



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

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 Khanyisile.Nkuku@sahpra.org.za
MD Clinical Trials and Section 21 RUO	Khanyisile Nkuku	012 501 0473/ 081 854 7109 Khanyisile.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)

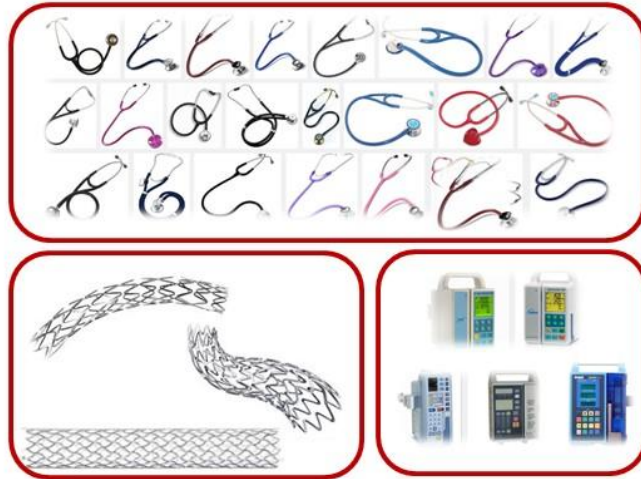
Dr Barry Daniels
Technical Lead
GMDN Agency



Get from this:



To this ?



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



Collective Terms

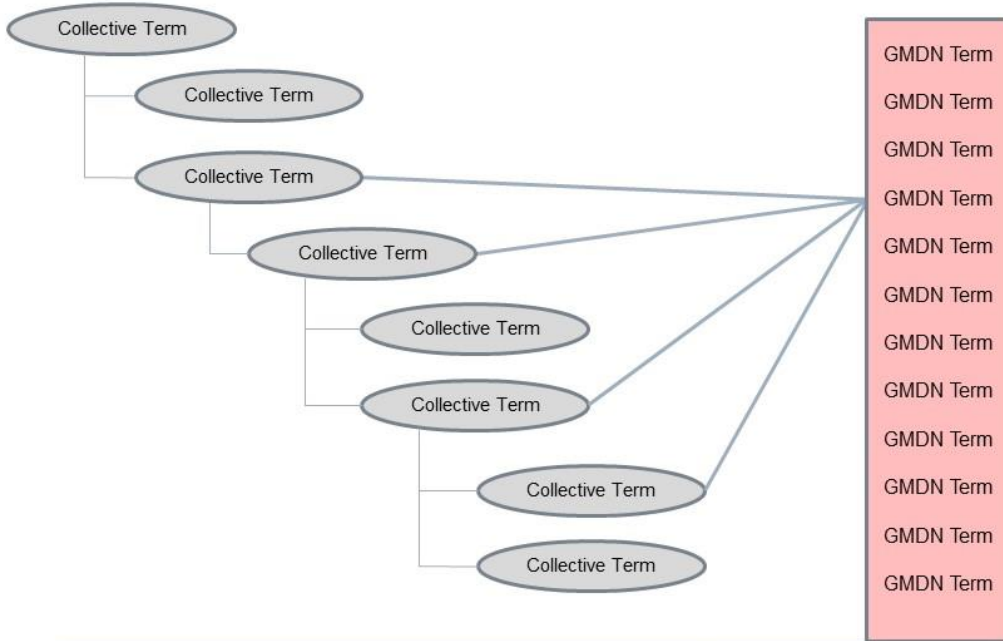
- GMDN uses **Collective Terms (CT's)** to group/organize related Preferred terms:
 - By clinical application (e.g., cardiovascular devices)
 - By name (e.g., prosthesis, scissors, catheter)
 - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)

- A hierarchical categorisation ...



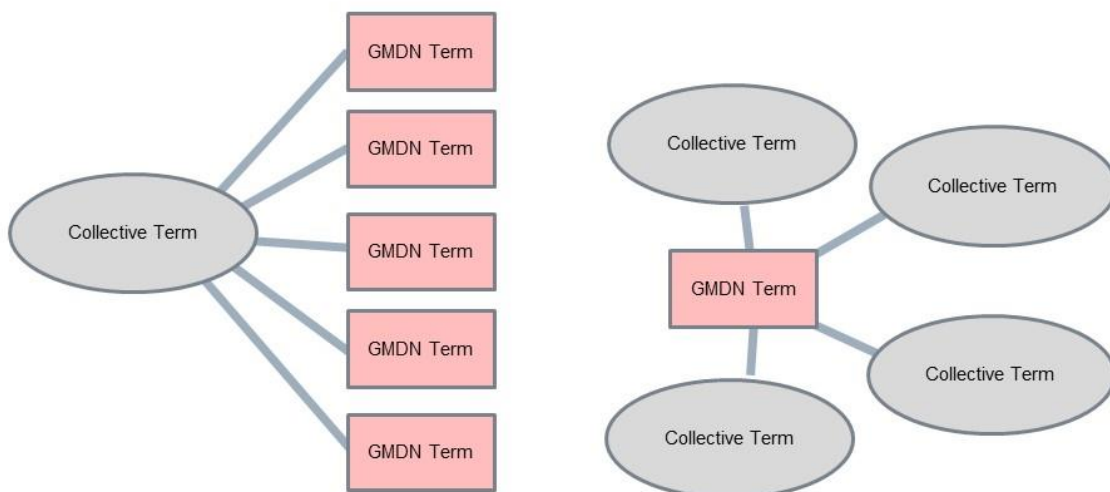
Hierarchical classification Collective Terms

Nomenclature GMDN terms



GMDN

CT relationships



GMDN

Explorer Find

Hide sub-group terms

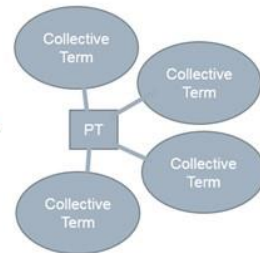
- ▲ Device Applications
 - Anaesthesia and respiratory devices
 - Body fluid and tissue management devices
 - ▲ Body tissue manipulation and reparation devices
 - ▲ Dressings and associated devices
 - ▲ Dressings
 - Body support/pressure dressings
 - ▲ Dermal dressings
 - Burn dressings
 - Exudate-absorbent dressings
 - Film dressings
 - Hydrogel dressings**
 - Skin closure/cover adhesive strips
 - Wound-nonadherent dressings
 - Gauze dressings
 - Mucosal dressings
 - Nail dressings
 - Scar dressings
 - Haemostatic agents
 - Hernia trusses
 - Hot/Cold therapy packs
 - Wound irrigation solutions

GMDN Records 1 - 5 of 5 RESULTS FOR GROUP: Hydrogel dressings

- 1
- Dermatological hydrogel dressing
 - Wound hydrogel dressing, non-sterile
 - Wound hydrogel dressing, non-sterile, antimicrobial
 - Wound hydrogel dressing, sterile
 - Wound hydrogel dressing, sterile, antimicrobial



13215 General-purpose infusion pump



Collective terms by use

- Device Applications
 - CT1000 Disability-assistive products
 - CT149 General hospital devices
 - CT268 Infusion pumps and associated devices
 - CT1821 Infusion pumps

Collective terms by name

- High-Level Device Groups
 - CT577 Bags and associated devices
 - CT370 Batteries and associated devices
 - CT645 Pumps and associated devices
 - CT1893 Pumps
 - CT1821 Infusion pumps

Collective terms by attribute

- Device Attribute Assortment
 - CT171 Electronic
 - CT325 Pharmaceutical
 - CT331 Portable/Transportable
 - CT332 Programmable
 - CT170 Software-associated
- Clinical Specialties
 - CT144 Anaesthesiology
- Device Power/Operation
 - CT314 Electrically powered/operated
- Device Materials
 - CT979 Inorganic materials
 - CT177 Metals
 - CT201 Synthetic polymers



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



GUDID

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



U.S. NATIONAL LIBRARY OF MEDICINE

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

AccessGUDID is in beta!
Contact us with your comments and suggestions for the site.

FDA TOOLS AND RESOURCES

coronary angioplasty

basic coronary angioplasty balloon catheter
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

ABOUT
The Global Identificatio have Uniqu
The FDA is identify dev patient use. download a web services for testing by the end of 2015. Please see the [API Documentation](#) for more information.
[MORE INFO](#)
[ABOUT UDI](#)
[ABOUT GUDID](#)

NEWS
[AccessGUDID News](#)
Posted: August 13, 2015
[AccessGUDID Release Files Notification](#)

Coming Soon!
Resources for application developers to get the most out of AccessGUDID.

HELP
Help using AccessGUDID
[Searching AccessGUDID](#)
[Downloading Release Files](#)
[NLM Web Guidelines](#)
[Still Need Help?](#)

FDA TOOLS AND RESOURCES
[FDA UDI Home](#)
[FDA Medical Devices Home](#)



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	XIENCE ALPINE - 08717648200380 XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 38 mm / Over-The-Wire	+
Brand Name	Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-38	
GMDN Term	XIENCE ALPINE - 08717648200373	+
FDA Product Code Name	XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 33 mm / Over-The-Wire	
FDA Product Code	Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-33	
Device Packaged as Sterile	XIENCE ALPINE - 08717648200366	+
Sterilization Prior To Use	XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 28 mm / Over-The-Wire	
Issuing Agency	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 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.



Collective terms: GMDN terms: 8 / 22,800 Products: 64 / 551,489

Device Applications

- [-] Anaesthesia and respiratory devices
- [-] Body fluid and tissue management devices
- [-] Body tissue manipulation and reparation devices
- [-] **Cardiovascular devices**
 - [-] Angioscopes
 - [-] Arterioscopes
 - [-] Cardiac catheters and associated devices
 - [-] Cardiac pacemakers and associated devices
 - [-] Cardiac physiology/mapping devices
 - [-] Cardiac resuscitators
 - [-] Cardiovascular guidewires
 - [-] Cardiovascular monitors/monitoring systems and associated devices
 - [-] **Cardiovascular prostheses and associated devices**
 - [-] Heart valve prostheses and associated devices
 - [-] Heart ventricle spatial modification implants
 - [-] **Vascular stents**
 - [-] Aortic stents
 - [-] Bioabsorbable vascular stents
 - [-] Carotid artery stents
 - [-] Coronary artery stents
 - [-] Drug-eluting vascular stents
 - [-] Endovascular stent-grafts
 - [-] Intracranial vascular stents
 - [-] **Peripheral artery stents**
- [-] Cardiovascular surgical devices
- [-] Circulatory assist devices
- [-] Defibrillators and associated devices

GMDN terms	Express	SD	Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Bare-metal renal artery stent	0871472944831	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Drug-eluting femoral artery stent	0871472944837	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Drug-eluting infrapopliteal artery stent	0871472944820	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Drug-eluting renal artery stent	08714729390527	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Iliac artery stent, bare-metal	08714729390510	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Iliofemoral artery endovascular stent-graft	08714729390480	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Multiple peripheral artery stent, bare-metal	08714729390473	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
Multiple peripheral artery stent, bioabsorbable	08714729390466	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390459	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390442	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390435	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390404	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390398	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390381	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	08714729390374	Express	SD Renal/Biliary	BOSTON SCIENTIFIC CORPORATION
	10827002185286	Formula		William Cook Europe ApS
	10827002185279	Formula		William Cook Europe ApS
	10827002185262	Formula		William Cook Europe ApS
	10827002185255	Formula		William Cook Europe ApS
	10827002185248	Formula		William Cook Europe ApS
	10827002185231	Formula		William Cook Europe ApS
	10827002569758	Formula		William Cook Europe ApS
	10827002569741	Formula		William Cook Europe ApS
	10827002569734	Formula		William Cook Europe ApS
	10827002569727	Formula		William Cook Europe ApS
	10827002569710	Formula		William Cook Europe ApS
	10827002569703	Formula		William Cook Europe ApS
	10827002569697	Formula		William Cook Europe ApS

A sterile non-bioabsorbable tubular device intended to be implanted in a renal artery to maintain arterial patency and improve luminal diameter in patients with symptomatic atherosclerotic disease. It is made of metal (e.g., stainless steel, cobalt-chrome (Co-Cr), nickel-titanium alloy (Nitinol)) typically in a tubular mesh structure, sometimes bifurcation (Y-shaped) design, and is typically delivered to the site of implantation with a balloon catheter which will expand the device upon balloon inflation. It is available in a variety of lengths and diameters.

Company	BOSTON SCIENTIFIC CORPORATION
Brand name	Express® SD Renal/Biliary
Version/Model	H74937912618900
Device description	Premounted Stent System

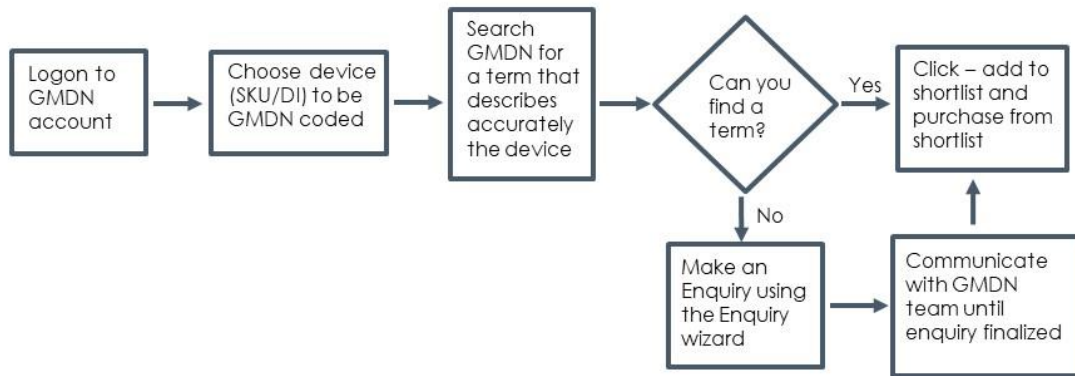


GMDN Website

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



The Process for Manufacturer members



GMDN Website – Membership

Membership

Is my organisation already a member?

Membership Type

Annual Sales

Additional Info

Currency

Total

Method Credit Card Invoice Quote
MasterCard, Visa (EUR, GBP, USD), Amex (USD), JCB, Maestro (GBP)

Purchase Order
Invoice purchase order number (optional)



GMDN Website – User Management

GMDN Agency About Terms Help English Test

Users.

Manage your users.

You have 3 remaining user credit(s). [Request User Credits](#)

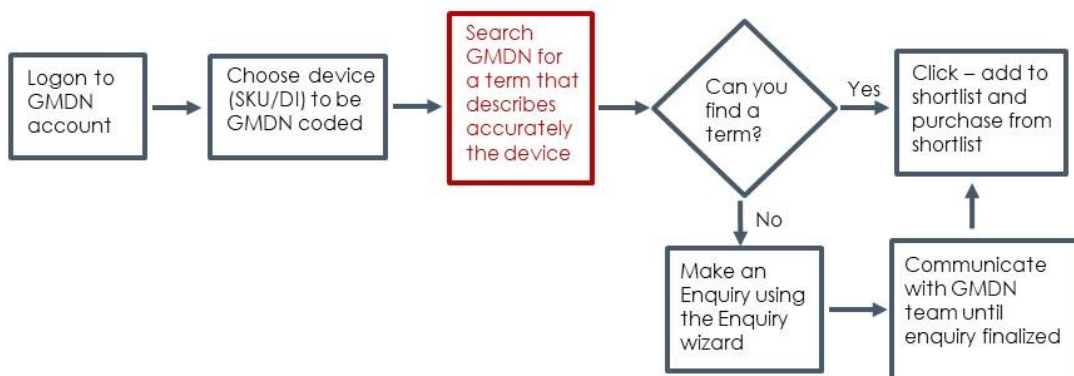
New User »

Full Name	Email	Group	Job Title	Edit Permission
Test One	test1@gmdnagency.org	Team 2		Users; Orders; Terms; Enquiry Edit
Test Two	test2@gmdnagency.org	Team 1		Terms; Enquiry Edit

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The Process for Manufacturer members



GMDN Website – Search 1

Search

Find device definitions by keyword(s).

English

[Advanced](#) [Reset](#) [Help](#) [My Shortlist](#)

Examples: stent ; aorta OR stent ; aorta stent ; "aortic stent" ; catheter -catheterization ; 45678 ; " stent "
Note: Translations may not be available for some terms.

1-25 of 26 term(s)

[Cardiac catheterization laboratory computer](#)

[Details](#) [Shortlist](#)

[Cardiac catheterization mobile medical facility](#)

[Details](#) [Shortlist](#)

[Cardiac catheterization monitoring system](#)

[Details](#) [Shortlist](#)

Chamber-decompression [cardiac catheter](#)

[Details](#) [Shortlist](#)

Diagnostic ultrasound [cardiac catheter](#), non-steerable

[Details](#) [Shortlist](#)



GMDN Website – Search 2

Term Details

Name	Butterfly skin-closure adhesive strip
Definition	A small, narrow piece of flexible material covered on one side with a pressure-sensitive adhesive, and with broad, wing-shaped ends that function to approximate the edges of a superficial wound. The device may be hypoallergenic and/or waterproof. This is a single-use device.
Code	
Status	Active
Created Date	2005-01-14
Modified Date	2011-10-04

[Add to Enquiry](#) [Add to My Shortlist](#) [Move to My Archive](#) [Return to My Terms](#)

Note: Terms in "My Archive" do not generate Alerts.

Explorer Groups

[Device Applications / Body tissue manipulation and reparation devices / Dressings and associated devices / Dressings / Dermal dressings / Skin closure/cover adhesive strips](#)
[Device Applications / Disability-assistive products / Personal care and protection assistive products / Skin cleaning/protecting devices](#)
[High-Level Device Groups / Adhesive strips / Skin closure/cover adhesive strips](#)



GMDN Website – Explorer

Explorer

Browse device definitions by group.

Advanced Reset Help My Shortlist

Explorer Find

- By Name
- By Use
 - CT996 Anaesthesia and respiratory devices
 - CT997 Body fluid and tissue management devices
 - CT1007 Body tissue manipulation and reparation devices
 - CT124 Dressings and associated devices
 - CT554 Dressings
 - CT2150 Body support/pressure dressings
 - CT2148 Dermal dressings
 - CT1342 Burn dressings
 - CT1345 Exudate-absorbent dressings
 - CT2154 Film dressings
 - CT1348 Hydrogel dressings
 - CT987: Skin closure/cover adhesive strips**
 - CT1352 Wound-nonadherent dressings
 - CT1344 Gauze dressings

1-4 of 4 term(s)

- Butterfly skin-closure adhesive strip
- Skin-closure adhesive strip
- Skin-cover adhesive strip
- Skin-cover adhesive strip, antimicrobial

1

Details Shortlist

Details Shortlist

Details Shortlist

Details Shortlist



Golden rule

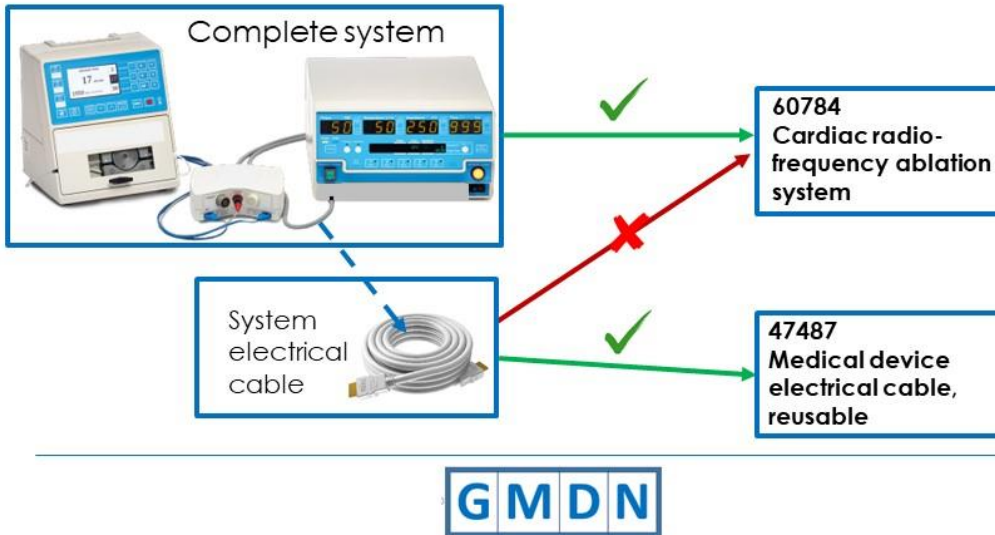
Every device (that is placed on the market separately) should be assigned to a single GMDN term that represents that device explicitly



Common mistake 1

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

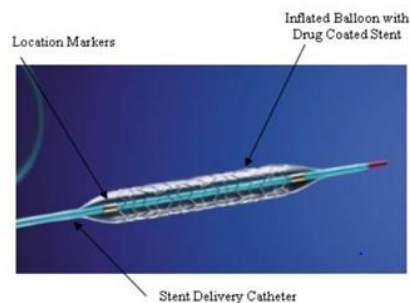
Example:



Common mistake 2

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

Example (in GUDID):



Common mistake 2

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

8714729844938
Coronary Stent System

Company Name: CORPORATION
Model Number:

Device IDs: (Primary)

Device Sizes:
• Device Size Text, specify : 4.00 mm Stent Diameter
• Device Size Text, specify : 28 mm Stent Length

GMDN Terms:
• Basic coronary angioplasty balloon catheter

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.**



Common mistake 3

Judging the term by the name without review of the definition

752SS11170071
CUSTOM SURGICAL KIT EYE PACK

Company Name: Version or Model:

Device IDs: (Primary)

GMDN Terms:
• General surgical procedure kit, non-medicated, single-use

Ophthalmic use

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 Website – Shortlist

My Shortlist

Compare and review your chosen definitions before purchase.

You have 39 remaining code credits. [Buy Code Credits](#)

[Buy All](#) [Remove All](#) [Export](#)

2 term(s)

Butterfly skin-closure adhesive strip

A small, narrow piece of flexible material covered on one side with a pressure-sensitive adhesive, and with broad, wing-shaped ends that function to approximate the edges of a superficial wound. The device may be hypoallergenic and/or waterproof. This is a single-use device.

[Details](#) [Buy](#) [Remove](#)

Skin-closure adhesive strip

A small, narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive, used to approximate the edges of superficial wounds. The device may be hypoallergenic and/or waterproof. This is a single-use device.

[Details](#) [Buy](#) [Remove](#)



GMDN Website – My Terms

My Terms

View your purchased GMDN Codes for your devices.

[Export](#)

Sort

Purchase Date

5 term(s)

[Arthroscopic gas distention system \(55555\) 2016-05-19](#)

[Details](#)

[Abdominal aorta endovascular stent-graft \(55555\) 2016-05-19](#)

[Details](#)

[Antibody-coated coronary artery stent \(55555\) 2016-05-19](#)

[Details](#)

[Aortic transcatheter heart valve bioprosthesis, stent-like framework \(55555\) 2016-05-19](#)

[Details](#)

[Antibody-coated coronary artery stent, drug-eluting \(55555\) 2016-05-19](#)

[Details](#)



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

GMDN Agency About Terms Help English Test

Enquiry

Can't find a term for your product?

[New Enquiry](#)

Make sure you have used the Search and Browse – if you still can't find a suitable term use this 'enquiry wizard' to tell us about your product and we will get back to you with a suitable term. It will usually take us about 3 weeks before we can supply you with a term/code.
Note: We only accept enquiries in English at the present time.

Filter: - All -

Ref	Status	Modified Date	Submitted Date	Generic Device Name	User	
EQ160028	In Progress	29 Feb 2016	29 Feb 2016	bone plus tendon	Mr. Test A One	View
EQ160026	In Progress	28 Jan 2016	28 Jan 2016	bd test 28_1_1	Mr. Test A One	View
EQ160025	Finished	26 Jan 2016	26 Jan 2016	bdtest1	Mr. Test A One	View



Enquiry - step 1

GMDN Agency About - Terms - Help - English Test -

Enquiry.

Step 1

Product details.

Your Email test1@gmdnagency.org
[My Profile](#)

Generic Device Name

Make

Model

Trade Name

Files No file chosen
We must have product documentation (e.g., IFU, brochure) which includes an image.

Url
http://www.example.com

Reason



Enquiry - choice

- Step 2**
- Software details
 - In vitro diagnostic (IVD) (not capital goods)
 - Similar to existing Term
 - Device details
- Please choose your enquiry type to proceed to the next step.



Enquiry - software

GMDN Agency [About](#) [Terms](#) [Help](#) English Test

Enquiry.

Step 1 Step 2

Software details.

Used For

Functionality

Technology

Platform

Features

Additional

[Back](#) [Cancel](#) [Next](#)



Enquiry - IVD

GMDN Agency [About](#) [Terms](#) [Help](#) English Test

Enquiry.

Step 1 Step 2

In vitro diagnostic (IVD) details.

Nature of Device

Target Analyte

Components
Select all components requiring GMDN Code

Components (Other)

Assay Type / Methodology
Assay analysis technique / methodology

Clinical application
Clinical application / Associated clinical condition

Usage

Additional

[Back](#) [Cancel](#) [Next](#)



Enquiry – similar term

GMDN Agency About Terms Help English Test

Enquiry.

Step 1 Step 2

Similar to existing term.
Use this form if you have found a similar or related existing GMDN term and can tell us how/why your product is not covered by that term.

My Terms Bare-metal biliary stent

Search >

Search and add term from GMDN terms.

Name Bare-metal biliary stent

Definition A sterile non-bioabsorbable tubular device intended to be implanted in an obstructed biliary duct (e.g., common bile duct) to maintain luminal patency. It may be a mesh structure or a continuous tube and is made entirely of metal (e.g., high-grade stainless steel, cobalt-chrome (Co-Cr), nickel-titanium alloy (Nitinol)). It may be expandable in situ (e.g., with a balloon catheter or self-expands) and disposable devices intended to assist implantation may be included.

470 / 700
Modify the definition above and explain below, or specify differences / additions.

Additional

Back Cancel Next



Enquiry - details

GMDN Agency About Terms Help English Test

Enquiry.

Step 1 Step 2

Device details.

Intended Use / Target

Components

Name	Use Frequency	Sterility	Invasiveness	Sold Separately	Power	Materials
Add						

Please complete this table to include all components only if supplied separately, i.e. outside of the system or kit.

Key Attributes - Multi Select -

Additional

Back Cancel Next



Enquiry - messaging

Enquiry

Update your product enquiry.

Ref	EQ160023
Status	Finished
Provisional Term(s)	Descending thoracic aorta endovascular stent-graft
User	GMDN test Academic <input type="button" value="v"/>
	Principle contact, receives email notifications from GMDN Experts. New User
Message	<input type="text"/>
Files	<input type="button" value="Browse..."/>
	Supports Images, Adobe Acrobat, Microsoft Word.
	<input type="button" value="Send"/>



Enquiry – purchase new term

Term Details

This term is in your shortlist.

Name	Descending thoracic aorta endovascular stent-graft
Definition	A sterile non-bioabsorbable tubular device implanted to repair the descending thoracic aorta [includes repair of thoracic aortic aneurysm (TAA), traumatic transections/dissections, fistulae, penetrating ulcers]. It is percutaneously inserted via the femoral artery to the site of implantation, with a disposable delivery device, where it self-expands or is balloon-expandable. It is typically made of a metal alloy [e.g., nickel-titanium alloy (Nitinol)] that forms an outer mesh structure with an inner synthetic polymer tube (endovascular graft). It is typically designed as a single continuous tube for insertion into the thoracic aorta and may be used in singular or modular configurations.
Code	
Status	Active
Created Date	04 Aug 2009
Modified Date	04 Jan 2013



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

Alerts

Notifications about your account and purchased terms.

To subscribe to email notifications, please see [My Profile](#).

System News

The new GMDN Website – Website launch date – 18 December 2016

02 Dec 2016

Dear Customers, After some time in development we are pleased to announce the GMDN website is going to be upgraded in the next few weeks. The expected launch date is Sunday 18th December 2016. Here is a list of some of the improvements we have made, many following your suggestions - Better site navigation, with a simple Start menu - A free Enquiry service for a quicker response to requests for new terms - New Search tools, including better use of Collective Terms - Easier management of users and their permissions - Ability to Archive terms you no longer use - New Alerts and less reliance on email communication - Self-service for all invoicing and account management - A website fully translated for your convenience - Better navigation for translated terms. We have a transition guide 'What's Changed' and other guides and videos are available on the website if needed. All your existing GMDN data and user information will be transferred to the new website at the same address <https://www.gmdnagency.org> and you will be able to login using your existing username (or alternatively email address) and password. The website will be unavailable for the weekend of 17 & 18 December while we do the data transfer, so sorry if any inconvenience this might cause. After the launch of the site, please let us know if you are experiencing any difficulty or you want any further improvements made and we will try to put any changes in place as quickly as possible. Please can you use the dedicated email address webmaster@gmdnagency.org if possible, but we will be providing an extended duration (7am until 7pm UTC) customer service helpline on our usual number +44 1235 799759 if needed.

My Account

Your account expires in 23 days. [Buy Membership](#)

You have 15 remaining code credits. [Buy Code Credits](#)

You have 4 remaining user credits. [Request User Credits](#)

My Terms

Modified - 24 Jan 2017 - Intracerebral infusion/drainage catheter, long-term AMEND (61376)

Purchased - 05 Dec 2016 - Intracerebral infusion/drainage catheter, long-term AMEND (61376)



Term details - amendments

Term Details

You purchased this term on 05 Dec 2016

Name Intracerebral infusion/drainage catheter, long-term AMEND

Definition A sterile, flexible tube intended to be surgically inserted through the skull for long-term (> 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it is typically used for measurement of intracranial pressure (ICP) and as part of a shunt system. It may include an attached port/reservoir at its proximal end that is placed subcutaneously to facilitate material infusion/collection, and/or accessory devices intended to facilitate catheter introduction and/or stabilization (e.g., stylet, catheter holder); it does not include a sensor. This is a single-use device.

Code 61376

Status Active

Created Date 16 Dec 2014

Modified Date 24 Jan 2017

[Add To Enquiry](#) [Add to My Shortlist](#) [Move to My Archive](#) [Return to My Terms](#)

Note: Terms in "My Archive" do not generate Alerts.

Previous Version

Name Intracerebral infusion/drainage catheter, long-term

Definition A sterile, flexible tube intended to be surgically inserted through the skull for long-term (> 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it is typically used for measurement of intracranial pressure (ICP) and as part of a shunt system. It may include an attached port/reservoir at its proximal end that is placed subcutaneously to facilitate material infusion/collection, and/or accessory devices intended to facilitate catheter introduction and/or stabilization (e.g., stylet, catheter holder); it does not include a sensor. This is a single-use device.



My term has been made obsolete

Term Details

Again from your 'Alerts' page open 'Term Details'

Name Abdominal wall prosthesis

Definition A sterile implantable device intended to substitute for part of the abdominal wall. It is made of synthetic polymer materials such as polytetrafluoroethylene (PTFE) or expanded polytetrafluoroethylene (ePTFE), and is used to close large abdominal wall defects that result from, e.g., trauma, tumour resection, or complications of previous surgery.

Code 35654

Status Obsolete

Explorer Groups

By Name / Prostheses and associated devices / Prostheses / Implantable prostheses

By Use / Body tissue manipulation and repair devices / Surgical mesh and associated devices

Clinical Specialties / General/Plastic surgery

Device Attribute Assortment / Implantable / Non-active implantable

Device Attribute Assortment / Single-patient use

Device Attribute Assortment / Surgical

Device Invasiveness / Surgical invasive / Long-term surgical invasive

Device Materials / Inorganic materials / Synthetic polymers / Plastics

Device Sterility / Sterile

Use the 'Explorer Groups' (aka Collective Terms) to help you find the term you need



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

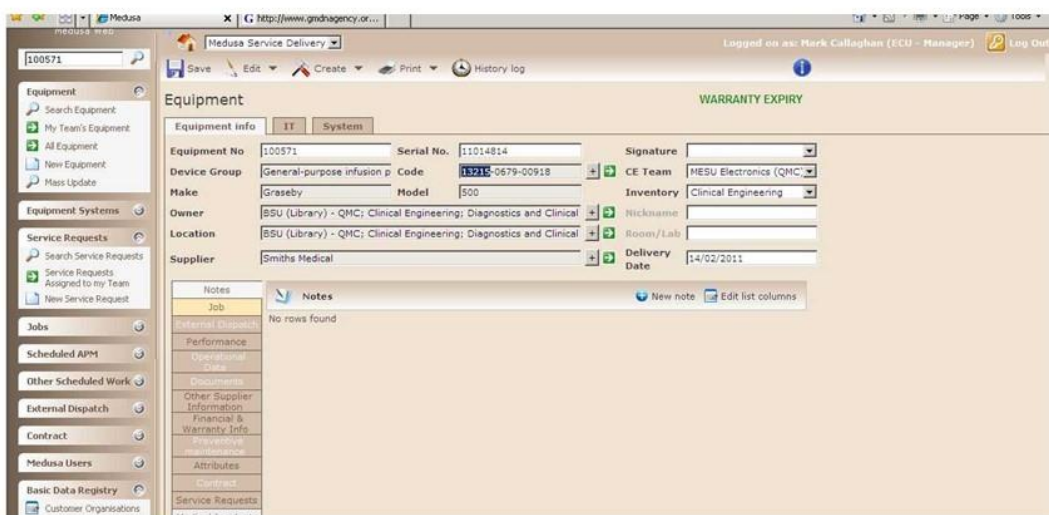
GMDN in Hospitals

- **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**



Equipment Commissioning

Nottingham University Hospitals NHS Trust



GMDN – Snomed link

- UDI database
- GMDN



- Linkage table



- Electronic medical record
- Snomed

GMDN

GMDN is improving communication

- GMDN is now the global language



GMDN