

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.

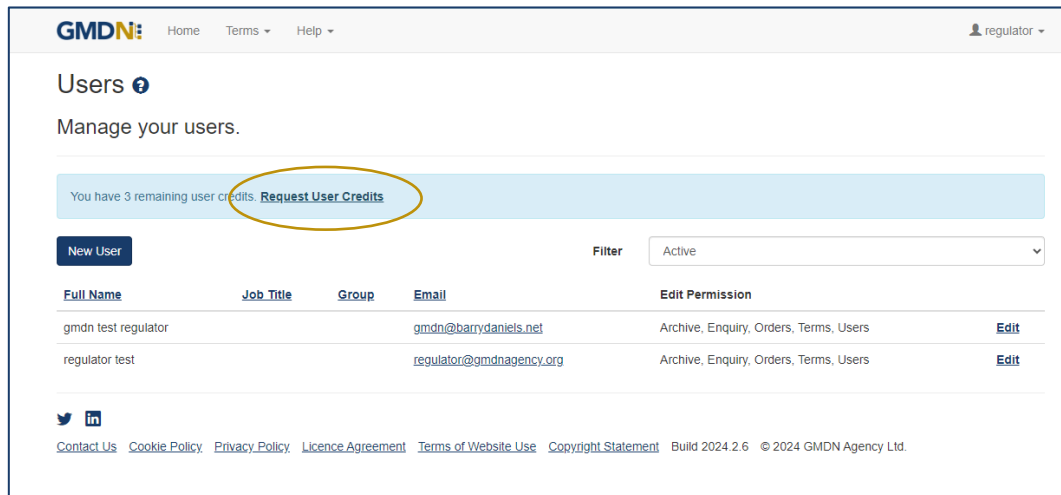
1. Login to the GMDN Database using your Username and Password.

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.



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.

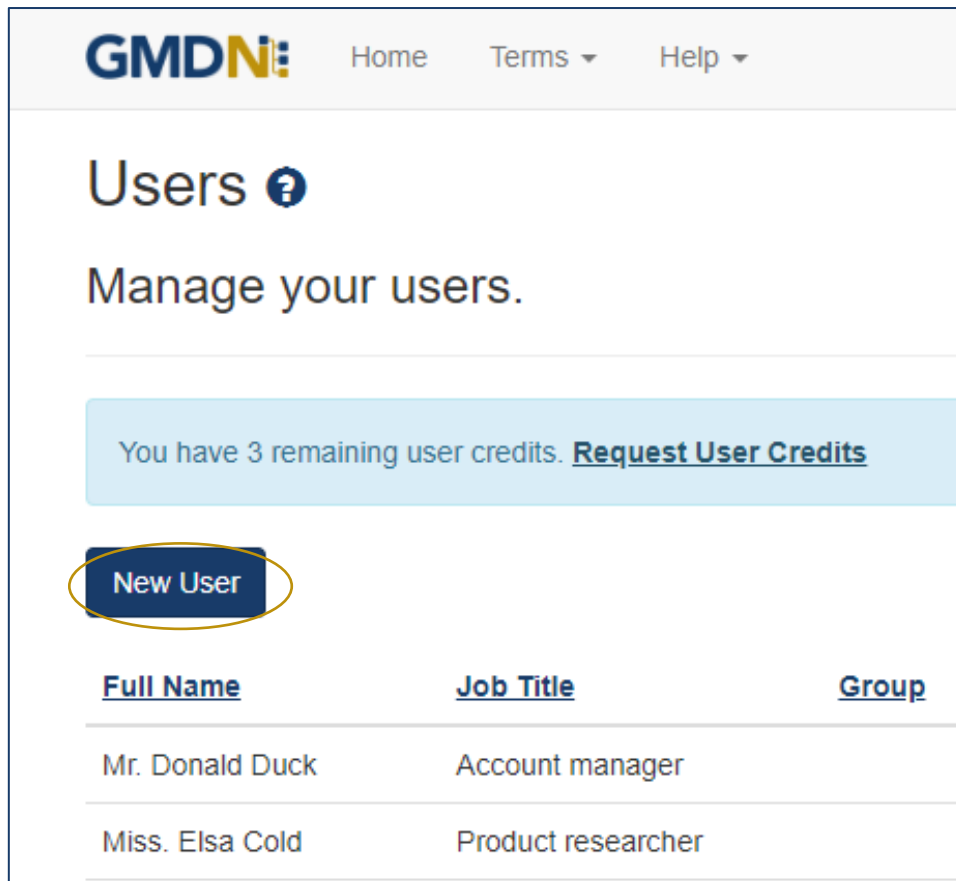
4. Each account when first activated, is provided with a certain number of user credits which are used to add more users. If you require more, they can be requested using the [Request User Credits](#) button.

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

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

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](#).



GMDN Home Terms ▾ Help ▾

Users ⓘ

Manage your users.

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

New User

<u>Full Name</u>	<u>Job Title</u>	<u>Group</u>
Mr. Donald Duck	Account manager	
Miss. Elsa Cold	Product researcher	

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.

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

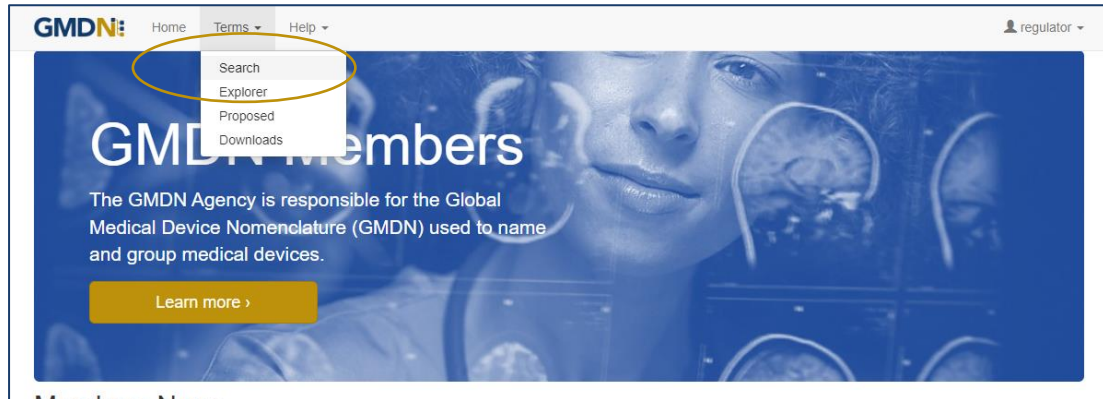
This is an automated message sent by GMDN Agency, please do not reply.

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

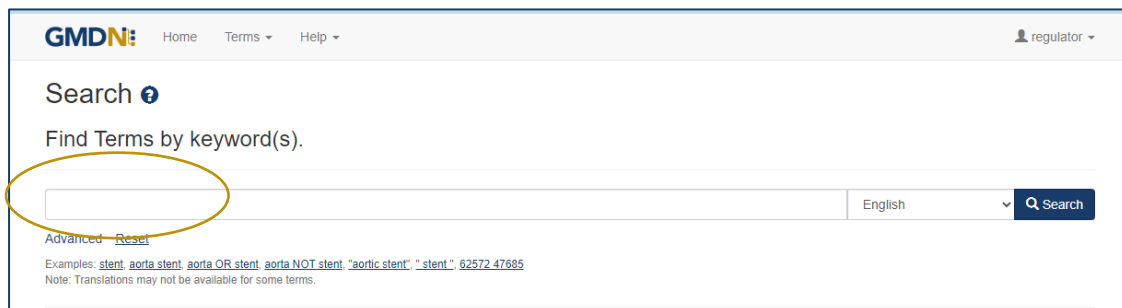
This is a Step-by-Step Guide for searching for GMDN Codes using the GMDN website.

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.



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.

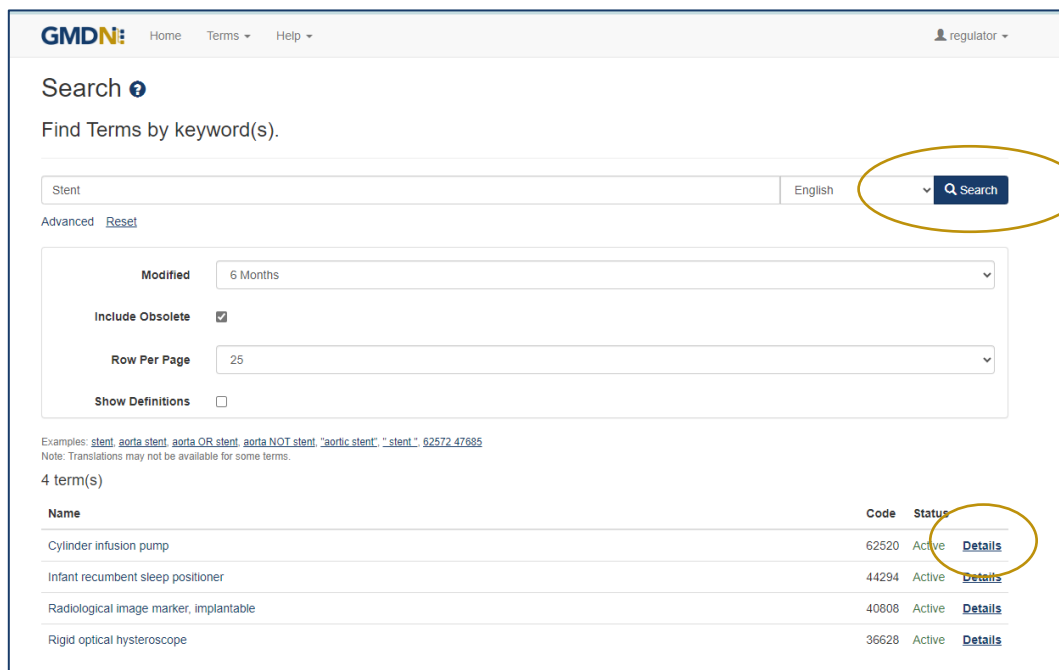
Specific searches can include 'obsolete' GMDN Terms.

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.



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.



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.

The screenshot shows the 'Term Details' page for 'Cylinder infusion pump'. The page includes the following information:

- Name:** Cylinder infusion 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 intravenous, subcutaneous, arterial, epidural, and intracavitary 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, filter, connectors, needle/catheter). This is a reusable device.
- Code:** 62520
- Status:** Active
- Created Date:** 19 Dec 2016
- Modified Date:** 12 Oct 2023

The 'Translations' section is also visible, showing a translation for the Spanish language:

- Language:** Español
- Name:** Bomba de infusión de cilindro
- Definition:** Dispositivo accionado eléctricamente destinado a facilitar la administración precisa y uniforme de medicamentos fluidos no específicos desde una bolsa de infusión, jeringa y botella estándar, a un paciente por vía 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 cilindro reemplazable, y que se conecta a un equipo de administración de infusión desechable (por ejemplo, tubo, filtro, conectores, aguja/catéter). Se trata de un dispositivo reutilizable.
- Translated Date:** 17 Jan 2023 (Outdated)

The 'Categories' section provides a list of related terms:

- [Please use shortcuts to find related Terms](#)
- [Device Function / Catheterization/Cannulation/Fluid cath. devices / Fluid infusion/injection devices / Infusion pumps and associated devices / Infusion pumps / Nonimplantable infusion/syringe pumps](#)
- [Featured Attributes / Analgesia](#)
- [Featured Attributes / Pharmaceutical](#)
- [Featured Attributes / Portable/Transportable](#)
- [Names Index / Infusion pumps and associated devices / Infusion pumps / Nonimplantable infusion/syringe pumps](#)
- [Names Index / Pumps and associated devices / Pumps / Infusion pumps / Nonimplantable infusion/syringe pumps](#)
- [Power / Active / Electrically powered](#)

One of the advance features of the *Term Details* view is the use of *Categories*. This uses the new *GMDN Explorer* to view all the Terms that are related by linking it to other GMDN Terms with similar characteristics. More information can be found in the 'Explorer Step-By-Step Guide'.

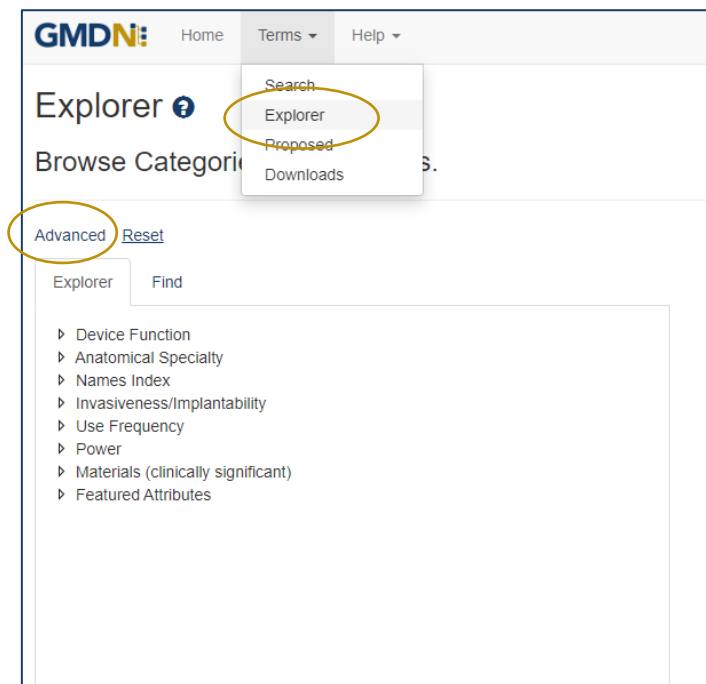
6. The 5-digit GMDN Code is also visible.

3. GMDN Website – Explorer – Step-by-Step Guide (unlimited users)

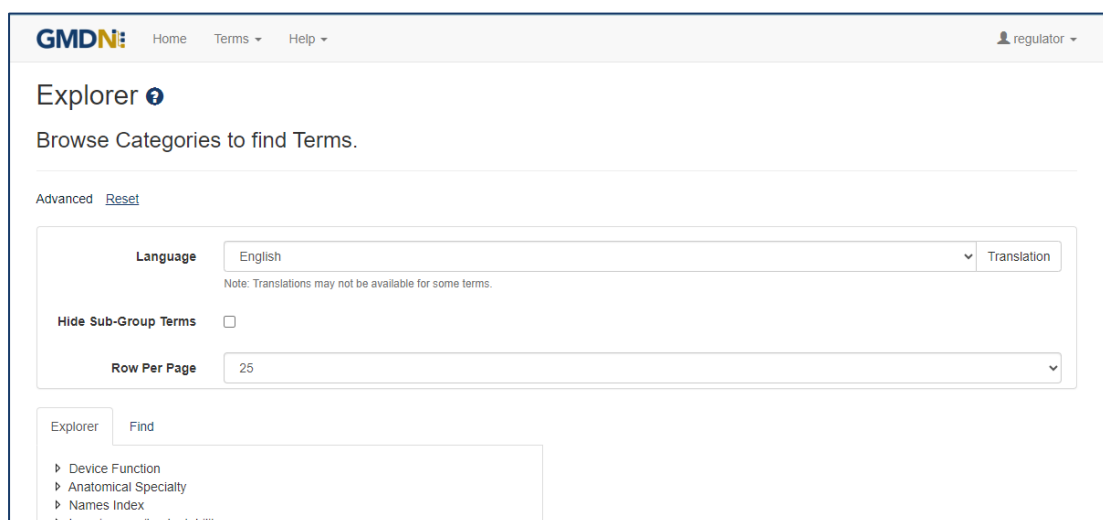
This is a Step-by-Step Guide for searching for GMDN Codes using the Explorer (Advanced Search) function on the GMDN website.

The Explorer uses the structured hierarchy of the GMDN Categories to find GMDN Terms by a higher level group of devices or 'Top Down' search.

1. Logon to the GMDN Database using your Username and Password.
2. Click on *Explorer* on the drop down *Terms* menu.

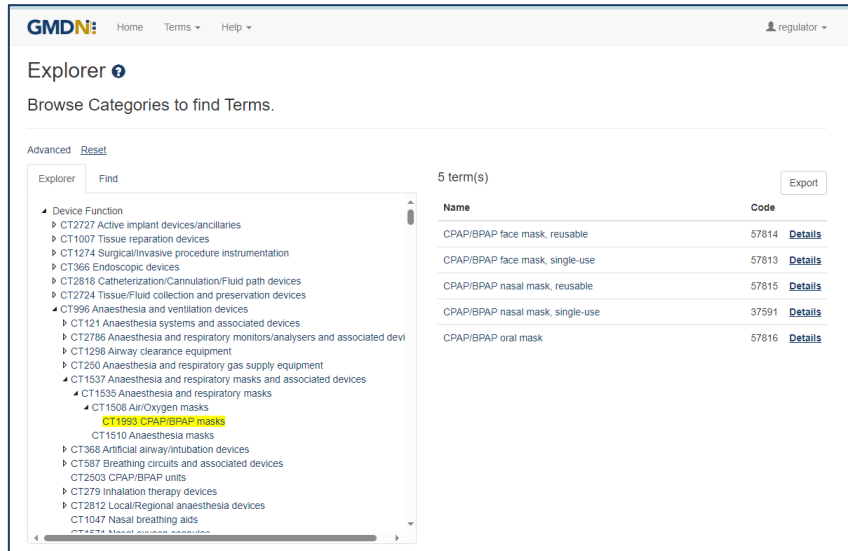


3. The choice of language can be selected using the *Advanced* tab, but the translation button will need to be used to update the hierarchy tables of groups.

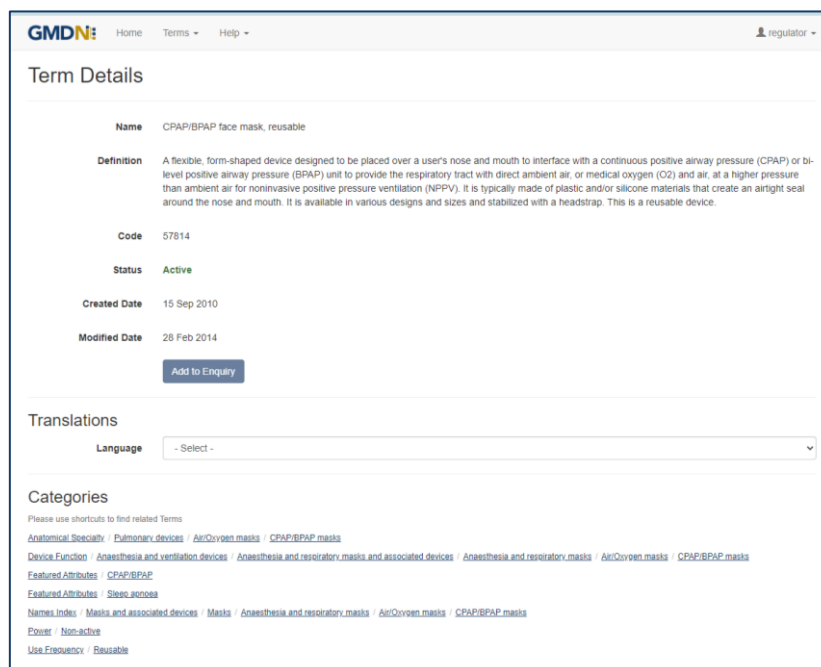


For unlimited users the *Explorer* displays the full set of eight Category groups. For example, those related to the device function (for example – Anaesthesia or Cardiology) those related to Anatomical Speciality (for example – Cardiovascular or Neurological) as well as a Names Index, Implantability, Power, Use Frequency, Materials and Featured Attributes.

The structure of the hierarchy is revealed by clicking on the arrows.



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



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

4. GMDN Website - Enquiry – Step-by-Step Guide

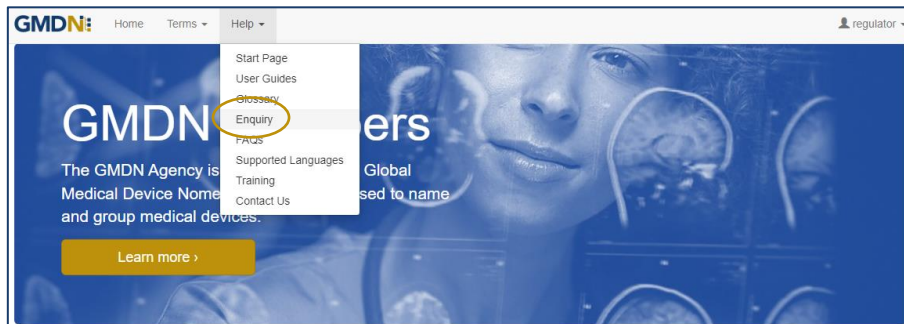
This is a Step-by-Step Guide for submitting an Enquiry for new or modified GMDN Codes using the GMDN website.

If after using the GMDN Search or Explorer 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:

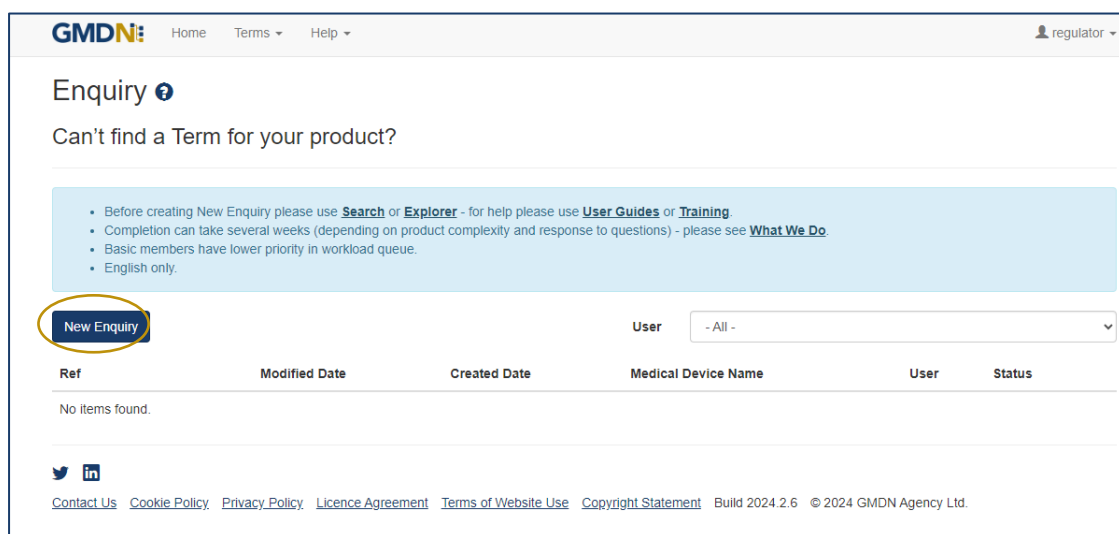
- a. The GMDN Agency identifies an existing GMDN Term.
- b. An existing GMDN Term is modified to include the new product's characteristics.
- c. A new GMDN Term is created.

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.



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

Step 1

Product details.

Your Email
[My Profile](#)

Medical Device Name
Brand/Trade/Proprietary Name or Common Name

Manufacturer

Model

Catalogue / Reference (REF)

Files No file chosen
Please supply documentation (e.g. IFU, brochure) which includes an image. Supports Images, Adobe Acrobat, Microsoft Word.

Uri
http://www.example.com

Reason

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.

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.

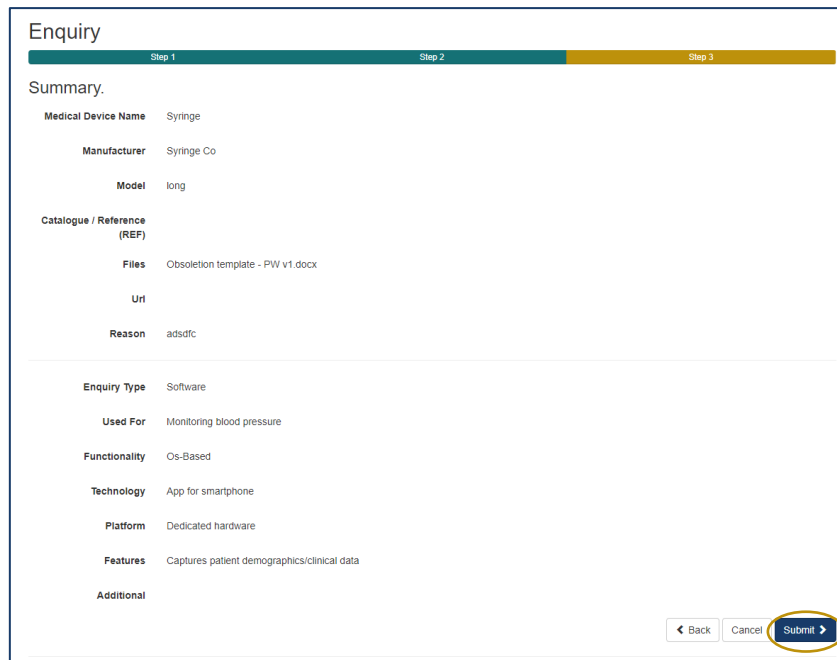
- a. **General medical device** – where the primary product is a general medical device.
- b. **In Vitro Diagnostic (IVD)** – where an IVD is the primary product.
- c. **Software** – where software is the primary product

- 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.

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

- 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.

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

Step 1 Step 2 Step 3

Summary:

Medical Device Name	Syringe
Manufacturer	Syringe Co
Model	long
Catalogue / Reference (REF)	
Files	Obsolescence template - PW v1.docx
Url	
Reason	adsdfc

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	

◀ Back 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 - [EQ160001](#)

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.

5. 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.

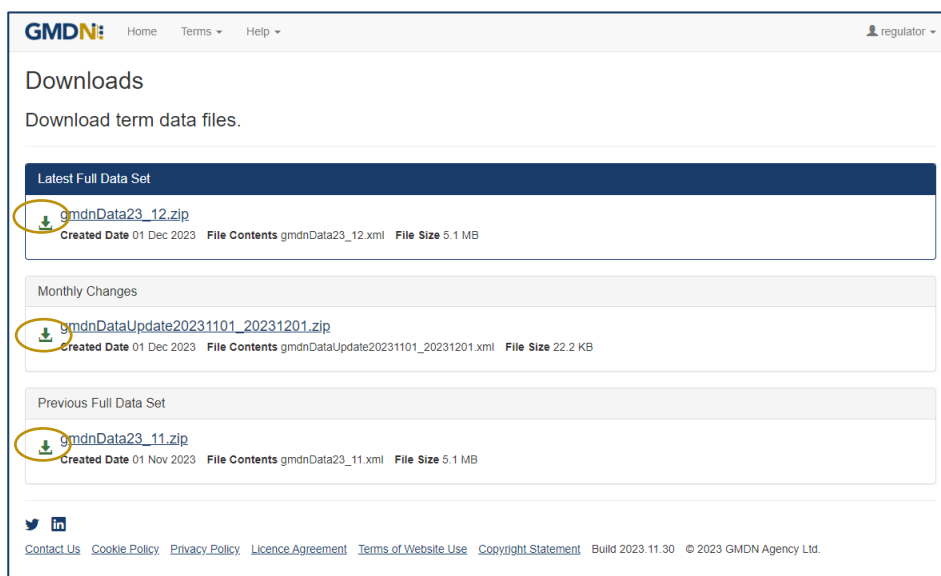
The user of the GMDN website with the appropriate account permission can export data from their membership account.

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 [contact us](#).

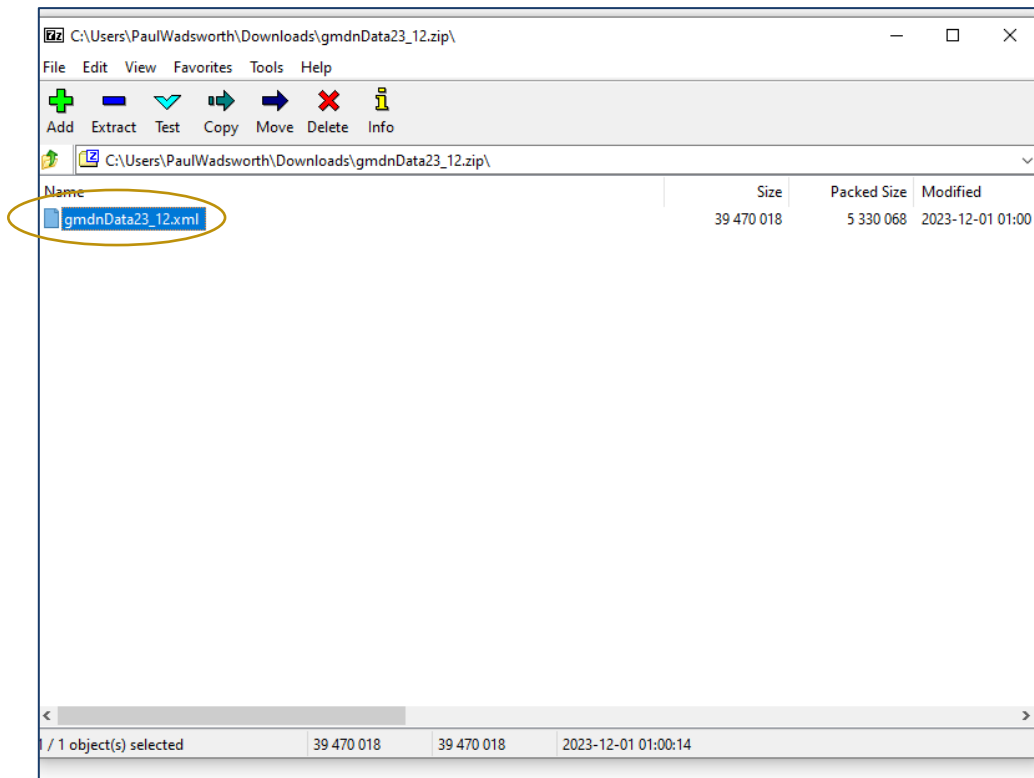


2. By clicking on [Downloads](#) the options for downloading the GMDN Database will be displayed.



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.

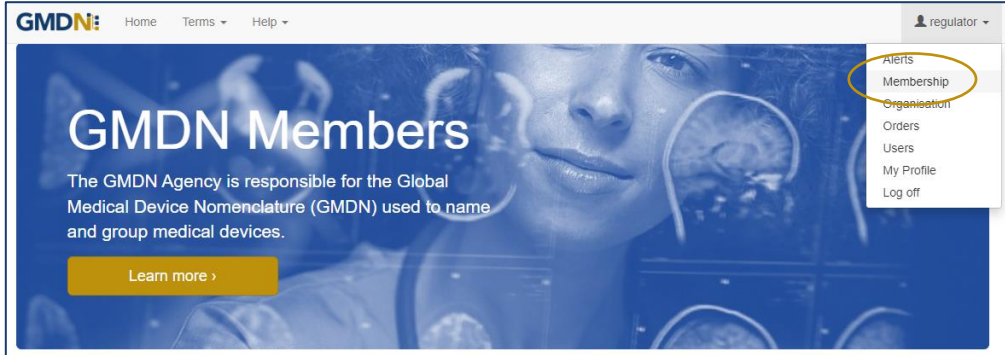
4. To import the data into your system double click on the .xml file and choose your relevant software package.



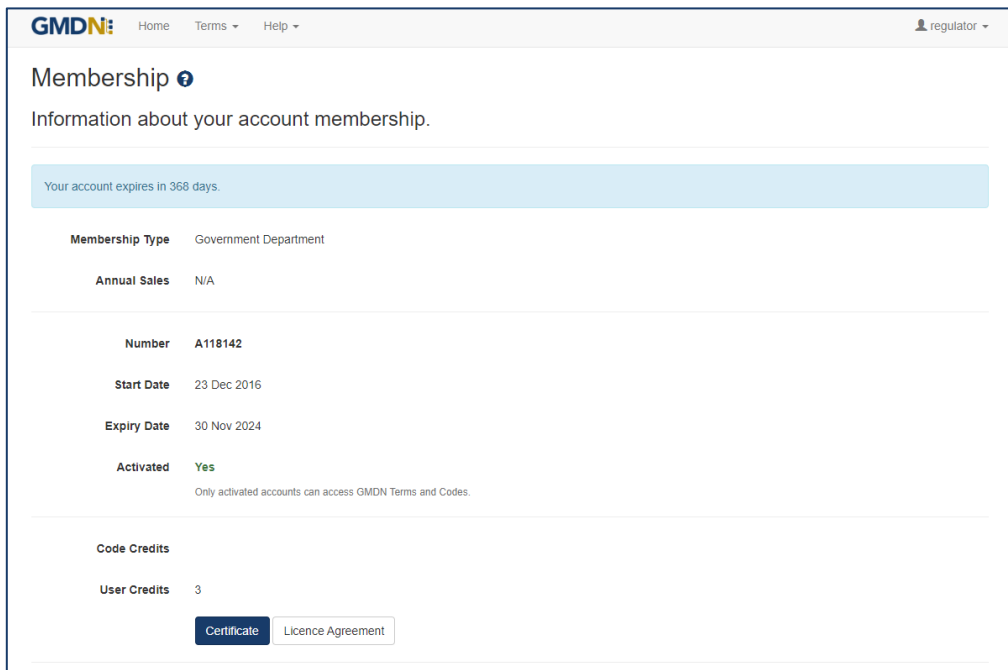
6. GMDN Agency – Membership Renewal Process (free membership access)

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

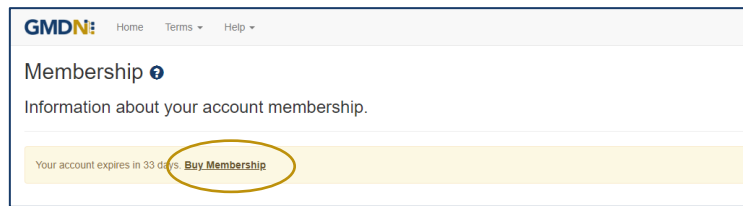
1. The Membership status is always available to view in the *Membership* tab and is found in the Account dropdown menu at the top right of the webpage (with the person icon).



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

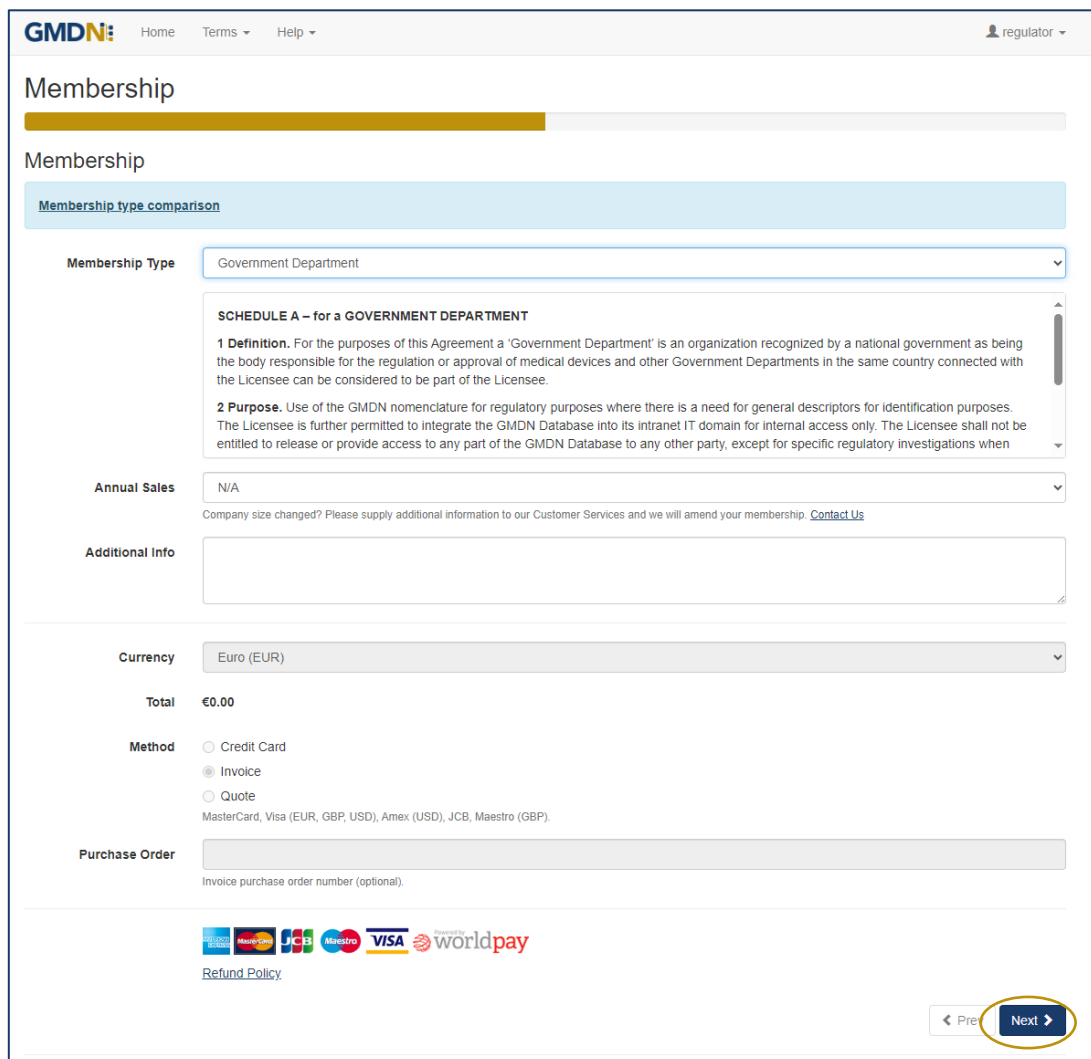


3. Membership can be renewed up to 3 months before it is due to expire and when available will be visible as a *Buy Membership* link on your *Membership* page.

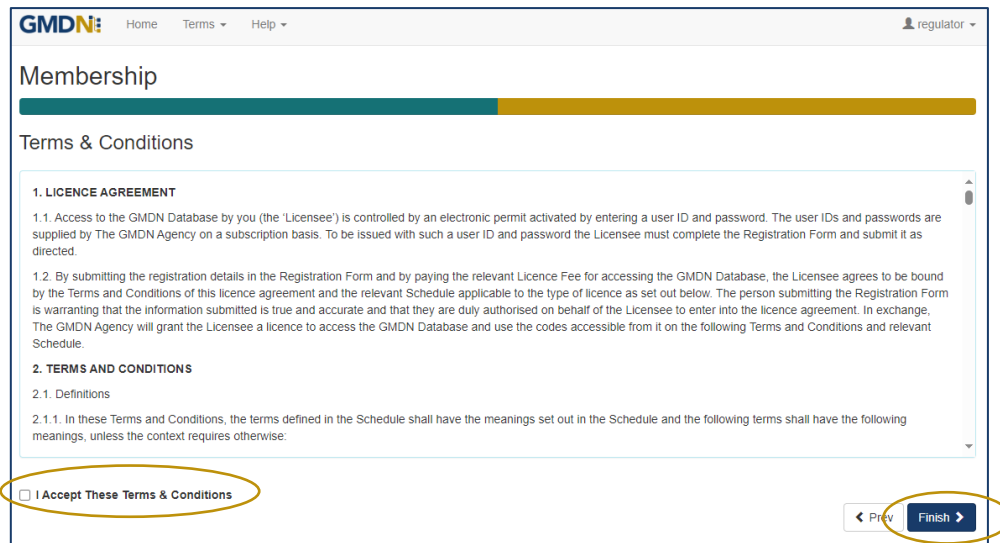


4. When the user clicks the *Buy Membership* button, the *Membership Renewal* screen will be displayed.

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

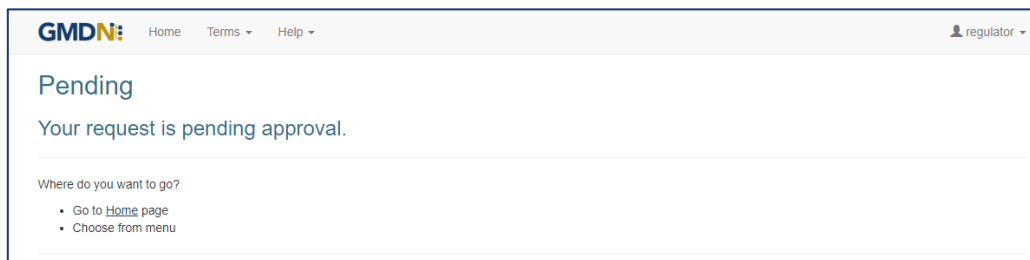


5. Next **Terms & Conditions** need to be accepted. Then click the blue **Finish** button.



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.



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 webpage (with the person icon).



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

7. 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).

My Profile
Modify your personal 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 communicate with you

Term Changes
Real-time email notifications about your purchased terms. See also [Alerts](#)

Account Summary
Periodic email notifications about your account and purchased terms. See also [Alerts](#)

GMDN Focus
Periodic email newsletter containing news and marketing material.

[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 [LinkedIn](#), where we share news and other interesting articles from within the MedTech industry.

If you have any questions, please contact us at this [link](#).