who uses a particular commodity or service.

6.4. Search words by qualifiers

This list of search words will target on terms that have one of these This list of search words will target on terms that have one of these words as a qualifier comprising the term name. In many cases they may also target a word in the definition. This list has been compiled to illustrate to the user the potential of word search in the GMDN, but it is by no means comprehensive. Search words dictionaries may be compiled by the user according to their own requirements.

accessory
adult
aerosol
airway
audio
automatic
balloon
blood
By body part - *hand*, *foot*, *etc.*
bone
calibrator
carbon dioxide
cardiac
circuit
component
contrast
control
control unit
custom-made
dental
diagnostic
dialysis
ear/nose/throat
electrical
electronic
emergency
endodontic
endoscope
external
fibreoptic
fixed
flexible
gas
general-purpose
gynaecologic
hand-held
hand piece
home use
hydraulic
implantable
infant
inflatable
infusion
internal
intrauterine
invasive
kit
laboratory
long-term
manual
mechanical
medicine
mercury
mobile
module
monitor
motorized
mount
MRI
multifunction
multiple
nitrogen dioxide
noninvasive
non-motorized
non-sterile
obstetrical
operating
operation
ophthalmic
orthopaedic
oxygen
pacemaker
partial
perfusion
peritoneal
pneumatic
portable
powered
programmable
pulmonary
radiation
radio frequency
radioactive
reusable
rigid
set
short-term
single
single use
software
solution
stand
stationary
stereotactic
sterile
strip
surgical
system
temporary
therapeutic
total
transcutaneous
transport
transportable
ultrasonic
ultrasound
unit
urine
vacuum
video
whole body
wire
x-ray

6.5. Bibliography

CEN Report CR 14230 1 Nov. 2001. (ISO.TS 20225)	Global Medical Device Nomenclature (GMDN)
Council of European Communities	Council Directive concerning medical devices (93/42/EEC)
Council of European Communities	Council Directive on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
Council of European Communities	Directive 98/79/EEC of the European Parliament and of the Council on in vitro diagnostic medical devices
Draft amendment ISO 15225:2000/DAM 1	Proposed text for amendment 1 to EN ISO 15225:2000
ENV 12611	Medical informatics – Categorial structure of systems of concepts – Medical devices
ECRI UMDNS	Universal Medical Device Nomenclature System – Product Categories Thesaurus (1197 and 1998)
EDMA	Product Classification for in vitro Diagnostic Products
EN ISO 15225	Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)
FDA CNMD	Classification Names for Medical Devices and In Vitro Diagnostic Products
ISO 1087:1990	Terminology – Vocabulary
ISO 9999	Technical aids for disabled persons – Classification
ISO/IEC 2382-1:1993	Information technology – Vocabulary – Part 1: Fundamental terms

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ISO/IEC 2382-17:1996	Information technology – Vocabulary – Part 17: Databases
ISO/IEC 8859-1:1998	Information processing – 8-bit single-byte coded graphic character sets
HHS Publ. FDA 91-4246	Classification Names for Medical Devices and In Vitro Diagnostic Products
MHW:1995	Nomenclature and Classification for Medical Devices (ISBN4-8408-0383-8 C3407 P5500E)
NKKN	Nomenclature for Medical Devices, version 3.00 1996 (ISBN 82-91328-04-08) including English translation

6.6. FORM A (Reader's Comment Form)

Reader's Comment Form GMDN User Guide - Issue 1

We would greatly appreciate your comments about this manual. Your feedback will be taken into account for the next issue. Please print out and complete this page with your comments.

◆ Did you find the information you wanted ? *Tick one box only*

☐ Yes, everything I wanted
☐ Only some of the information I wanted
☐ No

Additional comments:

_____

_____

◆ What are your thoughts about the way in which the information is presented ?

_____

_____

_____

◆ Your general comments: *(If there is not enough space, please send additional pages*)

_____

_____

_____

◆ How would you classify your own experience with nomenclature ? *Please tick one box only*

☐ First time user ☐ Some experience ☐ Experienced user ☐ Programme

Please send this completed form to:
GMDN Maintenance Agency
Attention Mr. Brock Hefflin
1350 Pickard Drive
HFZ-530
Rockville, MD 20850, USA **E-mail: bjh@cdrh.fda.gov**

Your name: _____

Your address: _____

_____

_____

Your e-mail: _____

6.7. FORM B (GMDN Proposal Form)

(Page 1 of 4)

GMDN Proposal Form

Please use this form to:

- suggest a **new** term
- improve an **existing** term
- correct an **existing** term

NOTE: Use only one form for each proposal.

Proposer's name: _____

Title: _____ Country: _____

Company Name: _____

City: _____ Postal Code: _____

House number and street: _____

P.O. Box: _____ Telephone: _____

Fax: _____ E-mail: _____

Form B (GMDN Proposal Form) continued (page 2 of 4)

PROPOSAL FOR REQUIRED GMDN ACTION IN RESPECT OF:
(1) new term
(2) improvement to an existing term
(3) correction to an existing term

New term

(1) Term name (maximum 120 characters)

(2) Device category code
1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐

(3) Definition (maximum 700 characters)

- intended use: _____
- has target: _____
- has context of use: _____
- is based on: _____
- has constituent: _____
- is presented as: _____
- has specification: _____

Reason for your submission:

_____

_____

Form B (GMDN Proposal Form) continued (page 3 of 4)

Improvement or Correction to Existing Term

tick one box only

(4) Suggestion for:

☐ **improvement** of a GMDN term ☐ **correction** of a GMDN term

term **name**: _____

term **code:** _____

your **suggestion**: _____

_____

_____

_____

_____

New synonym

(5a) New synonym name(s) (maximum 120 characters)

_____

(5b) This new synonym is to be linked to:

GMDN **term** _____

GMDN **code** _____

(6) If you use a *Local Coding System*, then please provide the following information:

Your **local code** for this new or improved or corrected **term**; or this new **synonym:**

_____

Form B (GMDN Proposal Form) continued (page 4 of 4)

Device documentation

(7) In order to validate your proposal you are required to fill out the following information and submit relevant device documentation:

Make | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Model | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Trade name | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Attach product literature (sales brochure, technical documentation, journal articles, etc.).

Date ______________ Signature ____

When you have completed these 4 pages send to:

GMDN Maintenance Agency
Att. Mr. Brock Hefflin
1350 Piccard Drive
HFZ-530
Rockville,
MD 20850,
USA

E-mail: bjh@cdrh.fda.gov

6.8. Instructions for filling in the GMDN Proposal form

(1) **Term Name**
Please enter your proposal for a new term name (generic device group). If possible, you should try to harmonize your proposal with similar products already named in the GMDN. Don't be put off if this seems difficult as your input can provide valuable information for the evaluation process.

(2) **Device category code**
You are required to tick at least one category box to indicate the category which applies to the term you are proposing. Please note that a device may be applicable to more than one category, in which case please tick all the boxes that apply.

EXAMPLE

GMDN term: Infusion pump, syringe
GMDN code: 13217
Categories: 2, 4, 11

This means that this particular device can be used for:

- anaesthesia (category 2)
- general hospital/institution use (category 4)
- as a technical aid (category 11)

The GMDN Device Categories as defined in EN ISO 15225 are:

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:** Examples of devices in this category are pacemakers, implantable infusion pumps, cochlear implants and their accessories. **Note:** 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 examination, nor have 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 interuterine devices, heart valves, bone prosthesis and their accessories.

Code 08 **Term:** Opthalmic 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 therapeutic radiation devices	This category includes devices which are diagnostic and/or therapeutic and use such modalities as x-rays, magnetic resonance imaging, ultrasound imaging, computed tomography scanners and their accessories. **Note:** Examples of devices in this category are x-ray equipment, computed tomography scanners and their accessories.

(3) **Definition (device descriptors)**
In order to provide uniform definitions for all the GMDN terms the following format for constructing a definition has been adopted. It is important that you attempt to provide information for each of the seven levels provided.

An explanation for each of these seven device descriptors is given below.

(1) **performs**	must express the intended purpose of the device
(2) **target**	must express the target area of intended use, but may indicate possible alternative usage if this is considered to be enlightening information
(3) **context of use**	elaborates upon the medical speciality; where the device is used; and in what context vis-à-vis the patient
(4) **is based on**	gives the technology/technical principle or working method
(5) **has constituent**	describes materials and/or components involved
(6) **is presented as**	gives the form/shape/physical state in which the device may be presented
(7) **specification**	describes some of the device's distinctive properties and characteristics

(4) **Improvements or Corrections**
This is where you can enter your suggestion for improving or correcting any already existing GMDN term. It is in the interests of all users, worldwide, that the GMDN is maintained to the highest possible standards of accuracy and quality. The GMDN maintenance agency recognizes as essential the need for input from users, and appreciates any suggestions you submit relating to improvements or corrections. It is extremely important that you fill in the GMDN code and term name so that a correct reference can be upheld.

(5) **New Synonyms**
In this section you are invited to provide your suggestions for adding new useful synonym terms to the GMDN. These can be synonyms for an already existing GMDN term, or a synonym for your newly proposed term. Please be sure to tick the appropriate box.

(6) **Local Codes**
In this section you are asked to provide your local code for the new, improved or corrected term; or new synonym.
(You may, of course, not use a local coding system, in which case please leave this section blank.)

(7) **Device Documentation**
In this section you are requested to submit factual device documentation verified by the Make, Model and Trade name.

■ **Make**
This is the collective company name under which the products are marketed.

EXAMPLE

Make	**Manufacturer**
Opel	General Motors
Ford	Ford Motorverken GmbH
Heraeus	Heraeus Instruments GmbH

■ **Model**
This is typically the manufacturer's identification of the product type, often identified by alphanumeric letters and reproduced on the product's ID label.

Note: When concatenated, the contents of the data fields *Make* and *Model* will be unique. This will represent the device type data. This is defined in ISO 15225 section 6.4 Device type data file.

■ Trade Name

This is typically the *popular* sales name of the product. This is often shown on the front of the product and is referred to in brochures. Not all devices have a trade name.

EXAMPLE	
make	3M
model	L300
trade name	Maxi-Driver II
make	B. Braun Melsungen
model	8715491
trade name	Infusomat Fms
make	Alm
model	PRX 4001 SA
trade name	Prismalix
make	Olympus
model	UH1-2
trade name	