# **GMDN – User Guide for Regulators**

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### 1. GMDN Website - Account Management - Step-by-Step Guide

This is a Step-by-Step Guide for account management by adding and modifying user settings on the GMDN website.

The user of the GMDN website with the appropriate account permission can add, modify, and delete user profiles associated with their membership account.

1. Login to the GMDN Database using your Username and Password.

The Users tab is found in the Account dropdown menu at the top right of the webpage (with the person icon).



2. By clicking on Users the list of existing users will be listed for your account.

Note: new accounts will only list the details of the user that registered the account.

GMDN: Home	Terms 👻 Helj	p 🕶				L regulator -
Users 🛛						
Manage your us	sers.					
You have 3 remaining us	er credits. <u>Request L</u>	Jser Credits	>			
New User				Filter	Active	~
Full Name	Job Title	Group	Email		Edit Permission	
gmdn test regulator			gmdn@barrydaniels.net		Archive, Enquiry, Orders, Terms, Users	Edit
regulator test			regulator@gmdnagency.org		Archive, Enquiry, Orders, Terms, Users	Edit
y in						
Contact Us Cookie Policy	Privacy Policy Lic	ence Agreeme	nt Terms of Website Use Cop	ovright Stateme	nt Build 2024.2.6 © 2024 GMDN Agency Ltd.	

3. The list can be sorted by username, Email address, Group or Job Title. The *Job Title* and *Group* fields are user defined and maybe useful to help organise and sort your users.



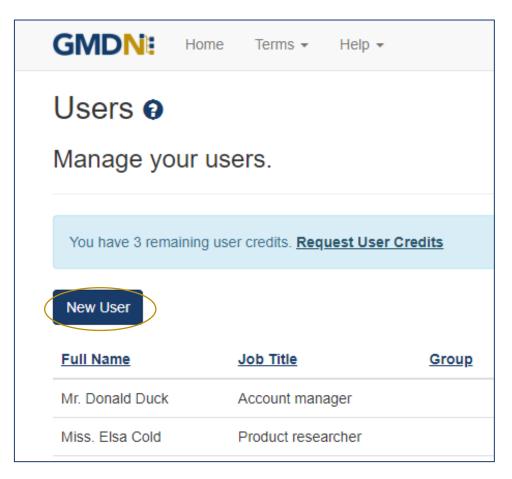
4. Each account when first activated, is provided with a certain number of user credits which are used to add more users. If you require more, they can be requested using the *Request User Credits* button.

Permission	Description
User	Can add, modify and delete users on their account
Orders	Can order and pay for membership
Terms	Can search for and reveal GMDN Codes
Enquiry	Can send a new product enquiry
Archive	Can add a Term to the Term Archive folder
Default (none of the above)	Can search the database, but cannot reveal GMDN Codes

5. The permissions can be added or removed according to your preference.

The membership applicant will have all permissions enabled and will thereafter be able to add new users and set permissions for them.

6. To add a new user select *New User*.





7. Fill in the user details and select the Save button.

Only the First Name, Last Name and Email Address are mandatory fields.

Remember to select the *Edit Permissions* options to give the user the access they need.

Users		
Modify the user of	letails.	
Prefix	- Select -	~
First Name		
Middle Name		
Last Name		
Job Title		
Group		
User Name		
Email		
Phone		
Edit Permission	- Select - Gragueser Edit permission to tasks. All users have Read permission by default.	•
Term Changes		
Account Summary		
GMDN Focus		
	Save Confin Email Archive	

8. When the Save button is pressed the user will be added to your list.

An email will be sent to the new user to inform them of their username and initial password. We recommend the password is changed when the new user accesses the GMDN website for the first time.

Dear Test Three,
Your GMDN user account has been created with the following details.
Username: test3@gmdnagency.org Password: gLCMhZiK
You can now access your GMDN account at www.gmdnagency.org
Regards GMDN Agency

This is an automated message sent by GMDN Agency, please do not reply.

### 2. GMDN Website - Search - Step-by-Step Guide

This is a Step-by-Step Guide for searching for GMDN Codes using the GMDN website.

The GMDN Search uses a 'browser like' search algorithm to find GMDN Terms using key words.

1. Logon to the GMDN Database using your Username and Password.

2. Click on Search on the Terms dropdown menu.



3. In the box, type in the keyword(s) for the medical device you are looking for.

GMDN: Home Terms - Help -	👤 regulator 👻
Search 🛛	
Find Terms by keyword(s).	
	English V Q Search
Advanced Reset	
Examples: <u>stent, aorta stent, aorta OR stent, aorta NOT stent, "aortic stent", "stent ", 62572.47685</u> Note: Translations may not be available for some terms.	

Formatting the search text can help narrow down the search. For example:

*cardiac OR catheter* creates an 'either of the words' filter and will produce over 1,170 results.

cardiac catheter is an 'all of the words' filter and will produce over 110 results.

"cardiac catheter" uses "the exact phrase" filter and will produce about 20 results.

cardiac NOT valve will remove the word 'valve' from the 'cardiac catheter' results.

GMDN Code (Example 12345) will return the relevant GMDN Term.



4. The *Advanced* tab provides additional filters to narrow the search by Term Modification Date.

Specific searches can include 'obsolete' GMDN Terms.

In the example below, the Advance search criteria is looking for all Terms that contain the word 'stent' that have been modified in the 'last 6 months' that will also include 'obsolete' Terms.

GMDN: Home Terms - Help -	💄 regulator 👻
Search I Stent English Q Search	
Find Terms by keyword(s).	
Stent	English v Q Search
Advanced Reset	
teret and a teret and a ford a field " acrite attert" ' 2572 47685	
Include Obsolete 🖾	
Row Per Page 25	~
Show Definitions	
Examples: <u>stent, aorta stent, aorta OR stent, aorta NOT stent, "aortic stent", "stent", 62572-47685</u> Note: Translations may not be available for some terms.	

5. Click on the Search button or press Return and the results are displayed in a list form.

The Term Definition is revealed by clicking on the Term Name.

GMDN: Home	Terms + Help +		L regulator -
Search 🛛			
Find Terms by key	word(s).		
Stent		English	✓ Q Search
Advanced Reset		Ligion	v v ocarch
Modified	6 Months		~
Include Obsolete			
Row Per Page	25		~
Show Definitions			
Examples: <u>stent, aorta stent, aorta C</u> Note: Translations may not be availa	R stent, aorta NOT stent, "aortic stent", "stent", 62572.47685 Die for some terms.		
term(s)			
Name		Cod	e Status
Cylinder infusion pump		6252	0 Active <u>Details</u>
Infant recumbent sleep position	ner	4429	4 Active Details
Radiological image marker, in	plantable	4080	8 Active <b>Details</b>

The results are prioritised according to if the search text is found in the Term Name or Term Definition. The list is presented in Term Name alphabetical order with the priority being when the search text is in the Terms Name and next if the search text is only found in the Term Definition. The search text is highlighted.

By clicking the Term *Details* link, you can see more information belonging to that Term, including a translation of the text, if available.

-			
(	GMDNE Home	Terms • Help •	Ŧ
-	Term Details		
1	Name	Cylinder influsion pump	
	Definition	An electrically-powered device intended to facilitate the accurate and consistent administration of non-specific fluid medications from a standard infusion bag, syringe, and bottle, into a patient via infravenous, subcutaneous, arterial, epidural, and infravarvial routes. Designed as an alternative to a standard infusion pump or syringe pump, it consists of a unit with a motor designed to drive pistons in a circular motion inside a replaceable cylinder, and which is connected to a disposable infusion administration set (e.g., tubing, fler, connectors, needlecratheter). This is a reusable device.	t
	Code	62520	
	Status	Active	
	Created Date	19 Dec 2016	
	Modified Date	12 Oct 2023	
1-	Translations		
$\[ \]$	Language	Español	-
	Name	Bomba de infusión de cilindro	
	Definition	Dispositivo accionado eléctricamente destinado a facilitar la administración precisa y uniforme de medicamentos fluidos no especificos desde una bolsa de infusión, jeringa y botella estándar, a un paciente por via intravenosa, subcutánea, arterial, epidural e intracavitaria. Diseñada como alternativa a una bomba de infusión estándar o a una bomba de jeringa. Consta de una unidad con un motor diseñado para accionar pistones en un movimiento circular dentro de un clindor emplazable, y que se conceta a un equipo de administración de infusión desechable (por ejemplo, tubo, filtro, conectores, aguja/catéter). Se trata de un dispositivo reutilizable.	а
	Translated Date	17 Jan 2023 (Outdated)	
$\sim$	Categories		
		a terms (Cannulation/Fluid path devices / Fluid influsion/injection devices / Influsion pumps and associated devices / Influsion pumps / Nonimelantable influsion/svringe.cumps	
	Featured Attributes / Analgesia		
E	Featured Attributes / Pharmaceuti	ical	
	eatured Attributes / Portable/Trai		
		id associated devices / Infusion pumps / Nonimplantable infusion/syringe.pumps	
		iated devices / Pumps / Infusion.pumps / Nonimplantable infusion/syringe.pumps	
	Power / Active / Electrically powe		

One of the advance features of the *Term Details* view is the use of *Categories*. This uses the new GMDN *Advanced Search* to view all the Terms that are related by linking it to other GMDN Terms with similar characteristics.

6. The 5-digit GMDN Code is also visible.

### 3. GMDN Website - Advanced Search - Step-by-Step Guide (non-basic users)

This is a Step-by-Step Guide for searching for GMDN Codes using the Advanced Search function on the GMDN website. It is available for all users, except those with a basic membership account.

The Advanced Search uses the structured hierarchy of the GMDN Categories to allow users to find GMDN Terms using a 'top down' search. To access the Advanced Search:

1. Logon to the GMDN Database using your Username and Password.

2. Click on Advanced Search on the Terms drop down menu.

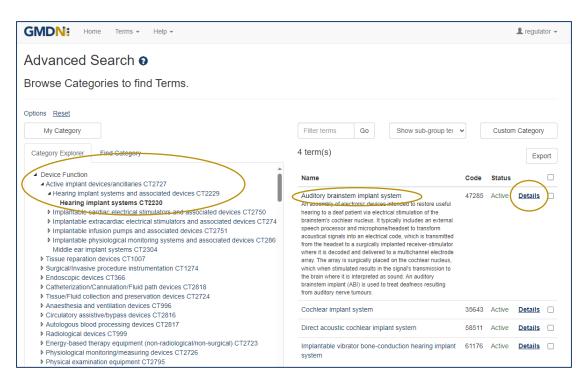
GMDNI: Home	Terms - Help -	1 regul
Advanced Se Browse Categori	Proposed	
Diptions <u>Reset</u> My Category Category Explorer Fil	Custom Categories Shared Custom Categories	Filter terms     Go     Show sub-group ter     Custom Category
<ul> <li>Device Function</li> <li>Anatomical Specialty</li> <li>Names Index</li> <li>Invasiveness/implantal</li> <li>Use Frequency</li> <li>Power</li> <li>Materials (clinically sig</li> <li>Featured Attributes</li> </ul>		

3. The *Advanced Search* displays the eight Category headers which group the GMDN Categories. For example, Categories such as Tissue reparation devices, Endoscopic devices, In-vitro diagnostic devices (IVDs) fall under the Device Function header, Cardiovascular devices, Neurological devices, Orthopaedic devices etc fall under Anatomical Speciality and so on. The structure of the hierarchy is revealed by clicking on the arrows to display the Categories under each Header.

GMDN: Home Terms - Help -	👤 regulator 🗸
Advanced Search   Browse Categories to find Terms.	
Options       Reset         My Category       Find Category         Category Explorer       Find Category         > Device Function       Anatomical Specialty         > Anames Index       Invasiveness/Implantability         > Use Frequency       Power         > Materials (clinically significant)       Featured Attributes	Filter terms     Go     Show sub-group ter     Custom Category



4. The list of GMDN Terms in each GMDN Category is revealed by clicking on the Category. The *Term Definition* is revealed by clicking on the *Term Name*. By clicking on the *Details* link, you can see more information relating to that Term, including a translation of the text, if available.



GMDN: Home	Terms • Help • Legulat
Term Details	
Name	CPAP/BPAP face mask, reusable
Definition	A flexible, form-shaped device designed to be placed over a user's nose and mouth to interface with a continuous positive ainvay pressure (CPAP) or level positive ainvay pressure (BPAP) with to provide the respiratory tract with direct ambient air, or medical oxygen (O2) and at, at a higher pressure than architeria fir for noninvasive positive pressure ventilation (NPPV). It is typically made or plastic and/or sitterion materials that create an airtight set around the nose and mouth. It is available in various designs and sizes and stabilized with a headstrap. This is a reusable device.
Code	57814
Status	Active
Created Date	15 Sep 2010
Modified Date	28 Feb 2014
	Add to Enquiry
Translations	
Language	- Select -
Categories	$\supset$
Please use shortcuts to find relate	
	(devices / Atr/Dovoen masks / CPAP/BPAP masks id ventilation devices / Anaesthesia and resolvatory masks and associated devices / Anaesthesia and resolvatory masks / Atr/Dovoen masks / CPAP/BPAP masks
Featured Attributes / CPAP/BPAF	
Featured Attributes / Sleep apno	8
Names Index / Masks and assoc	ated devices / Masks / Anaesthesia and resolratory masks / Air/Oxygen masks / CPAP/BPAP masks
Device / Mars. anti-us	
Power / Non-active Use Frequency / Reusable	

On each 'Terms Details' page is a breadcrumb trail of all Categories linked to that GMDN Term. These are all functional links, which lead back to the hierarchy on the Advanced Search page.



5. You can also multi-select up to five different GMDN Categories to narrow down your search for a GMDN Term . The example, below shows the result of a multi-select search, using the *Bariatric Therapy Devices* GMDN Category under *Device Function* and *Gastro-Urological Devices* GMDN Category under the *Anatomical Speciality* node.

The resulting 35 GMDN Terms have both of these categories in common. These can be further refined to create a shorter list of Terms to choose from, by selecting more Categories.

Additionally, the Advanced Search page also has independent scroll bars for the GMDN Categories and GMDN Terms so you can move up and down each column.

Advanced	Search 🛛						
Browse Cate	gories to find Terms.						
Options Reset							
My Category		<	Filter terms Go Show sub-group t	€ ✔	Cus	tom Cate	jory
Category Explorer	Find Category	•	35 term(s)				Export
	Jevices/ancillaries CT2727	A	Name	Code	Status		$\mathbf{A}$
Surgical/Invasiv	on devices CT1007 re procedure instrumentation CT1274		Appetite-suppression gastric balloon	17202	Active	Details	þ
<ul> <li>Endoscopic devices CT366</li> <li>Catheterization/Cannulation/Fluid path devices CT2818</li> <li>Tissue/Fluid collection and preservation devices CT2724</li> </ul>			Appetite-suppression gastric balloon capsule simulator	63342	Active	<u>Details</u>	Þ
<ul> <li>Anaesthesia and ventilation devices CT996</li> <li>Circulatory assistive/bypass devices CT2816</li> <li>Autologous blood processing devices CT2817</li> </ul>			Appetite-suppression gastric balloon deployment device/set	63405	Active	<u>Details</u>	
Radiological devices CT999     Energy-based therapy equipment (non-radiological/non-surgical) CT2723     Physiological monitoring/measuring devices CT2726			Appetite-suppression gastric balloon inflation gas cartridge	63343	Active	<u>Details</u>	
<ul> <li>Physical examination equipment CT2795</li> <li>Biomechanical rehabilitation equipment CT275</li> </ul>			Appetite-suppression gastric balloon inflation regulator	63320	Active	<u>Details</u>	
Bariatric therapy devices C1281     General hospital devices C1149     Disability-living products C11000			Dietary carbohydrate absorption inhibitor	56319	Active	Details	
Containing Interapy devices CT343     Sexual-activity/Contraceptive/Home-conception devices CT2800			Dietary cholesterol absorption inhibitor	56612	Active	Details	Þ
Laboratory instr	ruments and equipment CT202 tic medical devices (IVDs) CT954		Dietary fat absorption inhibitor	56314	Active	Details	D
<ul> <li>Software CT16</li> <li>Anatomical Speci</li> </ul>	51		Dietary multiple-macronutrient absorption inhibitor	58938	Active	Details	Ø
Cardiovascular devices CT145     Perimonary devices CT272		V	Duodenal bypass liner	57829	Active	Details	J
	ical devices CT1002		Duodenal-jejunal bypass liner	58110	Active	Details	

6. You can also further filter the results by keyword which will highlight within the GMDN Terms As in the example below. This search filter highlights the occurrence of the keyword in the Term name and the definition.

Advanced	Search 🥹					
Browse Categ	gories to find Terms.					
Options Reset						
My Category	Contract (1)	absorption Go Show	sub-group te 🗸	Custon	n Category	у
Category Explorer	Find Category	6 term(s)			Exp	port
	levices/ancillaries CT2727 on devices CT1007	Name	Code	Status		
Surgical/Invasiv	e procedure instrumentation CT1274	Dietary carbohydrate absorption inhibit	tor 56319	Active	<u>Details</u>	
	/Cannulation/Fluid path devices CT2818	Dietary cholesterol absorption inhibitor	56612	Active	Details	
Anaesthesia and	lection and preservation devices CT2724 d ventilation devices CT996	Dietary fat absorption inhibitor	56314	Active	Details	
Autologous bloc	stive/bypass devices CT2816 od processing devices CT2817	Dietary multiple-macronutrient absorption	ion inhibitor 58938	Active	Details	
	herapy equipment (non-radiological/non-surgical) CT2723	Duodenal bypass liner	57829	Active	Details	
<ul> <li>Physical examin</li> <li>Biomechanical r</li> </ul>	onitoring/measuring devices CT2726 nation equipment CT2795 rehabilitation equipment CT275 py devices CT2811	Ingested gastric satiety device	48146	Active	<u>Details</u>	



7. If you select the *Options* tab there are several additional choices for further filtering and settings.



8. You can select a different language settings within the *Options* tab from the drop-down filter.

Advanced S	earch 🛿					
Browse Catego	ories to find Terms.					
Options Reset						
English	Any device ~ Include Obsolete ~	100 rows V Hide definitions	~			
Dansk	available for some terms.					
Deutsch		absorption Go Show sub-group te	~	Custom	n Category	
English						
Español	Find Category	6 term(s)			Exp	ort
Français	ces/ancillaries CT2727	Name	Code	Status		
Italiano	levices CT1007 rocedure instrumentation CT1274	Dietary carbohydrate absorption inhibitor	56319	Active	Details	
Nederlands	s CT366					
Norsk	nnulation/Fluid path devices CT2818 ion and preservation devices CT2724	Dietary cholesterol absorption inhibitor	56612	Active	<u>Details</u>	
polski	entilation devices CT996	Dietary fat absorption inhibitor	56314	Active	<u>Details</u>	
Português (Brasileiro)	e/bypass devices CT2816 rocessing devices CT2817	Dietary multiple-macronutrient absorption inhibitor	58938	Active	<b>Details</b>	
Svenska	s CT999 apy equipment (non-radiological/non-surgical) CT2723	Duodenal bypass liner	57829	Active	Details	
Русский	toring/measuring devices CT2726					
日本語	on equipment CT2795 abilitation equipment CT275	Ingested gastric satiety device	48146	Active	<u>Details</u>	
简体中文	devices CT2811					
v General nospital o	evices CT149					

9. You can also filter by General Medical Device (GMD) or In Vitro Diagnostic (IVD)

Advanced Search o		
Browse Categories to find Terms.		
Options Reset		
English V Any device Include Obsolete	✓ 100 rows ✓ Hide definitions ✓	
Note: Translations may not be availat Any device		
My Category GMD	absorption Go Show sub-group te 🗸 Custom Category	
Category Explorer Find Category	6 term(s) Expr	ort
Device Function     Active implant devices/ancillaries CT2727	Name Code Status	
Tissue reparation devices CT1007     Surgical/Invasive procedure instrumentation CT1274     Sedecomin during CT06	Dietary carbohydrate absorption inhibitor 56319 Active Details	



10. You can also include obsolete GMDN Terms within your search if required. However, please note that obsolete GMDN Terms **should not** be used by any manufacturer for product registration or UDI purposes. They are included for reference purposes only. If you are in doubt about Term assignment or cannot find an appropriate active Term for your device, please contact the Term Development Team via the Enquiry service.

Advanced s	Search 🛛									
Browse Categ	pories to find Terms.									
Options Reset										
English	<ul> <li>Any device</li> </ul>	Include Obsolete	$\overline{\mathbf{\nabla}}$	100 rows	~	Hide definitions	~			
Note: Translations may not I	be available for some terms.	Active								
My Category		Include Obsolete		absorption	Go	Show sub-group te	~	Custor	n Category	
Category Explorer	Find Category			6 term(s)					Expo	ort
	evices/ancillaries CT2727		•	Name			Code	Status		
Surgical/Invasive	n devices CT1007 e procedure instrumentation CT1274			Dietary carbohyd	frate <mark>absorpti</mark>	on inhibitor	56319	Active	Details	
	ices CT366 Cannulation/Fluid path devices CT2818			Dietary cholester	rol absorption	inhibitor	56612	Active	<b>Details</b>	

11. You can select how many rows of GMDN Terms are displayed per page (Max. 1,000).

Advanced	Sea	arch 🛛										
Browse Cate	gorie	es to find Ter	ms.									
Options Reset												
English	~	Any device	~	Include Obsolete	<	100 rows	~	Hide definitions	~			
Note: Translations may no	t be avail	lable for some terms.				25 rows						
My Category						50 rows		Show sub-group te	~	Custor	n Category	y
Colores England	1	10-1				100 rows						
Category Explorer		d Category				1,000 rows					Exp	port
<ul> <li>Device Function</li> <li>Active implant</li> </ul>		/ancillaries CT2727			*	Name			Code	Status		
<ul> <li>Tissue reparat</li> <li>Surgical/Invasi</li> </ul>		ces CT1007 edure instrumentatio	n CT1274			Dietary carbohy	drate absorptic	on inhibitor	56319	Active	Details	0
Endoscopic de	vices C	T366				P. I. I. I. I. I.			500.10			-
		lation/Fluid path dev and preservation de				Dietary choleste	rol absorption	inhibitor	56612	Active	Details	Û
		lation devices CT996		24		Dietary fat abso	rption inhibitor		56314	Active	Details	
		ypass devices CT28 essing devices CT28				Dietary multiple-	macronutrient	absorption inhibitor	58938	Active	Details	0
Radiological de	evices C	CT999				Duodenal bypas	a linar		57829	Active	Details	0
		equipment (non-rad ng/measuring device		n-surgical) C12/23		Duodenai oypas	s liner		21023	Active	Details	U
		equipment CT2795	5012120			Ingested gastric	satiety device		48146	Active	Details	
Biomechanical	rohahili	itation equipment CT	275									

12. You can also choose to show the GMDN Term Definition as well.

Advanced	Search o							
Browse Cate	gories to find Terms.							
Options Reset								
English	✓ Any device ✓	Include Obsolete 🗸	100 rows 🗸 🗸	Show definitions	~	>		
Note: Translations may not	be available for some terms.			Hide definitions				
My Category			absorption Go	Show definitions		Cus	tom Cate	gory
Category Explorer	Find Category		6 term(s)					Export
	levices/ancillaries CT2727 on devices CT1007		Name		Code	Status		
<ul> <li>Surgical/Invasiv</li> <li>Endoscopic dev</li> <li>Catheterization</li> <li>Tissue/Fluid col</li> <li>Anaesthesia an</li> <li>Circulatory assis</li> <li>Autologous bloo</li> <li>Radiological de</li> <li>Energy-based tt</li> <li>Physiological</li> </ul>	re procedure instrumentation CT1274 vices CT366 Cannulation/Fluid path devices CT28 lection and preservation devices CT2 d ventilation devices CT2816 d processing devices CT2816 d processing devices CT2817 vices CT399 herapy equipment (non-radiological/m contoring/measuring devices CT2726	/24	Dietary carbohydrate absorptio An orally-administered device inten- lossicomora and treat deexity by red detary carbohydrate (s.g., stach), carbohydrate digestive enzymes, gat without being absorbed. It hysic materiata as active ingredentia. It is capsule, and powder sachet forms 1 heatificare facility. This is a single-up	ded to facilitate weight tucing absorption of sugar, complex erfere with the activity resulting in dietary d and excreted by the ally includes plant available in tablet, for use in the home or	56319	Active	<u>Details</u>	
<ul> <li>Biomechanical</li> <li>Bariatric therai</li> <li>General hospita</li> <li>Disability-living</li> </ul>			Dietary choiesterol absolution An orally-administered device inten- blood cholesterol levels by reducing cholesterol, and increasing choleste designed to be swallowed immediat blie acids and form a large bile acid- too large to be absorbed and is exci	ded to help manage absorption of dietary erol utilization. It is tely after meals to bind -fibre complex that is	56612	Active	<u>Details</u>	



13. Another way of searching for a GMDN Category is to use the *Find Category* tool.

Advanced Search <b>9</b> Browse Categories to find Terms.			
Options Reset My Category Category Explore Find Category Go	Filter terms Ge	o Show sub-group te 🗸	Custom Category

14. Type in a keyword for your search and select 'Go' and it will bring up the relevant GMDN Categories. Please note this search is based on keywords identified in the Category names only, it does not search by GMDN Term.

Advanced Search 🥑	
Browse Categories to find Terms.	
Options Reset	
My Category	Filter terms         Go         Show sub-group te         Custom Category
Category Explorer Find Category	
mesh	Go
18 matches Extraluminal mesh-sleeves CT2605 Device Function	
Extraluminal mesh-sleeves CT2605 Device Function	
Extraluminal mesh-sleeves CT2605 Anatomical Specialty	
Extraluminal mesh-sleeves CT2605 Names Index	
Surgical mesh-slings CT3037 Device Function	
Surgical mesh-slings CT3037 Names Index	
Surgical mesh-slings CT3037 Names Index	
Surgical meshes and associated devices CT455 Names Index	
Surgical meshes CT1400 Device Function	
Surgical meshes CT1400 Names Index	
Pelvic organ prolapse surgical meshes CT2473 Device Function Pelvic organ prolapse surgical meshes CT2473 Anatomical Specialty	
Pelvic organ prolapse surgical meshes CT2473 Names Index	
Extra-gynaecological surgical meshes CT3036 Device Function	
Extra-gynaecological surgical meshes CT3036 Names Index	
<u></u>	

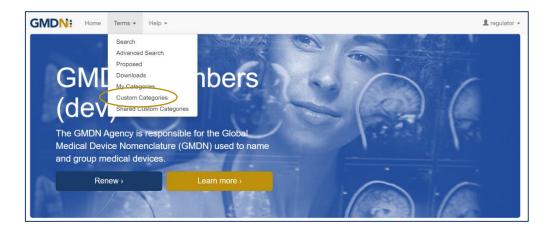
### 4. GMDN - Custom Categories - Step-by-Step Guide

This is a Step-by-Step Guide for using the Custom Categories function on the GMDN website.

The user of the GMDN website with the appropriate account permission can add, modify, and delete custom categories associated with their membership account.

1. Login to the GMDN Database using your Username and Password.

The Custom Categories option is found in the Terms dropdown menu.



2. By clicking on *Custom Categories* the list of existing Custom Categories on your account will be listed.

To create a new Custom Category select New Item.

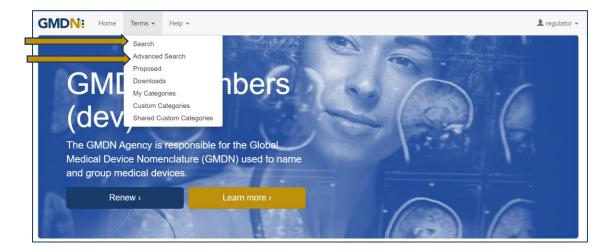
GMDN: Home Terms - Help -		👤 re	gulator
Custom Categories			
Manage your Custom Categories.			
New item 6 category(s)			
Name	Code	Shared	
	Code UCT3		Terms
Name			<u>Terms</u>
Name Coated Stents	UCT3	Edit     Edit	
Name Coated Stents Government Account Custom Category	UCT3 UCT5	Edit     Edit	Terms
Name Coated Stents Government Account Custom Category High risk bioabsorbable implants	UCT3 UCT5 UCT7	<ul> <li>✓ Edit</li> <li>Edit</li> <li>✓ Edit</li> </ul>	<u>Terms</u> <u>Terms</u>

3. For your new Custom Category, type in a Name and Definition, if you would like your Custom Category to be shared (visible to other GMDN members - Government Departments, Healthcare Providers and Conformity Assessment Bodies) then check the Shared box. Click the Save button to create your Custom Category.



GMDN: Home	Terms - Help -	👤 regulator 👻
Create Custo	m Category	
Modify this custo	m category.	
Name	Training Test	
	200 max disalacter.	
Definition	Training Test - Stents	
	300 max character.	
Code	Auto number.	
Shared	Share with other GMDN members (Government Department, Healthcare Provider, Conformity Assessment Body).	
	Save L elete	

4. There are two ways to add GMDN Terms to your Custom Category. You can use the Search function or the Advanced Search function via the Terms dropdown menu on the homepage.



5. If using Search. Enter a keyword or words and click Search.

	GMDN: Home Terms - Help -		L regulator -
	Search 🛛		
	Find Terms by keyword(s).		
_		Freih	Q Search
	stent Options Reset	English	v Q search
	Opuluts <u>KESEI</u> Examples: <u>stent</u> , <u>aorta stent</u> , <u>aorta OR stent</u> , <u>aorta NOT stent</u> , <u>"aortic stent"</u> , <u>"stent ", 62572 47685</u> Note: <u>Translations may not be available for some terms</u> .		
	2		

6. Select the GMDN Terms you wish to add to your Custom Category by clicking the check box next to Details and then click the Custom Category button.

GMDN: Home Terms - Help -	🧘 regulator 👻
Search o	
Find Terms by keyword(s).	
stent	English - Q Search
Options Reset	
Examples: <u>stent, aorta stent, aorta OR stent, aorta NOT stent, "aortic stent", "stent", 62572 47685</u> Note: Translations may not be available for some terms.	
1-25 of 180 term(s)	Custom Category
Name	Code Status
Abdominal aorta endovascular <mark>steni-</mark> graft deployment aid	56295 Active Details
Antibody-coated coronary artery stent	47826 Active Details
Aortic arch branch vessel endovascular steni-graft, basic	65227 Active Details
Aortic arch branch vessel endovascular steni-graft, drug-coated	62571 Active Details
Aortic arch endovascular <mark>stenl</mark> -graft	62573 Active Details
Aortic arch endovascular stender	63144 Active Details
Aortic stent implantation kit	64344 Active Details
Arteriovenous endovascular steml-graft	62528 Active Details
Bare-metal coronary artery stent	53616 Active Details

7. Using the dropdown menu on the pop-up box select which Custom Category or Categories you would like the Terms to be added to and click the *Save* button. Alternatively, you can click the *More* button.

GMDN: Home Terms - Help -		👤 regulator 👻
Custom Category ×		
Search 🛛		
Find Terms by keyword(s		
stent Save More. Cancel	English	V Q Search
Options <u>Reset</u> Examples <u>stent</u> , <u>aorta stent</u> , <u>aorta OR stent</u> , <u>aorta NOT stent</u> , <u>"aortic stent"</u> , <u>62572.47685</u> Note: Translations may not be available for some terms.		
1-100 of 180 term(s)		Custom Category
Name	Code Statu	is 🗆 🍵
Abdominal aorta endovascular stenl-graft deployment aid	56295 Active	e <u>Details</u>
Antibody-coated coronary artery stem	47826 Activ	e <u>Details</u>

8. This will take you to the Add Terms page. Select which Custom Category or Categories you would like the Terms to be added to and click the *Save* button.

GMDN: Home Terms - Help -			
Add Terms			
Select your Custom Categories to add Terms.			
Save			
8 category(s)			
Name	<u>Code</u> Share	d Add	
Coated Stents	UCT3 🖌		
Dressings	UCT11		
Government Account Custom Category	UCT5		
High risk bloabsorbable implants			
Home-use software IVDs	UCT4		
Long list category	UCT9		
Test Custom Category	UCT2		
Training Test	UCT10	2	

9. When the Save button is pressed the GMDN Terms will be added to the Custom Category.

GMDN: Home Terms - Help -	L regulator -
Success	
Your request has been successfully processed.	
Where do you want to go?	
Go to <u>Home</u> page     Choose from menu	

10. The *Advanced Search* displays the eight Category headers which group the GMDN Categories. For example, Categories such as Tissue reparation devices, Endoscopic devices, In-vitro diagnostic devices (IVDs) fall under the Device Function header, Cardiovascular devices, Neurological devices, Orthopaedic devices etc fall under Anatomical Speciality and so on. The structure of the hierarchy is revealed by clicking on the arrows to display the Categories under each Header.

GMDN: Home Terms - Help -	👤 regulator 👻
Advanced Search <b>e</b> Browse Categories to find Terms.	
Options         Beset           English         Any device         Active           Note: Translations may not be available for some terms.         My Category	100 rows <ul> <li>Hide definitions</li> <li>Filter terms</li> <li>Go</li> <li>Show sub-group ter</li> <li>Custom Category</li> </ul>
Category Explorer Find Category  Device Function Anatomical Specialty Names Index Invasiveness/implantability Use Frequency Power Materials (clinically significant) Featured Attributes	

11. The list of GMDN Terms in each Category group is revealed by clicking on the arrows. The GMDN Term Definition is revealed by clicking on the GMDN Term Name. By clicking on the *Details* link, you can see more information belonging to that GMDN Term, including a translation of the text, if available.

GMDNie Home Terms - Help -						👤 reg	ulator
Advanced Search o							
······································							
Browse Categories to find Terms.							
ptions Reset							
English • Any device • Active •	100 rows	~	Hide definitions	~			
te: Translations may not be available for some terms.							
My Category	Filter terms	Go	Show sub-group ter	~	Cust	om Categ	огу
Category Explorer Find Category	60 term(s)					E	Ехро
Device Function	News			Queda	Status		
Active implant devices/ancillaries CT2727	Name			Code			
<ul> <li>Hearing implant systems and associated devices CT2229</li> <li>Implantable cardiac electrical stimulators and associated devices CT2750</li> </ul>	Audiometric/heari	ng device s	oftware	60211	Active	<u>Details</u>	
<ul> <li>Inplantable extracardiac electrical stimulators and associated devices CT274</li> <li>Implantable influsion pumps and associated devices CT2751</li> <li>Implantable physiological monitoring systems and associated devices CT286</li> </ul>	Auditory brainster electrode	n implant in	raoperative test	64803	Active	<u>Details</u>	9
Middle ear implant systems CT2304	Auditory brainstem implant system			47285	Active	Details	
<ul> <li>Tissue reparation devices CT1007</li> <li>Surgical/Invasive procedure instrumentation CT1274</li> </ul>	Auditory brainstem implant system electrode array			47371	Active	Details	
Endoscopic devices CT366	assembly						
<ul> <li>Catheterization/Cannulation/Fluid path devices CT2818</li> <li>Tissue/Fluid collection and preservation devices CT2724</li> </ul>	Bone-conduction	hearing aid.	magnetic-implant	65092	Active	Details	
Anaesthesia and ventilation devices CT996			5				
Circulatory assistive/bypass devices CT2816	Bone-conduction	hearing imp	lant system	65087	Active	Details	
Autologous blood processing devices CT2817	implantation tool						
Radiological devices CT999	Dense see duration i			65088	Active	Detaile	_
<ul> <li>Energy-based therapy equipment (non-radiological/non-surgical) CT2723</li> <li>Physiological monitoring/measuring devices CT2726</li> </ul>	implantable abutn		lant system partially-	60066	Active	<u>Details</u>	
Physical examination equipment CT2795	Bone-conduction	hooring imp	lant evetom cound	65093	Active	Details	
Biomechanical rehabilitation equipment CT275	processor	nearing imp	iant system sound	00090	Active	Details	
Bariatric therapy devices CT2811	processer						
General hospital devices CT149     Disability living products CT1000	Bone-conduction	hearing imp	lant system sound	62209	Active	<b>Details</b>	
<ul> <li>Disability-living products CT1000</li> <li>Complementary therapy devices CT343</li> </ul>	processor/vibrator	r					
<ul> <li>Sexual-activity/Contraceptive/Home-conception devices CT2800</li> </ul>	Rona conduction	hearing ima	lant system vibration	65090	Active	Details	
<ul> <li>Laboratory instruments and equipment CT202</li> </ul>	transmission plate		ant system vibration	00090	Active	Details	
In vitro diagnostic medical devices (IVDs) CT954	a anomiosion plate						
▶ Software CT1651	Bone-conduction	hearing imp	lant system vibration	65089	Active	<b>Details</b>	
<ul> <li>Anatomical Specialty</li> </ul>	transmission scre	w					
Cardiovascular devices CT145	Barra analy it		land an advantage of the set	0.4005			_
Pulmonary devices CT2722		nearing imp	lant system vibrator	64989	Active	<u>Details</u>	
Gastro-urological devices CT1002     Neurological devices CT1005	assembly						
Neurological devices CT1005     Ophthalmic devices CT230	Cochlear electrod	e array dep	h gauge, reusable	62561	Active	Details	
Obstetrical/Gynaecological devices CT181			- • ·				
<ul> <li>Ear/Nose/Throat (ENT) devices CT1001</li> </ul>	Cochlear electrod	e arrav dep	h gauge, single-use	61603	Active	Details	

GMDN: Home	Terms - Help -	gulator +
Term Details		
Name	Cardiaciperipheral vascular guidewire, reprocessed	
Definition	A long this, stelle wire intended to be percutaneously placed into the cardiac vasculature (ventricles or coronary vessels) to function as a guide introduction, pushtoming, and/or operation of a device are, cathetier, placing lead), if my add be used in the perparam vasculature. In this possi- ricle are subscriptions sets, Warrol, will or warrol cardiary, and a statuble an avery of each possible. It is and to raiso stagenost a introvertinoaria procedures. This is a single-use device that has previously been used on a patient and has been subgranded to accurate an advance and pos- manducturing to a studious sets) evel possible application.	y made nd
Code	44839	
Status	Active	
Created Date	02 Nov 2004	
Modified Date	26 Sep 2017	
	Add to Custom Category	
Translations		
Language	- Select -	v

12. To add GMDN Terms to your Custom Category, click the check box next to Details and then click the Custom Category button. If you click the check box at the top this will *select all* the GMDN Terms on that page.

# Important: If there are several pages of GMDN Terms you need to save each page before proceeding to the next one.

You can choose how many GMDN Terms are displayed per page by using the *rows* dropdown menu.

Advanced Search <b>o</b> Browse Categories to find Terms.					
Dptions Reset					
English   Any device   Active	25 rows Hide definitions	~			
lote: Translations may not be available for some terms.					
My Category	Filter terms Go Show sub-group ter	~	Cust	om Categ	ory
Category Explorer Find Category	1-25 of 60 term(s)		(	E	xport
Device Function	Name	Code	Status	$\overline{}$	-
<ul> <li>Active implant devices/ancillaries CT2727</li> <li>Hearing implant systems and associated devices CT2229</li> </ul>	Audiometric/hearing device software	60211	Active	Details	
<ul> <li>Implantable cardiac electrical stimulators and associated devices CT2750</li> <li>Implantable extracardiac electrical stimulators and associated devices CT275</li> <li>Implantable infusion pumps and associated devices CT2751</li> </ul>	Auditory brainstem implant intraoperative test electrode	64803	Active	<u>Details</u>	0
<ul> <li>Implantable physiological monitoring systems and associated devices CT28 Middle ear implant systems CT2304</li> </ul>	Auditory brainstem implant system	47285	Active	Details	
<ul> <li>Tissue reparation devices CT1007</li> <li>Surgical/Invasive procedure instrumentation CT1274</li> <li>Endoscopic devices CT366</li> </ul>	Auditory brainstem implant system electrode array assembly	47371	Active	<u>Details</u>	
<ul> <li>Catheterization/Cannulation/Fluid path devices CT2818</li> <li>Tissue/Fluid collection and preservation devices CT2724</li> </ul>	Bone-conduction hearing aid, magnetic-implant	65092	Active	Details	
Anaesthesia and ventilation devices CT996     Circulatory assistive/bypass devices CT2816     Autologous blood processing devices CT2817	Bone-conduction hearing implant system implantation tool	65087	Active	Details	
Radiological devices CT999     Energy-based therapy equipment (non-radiological/non-surgical) CT2723     Physiological monitoring/measuring devices CT2726	Bone-conduction hearing implant system partially- implantable abutment	65088	Active	Details	
Physical examination equipment CT2795     Physical examination equipment CT2795     Biomechanical rehabilitation equipment CT275     Bariatric therapy devices CT2811	Bone-conduction hearing implant system sound processor	65093	Active	<u>Details</u>	
General hospital devices CT249     Disability-living products CT100     Complementary therapy devices CT343	Bone-conduction hearing implant system sound processor/vibrator	62209	Active	<u>Details</u>	
<ul> <li>Sexual-activity/Contraceptive/Home-conception devices CT2800</li> <li>Laboratory instruments and equipment CT202</li> </ul>	Bone-conduction hearing implant system vibration transmission plate	65090	Active	Details	
<ul> <li>In vitro diagnostic medical devices (IVDs) CT954</li> <li>Software CT1651</li> <li>Anatomical Specialty</li> </ul>	Bone-conduction hearing implant system vibration transmission screw	65089	Active	<u>Details</u>	
<ul> <li>Cardiovascular devices CT145</li> <li>Pulmonary devices CT2722</li> <li>Gastro-urological devices CT1002</li> </ul>	Bone-conduction hearing implant system vibrator assembly	64989	Active	<u>Details</u>	
<ul> <li>Neurological devices CT1005</li> <li>Ophthalmic devices CT230</li> </ul>	Cochlear electrode array depth gauge, reusable	62561	Active	<u>Details</u>	
<ul> <li>Obstetrical/Gynaecological devices CT181</li> <li>Ear/Nose/Throat (ENT) devices CT1001</li> </ul>	Cochlear electrode array depth gauge, single-use	61603	Active	Details	
<ul> <li>Audiometers and associated devices CT118</li> <li>Cephalometric x-ray systems and associated devices CT2102</li> </ul>	Cochlear electrode array introducer, reusable	61446	Active	Details	
Ear specula CT1927	Cochlear electrode array introducer, single-use	63161	Active	Details	
ENT burs CT1284	•				-

13. Then select which Custom Category or Categories you would like the Terms to be added to and select the *Save* button. The GMDN Terms will now be added to the Custom Category.

GMDN: Home Terms - Help -		👤 regu	ılator 👻
Add Terms			
Select your Custom Categories to add Terms.			
Save			
8 category(s)			
Name	<u>Code</u>	Shared	Add
Coated Stents	UCT3	•	
Dressings	UCT11		
Government Account Custom Category	UCT5		
High risk bioabsorbable implants	UCT7	•	
Home-use software IVDs	UCT4		
Long list category	UCT9		
Test Custom Category	UCT2	_	
Training Test	UCT10		



14. How to export data from your Custom Category. First select Custom Categories from the Terms dropdown menu on the page header. Then select the Terms button from the Custom Category you are wanting to export.

GMDN: Home Terms - Help -			👤 re	egulator 👻
Search         Advanced Search         Proposed         Downloads         My Categories         Stared Custom Categories         Stared Custom Categories				
Name	Code	Shared		
Coated Stents	UCT3		Edit	Terms
Dressings	UCT11		Edit	Terms
Government Account Custom Category	UCT5		Edit	Terms
High risk bioabsorbable implants	UCT7	<b>~</b>	Edit	Terms
Home-use software IVDs	UCT4		Edit	Terms
Long list category	UCT9		Edit	Terms
Test Custom Category	UCT2		Edit	Terms
Training Test	UCT10		Edit	Terms

15. Within the Custom Category Terms page click the Export button. Within this page you can also remove any Terms that you no longer require in your Custom Category.

GMDN: Home Terms - Help -				L regulator -
Custom Category Terms Terms within this Custom Category.				
Term codes	Add			
Category	17 term(s)			Export
Training Test	Name	Code	Status	
Training Test - Stents UCT10	Abdominal aorta endovascular stent-graft deployment aid	56295	Active	Remove Details
	Antibody-coated coronary artery stent	47826	Active	Remove Details
Blood donor set, double-pack		44034	Active	Remove Details
	Blood donor set, many-pack	47885	Active	Remove Details
	Blood donor set, quad-pack	46347	Active	Remove Details
	Blood donor set, quin-pack	47747	Active	Remove Details
	Blood donor set, single-pack	44033	Active	Remove Details
	Blood donor set, triple-pack	44037	Active	Remove Details
	Centrifuge rotor, adjustable angle	37531	Active	Remove Details
	Confocal endomicroscopy system	62287	Active	Remove Details
	Confocal endomicroscopy system probe	62288	Active	Remove Details
	Endoscope antifog solution	45225	Active	Remove Details
	Paediatric blood donor set	46346	Active	Remove Details

16. The Custom Category data will be downloaded as an .XML file to your device.

### 5. GMDN – My Categories – Step-by-Step Guide

This is a Step-by-Step Guide for using the My Categories function on the GMDN website. This function allows you to add specific GMDN Categories to your account that are of interest to you or your organisation.

The user of the GMDN website with the appropriate account permission can add, modify, and delete My Categories associated with their membership account.

1. Login to the GMDN Database using your Username and Password.

GMDN: Home	erms - Help -
	Search
	Advanced Search
	Proposed
GM	Downloads hy Categories here a construction of the construction of
The GMDN A	Custom Categories
Medical Devi	Shared Custom Categories Shared Custom Annual Categories Shared Custom Categories Shared to name
and group me	
Ren	D Learn more
A .	
Members Nev	6

The My Categories option is found in the Terms dropdown menu.

2. By clicking on *My Categories* the list of existing My Categories on your account will be listed.

To add a new My Category if you already know the GMDN Category Code you can input it in the text box and select *Add*.

My Categories				
Manage your favourite GMDN Categories.				
Advanced Search Category codes Add 2 category(s)				
Name	Code	Status		
Cardiac resuscitators	CT1910	Active	Remove	Terms
Hearing implant systems and associated devices	CT2229	Active	Remove	<u>Terms</u>

3. Another way to add a GMDN Category to your My Category list is to use the *Advanced Search* tool. This can either be found on the *Terms* dropdown menu or using the *Advanced Search* link from the My Categories page.

GMDN: Home	Terms - Help -		L regulator -
My Categorie Manage your fav	Proposed Downloads	ories.	
Advanced Search Category codes	My Categories Custom Categories Shared Custom Categories	Add	
2 category(s)			
<u>Name</u>		<u>Code</u> Status	
Cardiac resuscitators		CT1910 Active Rem	iove <u>Terms</u>
Hearing implant systems and	d associated devices	CT2229 Active Rem	ove <u>Terms</u>

4. On the Advanced Search page use the *Category Explorer* to select the Category that you would like to add, when a GMDN Category is selected it will become bold. Then click on the *My Category* button.

### Please note you can only add one GMDN Category at a time to your My Categories list.

Advanced Search 🛛					
Browse Categories to find Terms.					
Dptions Reset					
My Category	Filter terms Go Show sub-group	€ ✓	Cus	stom Cate	gory
Category Explorer Find Category	1-100 of 648 term(s)				Export
Device Function     Active implant devices/ancillaries CT2727	Name	Code	Status		
<ul> <li>Tissue reparation devices CT1007</li> <li>Surgical/invasive procedure instrumentation CT1274</li> </ul>	Anal fistula/pilonidal sinus cleaning brush	67284	Active	Details	
Endoscopic devices CT366	Arthroscopic access cannula seal, reusable	62457	Active	Details	0
Catheterization/Cannulation/Fluid path devices CT2818     Tissue/Fluid collection and preservation devices CT2724	Arthroscopic access cannula seal, single-use	62456	Active	Details	
<ul> <li>Anaesthesia and ventilation devices CT996</li> <li>Circulatory assistive/bypass devices CT2816</li> </ul>	Arthroscopic access cannula, reusable	62458	Active	Details	-
<ul> <li>Autologous blood processing devices CT2817</li> <li>Radiological devices CT999</li> </ul>					
<ul> <li>Energy-based therapy equipment (non-radiological/non-surgical) CT2723</li> </ul>	Arthroscopic access cannula, single-use	58752	Active	<u>Details</u>	
<ul> <li>Physiological monitoring/measuring devices CT2726</li> <li>Physical examination equipment CT2795</li> </ul>	Arthroscopic insufflator	36677	Active	<u>Details</u>	
Biomechanical rehabilitation equipment CT275	Arthroscopic irrigation/insufflation system	36003	Active	Details	0
Bariatric therapy devices CT2811     General hospital devices CT149	Arthroscopic obturator	58753	Active	Details	
▶ Disability-living products CT1000		30733	ACUVE	Details	
<ul> <li>Complementary therapy devices CT343</li> <li>Sexual-activity/Contraceptive/Home-conception devices CT2800</li> </ul>	Arthroscopic shaver system blade, reprocessed	61800	Active	<b>Details</b>	
<ul> <li>Sexual-activity/Contraceptive/Home-conception devices C12800</li> <li>Laboratory instruments and equipment CT202</li> </ul>	Arthroscopic shaver system blade, reusable	38654	Active	Details	0

5. The selected GMDN Category has now been added to your My Categories list.





6. On the My Categories page you can view the GMDN Terms within your selected GMDN Categories by selecting the *Terms* button. You can also remove any GMDN Category from your list if you no longer require it by using the *Remove* button.

My Categories			
Manage your favourite GMDN Categories.			
Advanced Search			
Category codes	Add		
3 category(s)			
Name		Code	Status
Cardiac resuscitators		CT1910	Active Remove Terms
Endoscopic devices		CT366	Active Remove Terms
Hearing implant systems and associated devices		CT2229	Active Remove Terms

### 7. You can also use the *Export* button to download the GMDN Category as an .XML file.

5 term(s)	Exp
Name	Code Status
Cardiac resuscitator, battery-powered	61908 Active Det
Cardiac resuscitator, line-powered	44780 Active Det
Cardiac resuscitator, manual	41882 Active Deta
Cardiac resuscitator, pneumatic	45748 Active Deta
Cardiopulmonary resuscitator	35309 Active Det
	Name           Cardiac resuscitator, battery-powered           Cardiac resuscitator, line-powered           Cardiac resuscitator, manual           Cardiac resuscitator, pneumatic

	Agency Ltd." title="Terms" group="CT1007" subGroups="True" lang="en" date="2024-11-08 16:32" count="1423">
w <term></term>	
<termdefinition>An imp therapeutically implan</termdefinition>	mStatus>
<pre><createddate>2021-08-0</createddate></pre>	
<termdefinition>A non- abdominal aortic aneur femoral artery to the and is typically avail</termdefinition>	ta endovascular stent-graft joabsorbable tubular device typically implanted at the junction of the abdominal aorta and the common iliac arteries to reduce pressure on an sm (AAA); it does not contain anticoagulants or pharmaceuticals that prevent narrowing of the vessels. It is percutaneously inserted via the site of implantation where it self-expands. It is typically made of a metallic outer mesh structure with an inner polymer tube (endovascular gu bble in two designs: 1) a single tube for insertion into one iliac artery; or 2) a two-part bifurcation design (e.g., Y-shaped tube) for inser rise.

8. If you would like to receive notifications if any of the GMDN Terms within your selected categories are amended, made obsolete or if a new Term is added then you need to have the correct settings in your profile.

Go to *My Profile* on the drop-down menu and then check the *Term Changes for My Categories* box under the "How we communicate with you" section.



GMDN: Home	Terms + Help +	👤 manufacturer 👻
My Profile		Alerts Membership
Modify your perso	onal details.	Organisation Orders Users
Prefix	- Select -	My Profile Log off
First Name	manufacturer	
Middle Name		
Last Name	test	
Job Title		
Group		
User Name	manufacturer@gmdnagency.org	
Email	manufacturer@gmdnagency.org	
Phone		
How we commun	icate with you	
Term Changes		
	Real-time email notifications about your purchased terms. See also <u>Alerts</u>	
Term Changes for My Categories	Real-time email notifications about Terms in your 'My Categories'.	

### 6. GMDN Website - Enquiry - Step-by-Step Guide

This is a Step-by-Step Guide for submitting an Enquiry for new or modified GMDN Codes using the GMDN website.

If after using the GMDN Search or GMDN Advanced Search tools a user cannot find a relevant GMDN Term for their product, they are invited to submit an *Enquiry*. The Enquiry process is the only method of seeking assistance from the GMDN Agency in identifying GMDN Terms. The outcome of an *Enquiry* will be one of the following:

- a. The GMDN Agency identifies an existing GMDN Term.
- b. An existing GMDN Term is modified to include the new product's characteristics.
- c. A new GMDN Term is created.

1. Logon to the GMDN Database using your Username and Password.

2. Click on *Enquiry* on the dropdown list in the *Help* menu.



3. The *Enquiry* screen displays all the previous enquiries submitted from the same account. A filter is available to list all enquires by a specific user applicant. This page is also used to monitor progress on all outstanding enquires.

GMD	Home Terms 🗸	Help 👻					👤 regulator 🗸
Enqui	ry 😧						
	nd a Term for your	product?					
Cor   Bas	fore creating New Enquiry pleas mpletion can take several weeks sic members have lower priority glish only.	(depending on product comple					
New Enqu	iry			User	- All -		~
Ref	Modifie	d Date Create	ed Date	Medical D	evice Name	User	Status
No items fo	bund.						
۳ 🖌							
Contact Us	Cookie Policy Privacy Policy	Licence Agreement Terms of	of Website Use Copy	<u>right Stateme</u>	nt Build 2024.2.6 © 2024 G	MDN Agency Ltd.	

4. Click on *New Enquiry* to start filling in product details.



All information provided to the GMDN Agency is confidential to us and is subject to current Data Protection Law. For more information, please see our *Privacy Policy*, found in the footer of all webpages.

Enquiry	
Product details. Your Email	manufacturer@gmdnagency.org <u>Mv. Profile</u>
Medical Device Name	Brand/Trade/Proprietary Name or Common Name
Manufacturer Model Catalogue / Reference	
(REF) Files	Choose Files No file chosen Please weet documentation (e.g. IFU, brochure) which includes an image. Supports Images, Adobe Acrobat, Microsoft Word.
Url	http://www.example.com
	Why do you require a GMDN term i.e. which Regulator or other body is asking you to provide a GMDN term?
Step 2	General medical device In Vitro Diagnostic (IVD) Software Please choose your enquiry type to proceed to the next step.
	K Back Cancel Next >

The *Medical Device Name, Manufacturer, Model* and *Reason* are mandatory data fields. This information is used by us to help identify the device but is not necessarily used in the final GMDN Term Name or Definition.

Please also attach a File which contains the product information by using the *Choose File* button. For example, an 'Instruction for Use' (IFU) or product brochure. This is also a mandatory field.

You can also provide a *Catalogue/Reference (REF)* and a relevant *URL* if applicable; this is not a mandatory field however it may increase the speed of the Enquiry process.

5. At the bottom of the page, Step 2 asks what type of device the enquiry relates to. This is used to determine the next set of questions we ask about the product. There are three options. Select the relevant option and click next.

- a. *General medical device* where the primary product is a general medical device.
- b. In Vitro Diagnostic (IVD) where an IVD is the primary product.
- c. Software where software is the primary product



a. *General medical device* is for products that are to be used as a medical device only and will ask questions related to that specific technology. Once you have completed the form click next.

inquiry	tep 1			Step 2			
eneral medical	device.						
Intended Use / Target							
Components	Name	Use Frequency	Sterility	Invasiveness	Sold Separately	Power	Materials
		plete this table to include all cor single-piece devices complete a		ed separately, i.e. outside of	the system or kit.		
Key Attributes	- Select						
Additional							
							_
						1 Dank	Can el Next

b. In Vitro Diagnostic (IVD) will ask questions only related to IVDs. Once you have completed the form click next.

Enquiry	
ទា	kp 1 Step 2
In Vitro Diagnosti	c (IVD).
Nature Of Device	- Select - *
Target Analyte	
Components	- Select -
	Select all components requiring GMDN Code
Components (Other)	
Assay Type / Methodology	
	Assay analysis technique / methodology
Clinical Application	Clinical application / Associated clinical condition
Usage	- Select · ·
Additional	
	Caren Ned >

c. **Software** is for software-based products only and will ask questions related to that specific technology. Once you have completed the form click next.

Enquiry				
Ste	p 1	Step 2		
Software.				
Used For				
Functionality				
Technology				
Platform	- Select -			•
Features	- Select -			•
Additional				
				Cantel Next >



6. The *Summary* page is used to provide a final check on the product details prior to submission. Review the summary and when happy with it press submit.

Enquiry	
5	Step 1 Step 2 Step 3
Summary.	
Medical Device Name	Syringe
Manufacturer	Syringe Co
Model	long
Catalogue / Reference (REF)	
Files	Obsoletion template - PW v1.docx
Url	
Reason	adsdr:
Enquiry Type	Software
Used For	Monitoring blood pressure
Functionality	Os-Based
Technology	App for smartphone
Platform	Dedicated hardware
Features	Captures patient demographics/clinical data
Additional	
	Cancel Submit >

7. Following submission, the GMDN Term is assessed by the GMDN Agency and allocated to a subject expert to review. The expert will contact you for more information if needed using a notification email. An example email is given below. The message contains a link to your *Enquiry*.

Dear XXXXXXXX
The GMDN Term Development Team has posted a message regarding your enquiry. This may be asking for more information or another comment regarding your enquiry. The Term development process cannot continue until the necessary information is received.
Enquiry - <u>EQ160001</u>
Regards GMDN Agency

Any change to the status of an *Enquiry* will also be made to the *Alerts* page and is found in the Account dropdown menu at the top right of the webpage (with the person icon). There will always be an opportunity to discuss the outcome of the Enquiry with the GMDN expert.

8. Following the satisfactory completion of the Enquiry, it will be closed. The history will still be available for future reference in the *Enquiry* page.

### 7. GMDN Website – Downloading the GMDN Data Set

This is a Step-by-Step Guide for Exporting the GMDN Database and importing into a spreadsheet such as Excel.

The user of the GMDN website with the appropriate account permission can export data from their membership account.

1. Logon to the GMDN Database using your Username and Password.

The *Downloads* page is found in the dropdown list in the *Terms* menu at the top of the webpage. PLEASE NOTE: If the *Downloads* option is unavailable, please <u>contact us</u>.



2. By clicking on *Downloads* the options for downloading the GMDN Database will be displayed.

GMDN: Home Terms - Help -	L regulator -
Downloads	
Download term data files.	
Latest Full Data Set	
Created Date 01 Dec 2023 File Contents gmdnData23_12.xml File Size 5.1 MB	
Monthly Changes	
SindnDataUpdate20231101_20231201.zip Freated Date 01 Dec 2023 File Contents gmdnDataUpdate20231101_20231201.xml File Size 22.2 KB	
Previous Full Data Set	
Greated Date 01 Nov 2023 File Contents gmdnData23_11.xml File Size 5.1 MB	
Contact Us Cookie Policy, Privacy Policy, Licence Agreement, Terms of Website Use, Copyright Statement, Build 2023, 11.30, © 2023, GMDN Agency Ltd.	

3. Click on the relevant *Download Icon* for the Data Set you require and this will be saved to the default location on your device (usually the 'Downloads' folder) as a .zip file in the XML format. The XML format has been chosen because it is compatible with the GMDN Database and is easily converted and imported into software packages for further analysis.

4. To import the data into your system double click on the .xml file and choose your relevant software package.



C:\Users\PaulWadsworth\Dowr	loads\gmdnData23_1	2.zip\			-		
File Edit View Favorites Tool	s Help						
🕂 🖿 🗸 📫 🖷	🕨 🗶 🧎						
Add Extract Test Copy Mo	ve Delete Info						
C:\Users\PaulWadsworth\	Downloads\gmdnData	23_12.zip\					
Name				Size	Packed Size	Modified	
gmdnData23_12.xml				39 470 018	5 330 068	2023-12-0	)1 (
<							
/ 1 object(s) selected	39 470 018	39 470 018	2023-12-01 01:00				-



### 8. GMDN Agency - Membership Renewal Process (free membership access)

Guide for membership Renewal for existing GMDN Members, showing screen shots and system email messages.

1. The Membership status is always available to view in the *Membership* tab and is found in the Account dropdown menu at the top right of the webpage (with the person icon).



2. If you click on the *Membership* link, it will take you to your *Membership* page.

GMDN: Home	Terms - Help -	👤 regulator 👻
Membership	θ	
Information abou	it your account membership.	
Your account expires in 36	i8 days,	
Membership Type	Government Department	
Annual Sales	N/A	
Number	A118142	
Start Date	23 Dec 2016	
Expiry Date	30 Nov 2024	
Activated	Yes Only activated accounts can access GMDN Terms and Codes.	
Code Credits		
User Credits	3	
	Certificate Licence Agreement	



3. Membership can be renewed up to 3 months before it is due to expire and when available will be visible as a *Buy Membership* link on your *Membership* page.

GMDN: Home Terms - Help -	
Membership	
Your account expires in 33 dates Buy Membership	

4. When the user clicks the *Buy Membership* button, the *Membership Renewal* screen will be displayed.

For membership with £0.00 value there are no payment options applicable. Click Next.

GMDN: Home	Terms - Help - Legul	ator 👻
Membership		
Membership		
Membership type compa	ison	
Membership Type	Government Department	~
	SCHEDULE A – for a GOVERNMENT DEPARTMENT	-
	1 Definition. For the purposes of this Agreement a 'Government Department' is an organization recognized by a national government as being the body responsible for the regulation or approval of medical devices and other Government Departments in the same country connected with the Licensee can be considered to be part of the Licensee.	
	2 Purpose. Use of the GMDN nomenclature for regulatory purposes where there is a need for general descriptors for identification purposes. The Licensee is further permitted to integrate the GMDN Database into its intranet IT domain for internal access only. The Licensee shall not be entitled to release or provide access to any part of the GMDN Database to any other party, except for specific regulatory investigations when	Ŧ
Annual Sales	N/A	~
	Company size changed? Please supply additional information to our Customer Services and we will amend your membership. Contact Us	
Additional Info		le
Currency	Euro (EUR)	~
Total	€0.00	
Method	Credit Card	
	Invoice	
	Quote MasterCard, Visa (EUR, GBP, USD), Amex (USD), JCB, Maestro (GBP).	
	unean and the front on Least much and least for t	
Purchase Order	Invoice purchase order number (optional).	
	and a feature and a second of the second by	
	🚾 🛶 Iga 🧼 VISA 🔿 Wörldpay	
	Refund Policy	
		t >



5. Next Terms & Conditions need to be accepted. Then click the blue Finish button.

Membership	
erms & Conditions	
1. LICENCE AGREEMENT	î
1.1. Access to the GMDN Database by you (the 'Licensee') is controlled by an electronic permit activated by entering a user ID and password. supplied by The GMDN Agency on a subscription basis. To be issued with such a user ID and password the Licensee must complete the Regis directed.	
1.2. By submitting the registration details in the Registration Form and by paying the relevant Licence Fee for accessing the GMDN Database, by the Terms and Conditions of this licence agreement and the relevant Schedule applicable to the type of licence as set out below. The person is warranting that the information submitted is true and accurate and that they are duly authorised on behalf of the Licensee to enter into the lic The GMDN Agency will grant the Licensee a licence to access the GMDN Database and use the codes accessible from it on the following Term Schedule.	n submitting the Registration Form ence agreement. In exchange,
2. TERMS AND CONDITIONS	
2.1. Definitions	
2.1.1. In these Terms and Conditions, the terms defined in the Schedule shall have the meanings set out in the Schedule and the following term meanings, unless the context requires otherwise:	ns shall have the following

6. A message will then be displayed stating the membership request is pending approval.

This will be evaluated by our Customer Services team and once approved a confirmation message will be sent to you.

GMDN: Home Terms - Help -	L regulator -
Pending	
Your request is pending approval.	
Where do you want to go?	
Go to <u>Home</u> page     Choose from menu	

7. For reference the order history on your account renewals can be seen in the *Orders* folder and is found in the Account dropdown menu at the top right of the webapge (with the person icon).



8. The GMDN website will now be fully functioning to search for GMDN Terms and Codes.

### 9. Stay in touch with the GMDN Agency

We have an 'opt-in' newsletter, which you can subscribe to, to stay ahead with news about the Agency and any key developments regarding the GMDN data set.

To opt-in to these options please tick the relevant box in *My Profile* as below. *My Profile* can be found in the Account dropdown menu at the top right of the webpage (with the person icon).

GMDN: Home	Terms - Help -
My Profile	
Modify your pers	onal details.
Prefix	- Select -
First Name	regulator
Middle Name	
Last Name	test
Job Title	
Group	
User Name	regulator@gmdnagency.org
Email	regulator@gmdnagency.org
Phone	
How we commun Term Changes	icate with you
Account Summary	Periodic email notifications about your account and purchased terms. See also <u>Alerts</u>
GMDN Focus	
	Save Confirm Email Change Password

From time to time, we may request your input when reviewing our GMDN Terms. This is an important part of maintaining the Terminology to ensure that it always represents devices on the market as accurately as possible. We also understand that this requires time on your part, and we are very appreciative of the responses and any additional information that you provide.

The GMDN is also on social media platforms such as <u>LinkedIn</u>, where we share news and other interesting articles from within the MedTech industry.

If you have any questions, please contact us at this link.