Guide to applying for a SAHPRA Medical Devices Establishment Licence

Version 3 – January 2024

Disclaimer: The South African Medical Technology Industry Association (SAMED) is providing this guidance in the context of current legislation, regulations and guidelines and policies, as well as industry practice, where available. The guidance is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions, or, liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the guidance provided.

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Introduction

Whether you are a wholesaler, manufacturer or distributor of medical devices, you are required by Law to have a Medical Device Establishment Licence from the South African Health Products Regulatory Authority (SAHPRA). A manufacturer, distributor, wholesaler of a non-sterile, non-measuring Class A medical device is exempt from licencing, as per the SAHPRA position statement on Class A medical devices.

You may apply for one of three types of licences for medical device establishments: manufacturer (manufacture, pack, label, service, import, export), distributor (import, export, distribute) and wholesaler (storage, transportation, delivery). No medical device may be manufactured, distributed, imported, exported, or sold without a valid SAHPRA medical device establishment licence. Providing evidence of a valid SAHPRA medical device establishment licence may be required to be eligible to bid for National and Provincial tenders.

Medical device establishments who have applied for a SAHPRA licence must appoint an Authorised Representative who must be a natural person based in South Africa. One representative is required for each site where the company carries out its business. The representative is responsible for adherence to the law, regulations, and guidelines.

As part of the application for a SAHPRA medical device establishment licence a company must list all the medical devices that it manufactures, distributes, or wholesales. The application includes a declaration regarding the status of the quality management system in place in the company. Upon renewal of the SAHPRA licence, manufacturers and distributors will have to provide evidence of ISO 13485 certification for the company by an accredited conformity assessment body.

Putting together your application, especially if you do not have dedicated staff and/or resources for the task can seem like a mountainous task. The South African Medical Technology Industry Association (SAMED) has put together this guideline to assist you in your efforts to become licenced.

Important Resources

Legislation

Before you start the application process it is important that you have also read/access the following important resources which can assist you in putting together your application.

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) is the ACT which governs medical technology.
2. It is also essential to adhere to the Regulations Relating to Medical Devices and IVDs, published in the Government Gazette No. 4048 on 9 December 2016.

Note: In 2021, SAHPRA published updated Draft Medical Device Regulations for comment which were later workshopped with industry. The publication of the updated regulations is still pending at the time this was updated and publication thereof may influence the guidance provided below.

SAHPRA Guidelines

SAHPRA has published a document providing answers to frequently asked questions as a guide for the medical technology industry. You can access this guide on their website. This can be a helpful tool when troubleshooting.

Furthermore, you can access additional guidelines on the SAHPRA website:

- Guideline on Questions and Answers Licensing of Medical Device Establishments
- Guideline for Classification of Medical Devices and IVDs
- Guideline for a License to Manufacture, Import, Export, or Distribute Medical Devices and IVDs
- Guideline on Medical Device Quality Manual
- Recalls Vigilance Medical Devices IVDs
- Medical Device IVD Essential Principles
- Guideline For Access To And Control Of Medical Devices And IVDs
- General Information Medical Devices And IVDs

SAHPRA Communications to Industry and Position Statements

MD038	SAHPRA position on EU regulatory transition for medical devices from MDD/AIMDD/IVDD to MDR 2017/745 /IVDR 2017/746
MD031	Medical Device Establishment Licence Renewal Process
MD032	ISO 13485 Conformity Assessment Body Communication
MD037	Withdrawal of Section 21 Authorisation for use of unregistered rapidly developed non-invasive ventilators
	Retention Fee Notification – 9 June 2022
MD036	COVID-19 Test Kits Batch Verification
	Conformity of assessment body DoC template
	Conformity assessment body(cab) requirements for recognition by Sahpra checklist
MD035	Usability studies for Covid-19 self-testing kits requirements
	Communication to Stakeholders with regards to the current status of the Medical Device Regulations

MD033	Specification criteria for COVID-19 rapid antigen selftests
MD034	Conditions for use of COVID-19 antigen self-test kits
	Upcoming SAHPRA and Industry workshop
MD015	Process Flow Imported COVID-19 Test Kits
MD030	Medical Device Establishment Licence Renewal – ISO13485 Certificate Communication
8.04	Contact details for Guideline 8.04 Recall, Adverse Event And Post- Marketing Vigilance Reporting Of Medical Devices And IVDs
MD029	Renewal of Section 21 Authorisation for use of unregistered rapidly developed non-invasive ventilators
MD028	Communication Retention Fees
MD027	Section 21 Authorisation for the Importation of Research Use Only (RUO) In Vitro Diagnostic Devices (IVDs)
MD025	Alternative licensing and regulatory pathway for masks
MD025	Licensing and Regulatory requirements for the manufacture and distribution of medical and respirator masks during Covid-19
MD024	Frequently asked questions: Performance evaluation of point-of-care COVID-19 serology antibody test kits
MD022	Application Clinical Evaluation Medical Device IVD
MD021	Use SARS CoV-2 Antibody Tests NDOH
MD012	Notice of Contravention of Act 101 of 1965
MD018	Specifications Molecular Test kits
MD014	Regulatory Requirements for Molecular Test Kits
MD013	Process Flow Locally Manufactured COVID-19 Test Kits
MD009	Alternative Regulatory Licensing Requirements Alcohol-based sanitisers
MD002	Regulatory Requirements for Serological Test Kits
MD019	Processing of licence applications
MD016	Conditions of Use COVID-19 Serological Test Kits
MD008	ISO Standards for Medical Devices and Protective Clothing
MD005	Expedited Regulatory Pathways for Medical Devices
MD001	Regulatory Requirements for Medical Devices COVID-19
MD017	Technical Review Application COVID-19 Molecular Test
MD011	Licence Conditions for COVID-19 Serological Test Kits
MD007	Specifications Serological Test kits
MD006	Laboratory Testing and Use of COVID-19 Serological Test Kits
MD003	Testing for COVID-19
MD020	Certificate of Free Sale
MD010	Guidance Rapidly developed ventilator
MD004	Extension – Use of acknowledgement letter in lieu of a licence
	Communication to Industry Licence Acknowledgement Letter
	Communication to Industry Licence Amendment
	Reprocessing of Single Use Medical Devices Communication to Stakeholders
9.105	Section 21 Authorisation of Sale Unregistered Medical Devices
9.103	Tissue Engineering Products
9.106	Class A Medical Devices
9.96	Transitional Arrangements for Medical Devices
9.79	Medical Device Establishments: License Requirements
9.78	Disinfectants Status of Antiseptics and Germicides

2.32	Wound Dressings

Applying for your Medical Device Establishment Licence

An application must be completed for each manufacturer of a medical device who wishes to manufacture, import or export a medical device or who wishes to renew their existing manufacture licence to manufacture, import or export a medical device. A separate application for a licence to manufacture must be submitted for each manufacturing site.

SAHPRA will be asking for your Quality Manual. If you have it please print it and include it with your application form. If you do not have it, indicate "no" on your application form and continue to submit your application anyway. You can amend your application and send it to them later when you have it.

Please note: Upon renewal of the SAHPRA licence, manufacturers and distributors will have to provide evidence of ISO 13485 certification for the company by an accredited conformity assessment body.

Global Medical Device Nomenclature (GMDN)

You need to apply for one at a GMS agency as the GMDN is required for applications even for Research Use Only (RUO). Please see the presentation slides from Dr Barry Daniels on GMDN and gmdnagency.org for more information.

Custom made medical device

Please note that the SAHPRA (then the Medicines Control Council) responded to SAMED's query on custom made devices stating that "establishments that make custom-made devices are not required to apply for a licence and are not required to list each custom-made device with accompanying codes". Please see the correspondence in the addendum.

Licencing application forms

In order to apply for your Medical Device Establishment Licence, you will need to download the correct application form. As mentioned, you may apply for one of three types of licences for medical device establishments: manufacturer (manufacture, pack, label, service, import, export), distributor (import, export, distribute) and wholesaler (storage, transportation, delivery).

- Download the Manufacturer Medical Device Establishment Licence application form here.
- Download the Distributor Medical Device Establishment Licence application form here.
- Download the Wholesaler Medical Device Establishment Licence application form here.

Licence application format

When applying for your Medical Device Establishment Licence (regardless of the type), it is important to note the application and all supporting documentation should be submitted to SAHPRA in English.

Applications should be properly bound on the left side as this allows for easy update/addition of pages and the use of lever-arch files and ring binders is not accepted.

Font, Paper and Printing

When compiling your application, the font size of the text and tables should be of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically. It is preferred that you use Arial 12 point for narrative text or Arial 10 point black on white.

Figures, tables, and photos should be clearly legible. Shading and/or coloured filling/background and/or print (e.g. in tables and headers, or across pages) is unacceptable and should be avoided.

Standard A4 paper should be used for all submissions. The documents must be printed on both sides of the page, legibility must not be impaired and there must be sufficient margin space on both the left and right side in order to prevent the information from becoming obscured when the page is placed in a binder.

Please use a "quote" folder or plastic sleeves for your application. The reason for this is so that it will be easier for SAHPRA to remove or insert specific pages when you make subsequent amendments.

Covering Letter

All applications should be submitted with a covering letter on a company letterhead, signed by the company director. We have included an example in the addendum. The covering letter should:

- Be addressed to the registrar
- State what the document is e.g. Licence application to manufacture, import, distribute or export medical devices
- Include the contents of the application, e.g.
    - Part A: Licence application
    - Part B: Proof of payment

Codes: Application and Amendments

It is a requirement to add the correct codes to your cover pages when submitting applications or amendments thereto to the Regulator. See Section 13 in the Guidelines for the registration of medicines: General information (August 2012) on coding of submissions.

We recommend that you print 3 copies of your covering letter together with 3 copies of your proof of payment. This will make 3 sets which you will use as follows:

- 1 set will be attached to your application.
- 1 set will be put in an envelope (properly addressed) and attached to your application, this will go to the finance dept.
- 1 set will be stamped by SAHPRA reception when you physically hand it in. This set will be retained by you as proof that your application was handed in.

Upon making any submission to SAHPRA, it is recommended to make a copy of the cover letter being submitted and get SAHPRA to place the "RECEIVED & DATE" stamp on this additional copy for you to retain this copy on file at your offices as proof of receipt of an application by SAHPRA.

Application Fees

The Registrar indicated that SAHPRA does not and will not provide an invoice nor a purchase order. If your company requires an invoice, ask them to accept the Gazetted fee schedule together with the cover letter of the application mentioned above in lieu of an invoice.

We want to recommend that you print 3 copies of your proof of payment together with 3 copies of your cover letter. This will make 3 sets which you will use as follows:

- 1 set will be attached to your application.
- 1 set will be put in an envelope (properly addressed) and attached to your application, this will go to the finance dept.
- 1 set will be stamped by SAHPRA reception when you physically hand it in. This set will be retained by you as proof that your application was handed in.

Method for the transfer of fees

Applicants may transfer fees directly into the bank account of the South African Health Products Regulatory Authority by electronic or manual deposit process. No cheque payments should be made.

Direct electronic payment should include a clear reference, e.g. the product application number or purpose of the payment. The proof of the electronic payment/direct transfer must be submitted in a separate envelope attached to a copy of the covering letter of the relevant submission(s).

Electronic transfers must include a reference to at least the applicant's name and telephone number, the product application number or purpose of the payment.

The reference field on the ABSA deposit slip is 20 characters. In some cases, the name of the company together with a telephone number will exceed 20 characters, but preference should be given to a telephone number to enable the officials to make contact with the person making the deposit.

As soon as the deposit has been made, confirmation of such deposit must be e-mailed to Ms Naazneen Babamia at naazneen.babamia@health.gov.za

For administrative control purposes it is preferable to have only one payment per transaction. If payments for more than item are made per transaction, a clear breakdown must be supplied with the proof of payment.

Fee Schedule

You can access the fees which are payable on the SAHPRA website or you can click here.

	Manufacturer*	Distributor*	Wholesaler*	Import*	Export*
New Licence Application Fee	R25 200	R15 000	R15 000	R15 000	R15 000
Licence Renewal Fee (after 5 years)	R22 000	R12 600	R12 600	R9 200	R9 200
Annual Licence Retention Fee	R4 200	R4 200	R4 200	R4 200	R4 200
Licence Amendment Fee	R5 300	R5 300	R5 300	R5 300	R5 300
Licence fee on an approve licence (due before collection)	R3 400	R3 400	R3 400	R3 400	R3 400

***Please Note**: We recommend that you first check the SAHPRA website as fees may be amended from time to time.

SAHPRA Banking Details

Transfers need to be made into the below bank account either via electronic fund transfer (EFT) or by direct deposit at a branch.

Account name:	South African Health Products Regulatory Authority
Special name:	The Medicines Control Council
Account type:	Cheque / Current Account
Account number:	40-5939-2080
Bank:	ABSA
Bank Branch Code:	632005
Bank physical address:	240 Vermeulen Street, Pretoria, 0001, South Africa
Swift Code:	ABSAZAJ

Application Submission Copy

Incomplete applications may be returned to the applicant and will not be processed. The signed printed application is mandatory. No alterations on the printed version will be accepted. Printed documents with "white out" will not be accepted and will be returned. All required copies of certificates should be certified before submitting them with the application.

Only add information into the designated cells within the electronic spreadsheet application form. The electronic format must be submitted on a compact disc (CD) and must be accompanied by a printed version. We recommend that you test the CD to make sure it works. Secure your CD to your application; a plastic sleeve works well.

Do not scan your application form on PDF and then send it. SAHPRA requires the excel spreadsheet so that they can go into the listings to be able to read the teeny tiny writing. Make sure that when you print a hardcopy of your spreadsheets that all the vertical columns fit to the page. You can insert as many lines as you like. This will make the writing very small which is why the CD copy is important.

As an alternative to submission of a signed printed application with an electronic version saved onto a compact disc (CD), prospective licence holders may submit a signed printed application and forward the application by e-mail to the Registrar at the following e-mail address: mdlicenceapplication@health.gov.za.

Make sure all the pages of your application are signed at the bottom by the Authorized Representative (AR). A full signature is required for the AR section as well as the declaration.
Ensure that you submit the CV of your AR. There is no specific format for this, just send it as it is, however, make sure you include a letter from the company appointing the Authorized Representative (see the example in the addendum).

An Authorise Representative can only be appointed at one premise. The AR is then located at that premises (usually head office). For the other premises, the company may formally appoint “designates”. The designates, who must be based at the other premises, are responsible for the Quality Management System (QMS) and represent the AR at their designated premises.

Submitting your application

There are two ways to submit your application. The first and more preferred method is to deliver it in person at the SAHPRA offices located at Building A, Loftus Park, 416 Kirkness Street, Arcadia, Pretoria . It is advisable to rather not make use of a courier service to do this on your behalf. This way you will also receive a logged acknowledgement of receipt of the application

Alternatively, applications can be posted to Private Bag X 828, Pretoria, 0001

Just as a reminder, all correspondence should be addressed to the Registrar of Medicines. SAHPRA will not take responsibility for documents posted or delivered to any other place or in any other manner.

After submission

Once your application is handed in you will receive a letter of acknowledgement from SAHPRA via email. This letter serves as acknowledgement that your licence is being processed.

Please note: Since 17 April 2020 this acknowledgement letter can no longer be used in lieu of a Medical Device Establishment licence.

SAHPRA will communicate with you if they require any further information.

Licence Collection

Once your Medical Device Establishment Licence has been issued, the primary contact on your submission will be informed. We recommend that you make this a general email address. This should avoid any issues that arise with staff turnover as SAHPRA will not contact anyone else should you fail to collect the licence.

Before you go to fetch your licence, you will need to pay the licence approval fee prior to collection as per the fee schedule. You will take this proof of payment together with a copy of your acknowledgement letter to hand collect the license from the SAHPRA offices.

Notifications and Amendments

Inevitably, your product offering will change. When this occurs you will either need to update your listing (notification), in the case the new product(s) are within the same classes listed on your existing license, or an amendment, when the class of the new products(s) is other than the classes listed on your existing license. To better understand when to do submit a notification and when to apply for an amendment, you can refer to SAHPRA's communication on the matter.

It is important to note that whether you are doing an amendment or submitting a notification of your listing update, the same documents are required. Notifications do not require payment, while amendments are charge according to the SAHPRA fee schedule. All amendments or notifications should be sent to MDnotifications@sahpra.org.za or tebogo.kalembo@sahpra.org.za

Once again, it is essential to have a comprehensive and clear covering letter that includes:

- Statement that you have an existing medical device establishment license (with license number)
- Declaration that you have not changed classes
- Highlight in which sections of the listing amendments have been made and state the line numbers of the listing for ease of reference

Other documents that need to be included in your submission are:

- Your quality manual
- The CV of your Authorised Representative (if this has changed, it is considered an amendment and not a notification)
- The updated listing excel spreadsheet. Make sure that you update all applicable listings (import, export and/or manufacture) for each product.
- Print the excel listing and make sure to have the Authorised Representative sign on the appropriate pages. Scan this to PDF to include in the submission. Where the document file size is too large, clearly state this in the *cover letter* and then only print scan and sign the first pages and any pages where changes in the listing appears.
- Certificates of Free Sale for all new listings. If you do not have this available, then do not mark yes on that section. Rather indicate no and when SAHPRA sends the observation letter you can inform them of the status of the certificates (pending/outstanding). Please bare this in mind, observation letters often only give 48 hours to respond and some certificates of free sale can take up to 3 months to obtain.
- For Class C and D listing updates, you will need to include the registration numbers from other recognised authorities

Please note that you will need to have the technical file available either with yourself or at the manufacturer for all new additions. This often requested with Class C and D products but may be requested for Class A and B products.

You should receive an acknowledgement of receipt from SAHPRA (this is often just an email acknowledging receipt of the update). Once you have received this notification, you are free to trade in the new product as but you must still conform to all existing license requirements.

In terms of an amendment, the same documents are required for submission, however, a payment need to be made in line with the SAHPRA fee schedule and the proof of payment should be included when submitting. Once this has been reviewed, and any observations have been addressed, SAHPRA will issue you with an updated license.

We recommend that within your internal quality management system, you ensure detailed version control over notifications of listing updates and amendments - tracking when what was submitted. This way, if queried, you can refer to relevant listing or amendment submission/acknowledgement.

Queries & Contacts

If you have further questions regarding the medical device regulations / licencing requirements, please make use of the following key contact at SAHPRA:

Senior Manager: Medical Devices and Radiation Control	Dr Dimakatso Theresa Mathibe	012 501 0358 / 071 701 3787 dimakatso.mathibe@sahpra.org.za
General licensing queries	June Searela	012 501 0464 / 072 828 2416 june.searela@sahpra.org.za
Applications for licences	Khanyisile Nkuku	012 501 0473/ 081 854 7109 Khanyisle.Nkuku@sahpra.org.za
MD Clinical Trials and Section 21 RUO	Khanyisile Nkuku	012 501 0473/ 081 854 7109 Khanyisle.Nkuku@sahpra.org.za
Adverse Event Reporting	Puseletso Mogano	012 501 0476 / 081 509 6131 mdvigilance@sahpra.org.za
Releases (Port Health)	Mokgadi Daphney Fafudi	012 015 5434 / 066 301 1878 Mokgadi.Fafudi@sahpra.org.za
Inspectorate (Pretoria)	Esther Matabane	0128427603/7607 / 076 402 8179 / Esther.matabane@sahpra.org.za
Inspectorate (Cape Town)	Malcolm April	021 957 7469 / Malcolm.april@sahpra.org.za

Please continue to check the SAHPRA website www.sahpra.org.za for any further updates to these documents and guidelines.

Addendum

Example of a Cover Letter

Please complete the highlighted sections

Date

Name of Company PTY Ltd
Street Address
Suburb
Site
South Africa
Code

South African Health Products Regulatory Authority
Building A
Loftus Park
416 Kirkness Street
Arcadia
Pretoria

To the Registrar of Medicines

REF:
Medicines and Related Substances Act, 1965 (Act 101 of 1065)
Company Pty Ltd Application for a Medical Device and / or IVD Manufacturer / Distributor (delete whichever is not applicable)

Regarding the callup notice No 157 relating to the Medicines and Related Substances Act 101 of 1965 and published Regulations 9 December 2016, Company Pty Ltd would like to make application for a license to Distribute / Manufacture Medical Devices and/ or In Vitro Diagnostic Devices in South Africa (delete whichever is not applicable).

Please find completed application form attached.

Kindly note that a payment of R[indicate amount] has been made to the council and proof thereof has been included.

Should you require any further information, please do not hesitate to contact [insert contact name and contact number]

Kind Regards

Example of an appointment letter of an Authorised Representative

Please complete the highlighted sections

Date

Name of Company PTY Ltd
Street Address
Suburb
Site
South Africa
Code

Decree of Appointment

Company PTY LTD, Complex Name, Street number, Street address etc., represented by name of company director, position held, hereby appoints:

AR name, date of birth: Month, DD, YYYY, Company address where the AR works, current position held, to the position of:

Authorized Representative

In relation to the establishment licensing of the company and the registration of medical devices and IVDs imported, exported, manufactured and distributed in South Africa. The Authorized Representative is responsible for the implementation and maintenance of the Quality Management System of the company and for the communication with the Regulatory Authority and all activities regulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.

This Decree of Appointment is valid until withdrawn.

DATE

Signature of Company Director

Name of Company Director

Position Held

Name of Company

SAHPRA letter on Custom Made Medical Devices

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL

The Registrar of Medicines, Private Bag X828, PRETORIA, 0001

Tel: 012 395 8000 Fax: 012 395 9201

Dear Ms. Tanya Vogt,

CUSTOM MADE MEDICAL DEVICES

The content of your correspondence, received on the 17 January 2017, has been noted.

With regard to your query, it is important to note the definition of a custom-made medical device, as set out in document 8.01 General Guideline Medical Device and IVDs, Sept 2014.

Section 2.6 of document 8.01 states:

"In accordance with the provisions of the Act, a custom-made medical device means any medical device specifically made in accordance with a written prescription given by a person authorised for the same by virtue of professional qualifications and in accordance with specific design characteristics and is intended for the sole use of a particular user and excludes mass produced medical devices which only need adaptation to meet the specific requirements of the health professional user."

Additionally, section 10.6 of document 8.01 states:

"Some Groups, systems and procedure packs and kits fit the definition of 'custom-made medical devices'. Custom-made medical devices are exempt from inclusion in the SA Medical Devices Register. A system or procedure pack that contains one or more custom-made medical devices and no other kinds of medicinal items is also a custom-made medical device, and therefore is exempt from inclusion on the SA Medical Devices Register. However, a system or procedure pack that contains one or more custom-made medical devices, as well as medicines, or non-custom-made medical devices, is not a custom-made medical device and must be included on the Medical Devices Register."

In response to your query, and in light of the definitions set out in the guidance document 8.01; establishments that make custom-made devices are not required to apply for a licence and are not required to list each custom-made device with accompanying codes. Establishments making mass produced custom-made devices, that require adaptation by the health professional user, are required to apply for a licence and such devices must be produced and sold in compliance with the guidelines applicable to medical devices.

Yours sincerely,

ANDREA KEYTER

FOR THE REGISTRAR OF MEDICINES

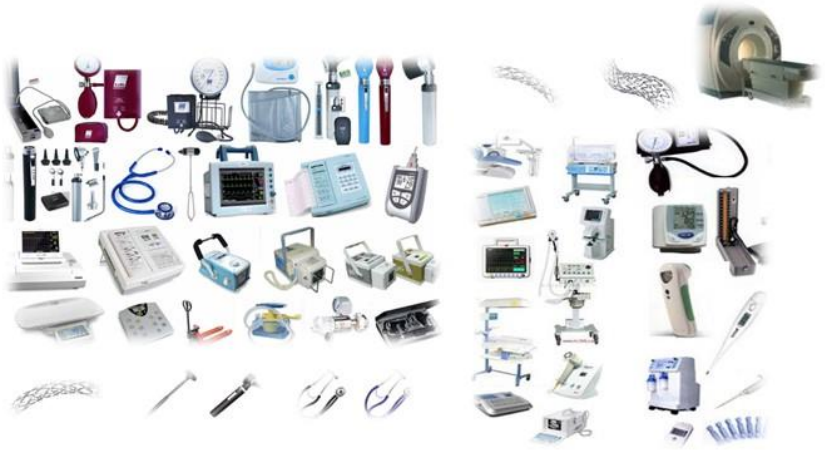
DATE: 15 MARCH 2017

Global Medical Device Nomenclature (GMDN)

Dr Barry Daniels
Technical Lead
GMDN Agency

GMDN

Get from this:



GMDN

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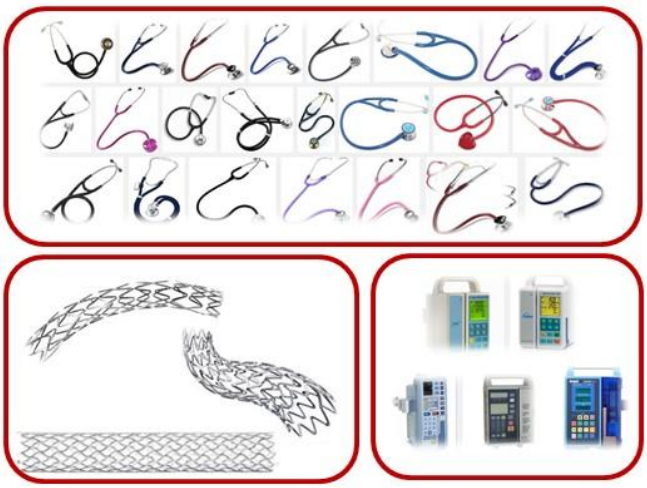
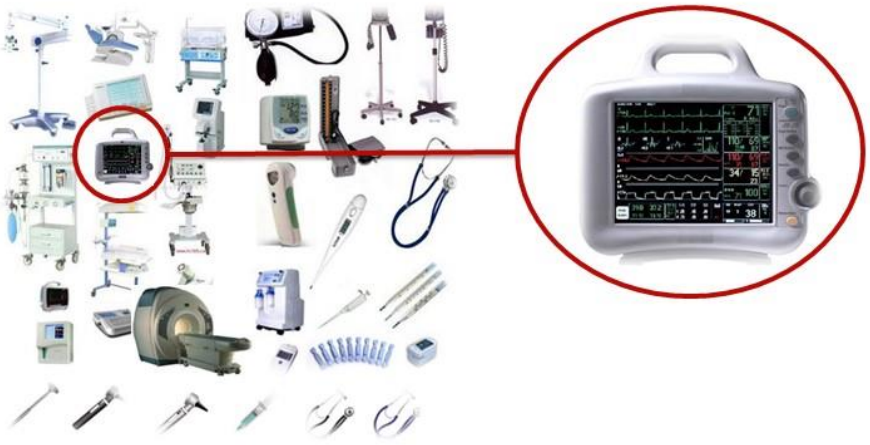


GMDN

Device Group



GMDN

Define the group

GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

GMDN

GMDN Term Definition:

A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

Intended use

Technology

Important attributes

e.g.,
Sterility
Use frequency
Power source

GMDN

Give the group a name

GMDN Term Name **Electrocardiographic monitor**

GMDN Term Definition:
A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

GMDN

Give the group a code

GMDN Code: **35195**
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition: A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

GMDN

GMDN Term

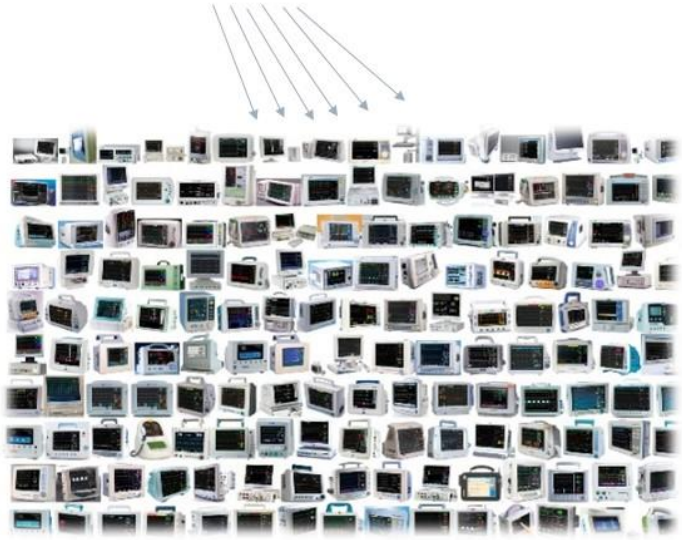
GMDN Code: 35195
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition:
A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG)…

GMDN

Device group = GMDN Term

GMDN

But all Electrocardiographic monitors have a different DI



GMDN

Collective Terms

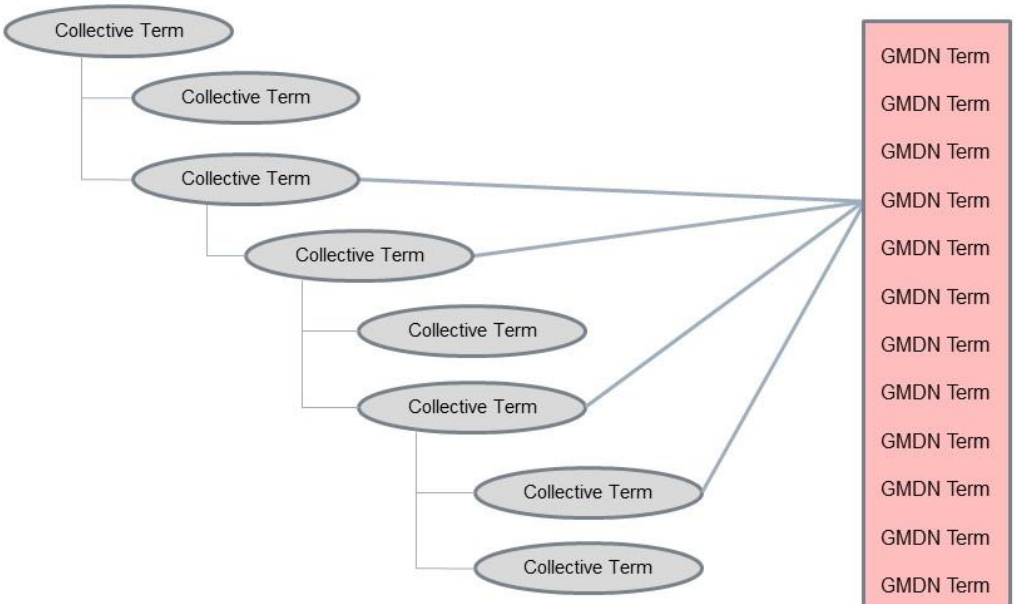
- GMDN uses **Collective Terms (CT's)** to group/organize related Preferred terms:
  - By clinical application (e.g., cardiovascular devices)
  - By name (e.g., prosthesis, scissors, catheter)
  - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)

- A hierarchical categorisation …

GMDN

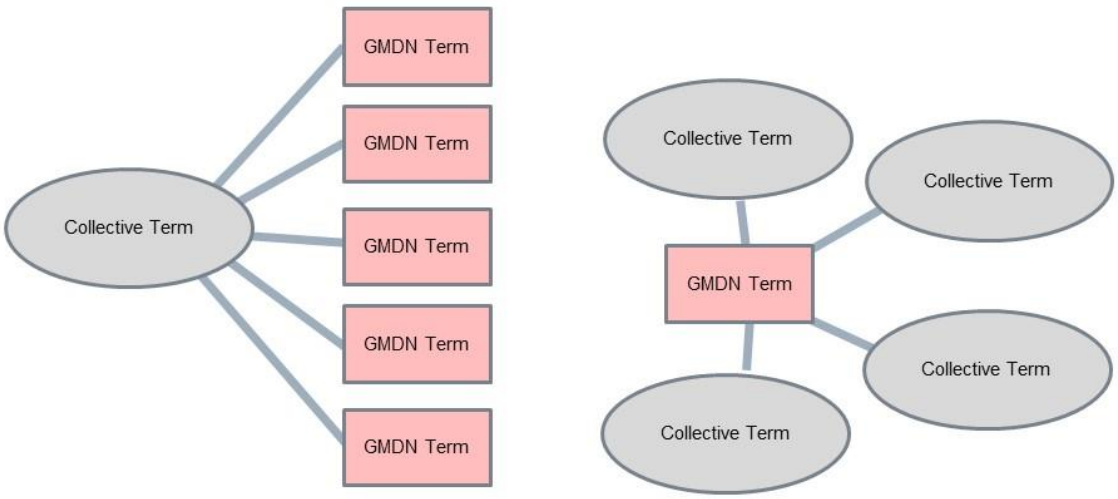
Hierarchical classification
Collective Terms

Nomenclature
GMDN terms



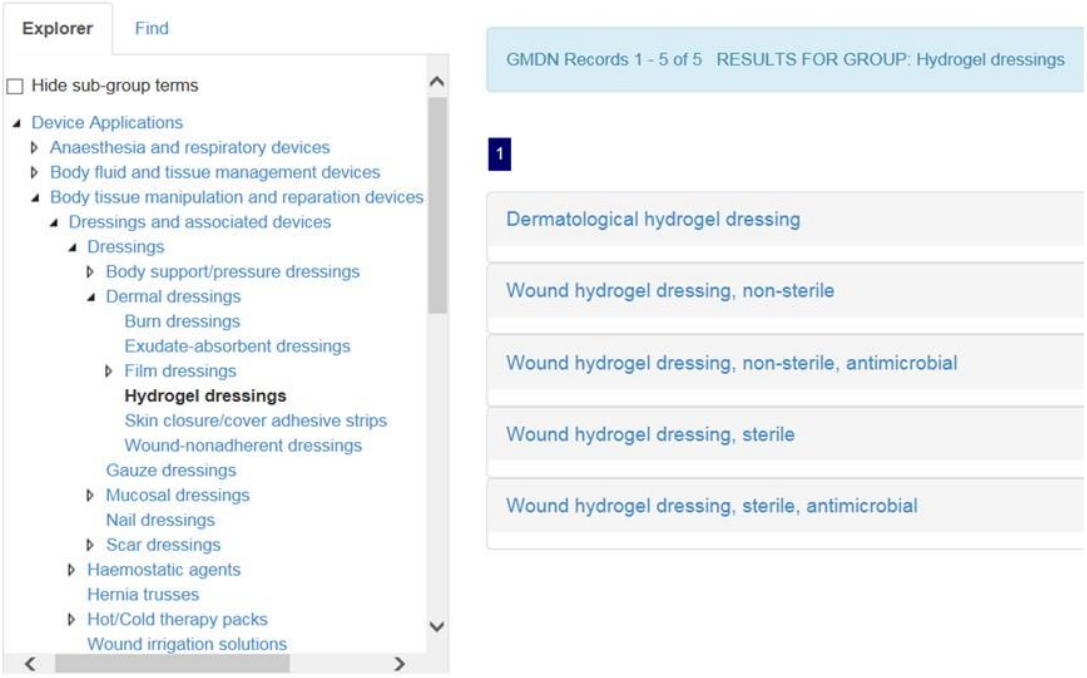
GMDN

CT relationships

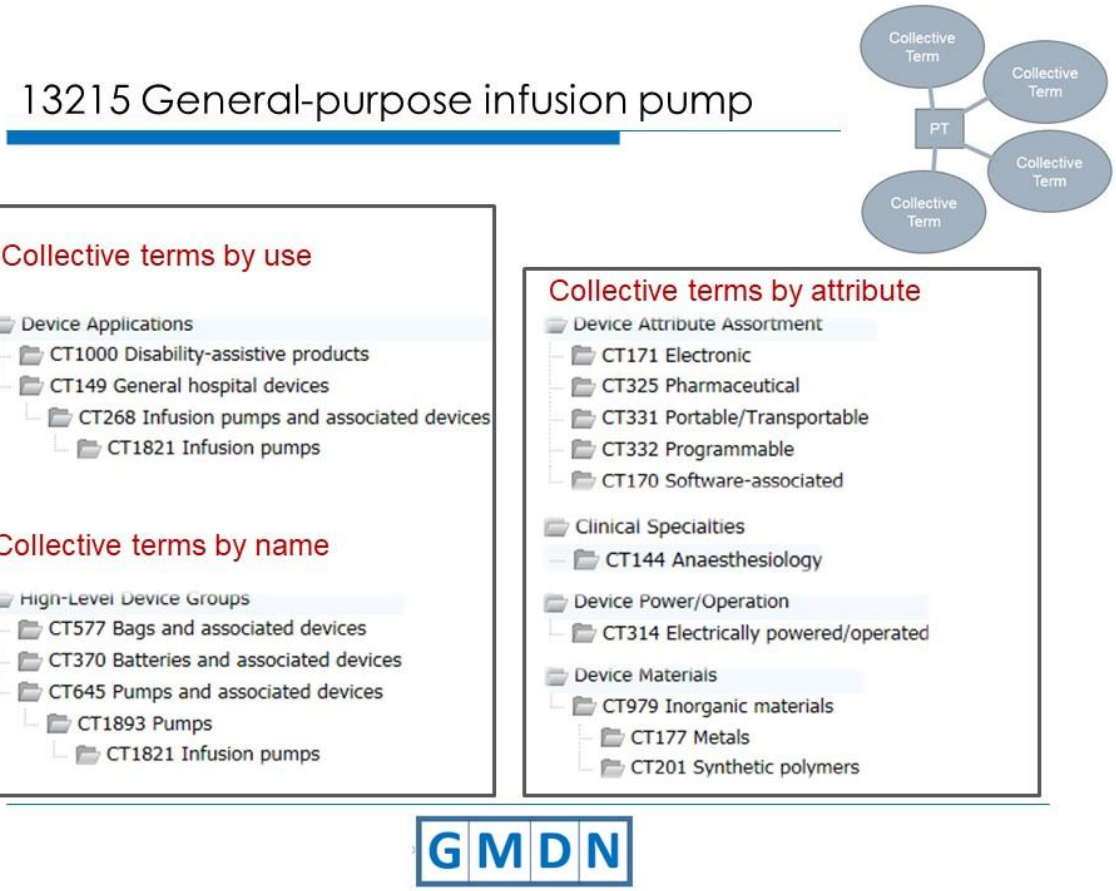


GMDN

SAMED
advancing patient care through MedTech



GMDN



GMDN

SAMED
advancing patient care through MedTech

GMDN Uses

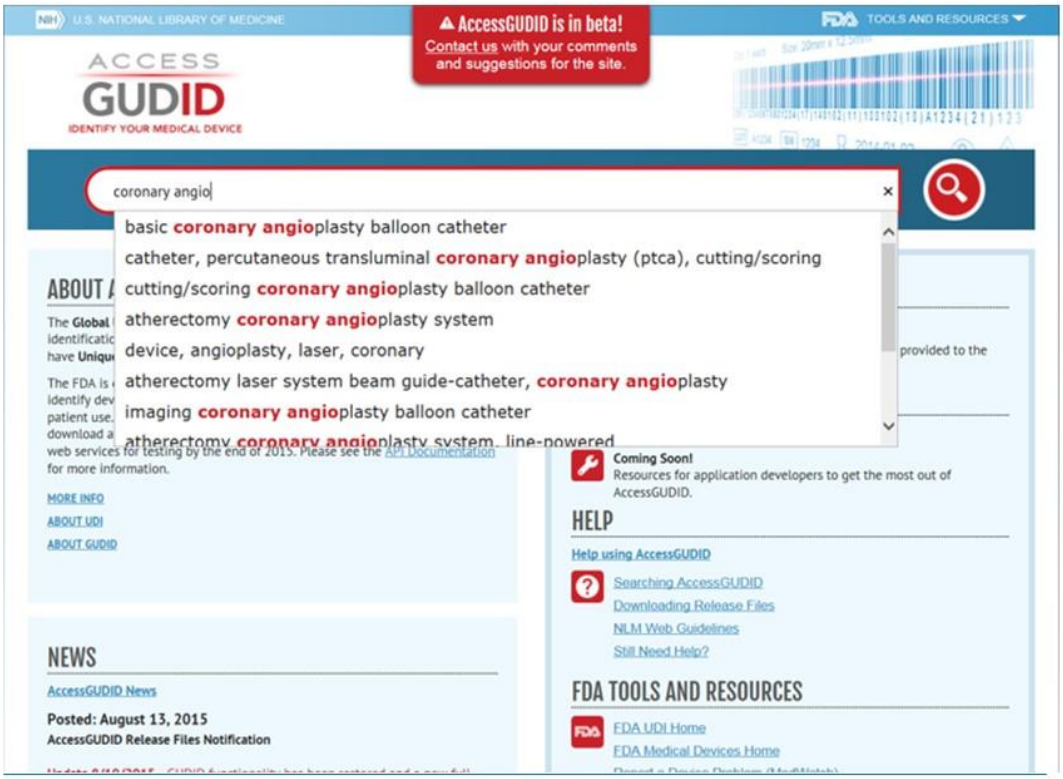
- Used by:
  - 70 national Medical Device Regulators
  - 4000+ Manufacturers worldwide
- US FDA implementation of UDI Rule
  - All medical devices sold in the US will need a GMDN code
- European Commission only use GMDN
  - New MD regulation due 2017 (UDI Europe)
- Regional Trade Associations (EUCOMED/ EDMA/ ADVAMED/ GMTA) recommend GMDN
- Complies with ISO15225

GMDN

GUDID

- US FDA UDI
- Database = GUDID
  - Mandatory field on record submission

GMDN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Contact us with your comments and suggestions for the site.
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ACCESS GUDID
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catheter, percutaneous transluminal coronary angioplasty (ptca), cutting/scoring
cutting/scoring coronary angioplasty balloon catheter
atherectomy coronary angioplasty system
device, angioplasty, laser, coronary
atherectomy laser system beam guide-catheter, coronary angioplasty
imaging coronary angioplasty balloon catheter
atherectomy coronary angioplasty system, line-powered
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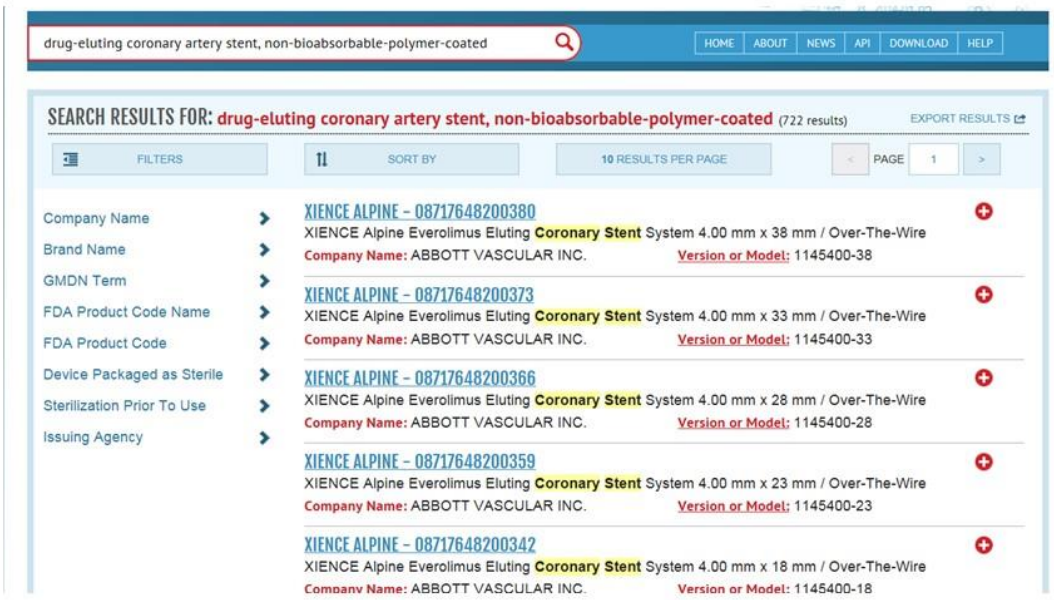

drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated
HOME
ABOUT
NEWS
API
DOWNLOAD
HELP
SEARCH RESULTS FOR: drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated (722 results)
EXPORT RESULTS
FILTERS
SORT BY
10 RESULTS PER PAGE
PAGE 1
Company Name
Brand Name
GMDN Term
FDA Product Code Name
FDA Product Code
Device Packaged as Sterile
Sterilization Prior To Use
Issuing Agency
XIENCE ALPINE - 08717648200380
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 38 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-38
XIENCE ALPINE - 08717648200373
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 33 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-33
XIENCE ALPINE - 08717648200366
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 28 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-28
XIENCE ALPINE - 08717648200359
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 23 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-23
XIENCE ALPINE - 08717648200342
XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 18 mm / Over-The-Wire
Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-18

UDI November 2016

- DI records: 1,140,006
- Unique GMDN codes: 7,114
  (Active GMDN = 7,035)
- Therefore ratio = 1:160

- Active implantable device records:
  2813
- Non-active implantable device records:
  524,094
- IVD device records:
  24,817

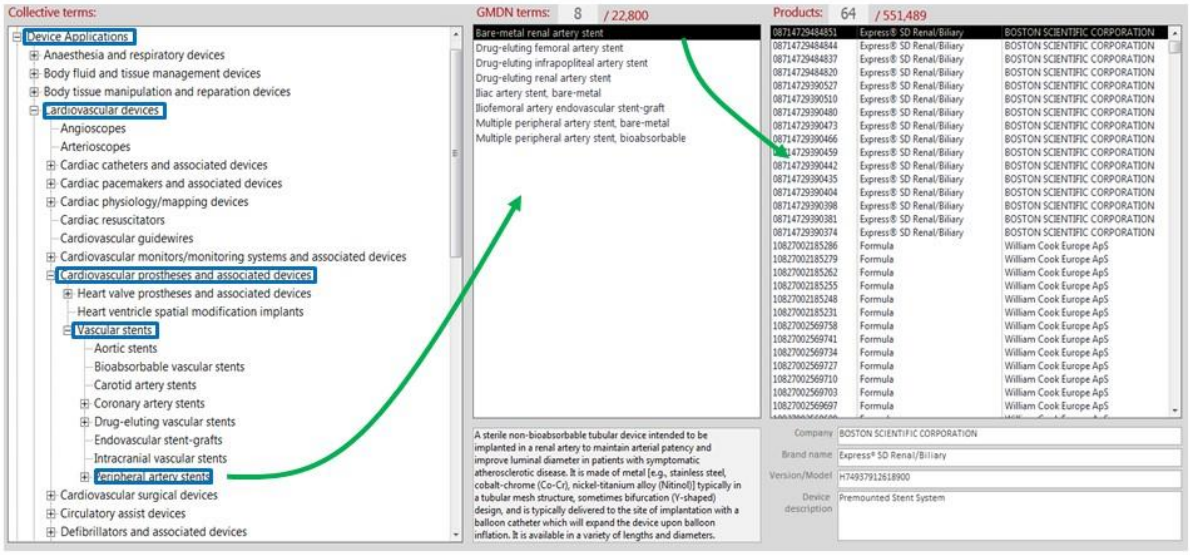
GMDN

GMDN Agency working with the FDA

- Leverage of UDI data for device registries
- Started with "RAPID project" (Pilot study MDEpiNet)
  - Trial project for peripheral vascular intervention (PVI) registry
  - Focus on peripheral stents
- FDA have now created a "Learning UDI Community" initiative with a focus on GMDN led device categorisation

Helping to improve GMDN definitions and user assignment of terms.

GMDN



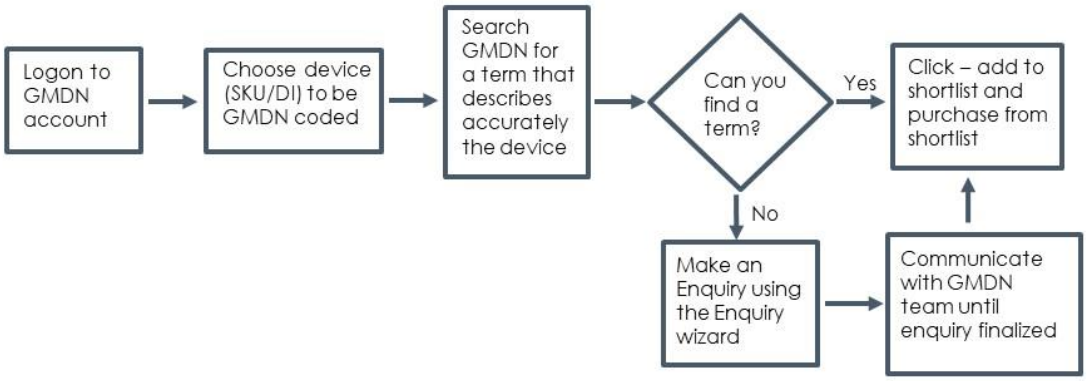
GMDN

GMDN Website

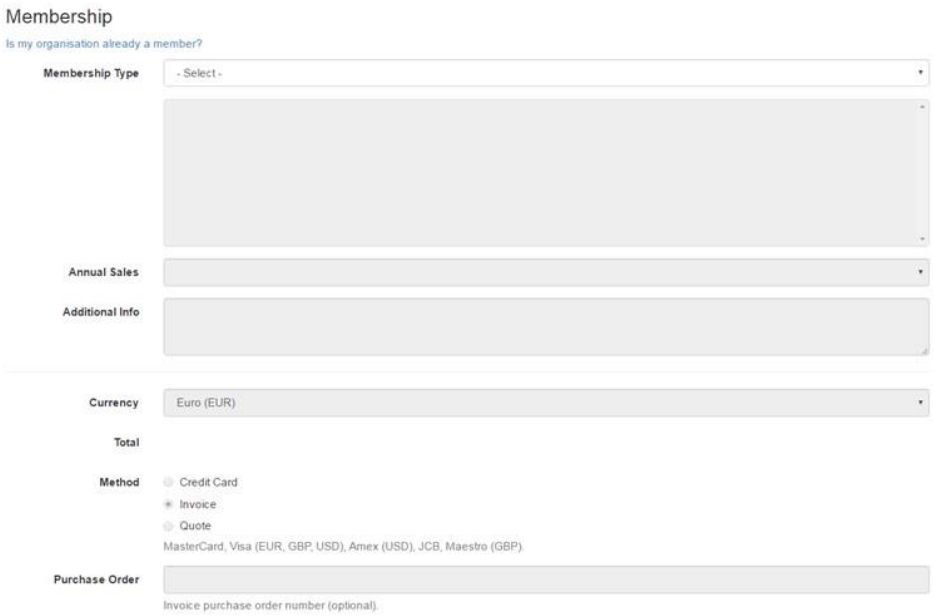
- Membership
- Search
- Explorer
- My Shortlist
- My Terms
- Enquiry

GMDN

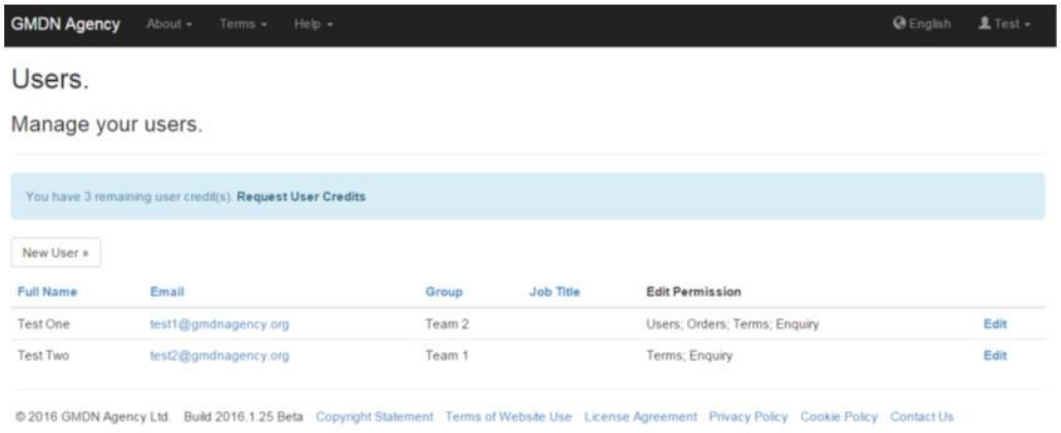
The Process for Manufacturer members



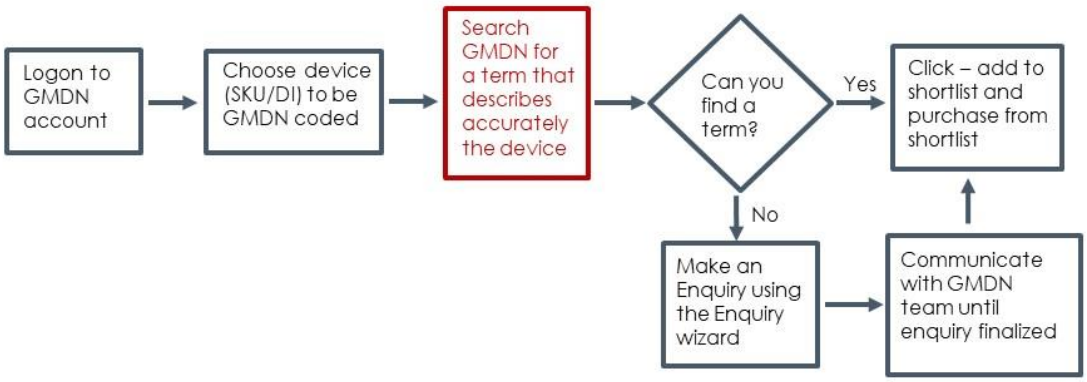
GMDN Website – Membership



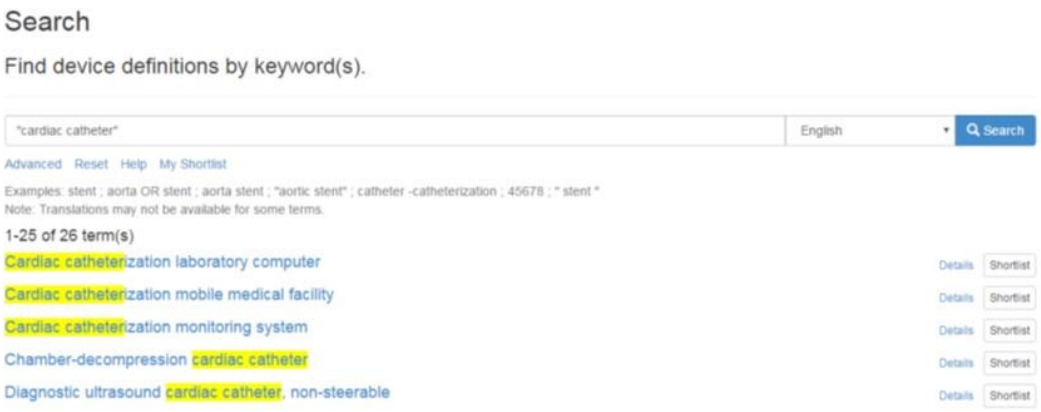
GMDN Website – User Management



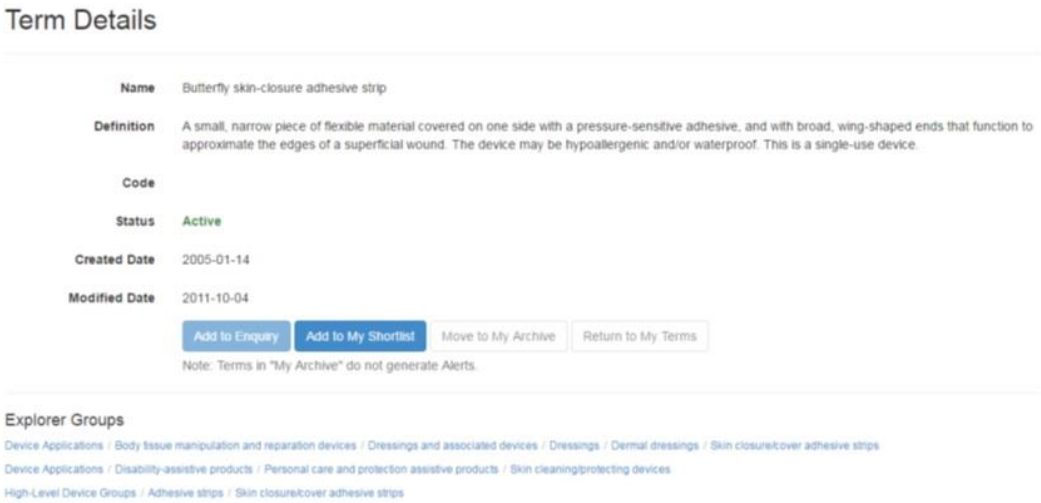
The Process for Manufacturer members



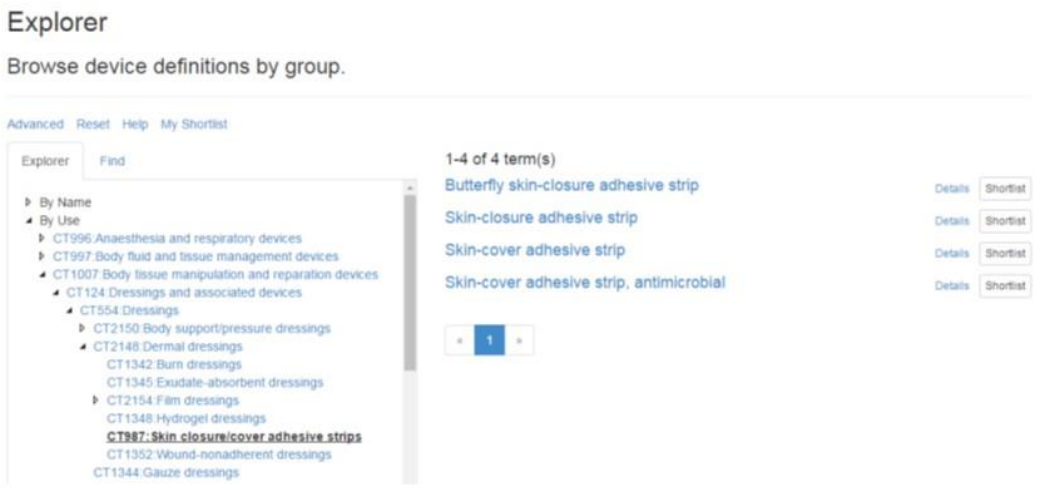
GMDN Website – Search 1



GMDN Website – Search 2



GMDN Website – Explorer



GMDN

Golden rule

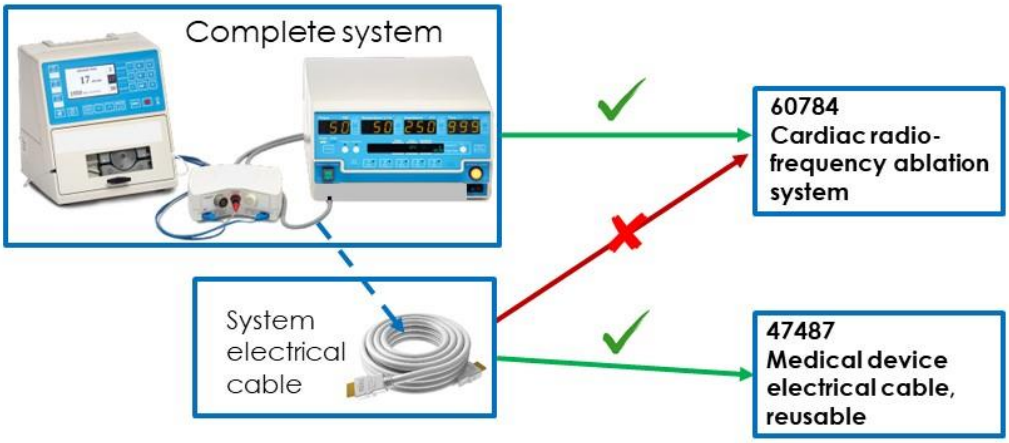
Every device (that is placed on the market separately) should be assigned to a single GMDN term that represents that device explicitly

GMDN

Common mistake 1

A GMDN term for a system term applied to a component of the system

Example:

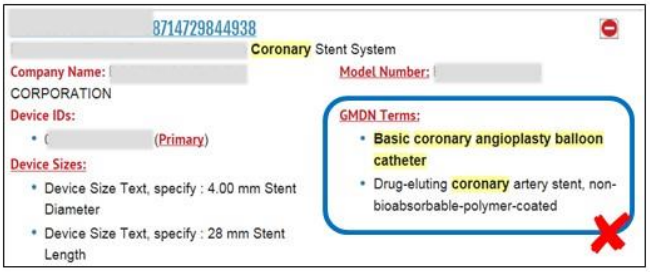


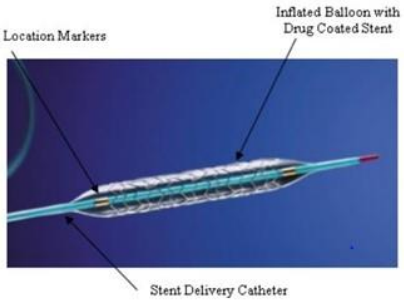
GMDN

Common mistake 2

Multiple terms assigned to a device (often with kits, systems or implant sets)

Example (in GUDID):

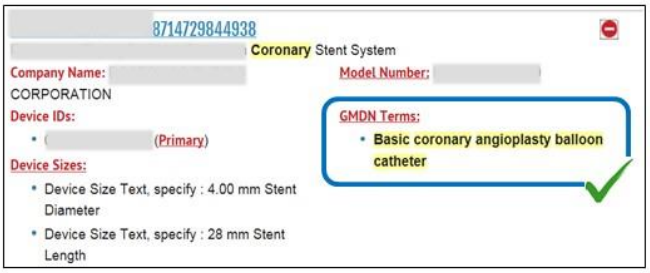




GMDN

Common mistake 2

Multiple terms assigned to a device (often with kits, systems or implant sets)

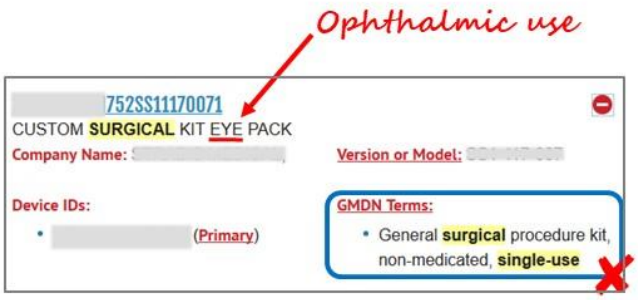


56284
Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated
A sterile non-bioabsorbable metal tubular mesh structure covered with a non-bioabsorbable polymer and a drug coating that is designed to be implanted, via a delivery catheter, into a coronary artery (or saphenous vein graft) to maintain its patency typically in a patient with symptomatic atherosclerotic heart disease. The drug coating is slowly released and intended to inhibit restenosis by reducing vessel smooth muscle cell proliferation. **Disposable devices associated with implantation may be included.**

GMDN

Common mistake 3

Judging the term by the name without review of the definition

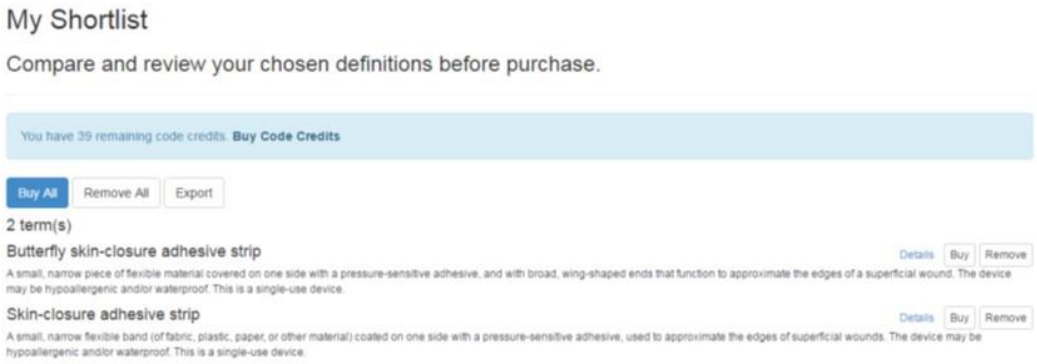


33961
General surgical procedure kit, non-medicated, single-use
A general-purpose collection of various sterile surgical instruments, dressings, and materials **intended to be used to assist a range of surgical procedures across multiple clinical specialities.** It does not contain pharmaceuticals. This is a single-use device.

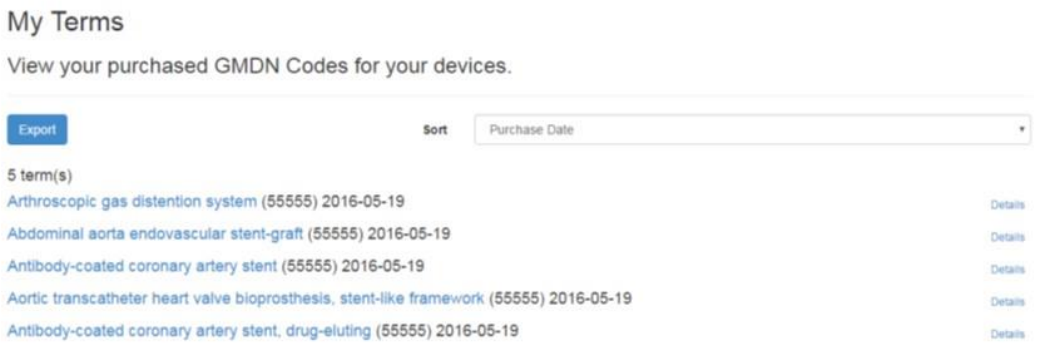
Is this term more appropriate?
Ophthalmic surgical procedure kit, non-medicated, single-use

GMDN

GMDN Website – Shortlist



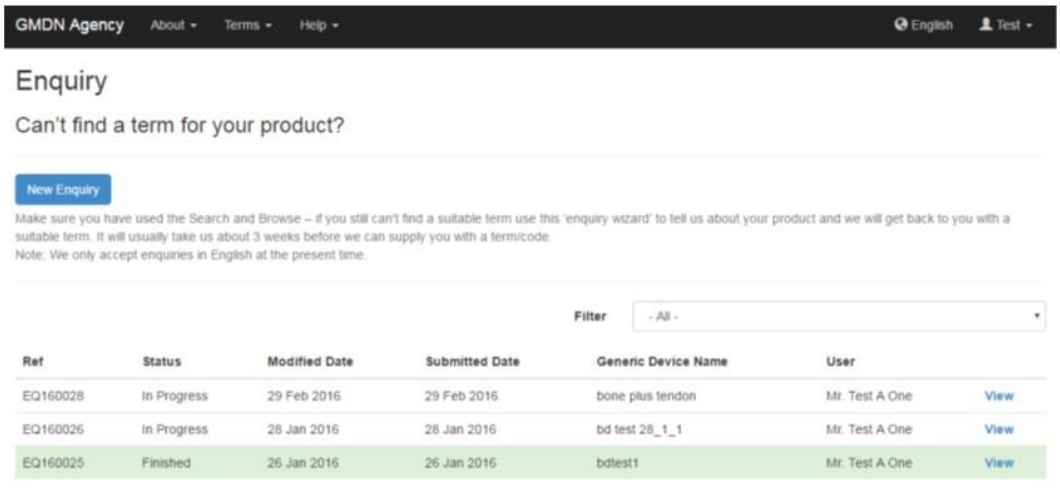
GMDN Website – My Terms



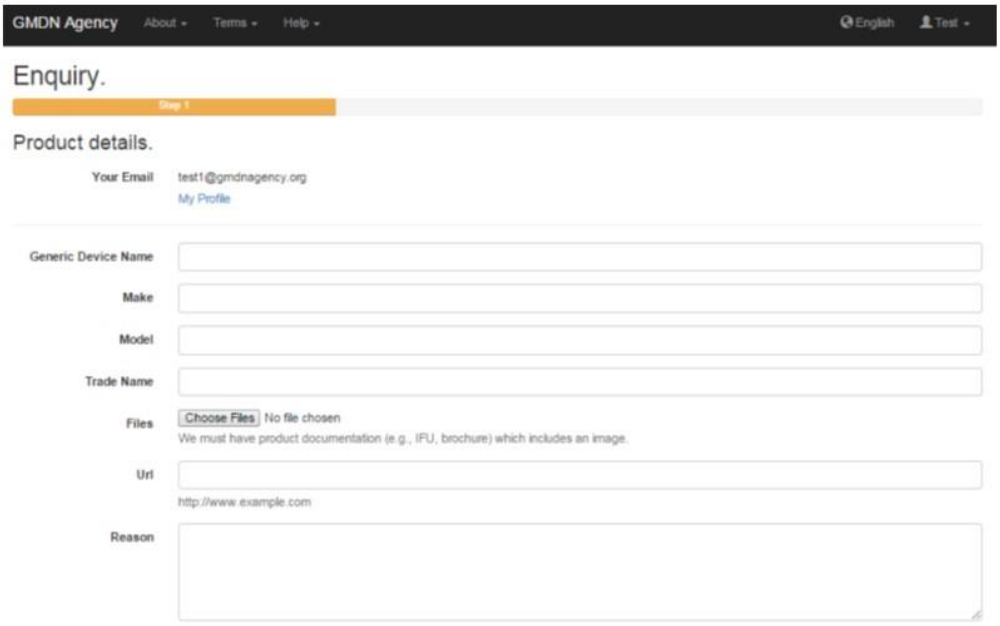
GMDN Website - Enquiry

- Search first – if cant find suitable term use Enquiry.
- Enquiry is the only way to get help from the GMDN Agency for assigning Terms to products. The outcome will be:
  - An appropriate existing Term.
  - Modification of an existing Term to include the new product's characteristics.
  - A new GMDN Term is created.

Enquiry - list



Enquiry - step 1

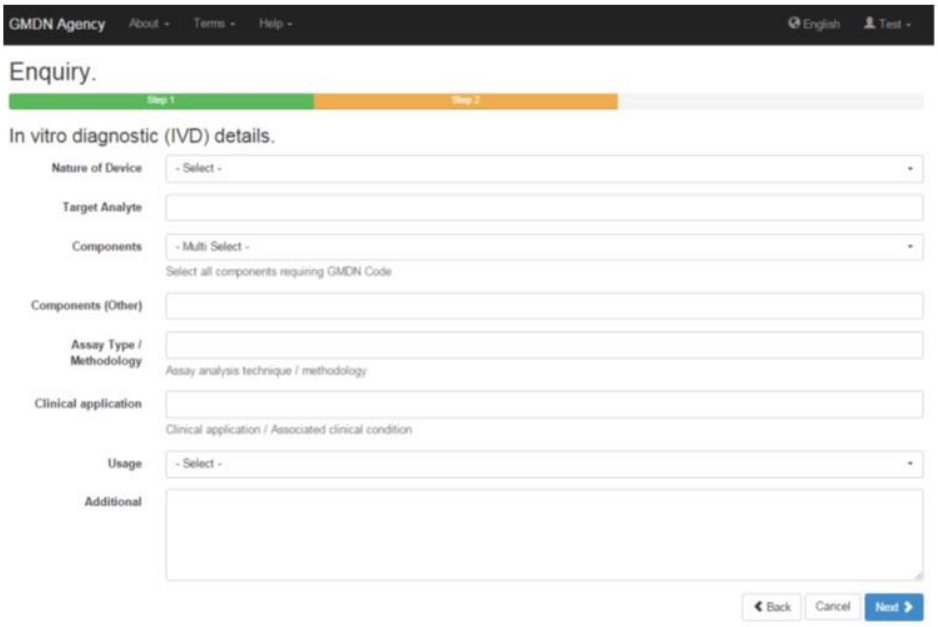


Enquiry - choice

Enquiry - software

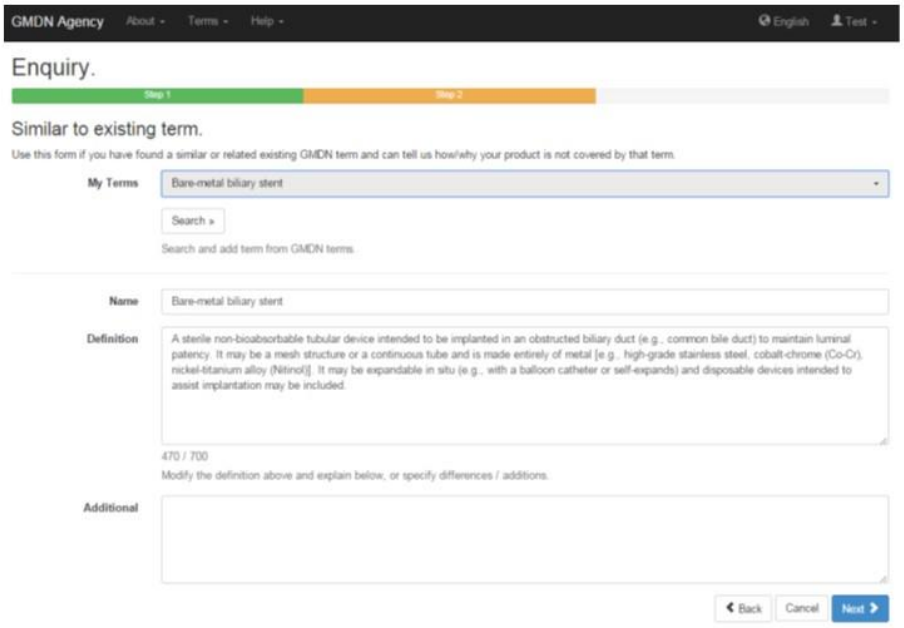
GMDN

Enquiry - IVD

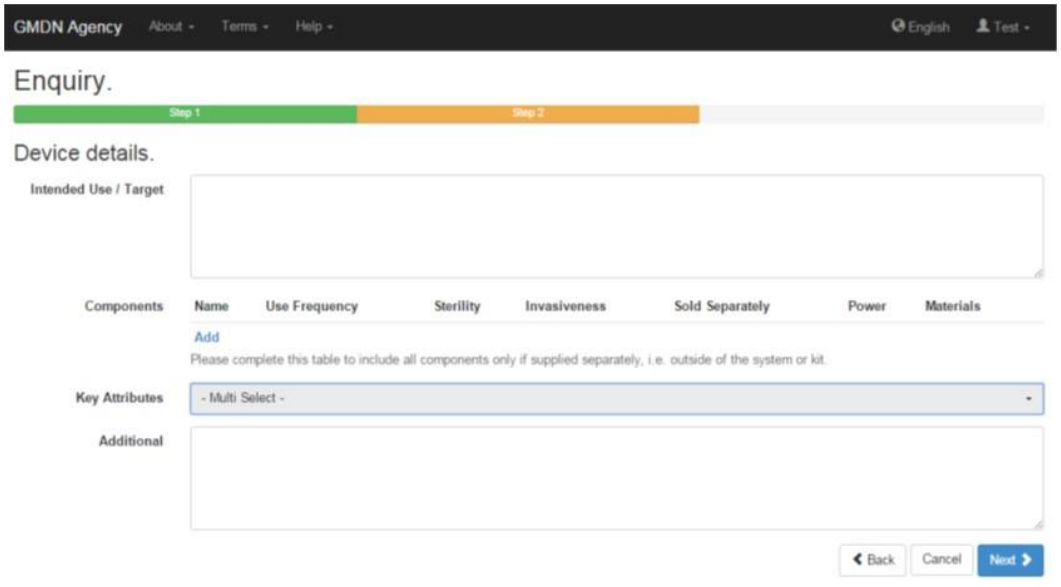


GMDN

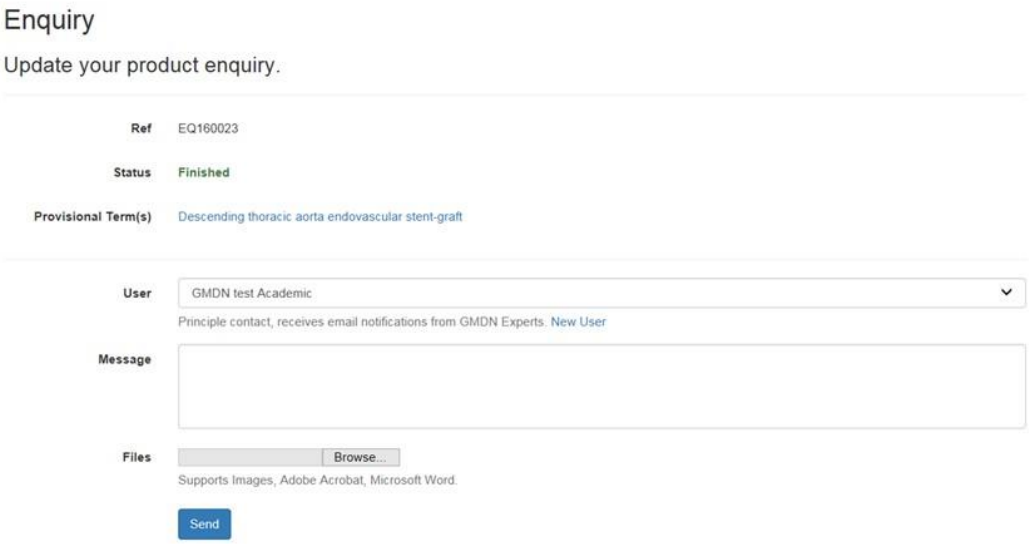
Enquiry – similar term



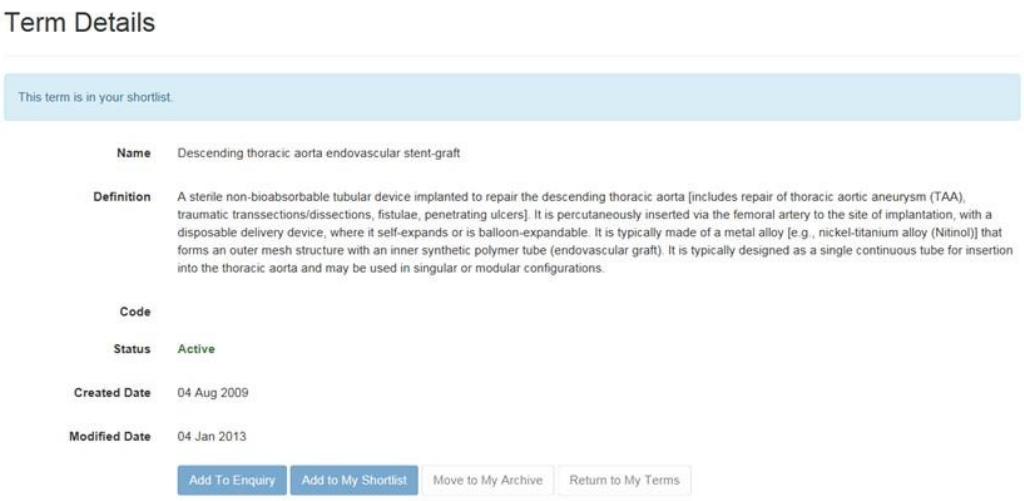
Enquiry - details



Enquiry - messaging



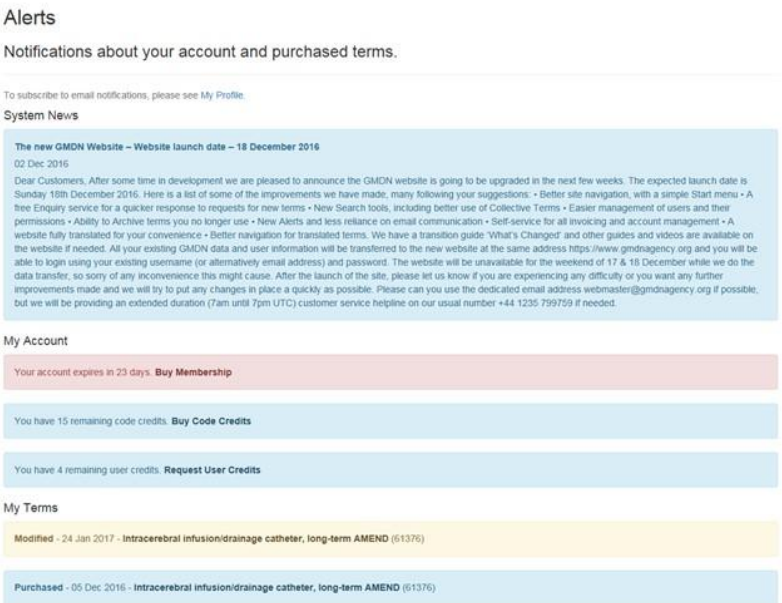
Enquiry – purchase new term



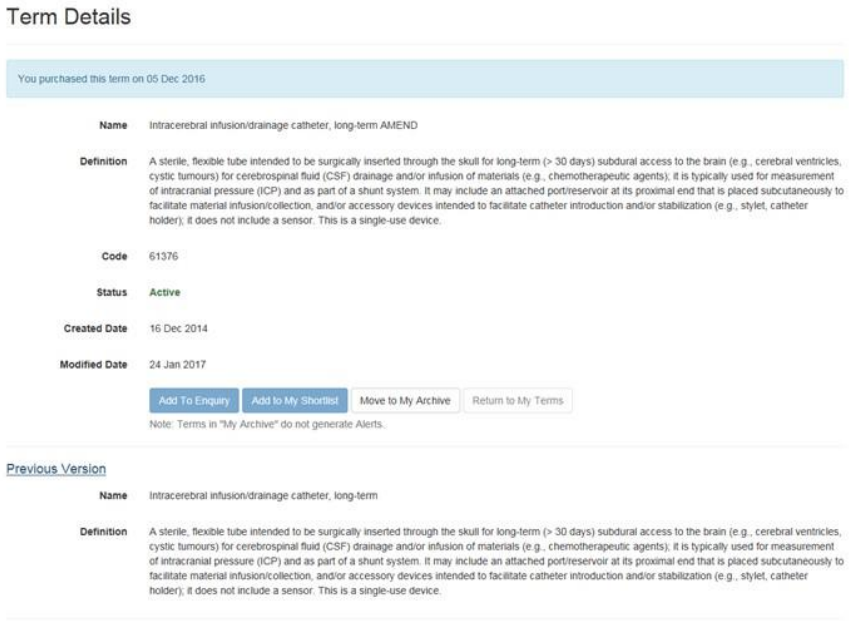
Changes to GMDN data

- Develop new terms (average 2-3 day)
- We only modify existing Terms (average 1-2 day)
  - To increase the scope / improve the definitions
- We obsolete Terms (average 10/m or 0.5% per year)
  - To remove ambiguity / term overlap
- GMDN is dynamic and current to keep up with innovation
- Members are notified about changes

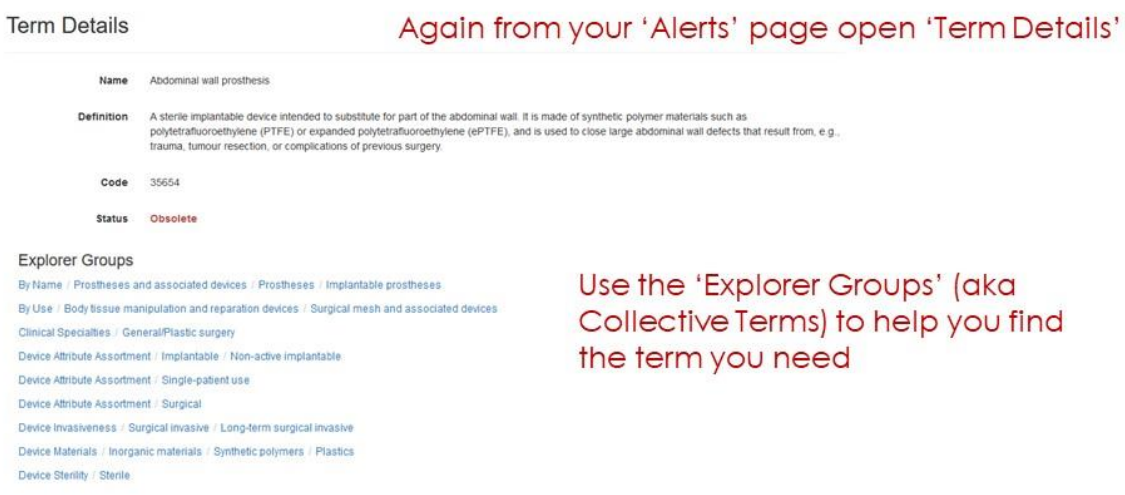
Term details - amendments



Term details - amendments



My term has been made obsolete



How should you manage GMDN Term changes?

- Who needs to receive notifications? (update your account)
- How is this communicated internally?
- GMDN is a data element in the DI record that can be edited after the Grace Period.
- Labelers are required (per UDI Rule) to keep their device information current and correct with any data that may have changed.

GMDN

Non-regulatory uses

- Registries
- Hospitals
- Clinical records

GMDN

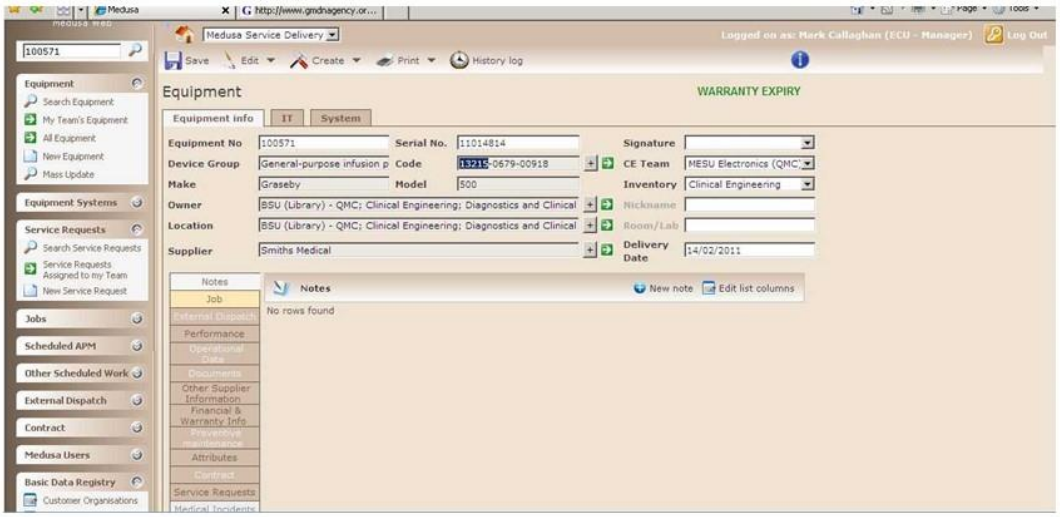
GMDN in Hospitals

- **Asset Management**
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes
- **Inventory Control**
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control
- Replace your existing inventory classification with an externally managed globally recognized nomenclature

GMDN

Equipment Commissioning

Nottingham University Hospitals NHS Trust



GMDN

GMDN – Snomed link

- UDI database
- GMDN

- Linkage table

- Electronic medical record
- Snomed

GMDN

GMDN is improving communication

- GMDN is now the global language

GMDN