G·M·D·N

Global Medical Device Nomenclature

USER GUIDANCE
Version 2008.1

To:

- become a GMDN member
- submit a GMDN application for a new term
- access the constantly updated GMDN information services
- access supportive GMDN terminology

go to the GMDN website at:

http://www.gmdnagency.org/ or http://www.gmdnagency.com/

Contents

NOTES

Examples of GMDN terms used in this user guidance are for demonstration purposes only and may not equate to actual GMDN terms.

This GMDN User Guidance has been compiled by the GMDN Core Experts, Mr. Alan Fields and Dr. Brockton Hefflin.

A grateful thank you is especially given to Mrs. Courtney Cooke and Mr. Leighton Hansel for their valuable input to this User Guidance.

July 2008

1. Abbreviations

BSI	British Standards
CD-ROM	compact disc read-only memory
CEN	Comité Européen de Normalisation / *European Committee for Standardization*
CNMD	Classification Names for Medical Devices and in Vitro Diagnostic Products
EC	European Commission
EDMA	European Diagnostic Manufacturers Association
EFTA	European Free Trade Association
EUDAMED	European Database for Medical Devices
EU	European Union
FDA	Food and Drug Administration
GMDN	Global Medical Device Nomenclature
ISO	International Organization for Standardization
ISO 9999	Assistive products for persons with disability – Classification and terminology
MAS	Maintenance Agency Secretariat
NKKN	*Norsk Klassifisering Koding & Nomenklatur,* Norwegian Nomenclature
PDA	personal digital assistant
UMDNS	Universal Medical Device Nomenclature System

2. Background

Prior to the GMDN, many nomenclature systems existed, all built upon different structures, and used locally or nationally for different purposes and with different approaches. 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 could be correctly identified and the related data safely exchanged between the involved parties. The advent of the European directives initiated a new era where national, and indeed international bodies, were given the opportunity to co-operate and harmonize their efforts in achieving the one thing that they all needed, namely, a standardized method of identifying the products placed upon the global market.

Work by the standards organizations CEN and ISO from 1993 to 1996 resulted in a standard that specified a structure for a new nomenclature for medical devices. This standard, now revised by ISO, is published as ISO 15225 *Nomenclature – Medical device nomenclature data structure*. Following this, a project was set up in 1997 by CEN with financial support from the European Commission (EC). The aim of the project was to create a comprehensive nomenclature for all medical devices suitable for use by all interested parties globally.

To facilitate the rapid production of the GMDN six existing nomenclatures of particular standing were adopted. These covered a wide range of terms defining medical devices and healthcare products that combined gave a total of 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) USA.
- 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 by Japan.
- NKKN *Norsk Klassifisering Koding & Nomenklatur,* Norwegian Nomenclature.
- UMDNS Universal Medical Device Nomenclature System. Developed by ECRI, USA.

On the 1st of November 2001 the Global Medical Device Nomenclature (GMDN) was published as a *CEN Report CR 14230* and as *ISO.TS 20225.* The first public release on CD-ROM as GMDN version 2002.1 was in November 2002.

Within all regulations concerned with medical devices there are a number of obligations placed upon the manufacturer. In addition, the authorities are faced with the task of regulating manufacturers and their devices, and there are the people involved in trade with these devices, e.g., the suppliers, before the devices themselves are brought into use. Finally, of course, there is the myriad of users who, when the devices initially arrive at the place of intended use, struggle with the quite hopeless task of trying to correctly identify and register these devices in their local databases. This means that there are a number of players, having quite different

responsibilities and levels of understanding of the processes, but all with the one common interest, that of ensuring the availability of sound medical devices to the general public. To assist in this very important process there is a need for a common method for describing and identifying these medical devices in an unambiguous manner. The GMDN now provides, for the first time, an international tool for identifying all medical devices at the generic level in a meaningful manner that can be understood by all users.

3. GMDN Agency

The need for a maintenance organization was identified and the structure approved within CEN.

Therefore, in order to manage the GMDN, a maintenance agency has been set up to form the necessary legal entity. This non-for-profit company, "GMDN Agency", acting as the Maintenance Agency Secretariat (MAS) and functioning as the hub in the running and maintenance of the GMDN, provides services and information for access to the GMDN data through this present Internet site or other means.

To ensure continuing permanency of the GMDN, revenues are generated through the licensing and sale of GMDN Agency products, particularly the GMDN codes which a user must buy in order to view them, and services, in particular the creation of new GMDN terms requested by persons needing an applicable new term and code for their product. Also, some funding may be allocated by relevant global regulatory bodies or other parties.

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes through the GMDN Internet site through a licence agreement and/or by direct credit card purchase.
- A link from the GMDN database to the user's in-house data system by a licence agreement and a purpose made software link.
- Application form for new terms or modification of existing terms/definition for the identification of the user's product.
- Access to GMDN terminology and information.
- Guidance on how to use the GMDN.
- Assistance to find an applicable GMDN code for a product.
- Access to Collective terms.
- GMDN translation software tool.

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3.1 Copyright

3.2 Disclaimer

The GMDN Agency is at all times working to create a best possible nomenclature containing descriptors for medical devices and related healthcare products at a generic level for the purpose of product identification. This provides a globally acceptable method so that related information can be utilised for a number of purposes. (It is the responsibility of the GMDN user to ensure that the appropriate term and code is applied when using the GMDN for product identification). The application of a GMDN descriptor (by way of the GMDN code) does not 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 Agency 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 inaccurate information presented in the GMDN, regardless of presentation medium. It is the obligation of the user to ensure notification of dubious or incorrect product representation in the GMDN to the GMDN Agency in the case of dissent between the user and the GMDN.

NOTE: "Search terms/entry terms" may include proprietary names when these are commonly accepted and used by the health care profession. This does not in any way give reference to a specific make or manufacturer, and must never be used for product identification. When proprietary names are used in the GMDN, there is no implied accuracy to the correct representation of the name as used by the manufacturer/legal owner.

A manufacturer/legal owner may submit suggestions to amend or enter a proprietary name into the GMDN data file. All submissions for new terms will be considered by the GMDN Expert Team.

4. Purpose

The foremost purpose of the GMDN is provide a single, global, nomenclature system by which the authorities can regulate medical devices; this also impacting upon the health care providers, that are the mainstay users of medical devices, the medical device manufactures, suppliers, conformity assessment bodies and other affiliated parties, so that there is only one single system that provides the generic product descriptors to support patient safety. The GMDN code represents the generic descriptor (this being the term name along with its definition) in order to internationally standardize device identification for reasons of safe data exchange between competent authorities and others, exchange of post-market vigilance information, research, medical record keeping, e-commerce, and inventory purposes.

Any authority, company, or user not using the GMDN will automatically exclude themselves from the above purpose.

4.1 Languages

The master copy of the GMDN data file (the nomenclature) is principally written in Oxford English. To accommodate North American English (that of the USA) and when applicable, the American spelling has been adopted.

The GMDN has been translated to some languages, but most of this work is still in progress. In the mean time, the EU has embarked upon translation of the GMDN to the 21 standard languages of the European Union.

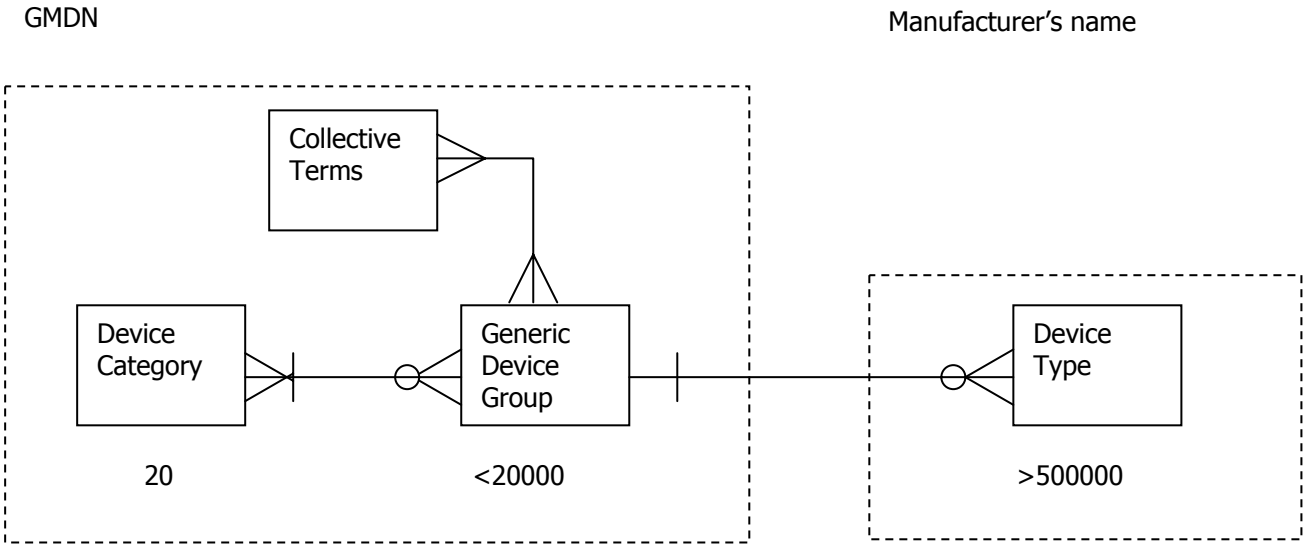
These translations will be made available in the GMDN web-based database once they are ready.

5. Structure

The general structure of the GMDN is regulated by requirements stipulated in the standard ISO 15225 *Nomenclature – Medical device nomenclature data structure*. This standard, together with this document, should provide the necessary understanding of the GMDN's features and utilization.

Figure 1 below shows the basic organization of GMDN data. The data is defined by three levels, associated with an external fourth level, each level containing data that differs in degree of specificity.

Figure 1 General organization of GMDN data



5.1 Device Category

The device category is the broadest level of the GMDN data. It divides the entire medical device product market into highest-level groups based on device application, technology, or other common characteristics. The standard allocates codes for a possible 20 categories; there are currently 16 established device categories. These 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
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable devices
10	Single use devices
11	Assistive products for persons with disability
12	Diagnostic and therapeutic radiation devices
13	Complementary therapy devices
14	Biological-derived devices
15	Healthcare facility products and adaptations
16	Laboratory equipment
17	Reserved
18	Reserved
19	Reserved
20	Reserved

5.2 Generic Device Group

The generic device group is the most specific level at which products are aggregated based on common technology or intended use. There are four different types of GMDN terms associated with the generic device groups. These terms, with their alpha identifiers, include the:

Preferred term	P
Template term	T
Synonym term	S
Multiple-linked synonym term	MS

There are also terms within the main database called "Equivalent terms". These are simply non-active terms from the original six source nomenclatures used to develop the GMDN and can be equal to a P, T, S, or MS term within the database. They are identified with the alpha identifier E.

EXAMPLE:

Bedpan	P	No source
Bedpan	E	ECRI
Bedpan	E	FDA
Bedpans	E	ISO 9999

Using the GMDN search engine, or using some of the view possibilities provided by the database E terms can be found and seen. The GMDN user is not to be concerned with equivalent terms since they are not active terms, they have no GMDN code allocated, and cannot be used by a user for any practical application.

5.2.1 Preferred terms

Preferred terms with their unique 5 digit codes are the only terms available for product identification. The preferred term is the optimal name selected to represent a group of devices (a collection of device types) that have the same or similar intended use or commonality of technology allowing them to be grouped in a generic manner, typically without reflecting specialized characteristics such as brand or trade names.

Each preferred term has an associated definition that describes the most prominent characteristics of the device types in the group [typically includes a physical description and an intended use(s)]. It is the definition that determines the scope of the preferred term and code.

The text, "Product Identifier" is associated with all active preferred terms to clearly show that these are the only terms valid for product registration.

EXAMPLE OF A PREFERRED TERM SHOWING Product Identifier

Click on the term of interest, e.g., Cardiac catheter guidewire, single-use and this will open the term details.

Term Details:

See the Product Identifier: text displayed.

The preferred term consists of a base concept, the first and principal component of the term (e.g., "Cardiac catheter"), which may be followed by one or more qualifiers, if appropriate, to increase the specificity of the term (e.g., "Cardiac catheter, balloon, intra-aortic"). Or it can be constructed as a compound noun (e.g., Cardiac catheterization kit).

The preferred term is associated with each of the following:

CODE - A unique numerical five-digit number.
DEFINITION – A generic description of the scope of the term, which includes the intended use(s).
CATEGORY - The highest device level to which a preferred term has been linked. All preferred terms have at least one linked category.
TERM TYPE IDENTIFIER - A capital letter or letters to denote the term type. For a preferred term, it is (P).
PRODUCT SPECIFIER - A text (a data field) that is displayed in the Term Details to indicate the product identification status of a term. In the case of an active preferred term it is "**Product Identifier**", indicating that the preferred term can be used and is valid for product identification (e.g., product registration).

The preferred term type identifier is (P).

5.2.2 Template terms

The template term is a general device name added to the nomenclature when multiple preferred terms have identical character strings forming a base concept and functions as a header term to create a simple hierarchy for lexically-related preferred terms.

Each template term has an associated definition that is inclusive of all subordinated preferred terms.

The template term type identifier is (T).

The template term is a navigational tool only and must NOT be used for product identification purposes.

The template term is formed from the common base concept followed by the qualifier "<specify>", making it easily recognizable. Depending on its hierarchical level, a template term may have additional qualifiers between the base concept and the "<specify>".

EXAMPLE:

T Cardiac catheter, <specify>
P Cardiac catheter, ablative
T Cardiac catheter, balloon, <specify>
P Cardiac catheter, balloon, intra-aortic
P Cardiac catheter, balloon, pacing electrode
P Cardiac catheter, balloon, pulmonary artery, basic

IMPORTANT NOTE: If a template term code has in the past been used to identify any products, this code has been wrongly applied and is not valid. A GMDN P term and code that is applicable to the product must be selected and assigned instead. If no current GMDN P terms are applicable, an application for a new term to be created or an existing P term to be modified must be submitted.

5.2.3 Synonym terms

The synonym term is a common use or familiar name used in the nomenclature. It is an alternative entry point in the nomenclature used to locate the preferred term or template term to which it is linked. It may or may not actually be synonymous with the term to which it is linked.

The synonym term type identifier is (S)

Selecting a synonym term in the GMDN database will automatically produce its linked preferred or template term.

If you clicked on and selected S term "Tube, capillary", it will automatically bring up the P term: **Blood capillary tube**

Synonym terms do NOT have definitions.

The synonym term is a navigational tool only and must NOT be used for product identification purposes.

Synonym terms commonly include hospital jargon commonly used for medical devices.

EXAMPLE:

ACT-meter	linked to P term	Analyser, haematology, coagulation
Dinamap	linked to T term	Sphygmomanometer, electronic, <specify>
Heartstarter	linked to T term	Defibrillator, <specify>
Hess-screen	linked to P term	Campimeter

NOTE: Trade names, inventor names, proprietary names and transitory terms, if they are well recognized, MAY be used as synonym terms when considered beneficial for providing a search to find the preferred term.

5.2.4 Multiple-linked synonym term

The multiple-linked synonym term is a medical device name, often from one of the GMDN source nomenclatures, that is typically higher-order and is therefore linked to more than one preferred term and/or template term.

The multiple-linked synonym term type identifier is (MS)

This multiple-linked synonym term is a navigational tool only and must NOT be used for product identification purposes.

EXAMPLE:

EDMA term: MS **Thyroid Function Hormones**

Is linked to the following GMDN related preferred terms:

- P Triiodothyronine uptake kit
- P Thyroxine kit
- P Triiodothyronine kit
- P Free triiodothyronine kit
- P Free thyroxine kit

5.3 Collective terms

Collective terms are used to aggregate medical device groups that have common features and are identified in the GMDN, published as CR 14230:2001 *Global medical device nomenclature for the purpose of regulatory data exchange (identical to ISO/TS 20225:2001)* and successive versions.

Whereas the GMDN is designed and was developed for regulatory data exchange in areas such as vigilance reporting and tracking of medical device safety, there is a need for a set of terms that are more refined than the GMDN category terms, yet broader than the GMDN generic device group terms, to be used in the application of the medical device directives; the use of collective terms satisfies this requirement.

Collective terms are intended to be used for a whole range of subject matters, such as:

- To illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system,
- To be used to identify the range of skills and general technological abilities for which a Notified Body has been approved, and is so appointed by the relevant Competent Authority,
- For the exchanges of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database for Medical Devices (EUDAMED).

There were several means identified to aggregate the generic device group terms of the GMDN using collective terms. These were:

- Devices covered by the application of common technology
- Devices manufactured using similar manufacturing procedures, and with common technical features.
- Devices manufactured for the application of similar Medical Procedures
- Devices manufactured using common materials requiring special skills.
- Devices developed to meet specific risk-associated considerations.

For ease of electronic transmission of data and code recognition, each collective term is assigned a four-digit incremental code with the prefix "CT" (Collective Term).

EXAMPLE:

CT162	Bone cement and ancillary device
CT287	Clinical chemistry
CT241	Dental orthodontic devices

The collective terms are linked to the appropriate P terms within the GMDN data file and are an intrinsic part of the GMDN Navigator, providing its search mechanism. See the section on the GMDN Navigator.

5.4 Device Type

The device type level is not part of the GMDN nomenclature. It is, however, importantly associated with GMDN data. 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.

Although the identification of types of devices, e.g., by make and model, is outside the scope of the GMDN nomenclature, it can be included as mandatory information required within obligatory registration systems (e.g., the European EUDAMED system, the FDA registration system, the Australian TGA registration system, and others).
EXAMPLE:

Make	Model
Heraeus Sepatech	3635
Heraeus Sepatech	75003490
Kubota	8100
Kubota	KS-5200C
Sigma	203

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

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

EXAMPLE:

Heraeus Sepatech 3635
Kubota 8100
Sigma 203

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:

Centrifuge, tabletop, low-/medium-speed, general-purpose
GMDN code 36465
A tabletop- or bench-mounted mains electricity (AC-powered) device used mainly in the clinical laboratory to separate the components of suspensions through low- or medium-speed centrifugal force (typically up to 6,000 or 12,000 rpm). It is typically a compact stationary structure with an electric motor, a vertical shaft, and a horizontal rotor attached to the upper end. This device is mostly used to centrifuge various patient samples (i.e., body fluids), either alone or after addition of reagents or other additives before measuring analytes.

6. Coding

All terms in the GMDN are assigned a unique code. This provides the security in cases of misunderstandings, language barriers, or discrepancies in data systems. The code is an incremental, sequential cardinal number comprising five digits starting from 10000. The codes in themselves are not created with an integral hierarchical structure and are simply unique numbers. The code are the carriers of the information to which it is linked and should always be used and referred to in any reference to the GMDN or data transaction.

6.1 Codes in the range of 1-9999

Codes in the range of 1-9999 are not represented in the GMDN. These, as stated in the standard, are exclusively reserved for assignment by any end user and may be used as desired in any user's local data system.

NOTE: It is important for users to understand that this range of codes should not be used for any kind of official purpose, e.g., as temporary codes, as national translated synonyms, or where the data is exchanged between users outside of the local data system. This will lead to ambiguity.

6.2 Codes in the range of 10000-30000

Codes in the range of 10000-30000 are represented in the GMDN and have been reserved exclusively to represent the original code used by the ECRI organization for their UMDNS terms that have been adopted for use in the GMDN. This will provide the GMDN user with automatic mapping from the ECRI code representing the UMDNS term to the identical GMDN code now used to represent the GMDN term. This has been done to assist in the transition for users who have previously used the ECRI UMDNS.

6.3 Codes above the range of 30000

Codes above the range of 30000 are all GMDN created for GMDN terms.

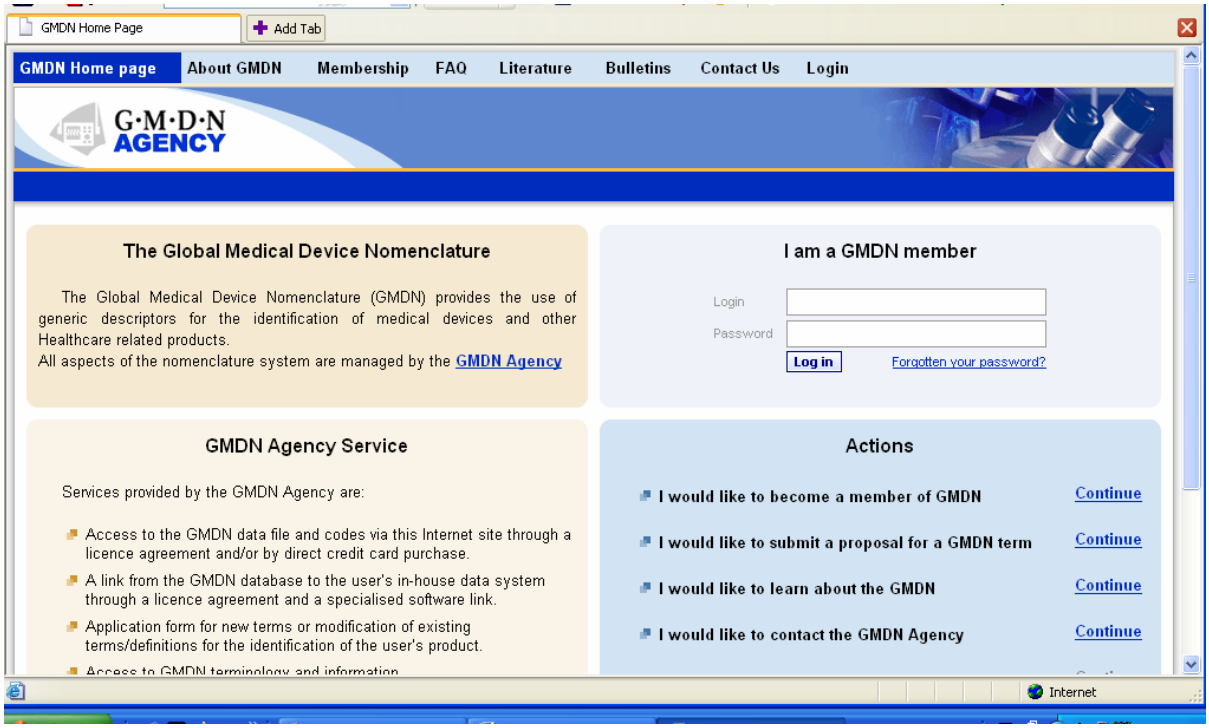
7. Access to the GMDN Data

The GMDN data, (i.e., the nomenclature, the codes, the categories and the collective terms with their links) and associated terminologies (i.e., GMDN glossary and abbreviations) are only available through the GMDN website.

This website will provide you with real-time data only, and as the GMDN experts work and edit the GMDN, this data is made available through the GMDN website instantaneously. This provides you, as a GMDN user, with the most recent data available. You no longer have to await the release of a new version of the data, as you would if using CD-ROM or printed matter.

To access the GMDN, you must first become a GMDN member. This you do by going to: http://www.gmdnagency.com/ or http://www.gmdnagency.org/ and this will bring up the GMDN Home page.

Home page:



Click on **Membership** on the top menu bar and select the membership schedule that is applicable to you.

The GMDN Agency also offers a service of creating a direct link from the GMDN database for automatic or manual download in accordance with a special negotiated license agreement. This provides the ability to import and use the GMDN data within a user's in-house data systems. To do this you must first obtain a special license issued by the GMDN Agency for incorporation of the GMDN data into a user software system. This allows a web service providing up to date information during the licence period.

Examples of such users are:

- Government bodies
- Large hospital organization
- Large manufacturers with a wide range of products
- Users of purpose-designed software systems containing GMDN data

Specific interfaces can be developed for clients by our GMDN technology partner Euro-Soft Developments Ltd.

7.1 Benefits of being a GMDN member

The benefits of being a GMDN member are:

- Access to the very latest information, there are no version releases – it is always real-time data.
- Access to the GMDN database from anywhere in the world; even through your personal digital assistant (PDA) or other electronic handheld information device.
- Customized selection and purchase of the number of GMDN codes. These will be stored in a personalized section of the GMDN called "My GMDN".
- Access to all of the GMDN terminologies and supporting files.
- Reduced annual membership and reduced new-term proposal costs.
- Access to the bulletins which provide current information on retired preferred terms that have been made obsolete (See section on Retired preferred terms).

7.2 Use of old GMDN data and illegal websites

It is the absolute advice of the GMDN Agency not to use outdated GMDN data for identifying products and/or transmission of GMDN data. Because the FDA of the USA works together with the GMDN Agency to fully integrate and harmonize their Product Code (Procode) nomenclature system into the GMDN, with the intent of utilizing the GMDN for their Postmarked Surveillance Systems, there has been a continuing period of intense ongoing upgrading of the GMDN data file. This activity, of course, brings about many changes to the GMDN data file. The upside will, at the end of this updating process, be of massive advantage to the users, whereby products and registration records will, in the future, be recognized by the GMDN code.

This also means that the GMDN users must remain astute and not fall into the trap of using outdated data, which can be found on the Internet or old versions of GMDN on CD-ROM, or websites other than the official GMDN website, in order to obtain GMDN codes. Such methods could be extremely harmful to your business.

7.3 GMDN fees

The GMDN Agency is a non-for-profit organization. However, in order to maintain the GMDN, it must generate an annual income. This is done by charging for its services. These fees have been set to modest levels so that they are advantageous to you as a GMDN member, bearing in mind the very specialized nature of the services provided.

7.3.1 Membership fees

Membership of GMDN is available to a range of users and is regulated by the following set of licenses:

Type	Applied to
A Membership	For Medical Devices National Regulatory Bodies
B Membership	For Manufacturers or Distributors of Medical Devices
C Membership	For Engineering Bodies dealing with Medical Devices and their Maintenance For Hospitals and Health Authorities using GMDN for inventory, purchasing, e-commerce
D Membership	For Conformity Assessment Bodies For Authorised Medical Device Inspectorates
E Membership	GMDN Agency Licence Agreements for links between the GMDN data-base and the users of IT systems negotiated facility arranged with GMDN Agency official software provider.
F Membership	GMDN Agency Licence Agreement with Translating Bodies Recognised by the Agency as appropriate translators for a given specific language version of GMDN.
G Membership	Special membership formulated for particular Medical Device Consultancy Organisations
H Membership	Others

Membership must be renewed annually (except where specifically excluded) to ensure continued access and search capability to the database. In most cases renewal costs are at a reduced rate from the initial joining fee.

7.3.2 Application for new or modified term fees

If an appropriate GMDN term in not found in the GMDN database that is applicable to your product, or you wish to suggest a modification to an existing GMDN term so that it can be applied to your product, users are encouraged to submit a GMDN application form. Because the GMDN is a complex matrix of information, to create a new GMDN term and definition, or modify an existing term, the GMDN Agency does charge a fee to the applicant to cover some of the development cost. These fees are set to:

400 Euros - per request for a brand new GMDN term by a non-GMDN member.
200 Euros - per request for a brand new GMDN term by a GMDN member.

NOTE 1: an extra term or terms will be created, upon assessment by the GMDN expert dealing with your application, when this is deemed necessary to complete the wholeness of the GMDN data file resulting through the application.
For example, an applicant can apply for a device that is a system (a collection of several medical devices or system component devices that acting together fulfils the intended purpose of the system), then one P term for the entire system must be created and one P term for each of the devices the system consists of, including software. Or, in the case of a kit which contains devices that are also available to the market as individual devices as well as being part of that kit, the same logic applies, one P term for the entire kit must be created, and one P term for each of the devices available to the market that the kit consists of.

100 Euros - for each extra required P term.

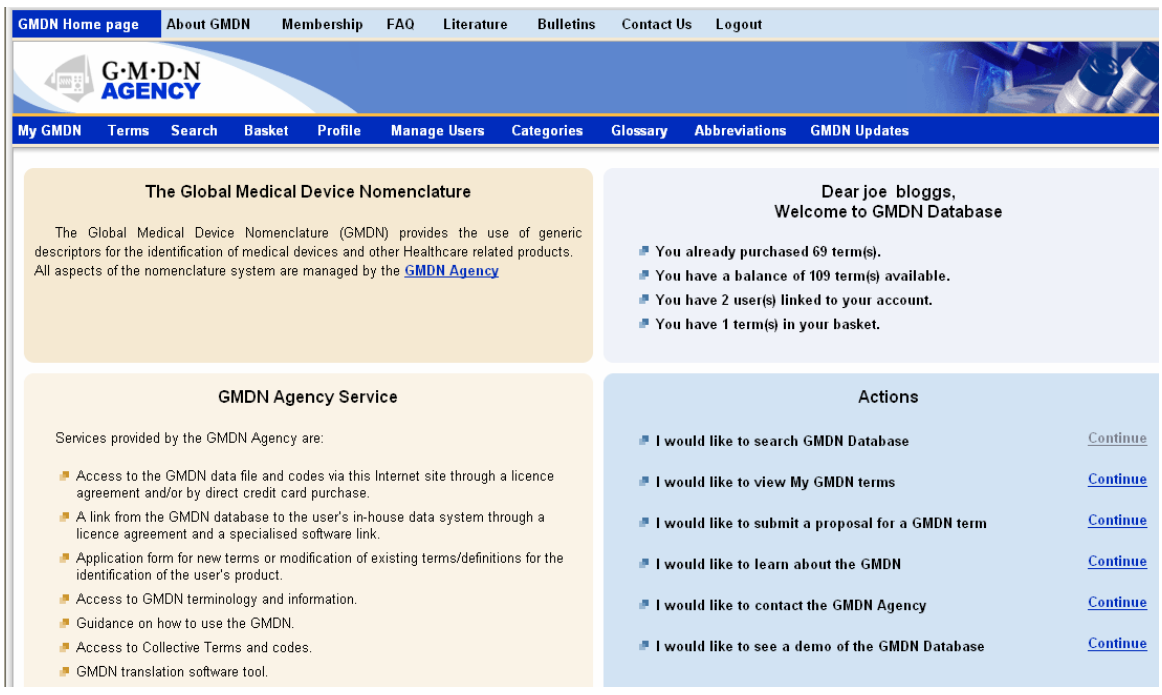
NOTE 2: the use of the above condition must not be applied by the applicant; this can only be applied by the GMDN expert dealing with the application.

7.3.3 Consultancy services

The GMDN Agency does reserve the right to charge a nominal fee when providing assistance to users who submit queries, especially in cases where the GMDN experts are involved and the query involves excessive usage of their time.

7.4 Becoming a GMDN member

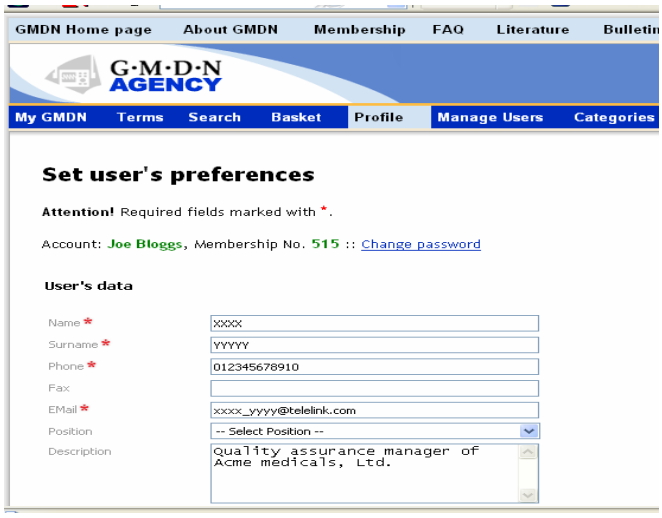
Once you have become a GMDN member and have logged in using your login and password, you will enter the database via this view:



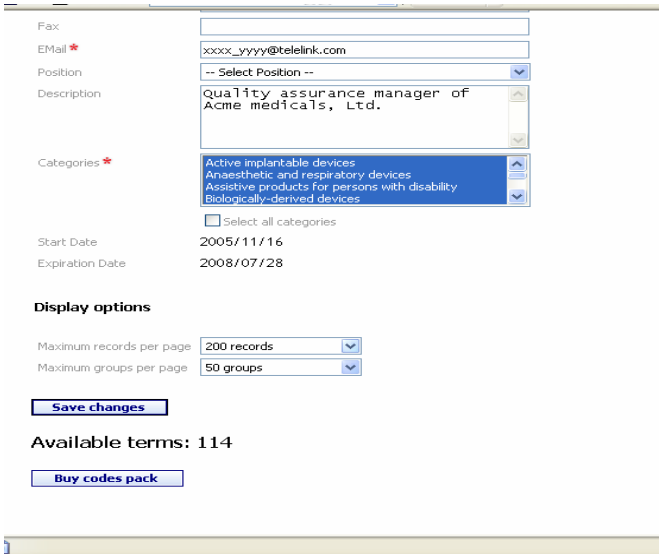
7.4.1 User Profile

You can now enter the section called **Profile** at any time to **Set user's preferences**. This is your personal profile.

Click on **Profile** to change your preferences:



At the bottom of this screen view you can change the **Display options**. This decides how many terms you can see on your computer screen.



Remember to click on **Save changes**.

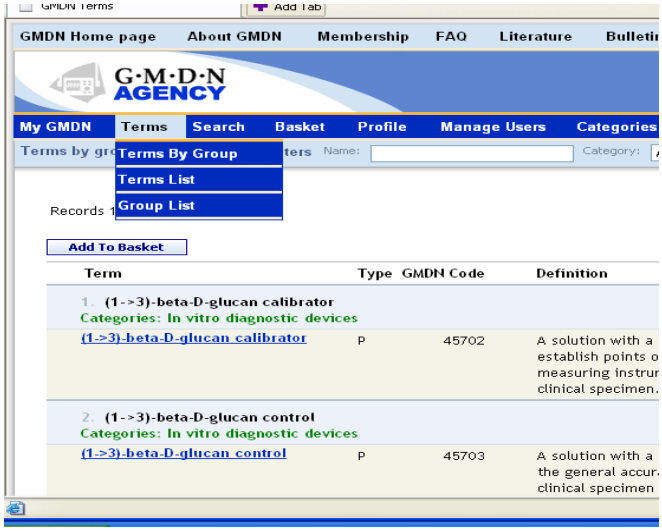
8. GMDN Search Systems

The GMDN nomenclature system is constructed so that it is fully compliant with the relative standards and conventions for a medical device nomenclature. In doing this, the GMDN provides a rich "multi-axial" approach giving many ways of searching the data for particular terms, selection of a single term, or even a word.

8.1 Searching the listings

The GMDN can be viewed in three formats of listing. They are found on the second horizontal menu bar under **Terms** and are:

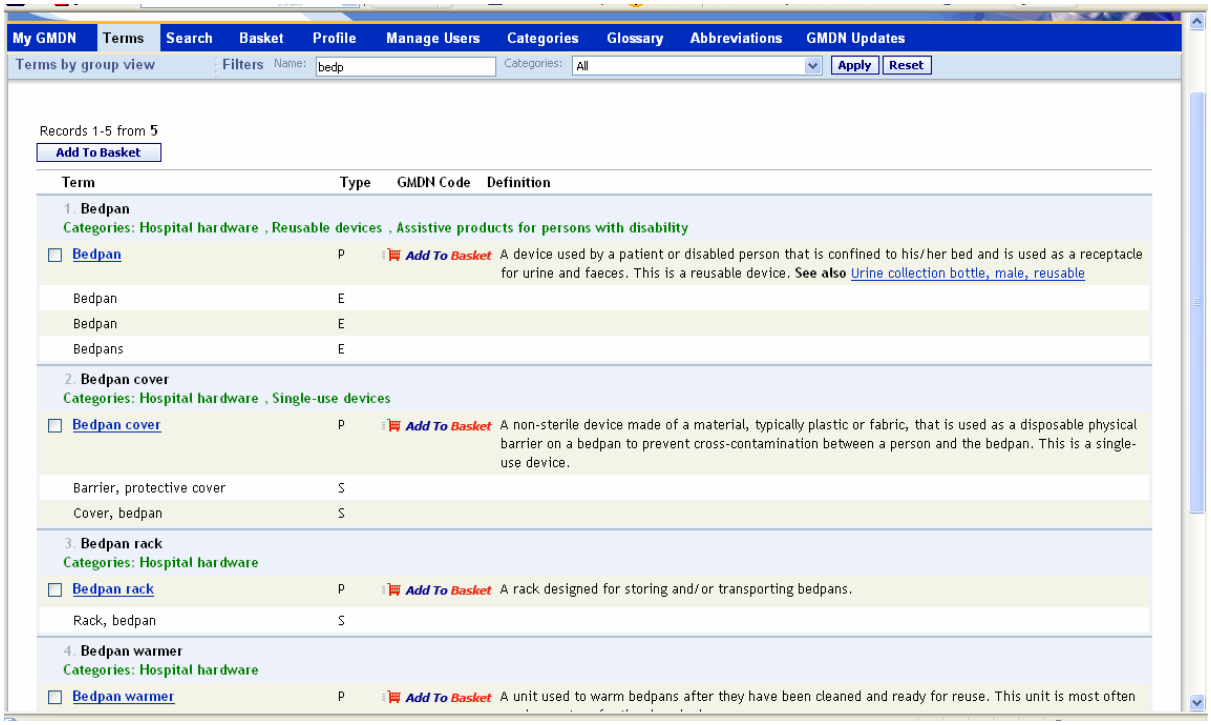
Terms By Group
Terms List
Group List



Terms By Group: To perform this search, the user would click on **Terms** from the second horizontal menu bar and select **Terms By Group** from the drop down menu. This view gives an alphabetical listing of all the P and T terms (terms that begin with numbers precede the alphabetical listing).

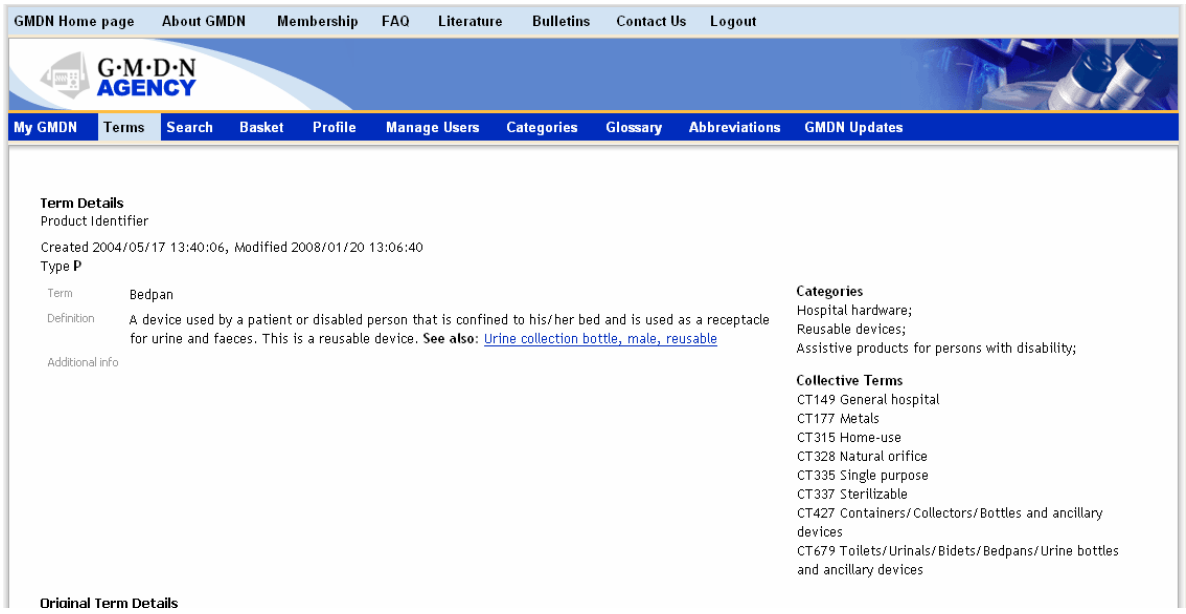
The listing displays the preferred term or template term as a blue hyperlink with its term type identifier and the definition (the GMDN code must be purchased). Below this term will be displayed linked S, MS, and E terms, if any are linked.

Terms By Group:



Clicking on any of these P or T term hyperlink names will open up the term to display the term details as shown below:

Term Details:

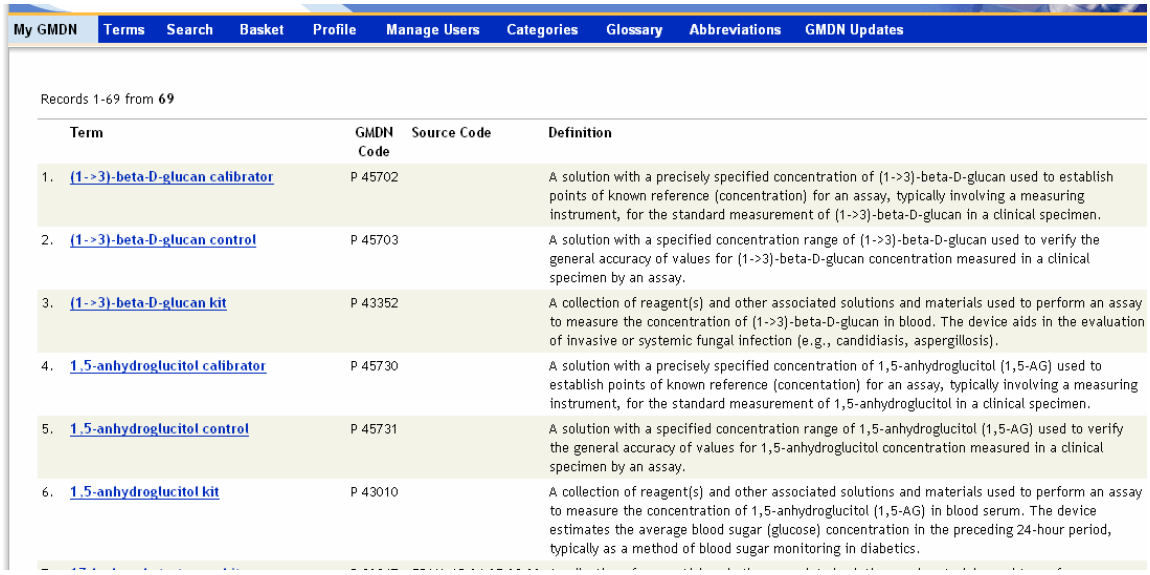


Please note the Add To Basket icon, which is the way that you would purchase this code. Along with your membership, you also purchased a pack of GMDN codes and it is these codes that you are now using when buying GMDN codes. As you buy

the codes, the number of codes in your code pack diminishes. It is an easy process to top up your code pack, go to Profile and click on the button **Buy codes pack**.

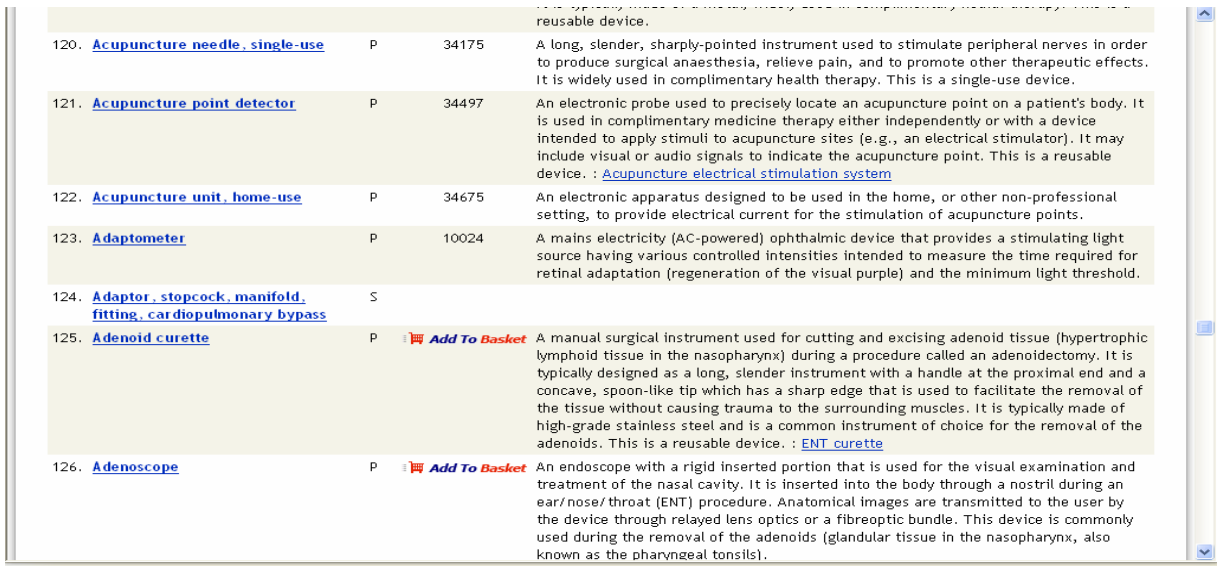
As you purchase GMDN codes, these are displayed to you only and stored in **My GMDN** this is your personal cache of purchased GMDN codes that only your password will allow access to.

My GMDN:



Terms List: To perform this search, the user would click on **Terms** from the second horizontal menu bar and select **Terms List** from the drop down menu. This gives an alphabetical listing of all terms regardless of their term type P, T, S, MS.

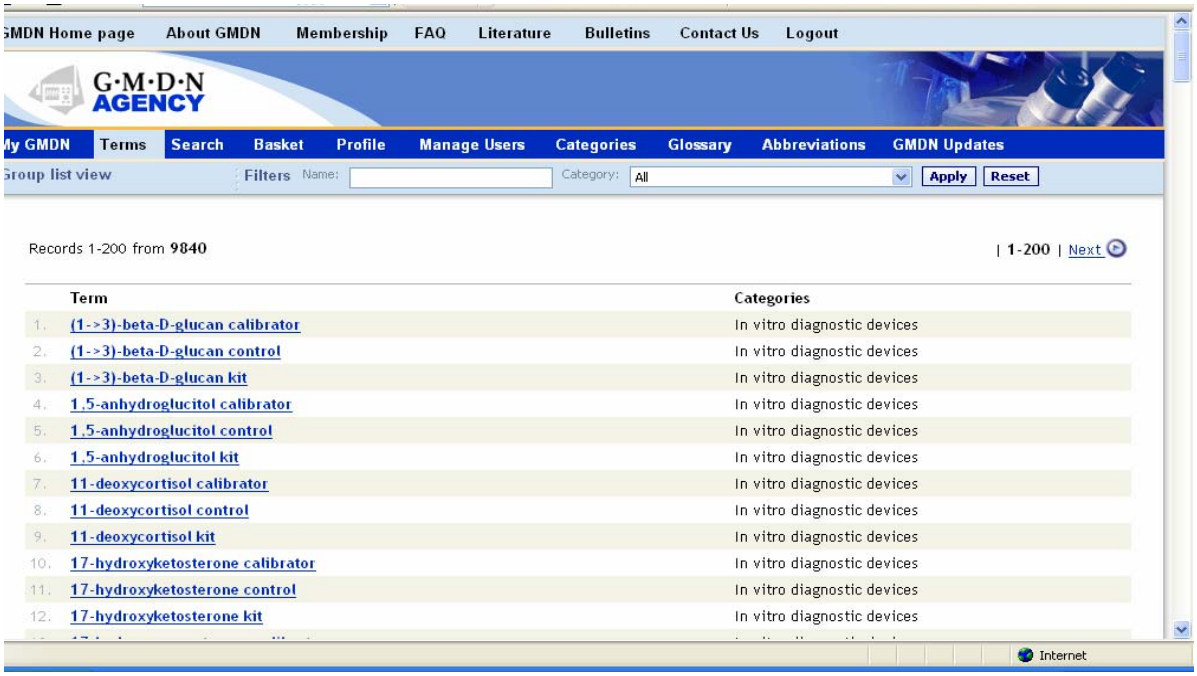
Terms List:



Please note, that as you buy GMDN terms, the codes are displayed in the views.

Group List: To perform this search, the user would click on **Terms** from the second horizontal menu bar and select **Group List** from the drop down menu. This view gives an alphabetical listing of all the P and T terms (terms that begin with numbers precede the alphabetical listing). This presentation gives you more terms per screen to view at one time. By clicking on any one of the term hyperlinks, you can open up the view to the **Terms By Group** view.

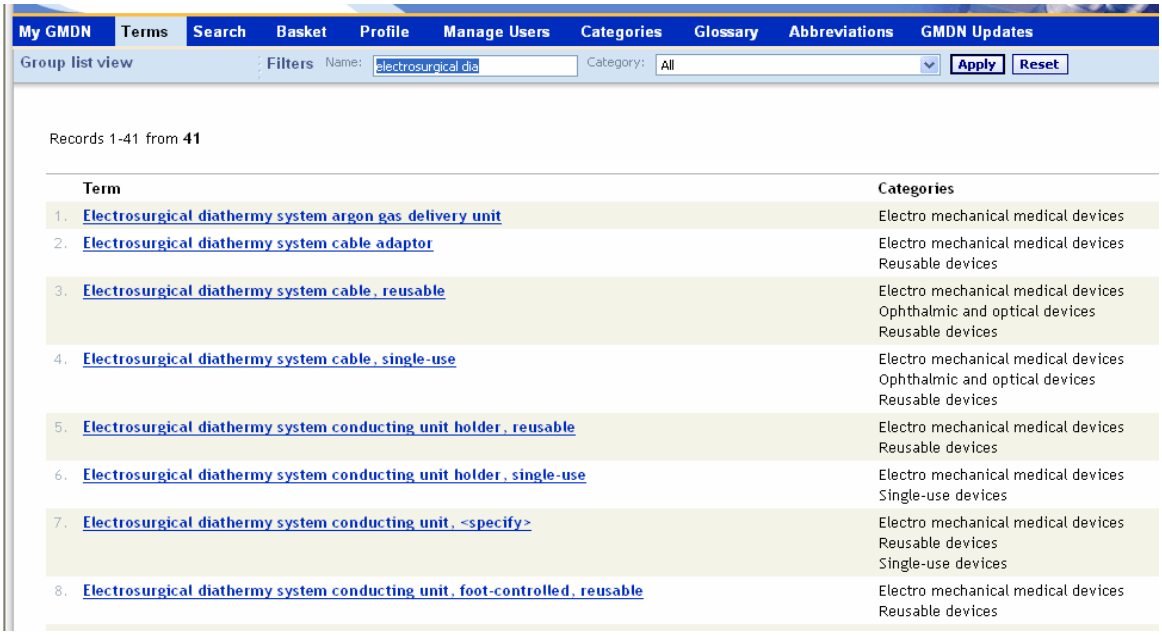
Group List:



8.2 Term search using Filters

Since the terms are listed alphabetically one can scroll up and down the list until the term or similar groups of terms are found. However, with the total number of P and T terms close to 10,000 and the maximum number of terms available in one view being 200 this process would be very tiresome.

Using the **Filters** you can narrow this search by putting search criteria into the **Filters** field, for example, by searching on **electrosurgical dia** you get all the P and T terms beginning with this search string:



Furthermore, if you know the category of interest, e.g., Dental devices, Reusable devices, you could add this into the Category: filter and this again would narrow the search.

To clear this search, click on the **Reset** and then the **Apply** button, or type in new search criteria and click on **Apply**.

8.3 Synonym 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. To find P terms using the synonyms, use the search engine.

8.4 Category search

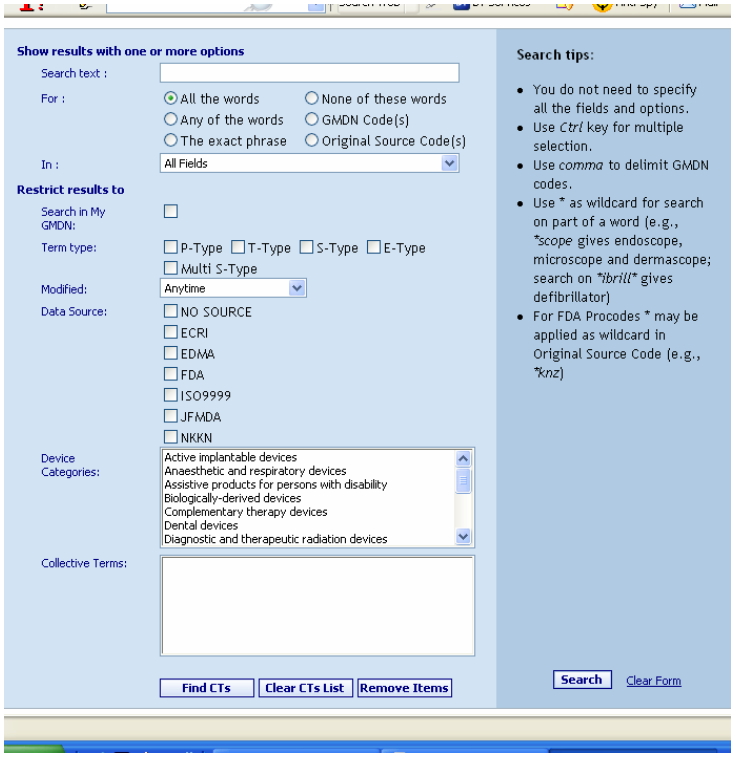
A search by Category can be performed to narrow the data to a specific medical specialty, technology, or intended use (e.g., dental devices, in vitro diagnostic devices, or electromechanical medical devices).

A product made, for example, for dental use will be found in Category 3 (Dental devices). Selecting Category 3 will produce a listing of specialized terms. Remember to click the **Reset** and then **Apply** buttons when you are finished.

The Categories with their definitions can be viewed at any time by clicking on the quick link **Categories** found on the dark blue horizontal menu bar at the top of the database.

8.5 GMDN Search engine

The GMDN search engine has been designed to provide the user with a rich search system that can refine the search criteria, limiting the search and search results to the specific terms of interest of the user. By clicking on **Search** on the second horizontal menu bar the search engine will appear. It looks like this:



The search criteria, whether this be a word, a word string, a partial word, a GMDN code, or an original source code, has to be entered into the **Search text:** field and the correct selection at **For:** must be chosen. Searching by a chosen word can have two targets, it can target the term or by hitting the word in the definition.

Search tips are:

- You do not need to specify all the fields and options.
- Use *Ctrl* key for multiple selection.
- Use *comma* to delimit GMDN codes.
- Use * as wildcard for search on part of a word (e.g., **scope* gives endoscope, microscope and dermascope; search on **ibrill** gives defibrillator)
- For FDA Procodes * may be applied as wildcard in Original Source Code (e.g., **knz*)

Remember, for each search criteria that you add per search, this will narrow the number of terms that you will hit. By adding too many search criteria, the search engine may not find any hits at all.

Click on the **Search** button to start the search, and click on Clear form to clear the search criteria.

8.6 Search using codes

It is possible to search on terms by using a code.

GMDN codes: if you already know a GMDN code, then enter this in Search text: field of the search engine, click on the "Radio button" **GMDN Code(s)** and the database will display the related term or terms to which it is linked. Try for example 45717.

ECRI (UMDNS) codes: if you already know an ECRI (UMDNS) code, then enter this in Search text: field of the search engine, click on the "Radio button" **Original Source code(s)** and the database will display the related term or terms to which it is linked. Try for example 16-168 but always remove the hyphen and enter like so 16168.

EDMA codes: if you already know an EDMA code, then enter this in Search text: field of the search engine, click on the "Radio button" **Original Source code(s)** and the database will display the related term or terms to which it is linked. Try for example 11 70 02 01 00 (always enter the EDMA code in the original format with spaces).

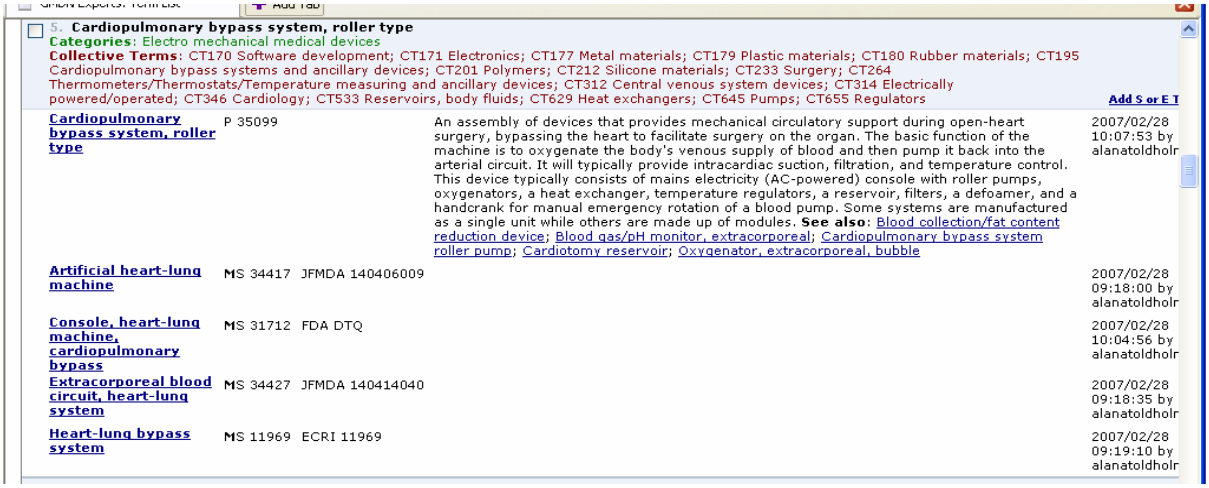
FDA Procodes: if you already know an FDA Procode, then enter this in Search text: field of the search engine, click on the "Radio button" **Original Source code(s)** and the database will display the related term or terms to which it is linked. Try for example CBK.

JFMDA codes: if you already know a JFMDA code, then enter this in Search text: field of the search engine, click on the "Radio button" **Original Source code(s)** and the database will display the related term or terms to which it is linked. (always enter the JFMDA code in the original format with spaces).

NKKN codes: if you already know an NKKN code, then enter this in Search text: field of the search engine, click on the "Radio button" **Original Source code(s)** and the database will display the related term or terms to which it is linked. Try for example 12002.

8.7 Cross-referenced Preferred terms

To indicate related or alternative preferred terms that may be of interest, the GMDN database includes a system of cross-referenced preferred terms. These are the dark blue hyperlinked term names preceded by **See also:** Blood collection/fat content reduction device at the end of each definition seen in this view only.

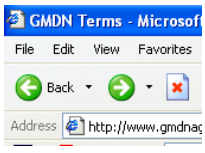


EXAMPLE as in the above screen shot:

An assembly of devices that provides mechanical circulatory support during open-heart surgery, bypassing the heart to facilitate surgery on the organ. The basic function of the machine is to oxygenate the body's venous supply of blood and then pump *it* back into the arterial circuit. *It* will typically provide intracardiac suction, filtration, and temperature control. This device typically consists of mains electricity (AC-powered) console with roller pumps, oxygenators, a heat exchanger, temperature regulators, a reservoir, filters, a defoamer, and a handcrank for manual emergency rotation of a blood pump. Some systems are manufactured *as* a single unit while others are made up of modules. **See also**: Blood collection/fat content reduction device; Blood gas/pH monitor, extracorporeal; Cardiopulmonary bypass system roller pump; Cardiotomy reservoir; Oxygenator, extracorporeal, bubble

By clicking on any one of the referenced hyperlinked P terms (in blue) with a click the system will take display to you the term details of that hyperlinked term.

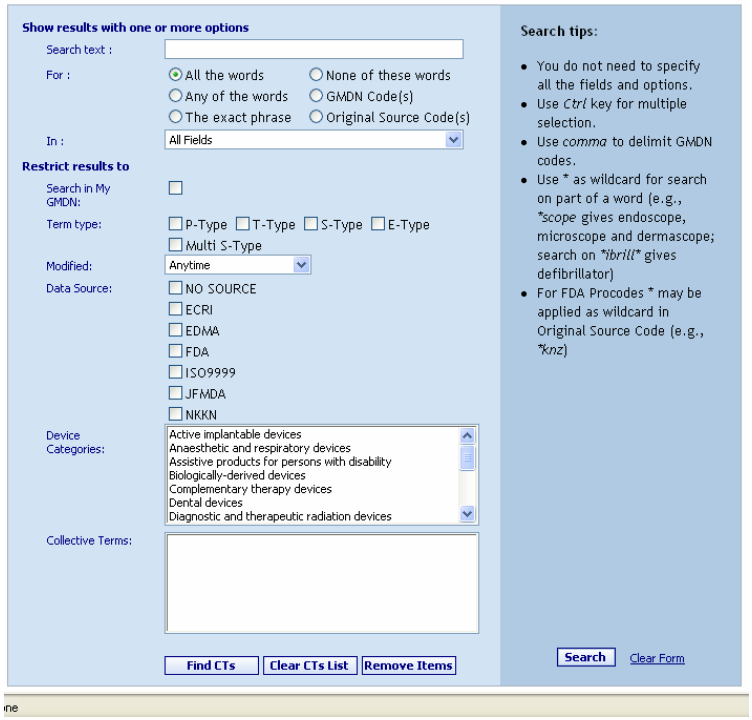
Use the Back arrow on your Browser to return to the previous term view.



9. GMDN Navigator

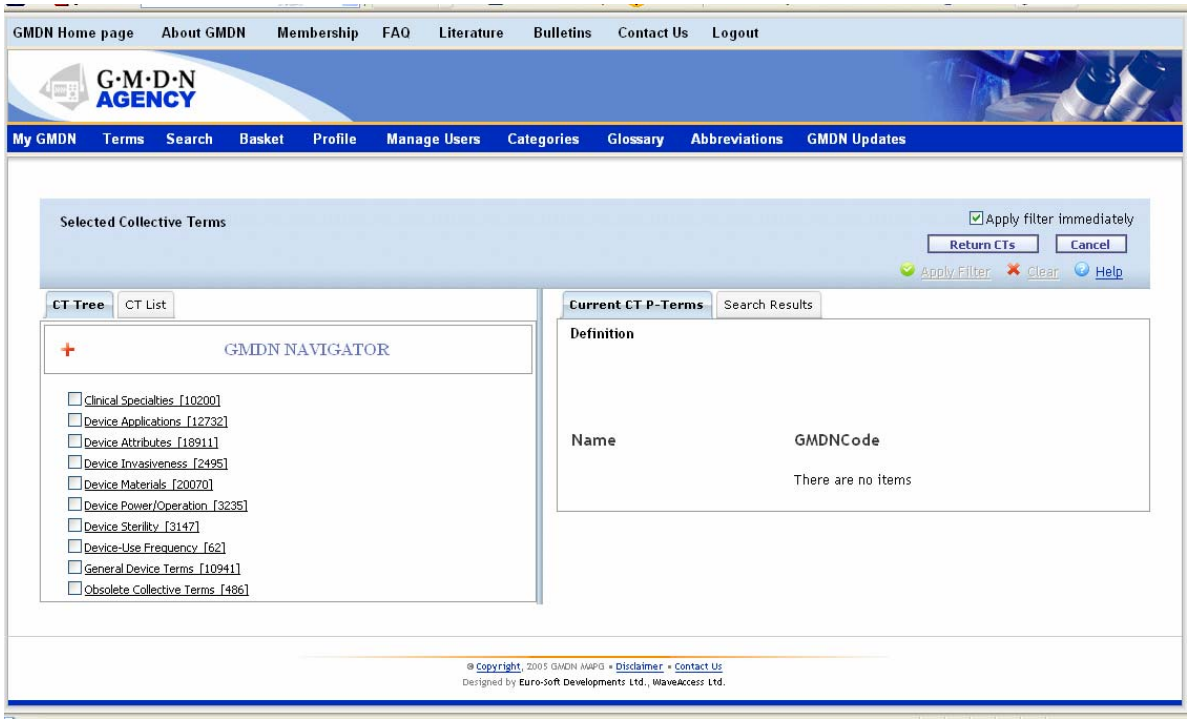
The GMDN Navigator is a state-of-the-art system that organizes the GMDN's rich array of collective terms into subject-specific groupss (e.g., device materials, unique device attributes, device applications, clinical specialties, and more). The system includes hierarchical constructs that are polyhierarchical in nature, meaning that a particular preferred term or collective term is capable of existing in more than one hierarchy, which maximizes flexibility and utility to provide a unique system for searching, locating, and viewing GMDN P terms.

To enter the Navigator you must use the GMDN search engine – select Search on the lower dark blue horizontal menu bar – this brings up the search engine – and scroll down to the bottom of the following search form:



Select the **Find CTs** button, and this will take you to the Navigator.

The main Navigator view looks like this:



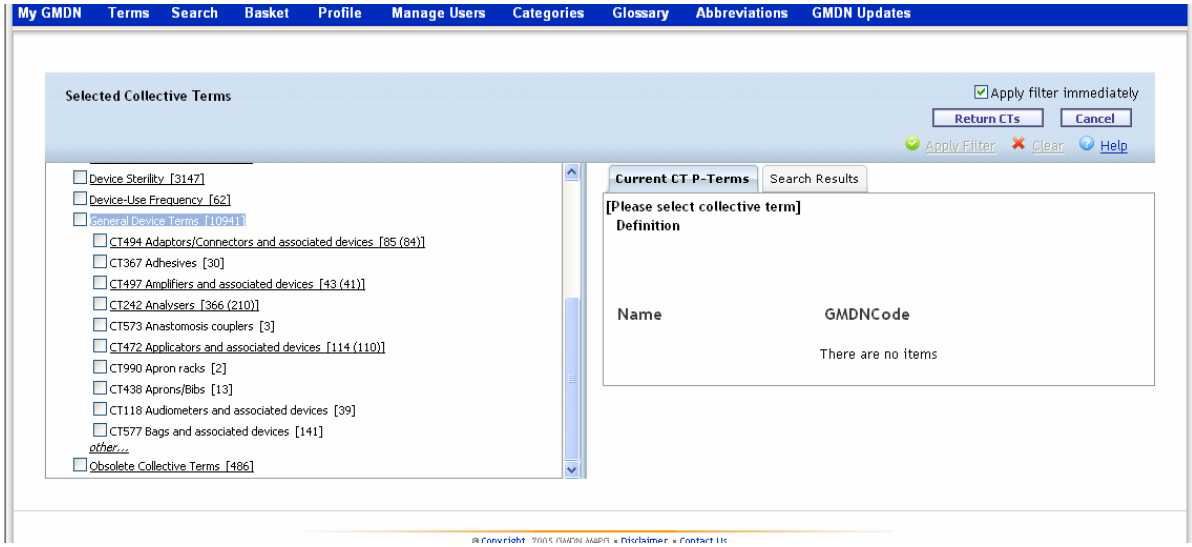
The Navigator is designed with a split (divided) screen, enabling users to drill from the highest level collective terms to the lowest level collective terms on one side, while viewing each collective term's definition and their linked preferred terms with their definitions on the other side.

Using the **CT Tree** tab you can view the collective terms are associated with the Navigator search groups:

- Clinical Specialities [10200]
- Device Applications [12732]
- Device Attributes [18911]
- Device Invasiveness [2495]
- Device Materials [20070]
- Device Power/Operation [3235]
- Device Sterility [3147]
- Device-Use frequency [62]
- General Device Terms [10941]
- Obsolete Collective Terms [486]

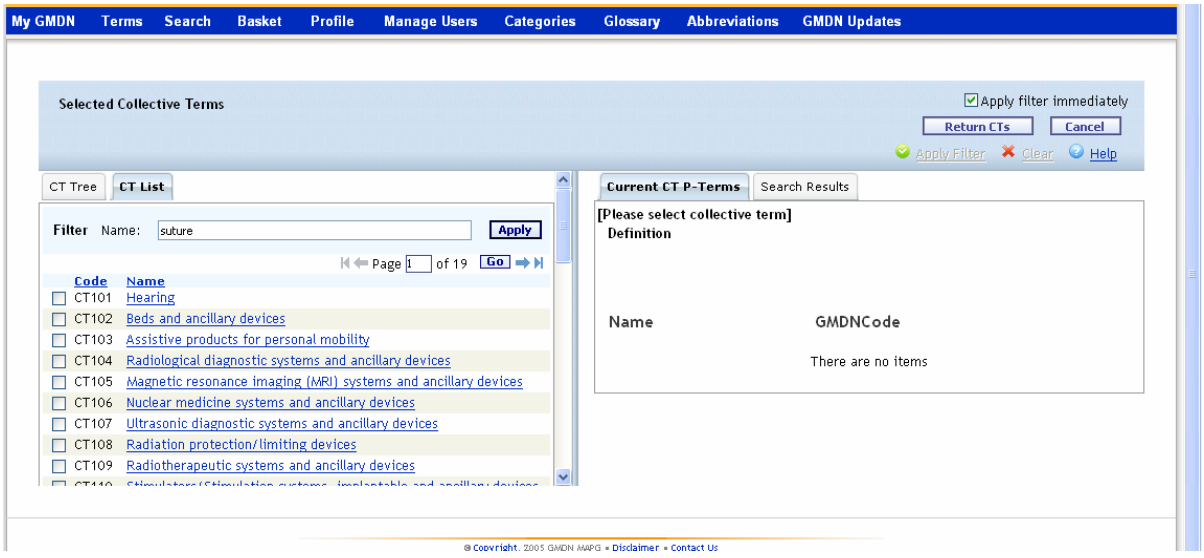
Selecting General Device Terms [10941], for example, will open the view up to the first level of collective terms.

First level of collective terms under General Device Terms [10941]



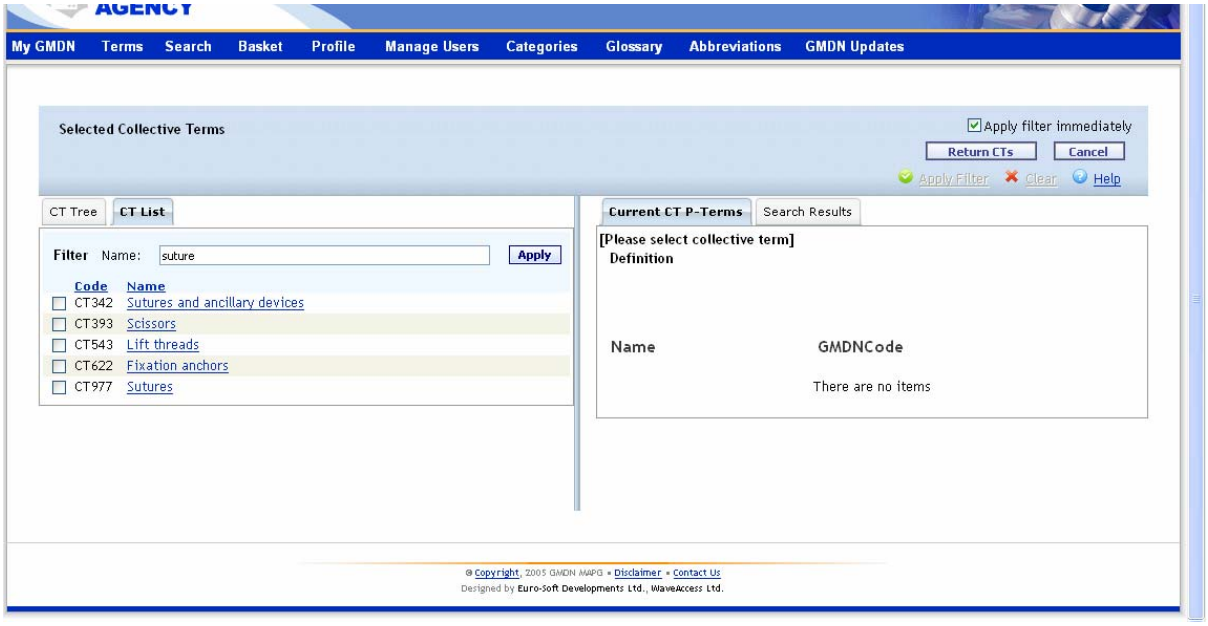
To view more collective terms in this list, select ***other...***

To find a specific collective term, or a collective term containing a certain word, select the **CT List** tab, and you can do a search, for example using the word "suture" and click on the **Apply** button.



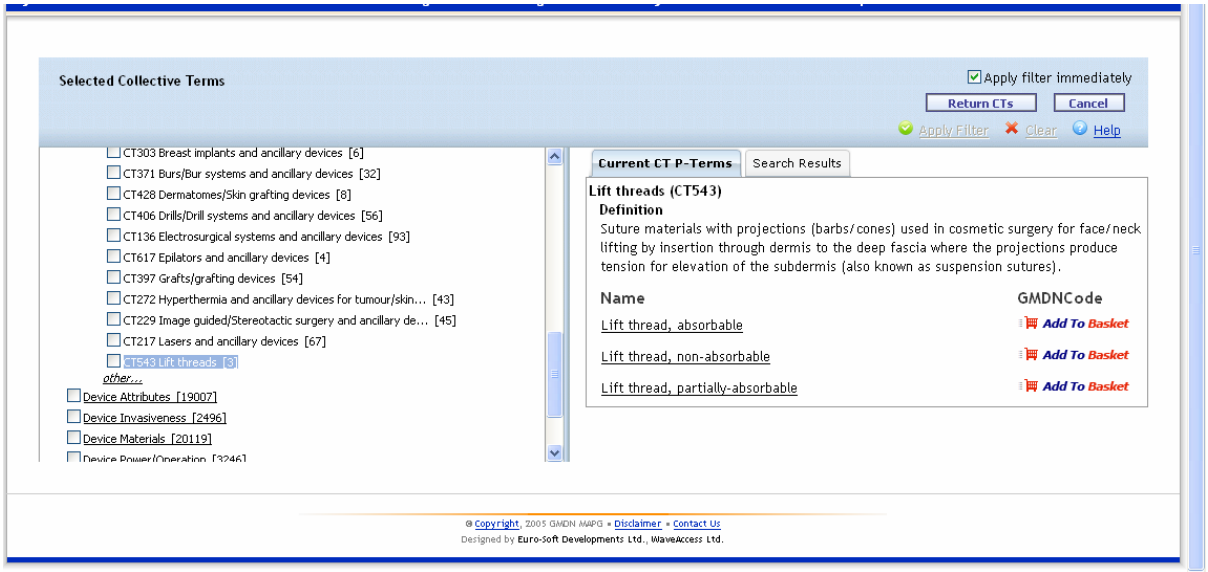
This will locate and display collective terms having "suture" in the term name.

“Suture-based” collective terms found and displayed:



By simply clicking on the collective term name (the hyperlink) that you want, e.g., CT543 Lift threads this will open the **CT Tree**, where you can scroll down the collective term list until you arrive at the collective term you selected.

CT543 Lift threads:



You will now see in the right hand pane, all of the preferred terms that are linked to this collective term. Here you can also buy terms to get their codes, or you can select the **Return CTs** button at the top to re-display the main view of preferred terms.

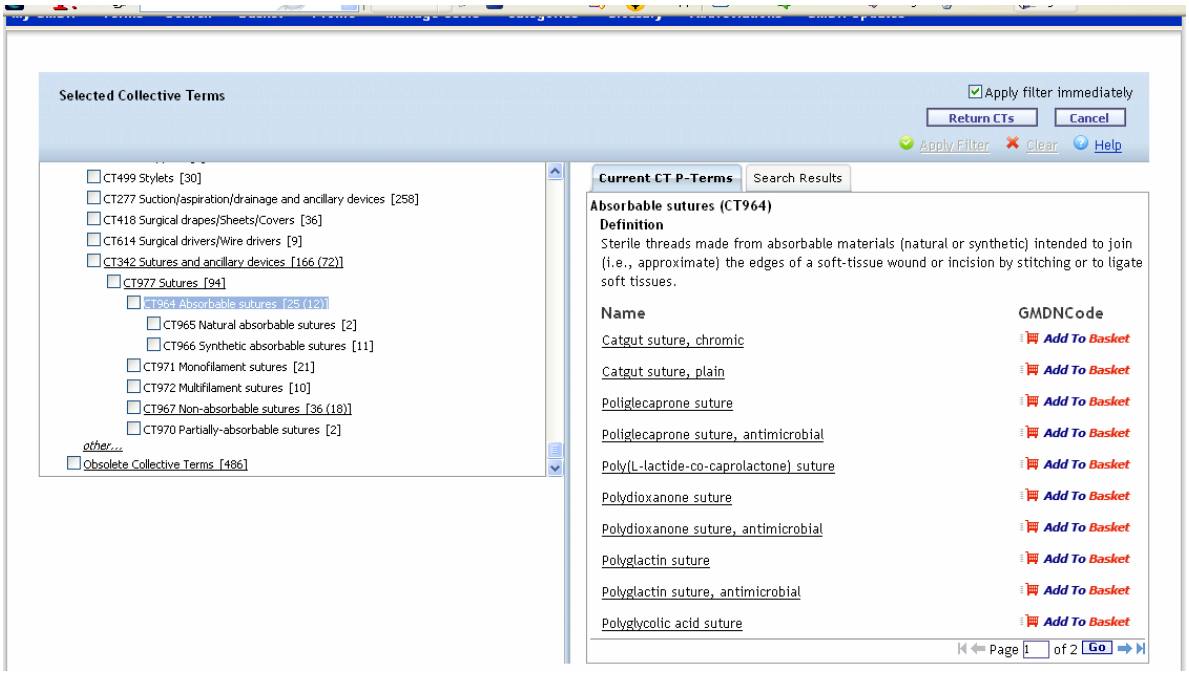
NOTE: The collective term name, its code and definition displayed at the top of the right hand pane.

However, by selecting **CT342** Sutures and ancillary devices the tree of suture collective terms will expand:

CT977 Sutures
- **CT964 Absorbable sutures**
  - **CT965 Natural absorbable sutures**
  - **CT966 Synthetic absorbable sutures**
- **CT971 Monofilament sutures**
- **CT972 Multifilament sutures**
- **CT967 Non-absorbable sutures**
  - **CT968 Natural non-absorbable sutures**
    - **CT985 Metallic sutures**
  - **CT969 Synthetic non-absorbable sutures**
- **CT970 Partially-absorbable sutures**

If, for example, the collective term "CT964 Absorbable sutures" were to be selected, (remember to put a tick in the tick box preceding your collective term of interest) the following would be displayed on the right side of the screen.

CT964 Absorbable sutures:

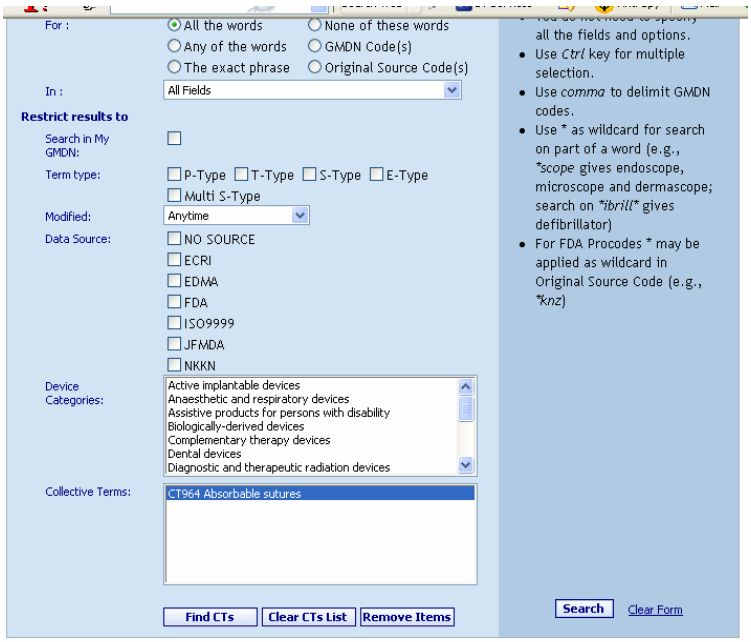


NOTE 1: At the bottom of this pane is displayed the page counter, using this you can move back and forth through the list of displayed preferred terms.

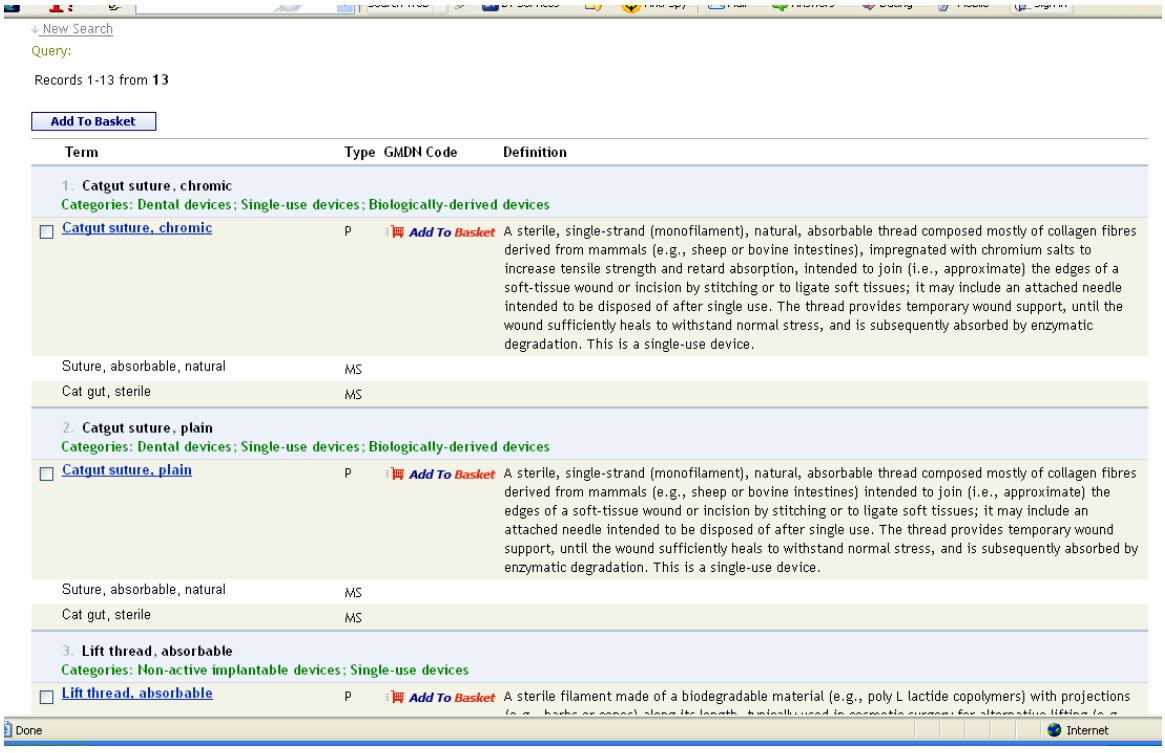
NOTE 2: By putting a tick into more than one (several) tick boxes preceding the collective terms you will get a return on all of the linked preferred terms of interest.

Select the **Return CTs** button at the top and this will re-display the main view of preferred terms. The search engine displays the selected collective term CT964 Absorbable sutures.

Return of selected collective term CT964 Absorbable sutures:



Select the Search button and this will give the view of linked preferred terms:



The electronic links between collective terms, and between collective terms and preferred terms, permit the creation of simple and concise preferred terms in the GMDN without sacrificing the ability to easily select important groups of preferred terms.

10. Product Identification Using a GMDN Code

10.1 GMDN Term Selection

Identifying a medical device or product with the correct GMDN is very important and a matter to be taken seriously. The days of cavalier code assignment are over.

It is the definition that describes the scope of the term and code. If the definition does not accurately describe a product then its associated code should not be applied to the product. If no GMDN term with its definition is appropriate then a GMDN application form should be submitted to the GMDN Agency for a modification or new term.

PLEASE NOTE:

Specific examples are often used in GMDN definitions to facilitate conceptualization of a medical device group (e.g., physical description, clinical application, material). The examples are not meant to be exhaustive, or to exclude products that fit the general description of the definition but are not specifically described by the examples.

10.1.1 Rules for Specific Product/Term Selection

Within the GMDN system, products are to be assigned a GMDN code based on the following list of rules:

1. All devices that are placed onto the market shall be identified using an applicable GMDN code, which through its term and definition shall clearly define the intended use of the device, the clinical field and/or the anatomical target site of application, the technology employed, and the specific criteria attributed by the manufacturer of the device, e.g., sterile, non-sterile, reusable, single-use, drug-eluting, indwelling, etc.
2. Each device that is placed onto the market as an individual product shall have a GMDN code.
3. Each device that is placed onto the market as a system (meaning an assembly of component devices) shall have a GMDN code.
4. Each component device of a system that can be placed onto the market as a single product, e.g., sold as a replacement for a defect component device of the system so that the system can continue to function for the user, shall have a GMDN code.
   NOTE: If the component devices are always marketed as a package and are never as individual device, then rule 2 is applied.
5. Each device that is placed onto the market as a kit or a set (meaning a collection of devices) shall have a GMDN code.
6. Each device that is included in a kit or a set, but that can also be placed onto the market as an individual product (meaning it is also available as an individual device as well as being available in the kit or set) shall have a GMDN code.
   NOTE: If the devices in a kit or a set are always sold packaged together and are never placed onto the market as individual device, then rule 5 is applied.

7. Each device that is an accessory to a device and that is placed onto the market shall have a GMDN code. An accessory is defined as a significant component of a device critical to its function (e.g., the rotor head of a centrifuge).
8. No device that is placed onto the market as an individual product, system, set or kit, or an accessory, can be represented by using two GMDN codes to achieve an appropriate description, e.g., a tubing set that has a dual function for irrigation and suction cannot use the two GMDN terms for these two individual intended purposes, the device must have one applicable GMDN term and code describing this combined function.

The method for device/product identification used should be:

(1) Search the GMDN database for the most specific applicable preferred term.
(2) Check that the definition is appropriate. If not, submit a GMDN application form for a suggestion for an improvement, correction, or new term.
(3) Check that the device category or at least one of the categories already indicated and linked to the selected preferred term is applicable for your device/product. If not, submit a GMDN application form for an additional category.
(4) Register the product using the GMDN 5 digit code, and the related data (term and definition) if asked for, to the regulatory authority, hospital, or body requesting this information.

A non-exhaustive list of term specificity is provided in a table at the end of this user guidance to provide the user with an indication of how specific GMDN preferred terms are and by the criteria required by regulatory bodies to generically group and register devices.

10.2 Category linkage

A preferred term is linked to at least one category, although in many cases it will be appropriately linked to more than one category.

EXAMPLE:

Preferred term: Infusion pump, general-purpose
Code: 13215
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 person with a disability. The product's intended purpose does, of course, totally depend upon the manufacturer's device type design.

A preferred term should be assigned to all applicable categories.

NOTE: In the GMDN application form for a new term or modification to an existing term, the applicant is requested to put forth an indication of what category or categories the product should be linked to. Ultimately, it is the GMDN expert that will make this final decision.

10.3 Products in the clinical testing phase

For medical devices that are in the clinical testing phase there may arise problematic circumstances for the manufacturer, such as the regulatory authority may demand a GMDN code for the product as part of the final documentation and approval process. The GMDN Agency, on the other hand, does not want to have its database full of terms and codes for devices that have not yet been put onto the market, or that may never be marketed. In order to alleviate this situation, the GMDN Agency has made the provision that such applications from manufacturers can be allowed on an ad hoc basis as deemed best by the GMDN Expert Team and with the explicit cooperation of the manufacturer.

10.4 No GMDN term available

If you cannot find an appropriate compatible generic device group (preferred term) for the identification/registration of your product you will need to submit a GMDN application form requesting a new term or a modification to an existing term. This you do by going to the GMDN website homepage. Go to the bottom right hand frame and click on:

I would like to submit a proposal for a GMDN term **Continue**

11. Retired preferred terms

Requirements and processes for retiring a GMDN preferred term.

All nomenclature systems must be dynamic; this means that they must, if and when necessary, be adjusted to reflect the current situation. Therefore, with all nomenclature systems, there are factors that create situations where it is necessary to remove (make obsolete) preferred terms from an active status. These factors are as follows:

Historical data – most nomenclature have a historical background, i.e., they are based on earlier systems, methodologies, or in the case of the GMDN, a project involving the merger of six established terminologies. Obviously, in doing this, it is inevitable that some duplication and inclusion of ambiguous terms would result, and as the GMDN is maintained these anomalies would be discovered and corrected (i.e., a duplicated or ambiguous preferred term would be removed).

Technology – As technology expands the number and variety of medical devices, so too must a nomenclature expand to make accommodation. For example, ***Screw, bone*** would have been an appropriate preferred term for all orthopaedic bone screws for some period. However, with the introduction of an absorbable bone screw, it becomes apparent that the single term ***Screw, bone*** described as being made of metal, no longer holds good. Therefore two new GMDN preferred terms must be made, one for the metal or non-absorbable types, ***Bone screw, non-absorbable*** and a second for the new absorbable material types ***Bone screw, absorbable***. The old term ***Screw, bone*** now becomes ambiguous and has to be made obsolete.

Socioenvironmental factors – Political and cultural changes in a society as well as the emergence and discovery of new diseases and disorders impact a medical device nomenclature. For example, the advent of HIV and its effect on blood related products, concerns related to infection from animal-derived products, and the recognition of latex-derived product allergies are all issues that may promote the revamp of certain sections of the GMDN to maintain currency. Such changes frequently result in the need to remove preferred terms and create replacements.

Understanding that a preferred term has been used in good faith to represent a product in many records and databases, the GMDN has a system for making preferred terms obsolete that does not create a disruptive situation for the GMDN user.

The procedure is as follows:
When a preferred term is retired, a series of automated processes will happen.

A fixed text phrase will supersede the terms definition, explaining that this preferred term has been made obsolete.

This text phrase is:

This GMDN preferred term has been made obsolete and the code must not be newly applied to a device/product from the date it was made obsolete. If this preferred term code was applied to a device/product before the date it was made obsolete, it may continue to be used for the life of this unchanged device/product. For device/product identification starting from the date this term was made obsolete, please use the referenced, other, or new/improved GMDN preferred term code(s).

The GMDN experts will point to new possible replacement preferred terms. However, the user must check the appropriateness of the selections for their particular use.

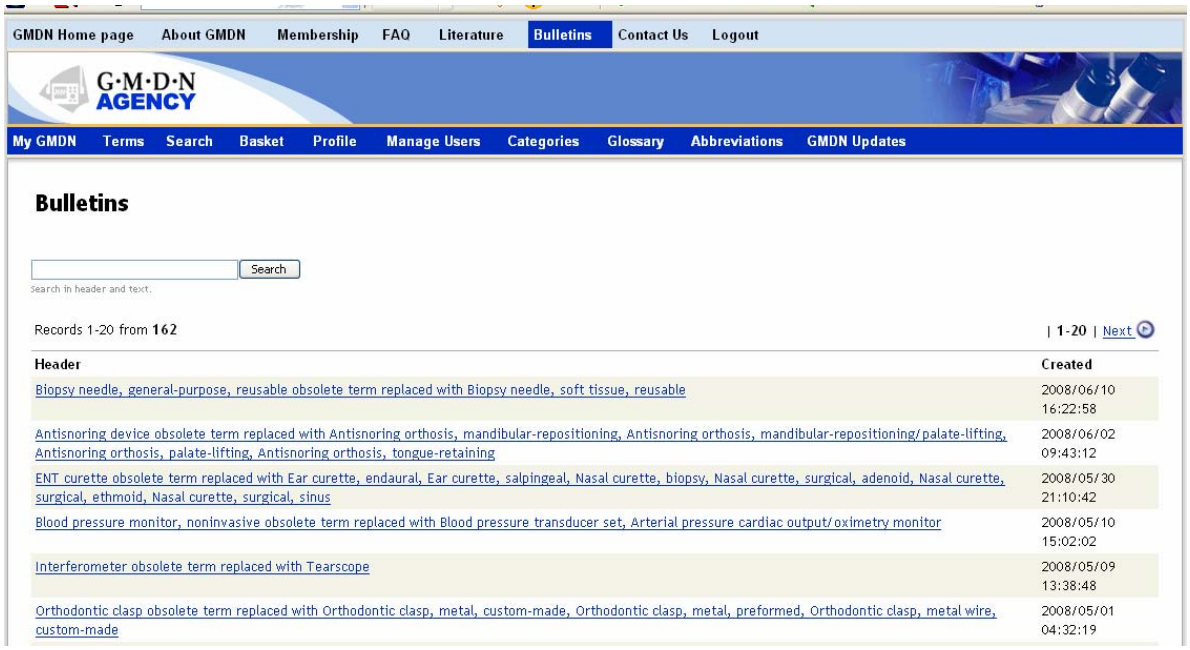
11.1 Bulletin board

When the preferred term has been made obsolete, it will be automatically pasted to the GMDN Bulletins.

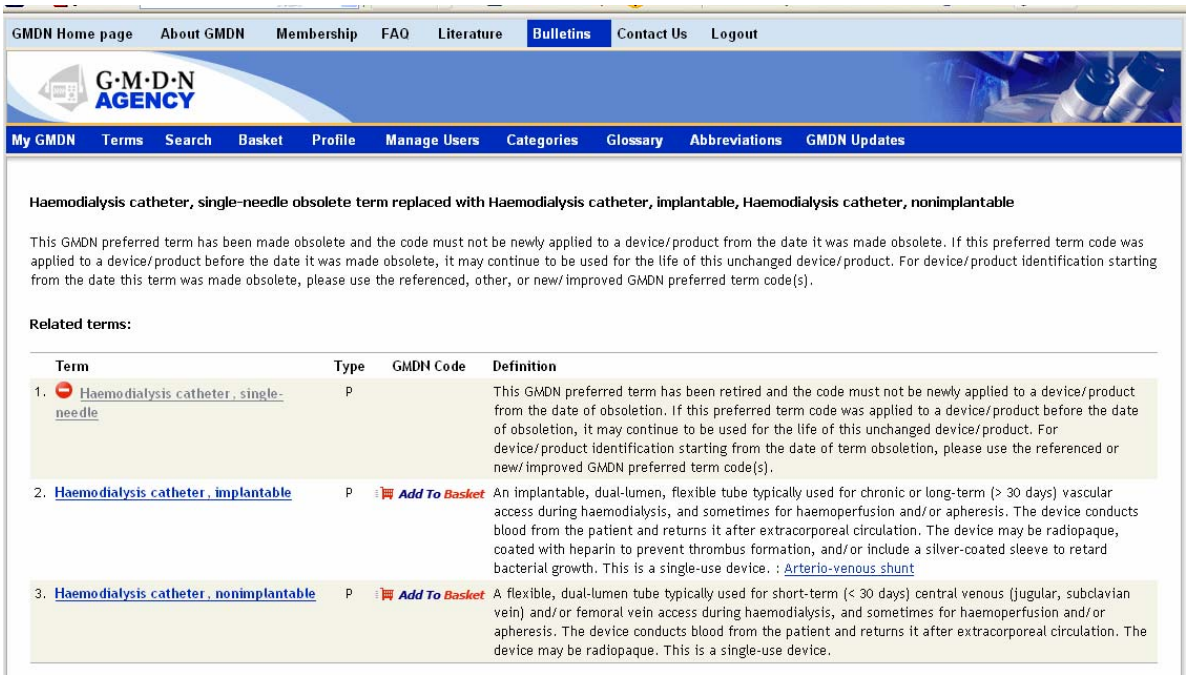
If you are a member of the GMDN, and you have previously purchased a preferred term that has been made obsolete, the system will alert you via the email address that you provided in your membership application, that this term is now obsolete.

The standard text phrase conveys that if a device/product has been identified and registered (e.g., with an authority) using the code of the preferred term that has since been made obsolete, the identification of the device/product via that GMDN code is valid as long as the device/product remains unchanged. If the intended use or technology of the device/product changes then a new GMDN code would be required.

EXAMPLE OF THE BULLETIN BOARD:



By clicking on any of the term names (this is the preferred term that has been made obsolete) in the list of hyperlinked term names this will expand the view to display the definition:



The stop icon indicates that this is a term that has been made obsolete, whilst the term(s) displayed below it are the preferred terms that the GMDN expert is suggesting may be appropriate substitute terms. This is, however, only a suggestion, and you, as the user must make the final decision if this is applicable to the product in question.

12. GMDN Glossary

Terminology used to reference the GMDN is provided below as taken, in part, from the standard ISO 15225 *Nomenclature – Medical device nomenclature data structure.*

base concept: The broadest representation of the generic device group, and the primary listing basis of the GMDN. [Source: GMDN Maintenance Agency]

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

code: A system of alpha, alphanumeric, or numeric characters and rules by which information is represented and/or communicated.

collective term: A descriptor used to aggregate generic device groups by common feature or characteristic (e.g., may be a high-level device term or attribute).

concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087:2000].

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

definition: A formal concise statement of the meaning of a preferred, template, or collective term.

device category: The broadest grouping within the nomenclature.

device intended for clinical investigation: A device intended for use in a designed and planned systematic study involving human subjects to verify device safety and/or performance.

device type: The identification of a manufacturer's specific product (i.e., make and model).

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

generic device group: A set of devices having the same or similar intended use and/or common technology.

GMDN (Global Medical Device Nomenclature): A nomenclature based on the structure of an international standard used to name, define, and code medical device products for data exchange between competent authorities and others, exchange of post-market vigilance information, research, medical record keeping, e-commerce and inventory purposes.

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

maintenance agency: Organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the GMDN.

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

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

- diagnosis, prevention, monitoring, treatment of alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

multiple-linked synonym: An alternative name for a preferred or template term linked to more than one preferred or template term; it is used to enter and navigate the nomenclature and may or may not actually be synonymous with the term to which it is linked. [Source: GMDN Maintenance Agency]

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

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

preferred term: The name established to describe devices (or a device) having the same or similar intended use or commonality of technology.

product specifier: A marker used to indicate whether a term can and cannot be used for product identification. [Source: GMDN Maintenance Agency]

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

synonym term: An alternative name for a preferred or template term; it is used to enter and navigate the nomenclature and may or may not actually be synonymous with the term to which it is linked. [Source: GMDN Maintenance Agency].

template term: A general device name used to create a simple hierarchy for lexically-related preferred terms.

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

13. GMDN Term Specificity Indication

The following table shows a non-exhaustive list of qualifiers that are used to make a preferred term more specific. These may be part of the term itself or be embedded in the term definition, or both.

Animal-derived	Devices made from or containing a substance that is manufactured from animal tissue/body fluid
Antimicrobial	Devices containing an agent/substance to combat the growth of microorganisms
Automatic	Devices able to activate, move, and regulate itself
Battery-powered	Devices that are powered/operated by batteries – usually internal
Combination	Devices using two combined integral technologies or clinical functions
Drug-eluting	Devices containing a drug or drug coating that is slowly released into the body.
Electrically-powered	Devices that are powered/operated by a source of electrical power
Electronic	Electrically-powered devices that use electronics as opposed to mechanical means to function
External	Devices used on the exterior of the body
General-purpose	Devices are not designed with a particular special purpose and can be used for several of many purposes
Guayule-latex	Devices made from guayule natural rubber latex (NRL)
Hevea-latex	Devices made from Hevea natural rubber latex (NRL)
Human-derived	Devices made from or containing a substance that is manufactured from human tissue/body fluid
Hydraulically-powered	Devices that are powered/operated by a source of pressurized oil
Implantable	Devices implanted inside the body – usually to remain there
Indwelling	Devices resident within a bodily organ or passage, especially to promote drainage
Internal	Devices used inside the body – usually implantable
Intraoperative	Devices used during, or in the middle of a procedure (e.g., a surgical procedure), as opposed to before or after a procedure
Manual	Devices that are powered/operated by human hand power
Mechanical	Devices that use only mechanical means to function
Medicated	Devices containing a medication/drug
Multi-purpose	Devices that can provide many different clinical functions or take many different readings as opposed to one or two
Non-latex	Device not containing latex
Non-powered	Devices that have no inherent power source
Percutaneous	Devices effected or performed through the skin
Pneumatically-powered	Devices that are powered/operated by a source of pressurized gas
Powered	Devices that are powered by some means other than by hand
Programmable	Devices that can be set to various programmes
Refurbished	Reusable devices that have previously been used on patients, and that have been subjected to additional processing and manufacturing for the purpose of additional uses on patients

Reprocessed	Single-use devices that have previously been used on a patient, and that have been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient
Reusable	Devices used more than once after disinfection/sterilization
Self-applied	The use of a medical device upon one's own body
Short-term	Device normally intended for continuous use for not more that 30 days
Single-patient	Used for one patient only
Single-use	Device used only once, then disposed of