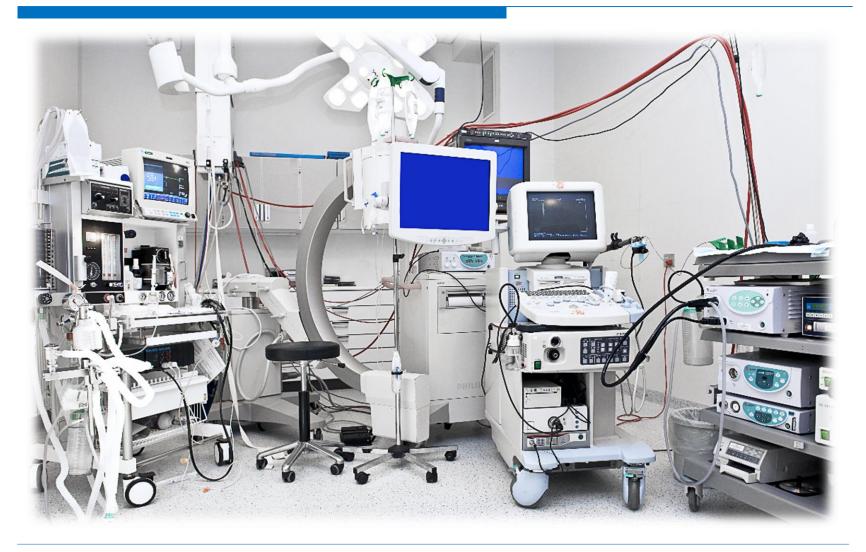
Global Medical Device Nomenclature (GMDN)

Dr Barry Daniels Technical Lead GMDN Agency



- GMDN introduction
- GMDN website
- GMDN uses in UDI





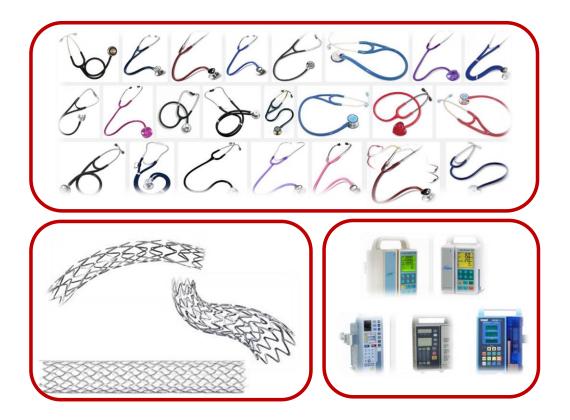


Get from this:





To this?





Naming and grouping – The role of GMDN



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 grouping (GMDN Term)

- The GMDN term defines a lowest level generic device group
- Many Products assigned to 1 GMDN term





Products assigned to 35195
Electrocardiographic monitor



Golden rule

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

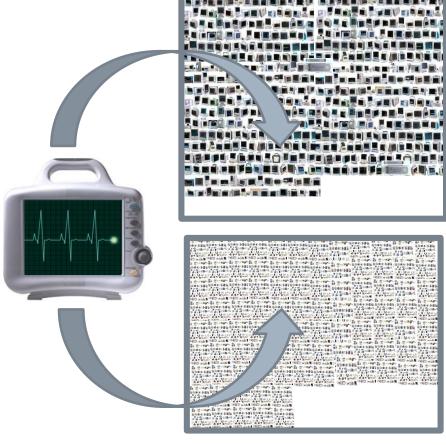
■ A thought: If you have the device in front of you and someone asked "What is that?" – would the GMDN term be a reasonable answer? Hopefully yes.



GMDN grouping (CT's)

- Each GMDN term is linked to many higher level (broader) Collective terms (CT's)
- CT's arranged in a hierarchy
- Therefore each Collective term creates a broader group of devices

CT1444 Patient monitors/monitoring systems



CT314 Electrically powered/operated



What does GMDN give the user

The GMDN data gives the user (Regulator, Registry, Hospital, Manufacturer):

- A name and definition that describes the device clearly and succinctly without proprietary jargon (in up to 20 languages)
- A way to group the device at many levels (e.g., for inventory management, regulatory risk trending, recall analysis)
- A global solution:
 - Only one code needed worldwide
 - Allows for global analysis of data
 - Consistent communication of data across borders





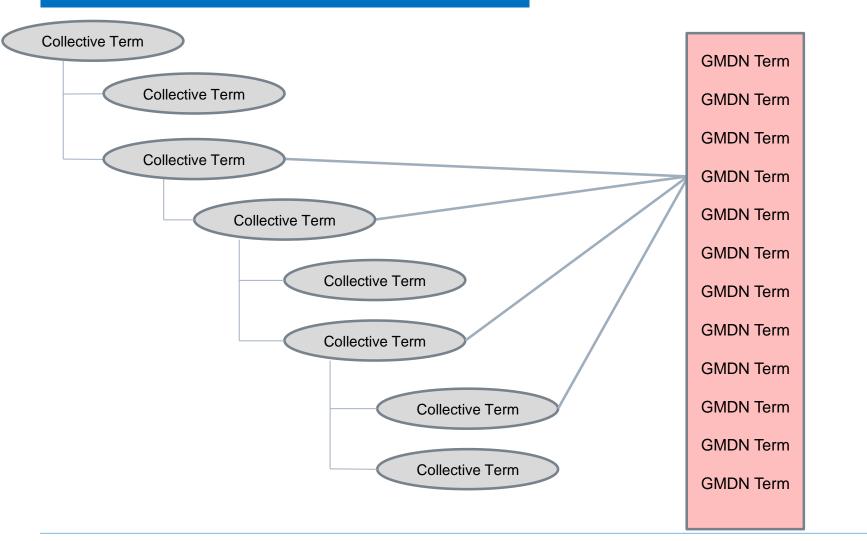
Collective Terms

- ☐ 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 ...



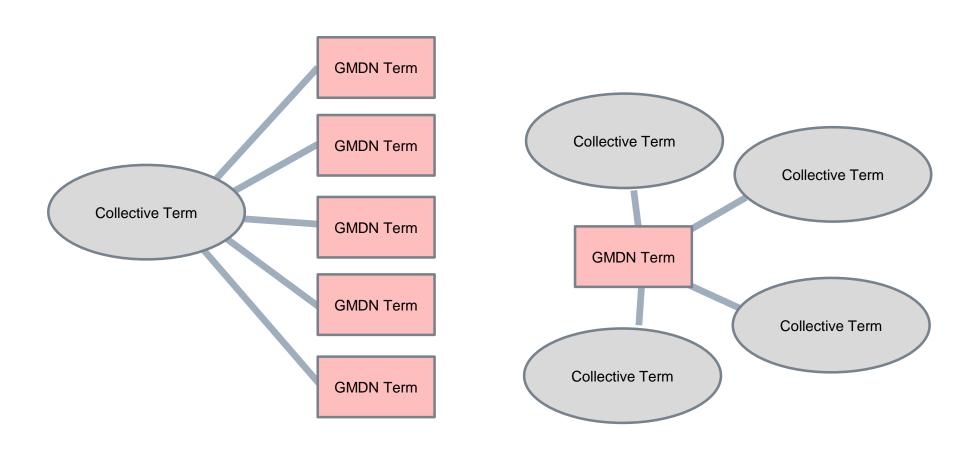
Hierarchical classification Collective Terms

Nomenclature GMDN terms





CT relationships



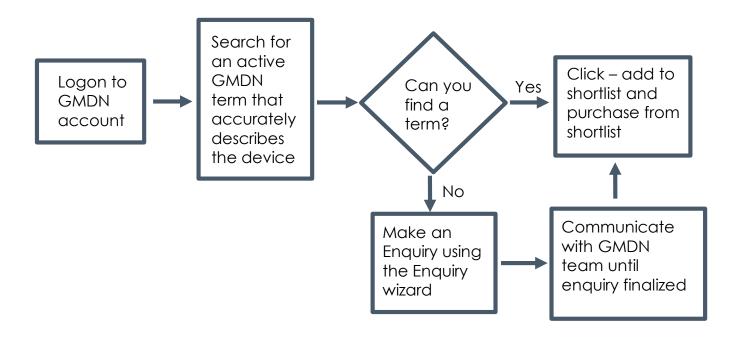


GMDN Website

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



The Process for Manufacturer members



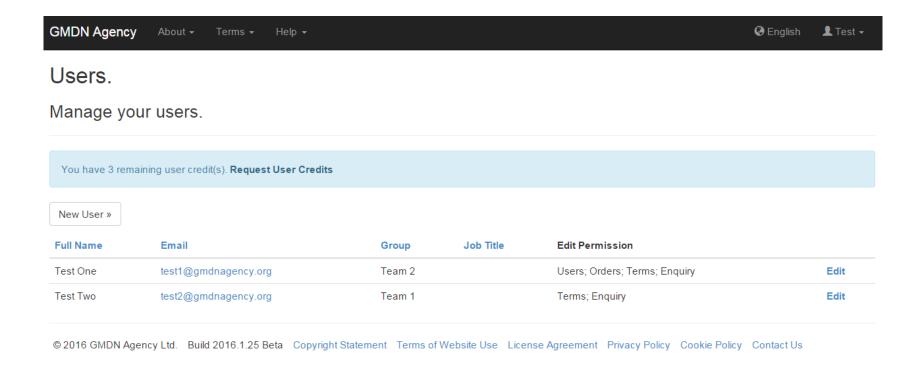


GMDN Website – Membership

Membership Is my organisation already a member? Membership Type - Select -**Annual Sales** Additional Info Currency Euro (EUR) Total Method Credit Card Invoice Quote MasterCard, Visa (EUR, GBP, USD), Amex (USD), JCB, Maestro (GBP). Purchase Order Invoice purchase order number (optional).

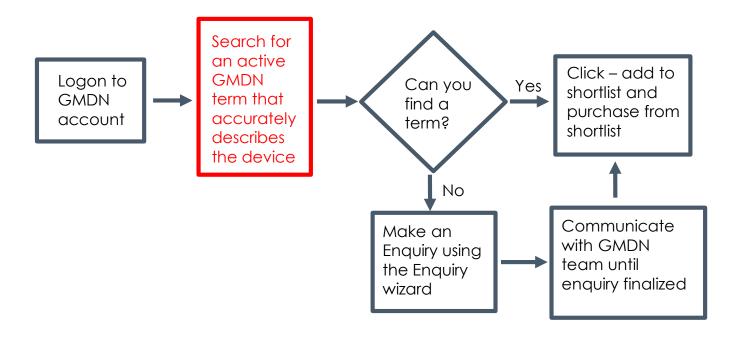


GMDN Website – User Management





The Process for Manufacturer members

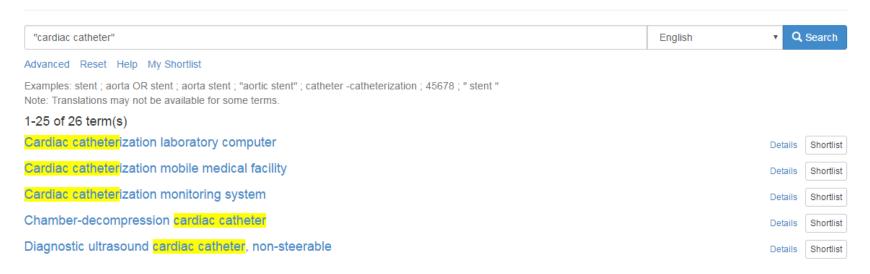




GMDN Website - Search 1

Search

Find device definitions by keyword(s).





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 M

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

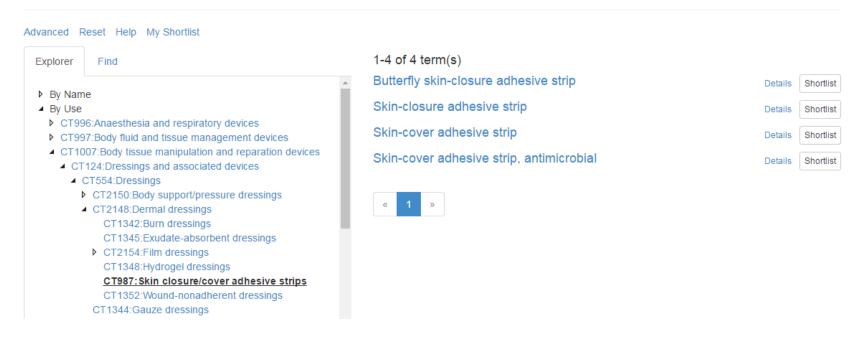
High-Level Device Groups / Adhesive strips / Skin closure/cover adhesive strips



GMDN Website – Explorer

Explorer

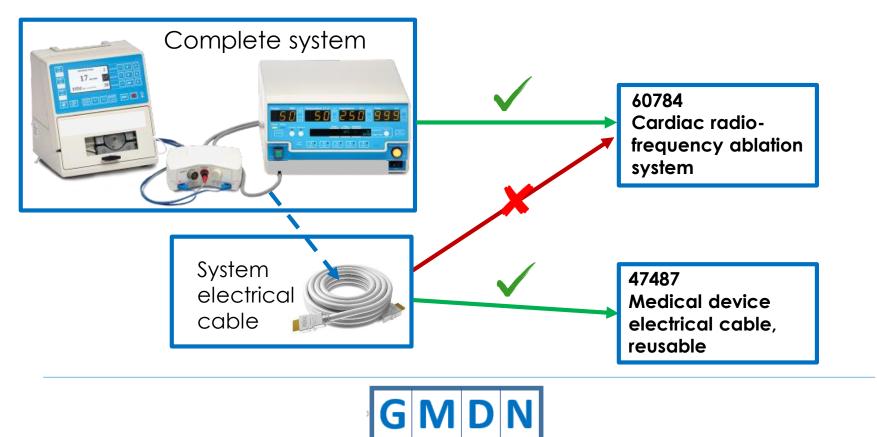
Browse device definitions by group.





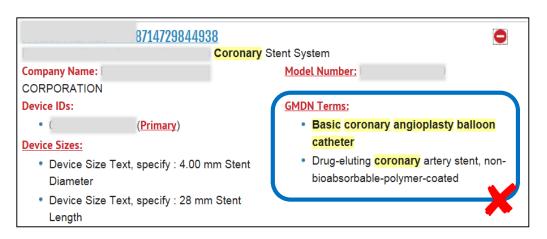
A GMDN term for a system term applied to a component of the system

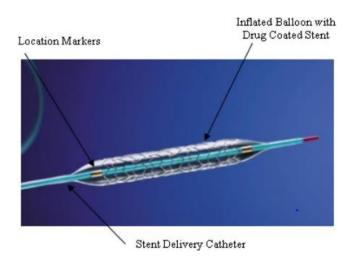
Example:



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

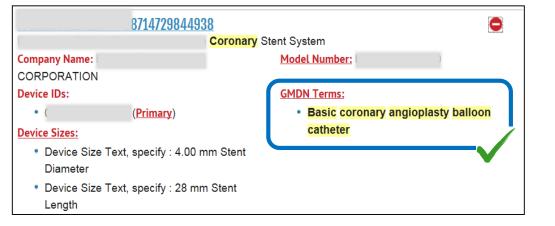
Example (in GUDID):







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



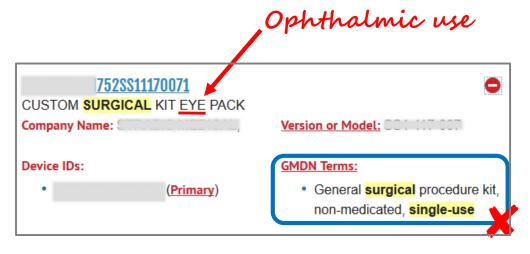
56284 Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated

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.



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?

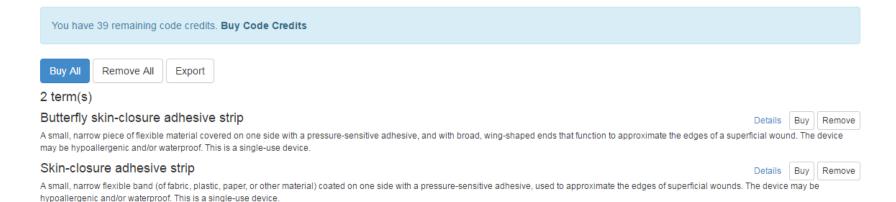
Ophthalmic surgical procedure kit, non-medicated, single-use



GMDN Website – Shortlist

My Shortlist

Compare and review your chosen definitions before purchase.

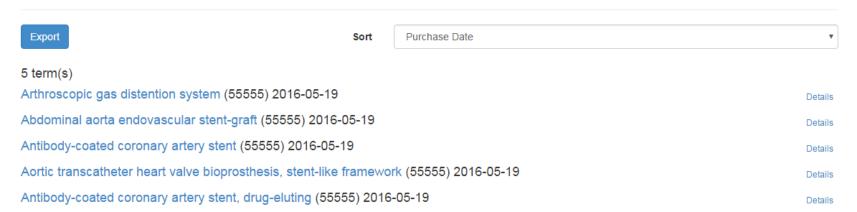




GMDN Website – My Terms

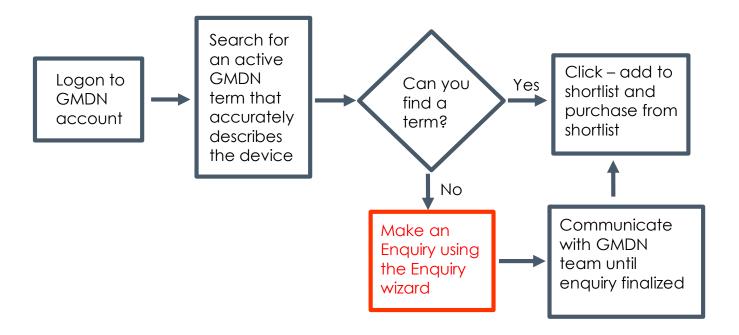
My Terms

View your purchased GMDN Codes for your devices.





The Process for Manufacturer members



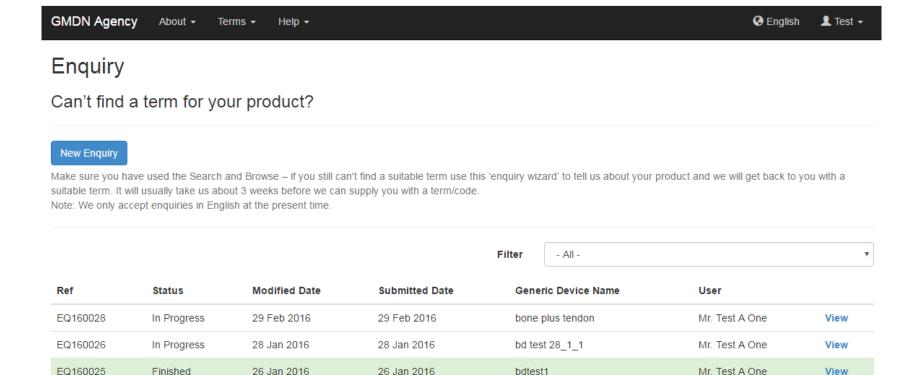


GMDN Website - Enquiry

- 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

GMDN Agency Abo	ut + Terms + Help +	@ English	Test ▼
Enquiry.			
Step 1			
Product details.			
Your Email	test1@gmdnagency.org		
	My Profile		
Generic Device Name			
Make			
Marc			
Model			
Trade Name			
Files	Choose 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 O Software details

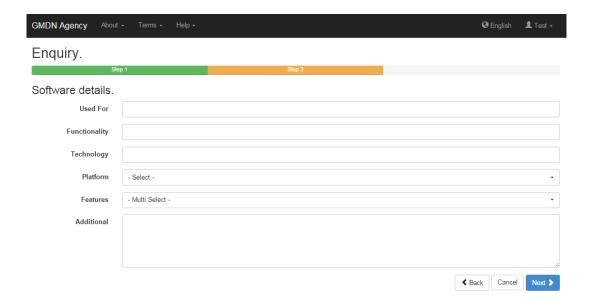
- In vitro diagnostic (IVD) (not capital goods)
- Similar to existing Term
- Device details

Please choose your enquiry type to proceed to the next step.



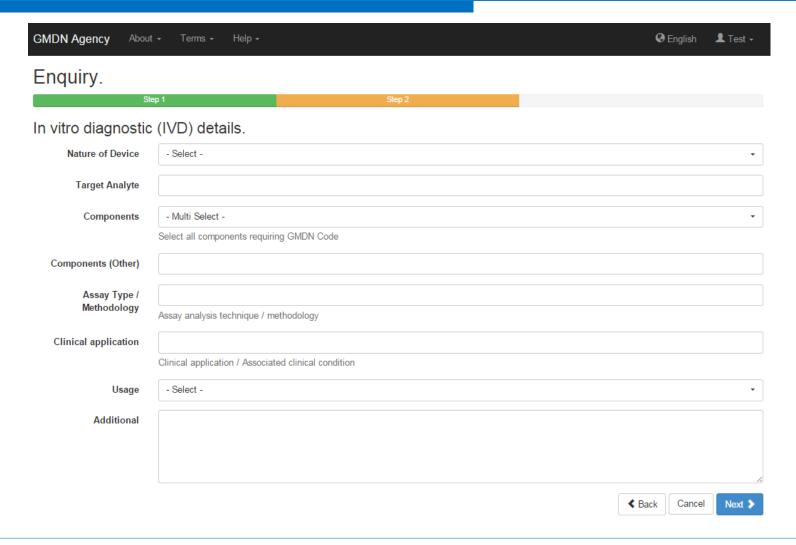


Enquiry - software



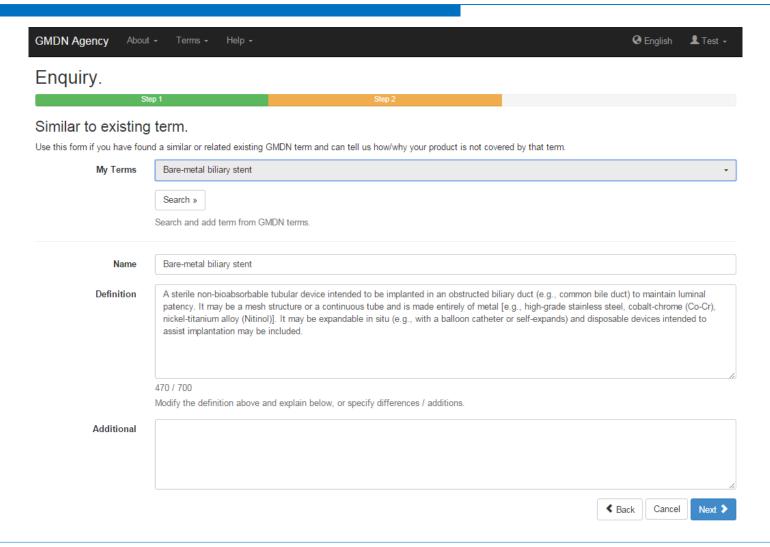


Enquiry - IVD



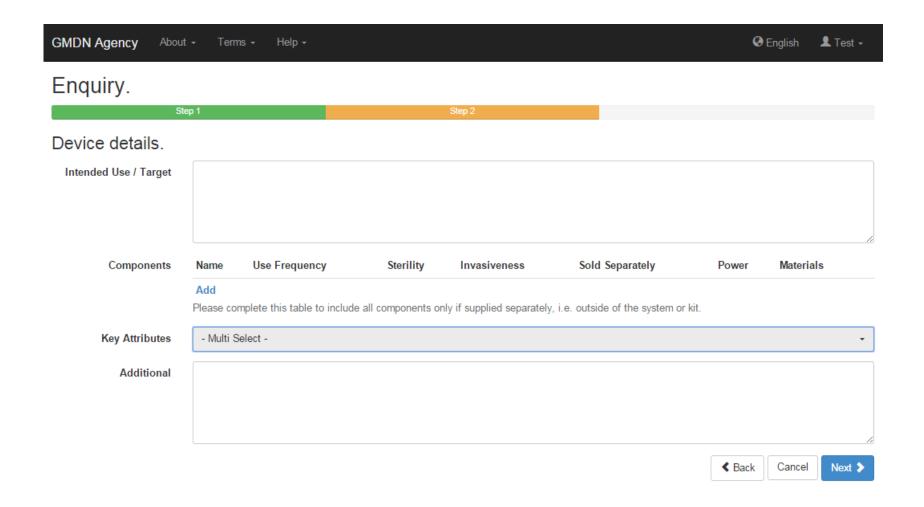


Enquiry – similar term





Enquiry - details

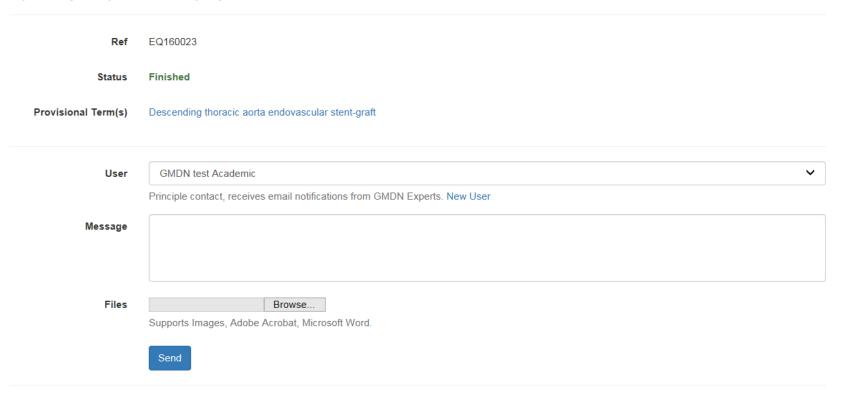




Enquiry - end

Enquiry

Update your product enquiry.





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 transsections/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

Add To Enquiry

Add to My Shortlist

Move to My Archive

Return to My Terms



Changes to GMDN data

- Develop new terms (average 2-3 day)
- We only modify existing Terms (average 3-4 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...



Notifications to manufacturers

- You will receive alerts relating to any changes
 - □All changes will be seen at the alerts page on your account
 - □Notification e-mails will be sent out ensure these are received by the appropriate person
 - ☐You also will receive a monthly newsletter by e-mail detailing these changes



Regulator updates

- Dataset for regulators:
 - ■Monthly updates:
 - Full dataset
 - Delta
 - **I**FTP
 - □API in development



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

12 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 of 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 a 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

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.

Return to My Terms



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 reparation 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.



GUDID

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







Q) drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated SEARCH RESULTS FOR: drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated (722 results) EXPORT RESULTS & 1Į **₹ PAGE FILTERS** SORT BY **10 RESULTS PER PAGE** XIENCE ALPINE - 08717648200380 Company Name 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 0 FDA Product Code Name 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 FDA Product Code Device Packaged as Sterile 0 XIENCE ALPINE - 08717648200366 XIENCE Alpine Everolimus Eluting Coronary Stent System 4.00 mm x 28 mm / Over-The-Wire Sterilization Prior To Use Company Name: ABBOTT VASCULAR INC. Version or Model: 1145400-28 Issuing Agency XIENCE ALPINE - 08717648200359 0 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 0 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



FDA GUDID August 2017

- □ DI records: 1 895 416
- Unique GMDN codes: 8187
- ☐ Therefore ratio = 1:232
- Active implantable device records:2813
- Non-active implantable device records: 524,094
- IVD device records: 24,817



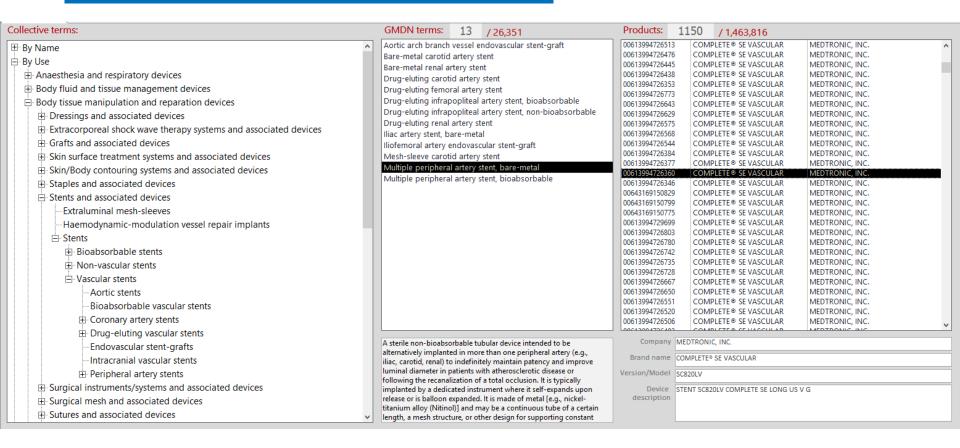
GMDN Agency working with the FDA

- Leverage of UDI data for downstream users e.g. registries, hospitals
- 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.



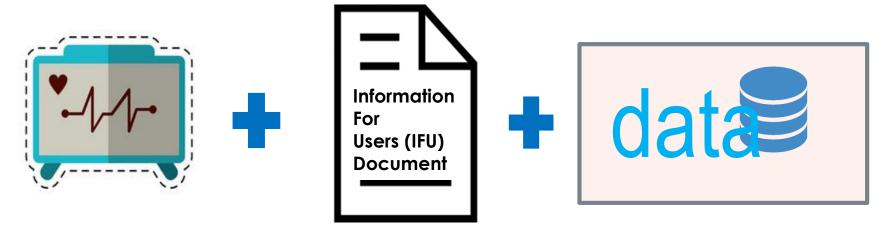
Device Identification - UDI



GMDN CTs — GMDN Terms — Devices



A device has a new component – Shared Data



Publically shared data (inc. GMDN term assignment) sent to Regulators and Customers (e.g., via GDSN)



GMDN in Hospitals

Asset Management

- Support equipment commissioning
- Help identify equipment location
- Support maintenance programmes

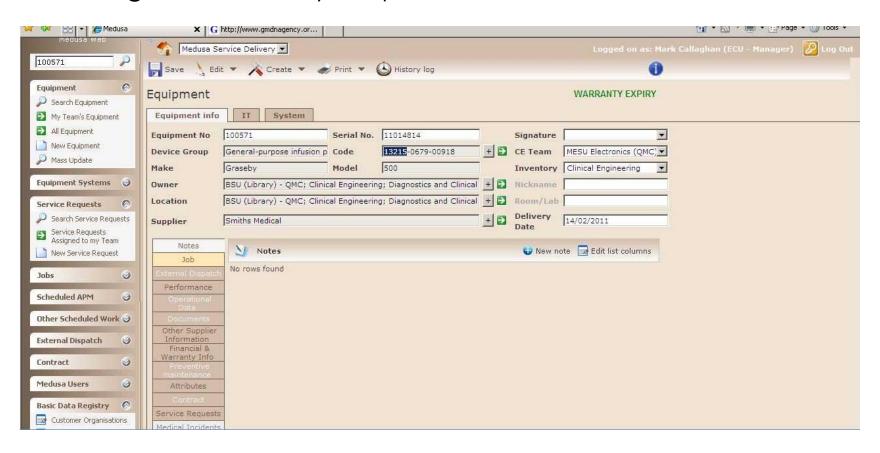
Inventory Control

- Reduce wastage
- Translate product labels with poor descriptions
- Improve stock control
- Replace existing inventory classification with an externally managed globally recognized nomenclature



Equipment Commissioning

Nottingham University Hospitals NHS Trust





What's UDI?

provides |THE MANUFACTURER| with |A UNIQUE NUMBER| to be put in |A BARCODE| A UDI ISSUING AGENCY





0) 1 0614141 012345678



for |THE DEVICE|



allowing accurate



of



| DEVICE DATA |

| A DATABASE | from





What does the GMDN do?

A DEVICE

is assigned to

A GMDN Term

which creates

| A GENERIC DEVICE GROUP |



GMDN Code: 35195
GMDN Term Name: Electrocardiographic monitor
GMDN Term Definition: A mains electricity (ACpowered) 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.



within

| A DATABASE |

and allows for

|HARMONIZED NAMING|









What's the GMDN Process?

|THE GMDN Term|

is assigned to

|THE DEVICE|

THE MANUFACTURER

by



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.





for

|REGULATORS|

and

|HOSPITALS|









GMDN is improving communication

☐ GMDN is now the global language





Thank you for listening

Any questions now?

Website: gmdnagency.org

- Enquiry product/term
- Contact us anything else

