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.

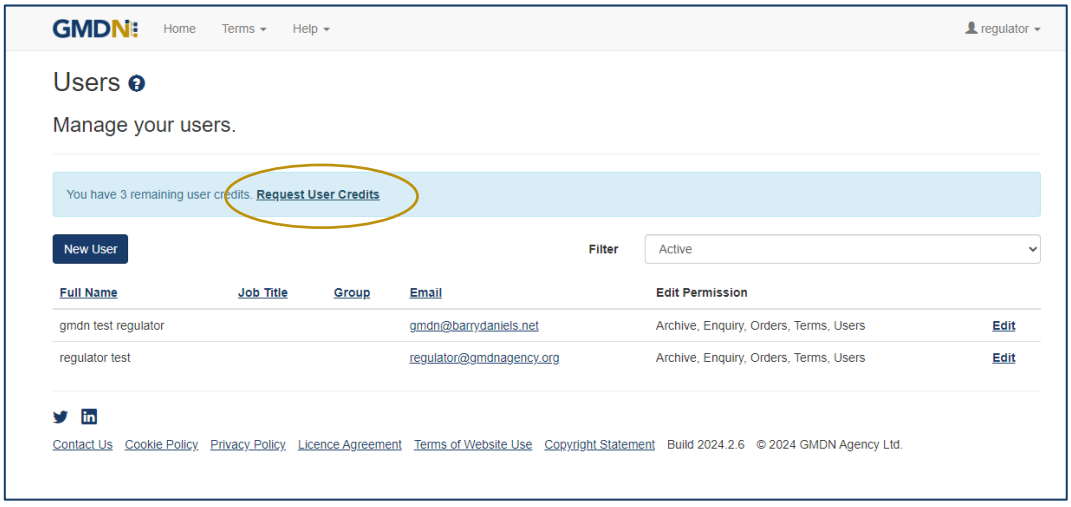
The user of the GMDN website with the appropriate account permission can add, modify, and delete user profiles associated with their membership account.

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.

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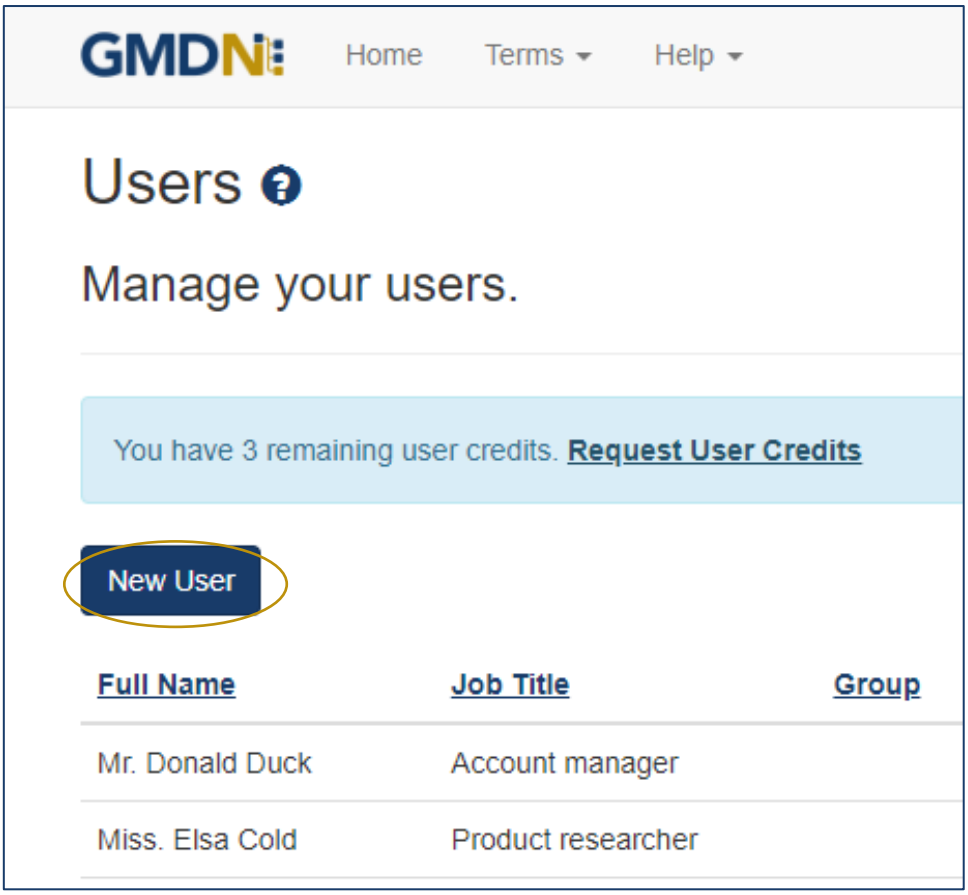
4. Each account when first activated, is provided with a certain number of user credits which are used to add more users. If you require more, they can be requested using the *Request User Credits* button.

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*.



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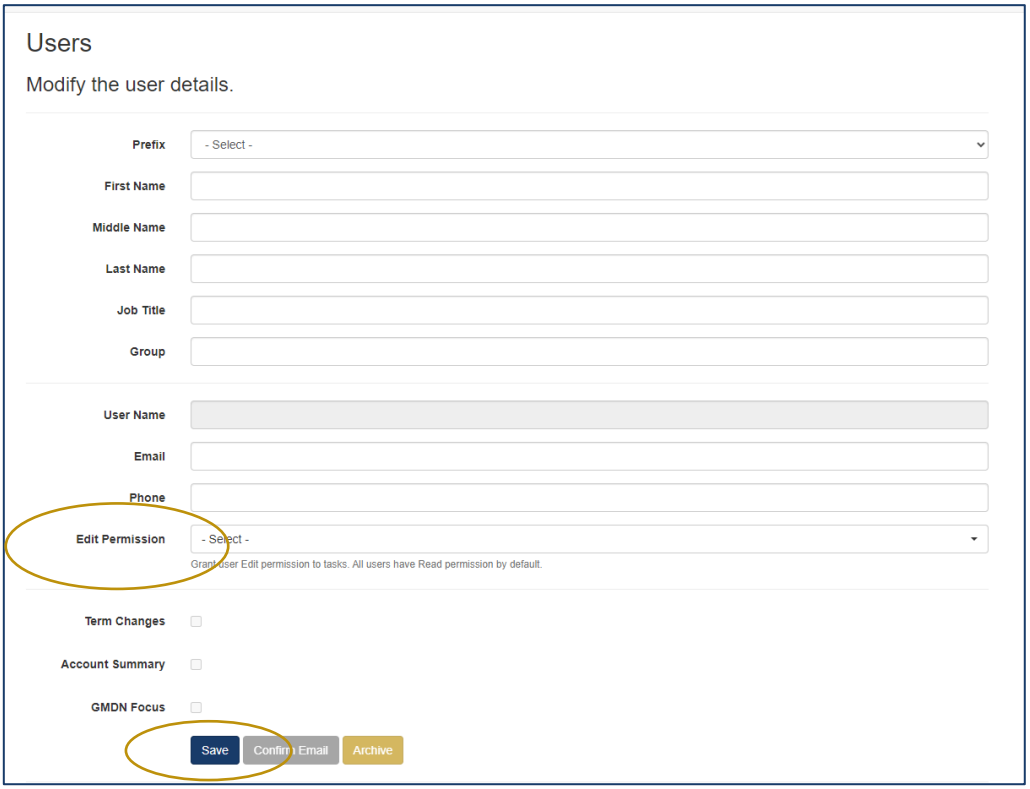
7. Fill in the user details and select the *Save* button.

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.

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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.

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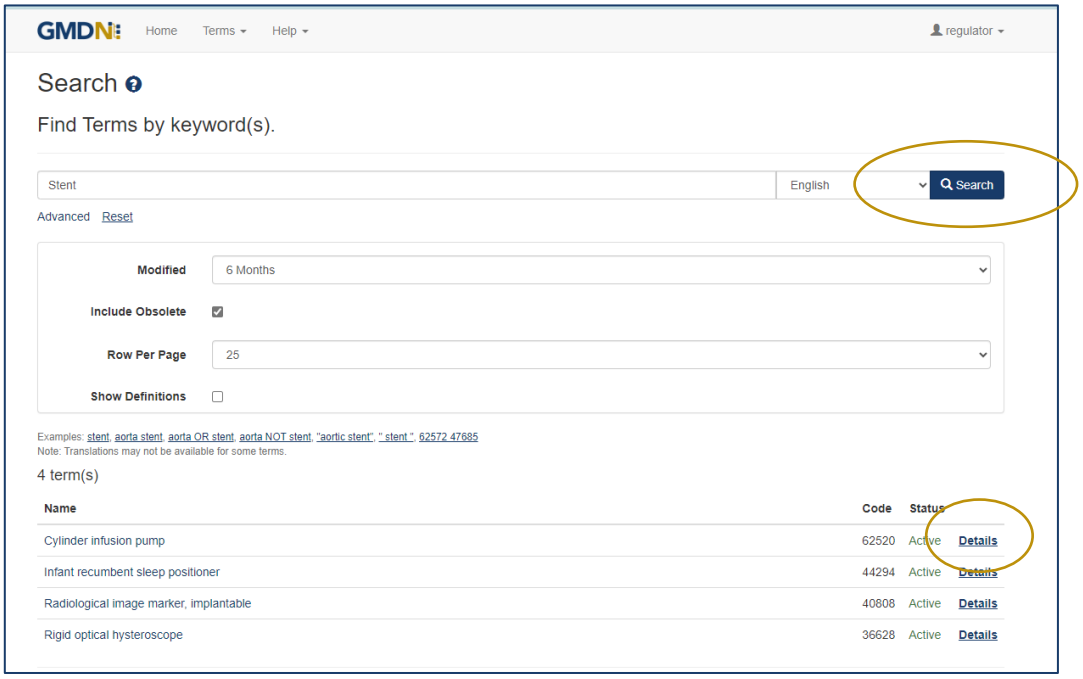
4. The *Advanced* tab provides additional filters to narrow the search by Term Modification Date.

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.

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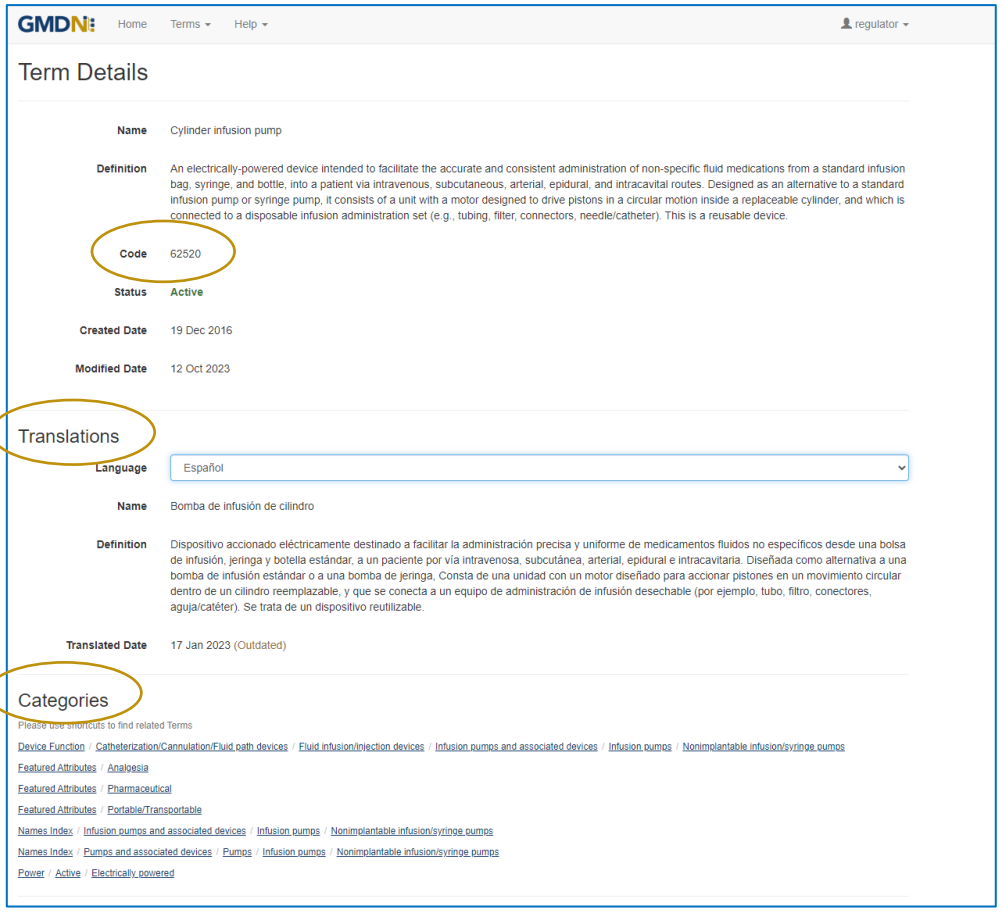
By clicking the Term *Details* link, you can see more information belonging to that Term, including a translation of the text, if available.



One of the advance features of the *Term Details* view is the use of *Categories*. This uses the new GMDN *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.

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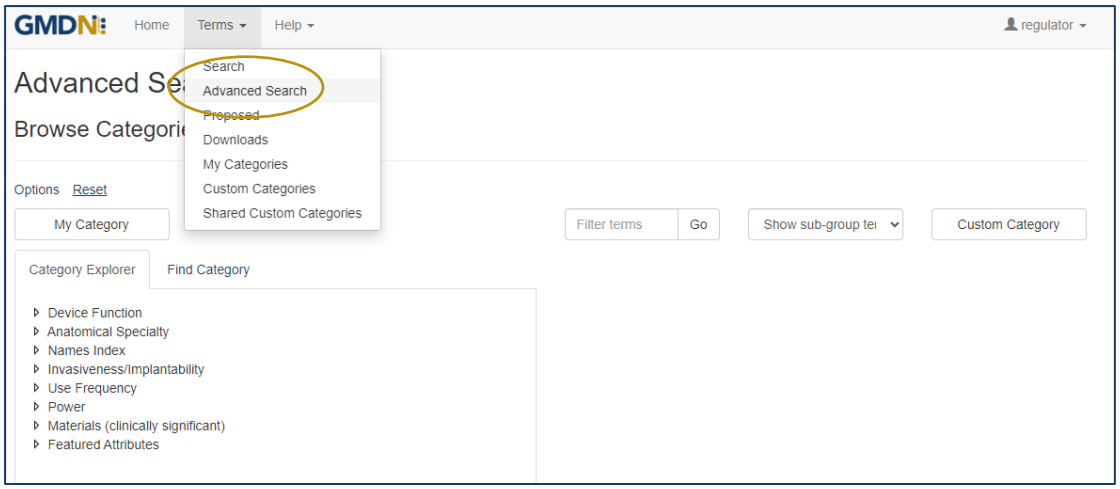
3. GMDN Website – Advanced Search – Step-by-Step Guide (non-basic users)

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.

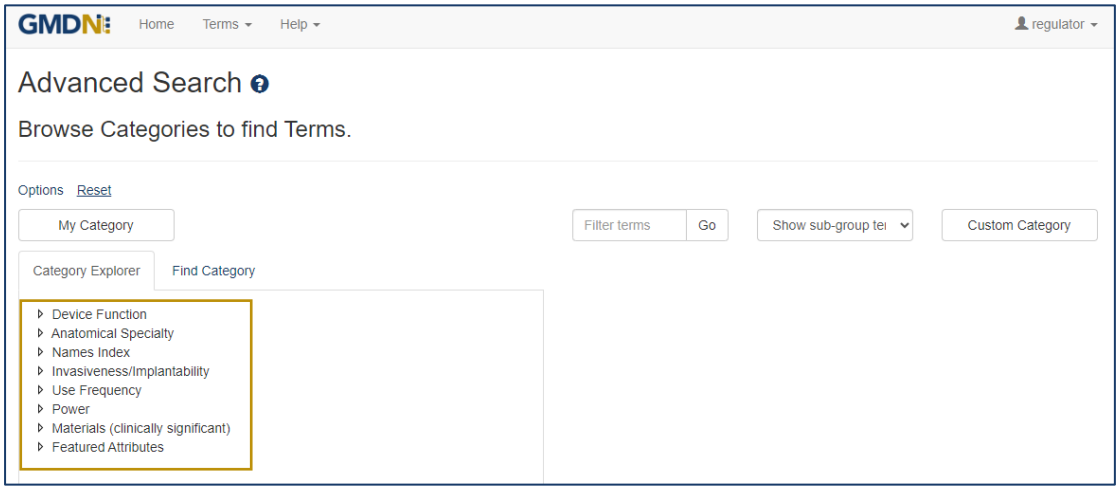
The Advanced Search uses the structured hierarchy of the GMDN Categories to allow users to find GMDN Terms using a 'top down' search. To access the Advanced Search:

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

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



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.



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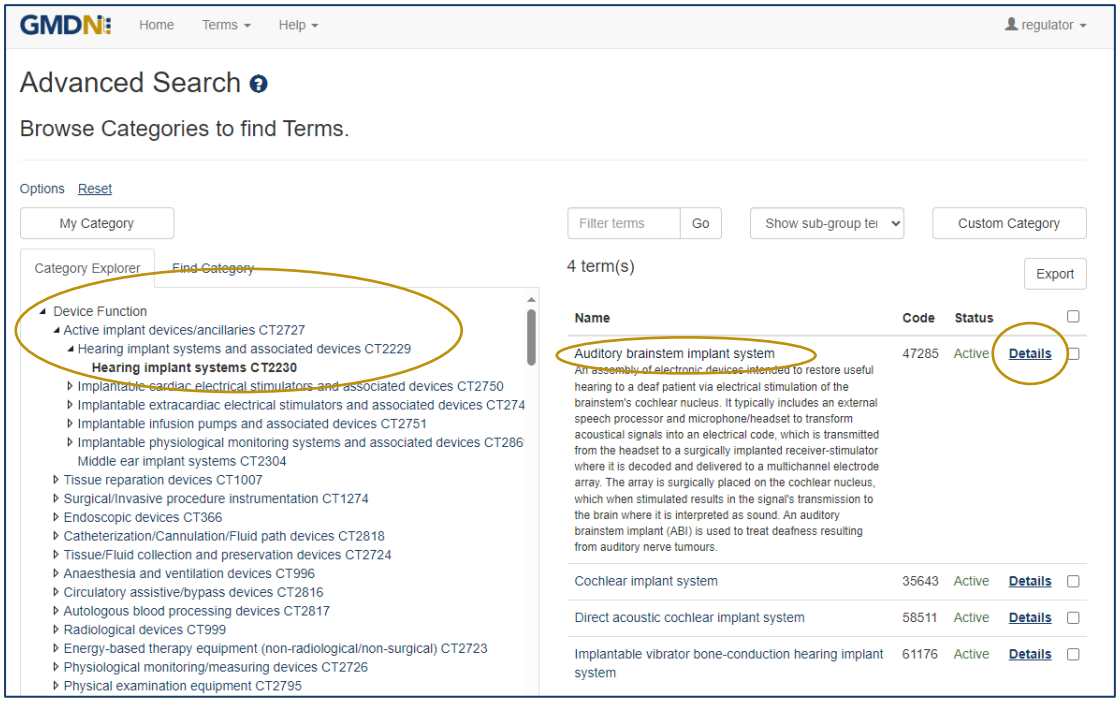
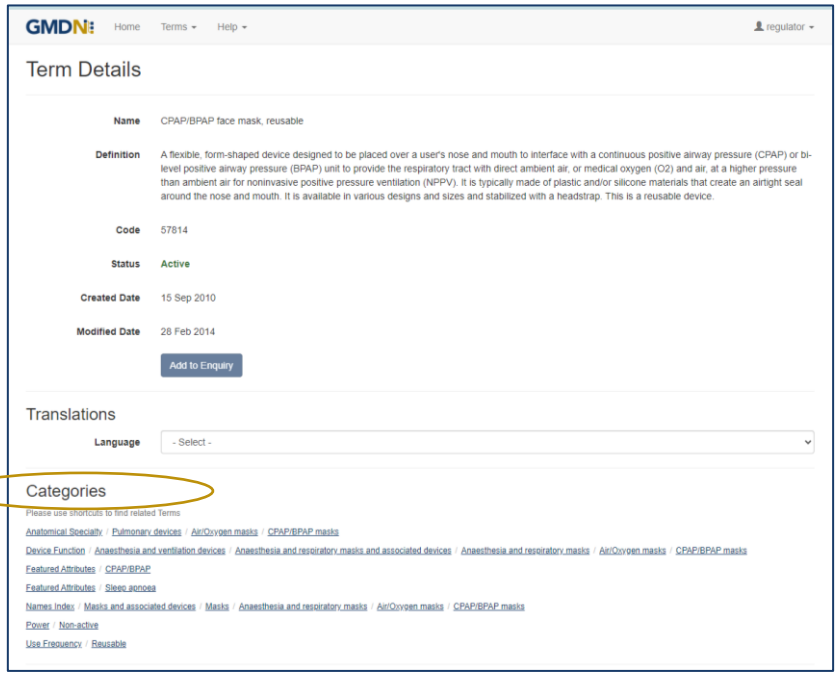
4. The list of GMDN Terms in each GMDN Category is revealed by clicking on the Category. The *Term Definition* is revealed by clicking on the *Term Name*. By clicking on the *Details* link, you can see more information relating to that Term, including a translation of the text, if available.





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.

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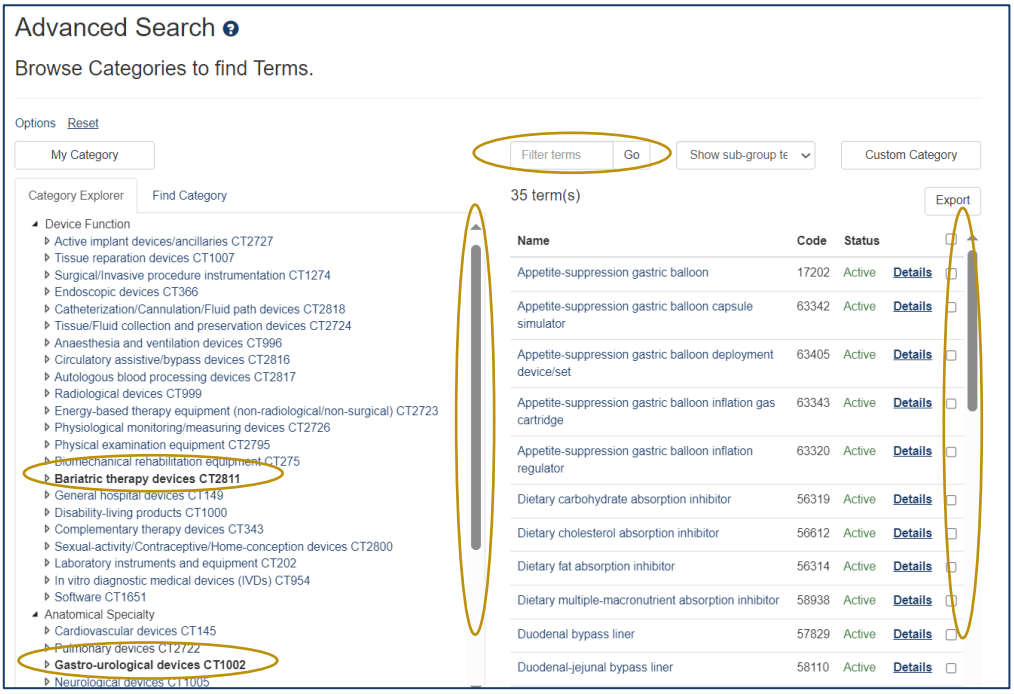
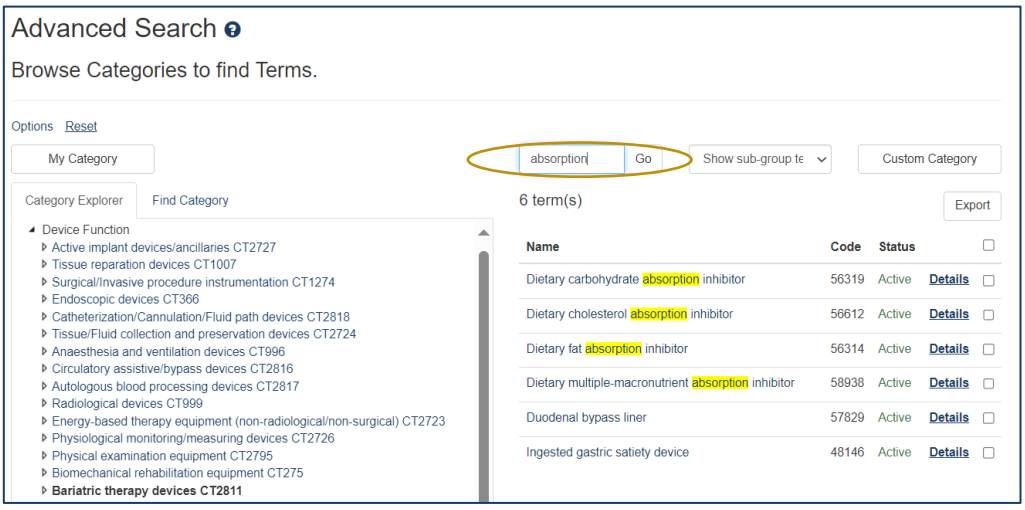
5. You can also multi-select up to five different GMDN Categories to narrow down your search for a GMDN Term . The example, below shows the result of a multi-select search, using the *Bariatric Therapy Devices* GMDN Category under *Device Function* and *Gastro-Urological Devices* GMDN Category under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



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.



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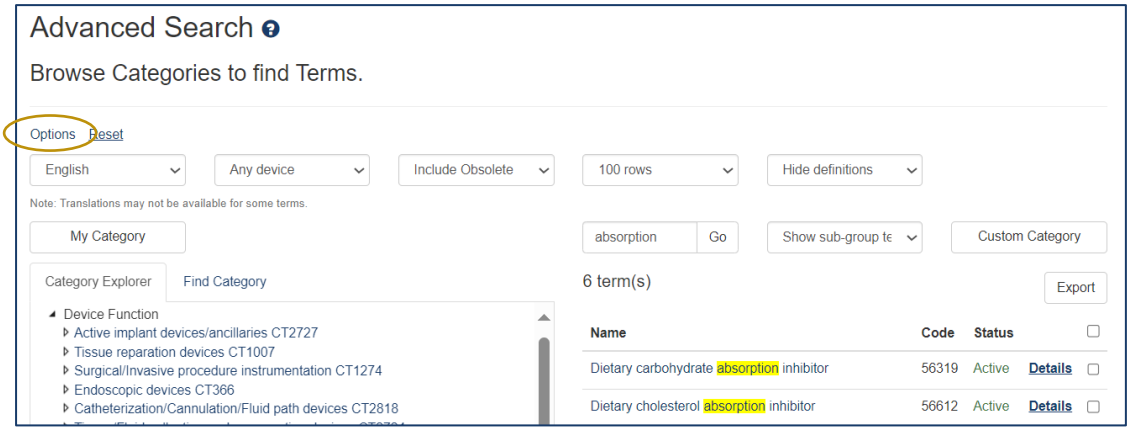
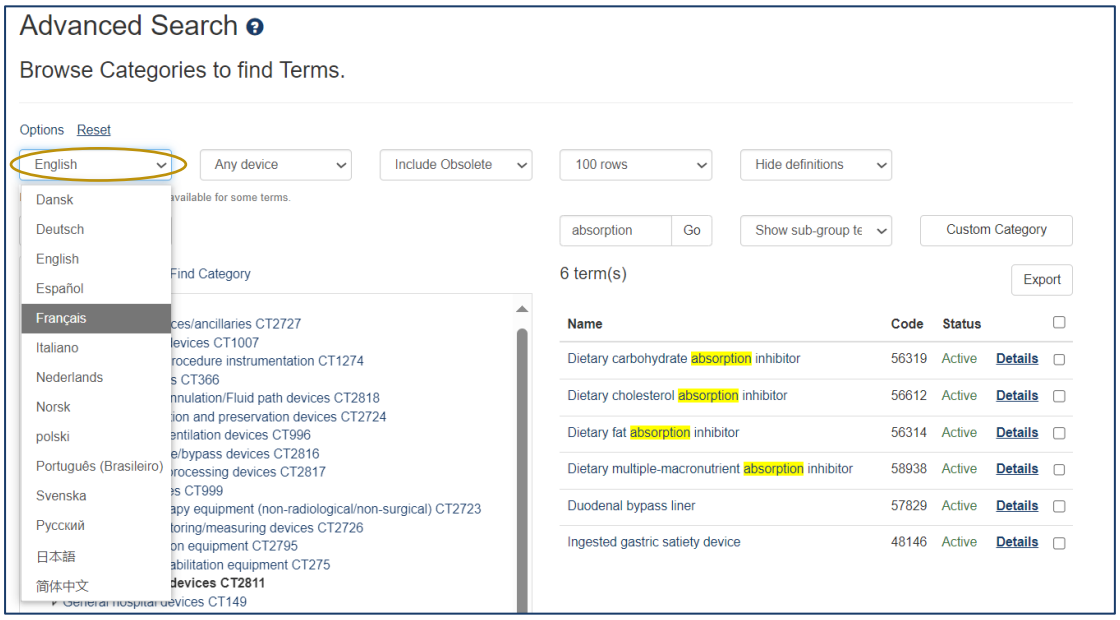
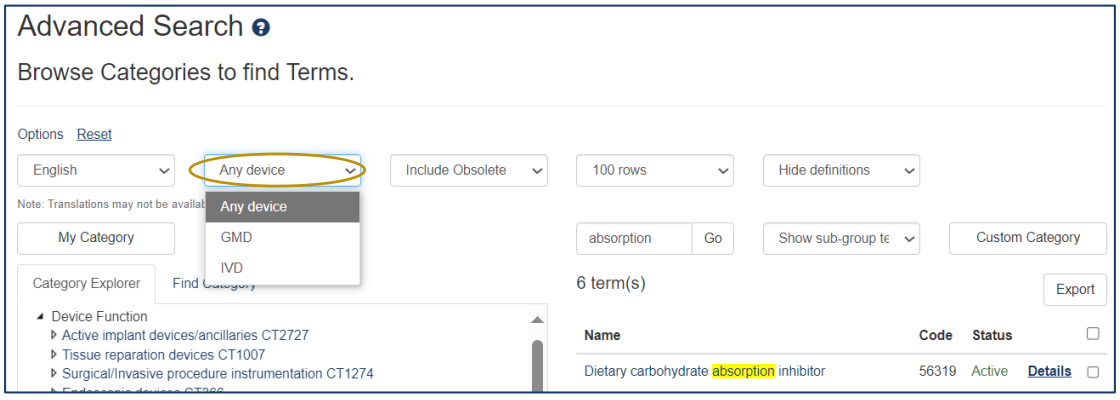
7. If you select the *Options* tab there are several additional choices for further filtering and settings.



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



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



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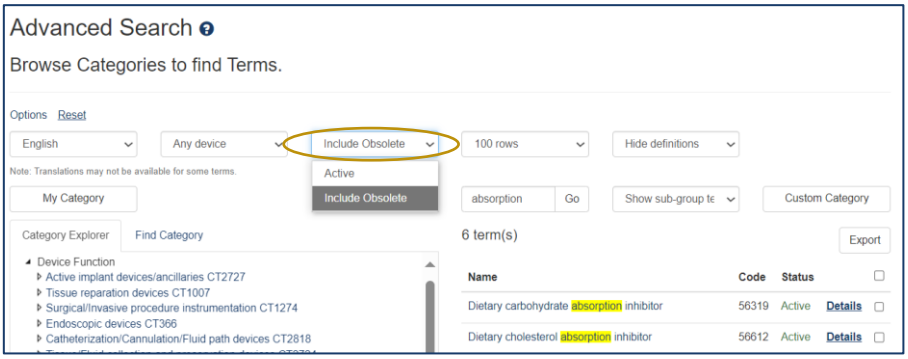
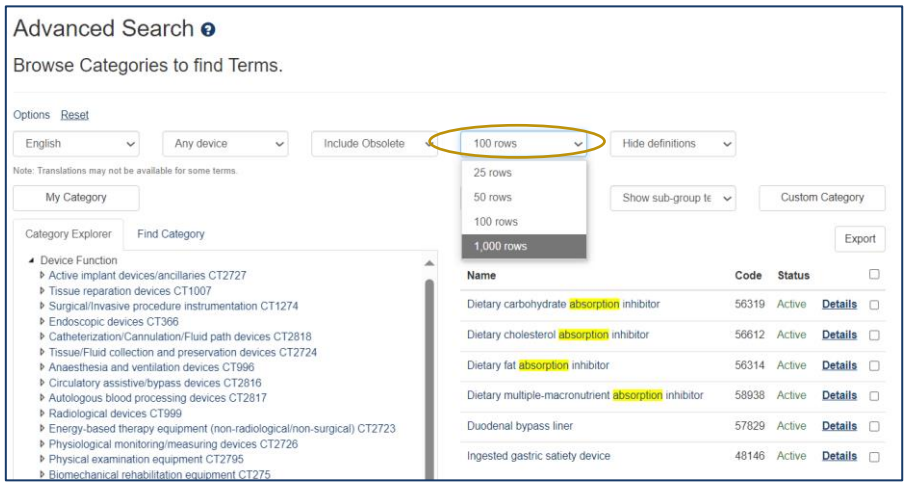
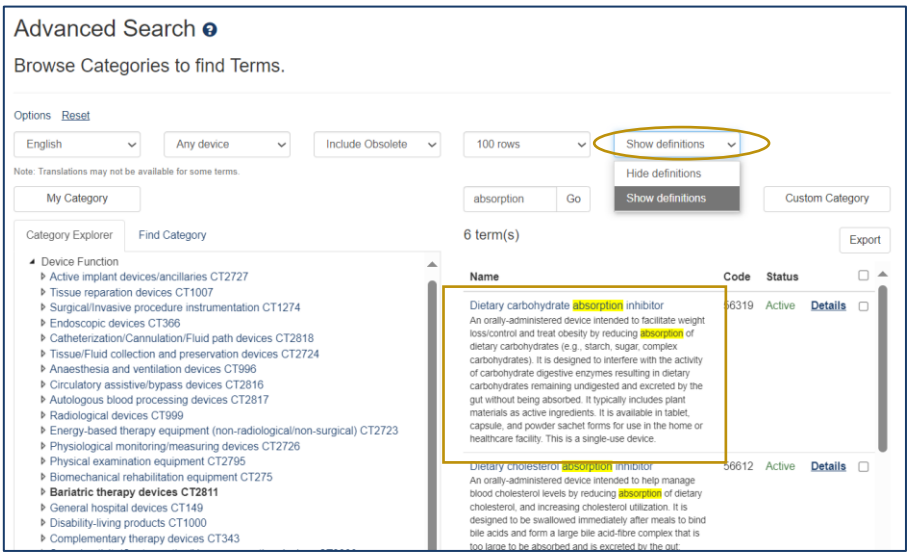
10. You can also include obsolete GMDN Terms within your search if required. However, please note that obsolete GMDN Terms **should not** be used by any manufacturer for product registration or UDI purposes. They are included for reference purposes only. If you are in doubt about Term assignment or cannot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



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



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



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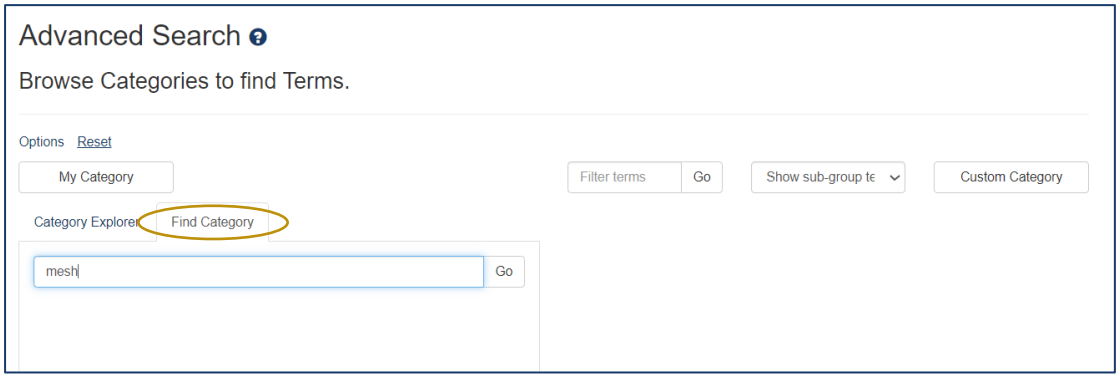
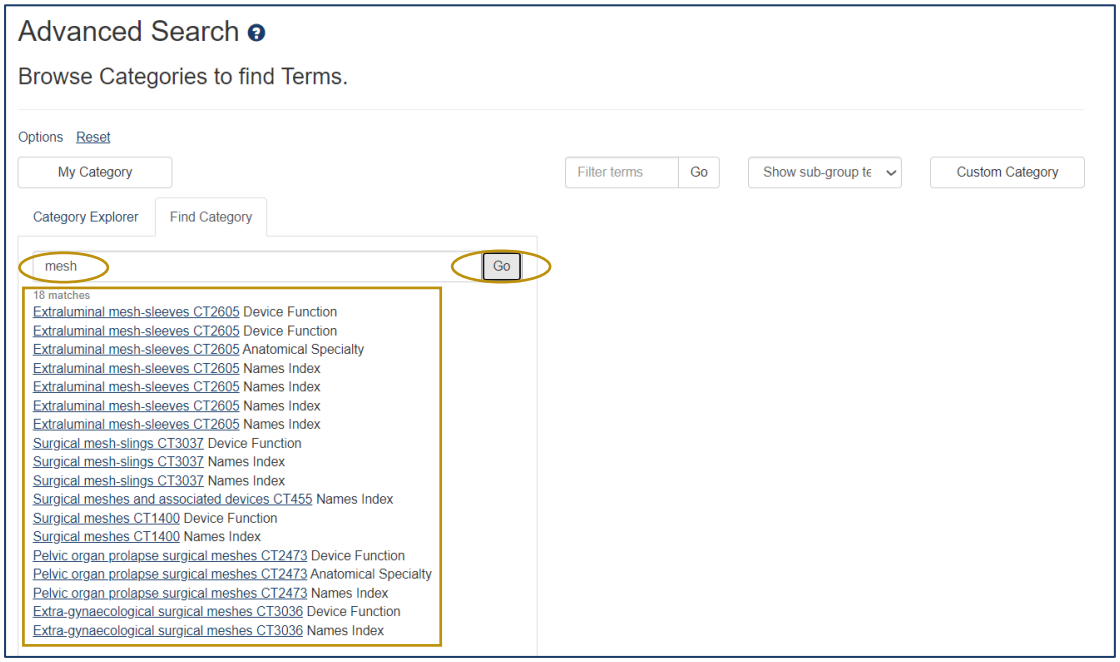
13. Another way of searching for a GMDN Category is to use the *Find Category* tool.



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.



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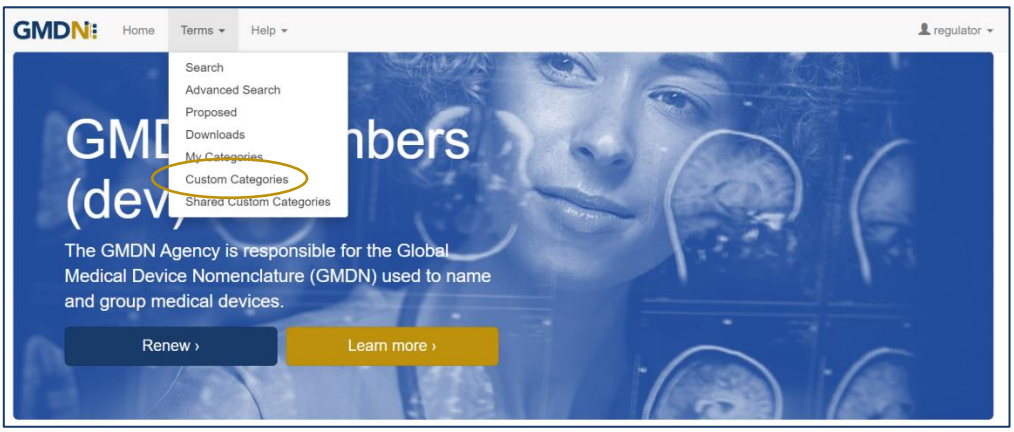
4. GMDN – Custom Categories – Step-by-Step Guide

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.

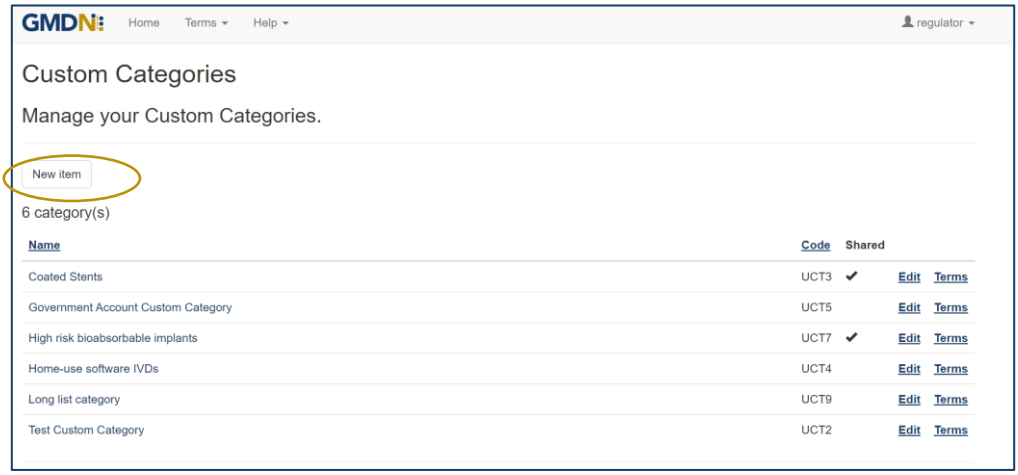
1. Login to the GMDN Database using your Username and Password.

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*.



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.

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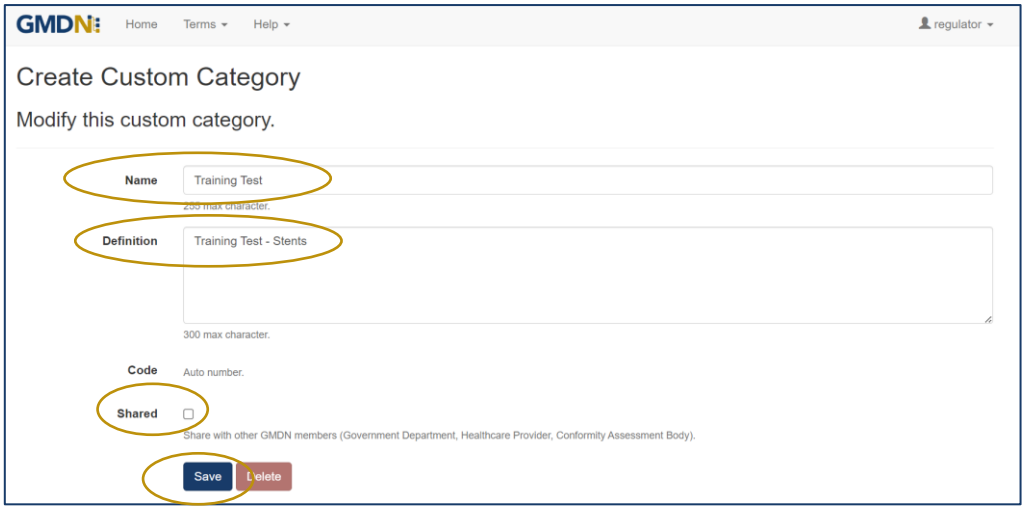
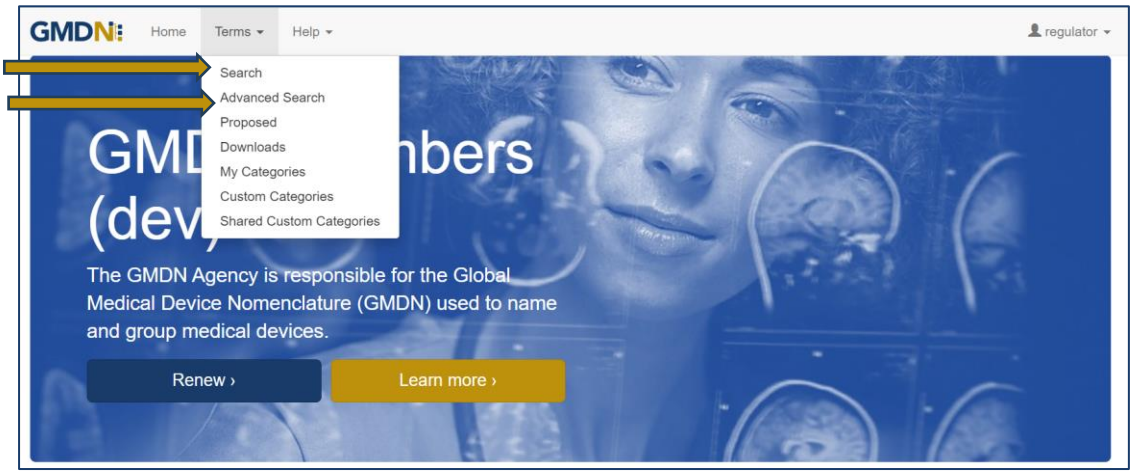
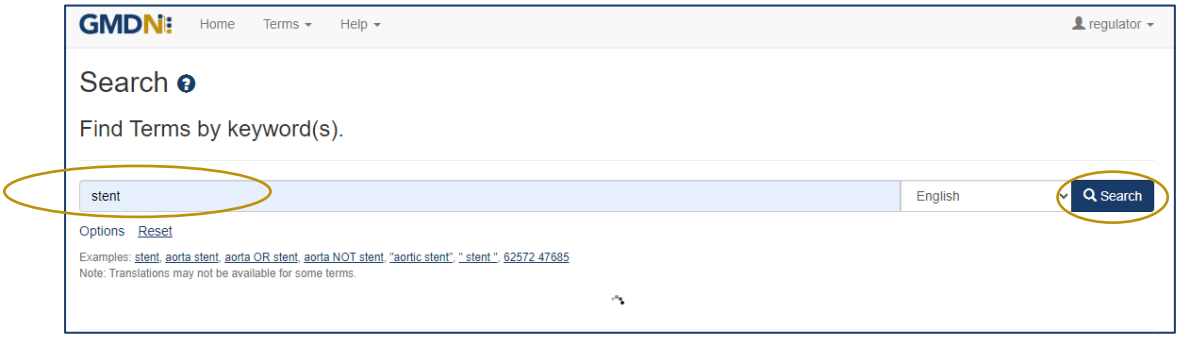


4. There are two ways to add GMDN Terms to your Custom Category. You can use the Search function or the Advanced Search function via the Terms dropdown menu on the homepage.



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



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.

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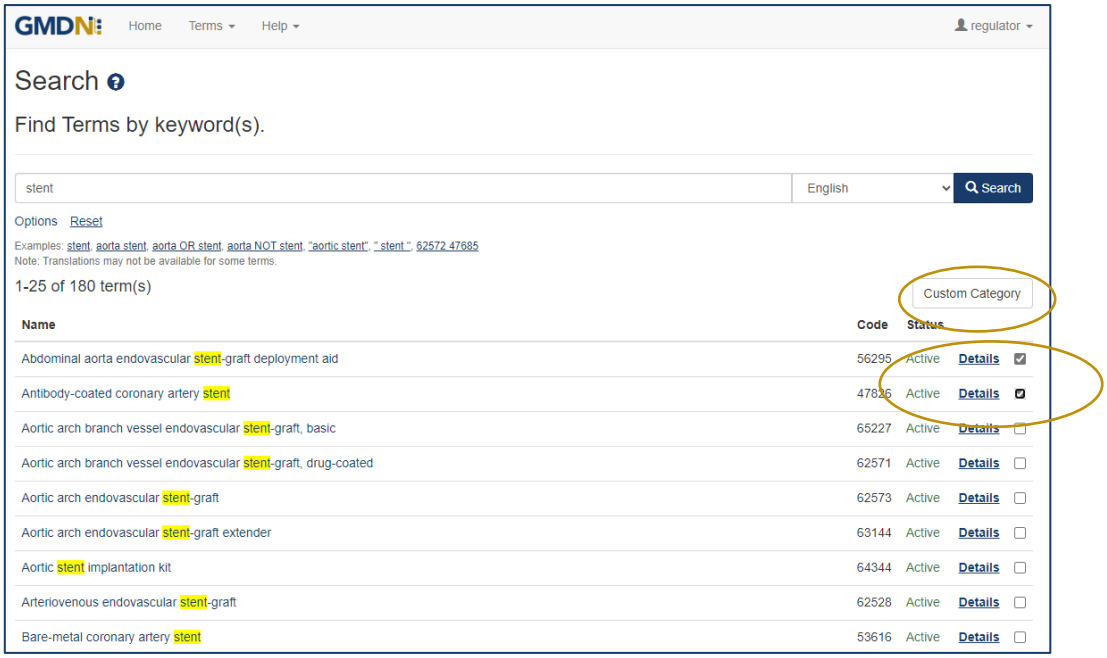
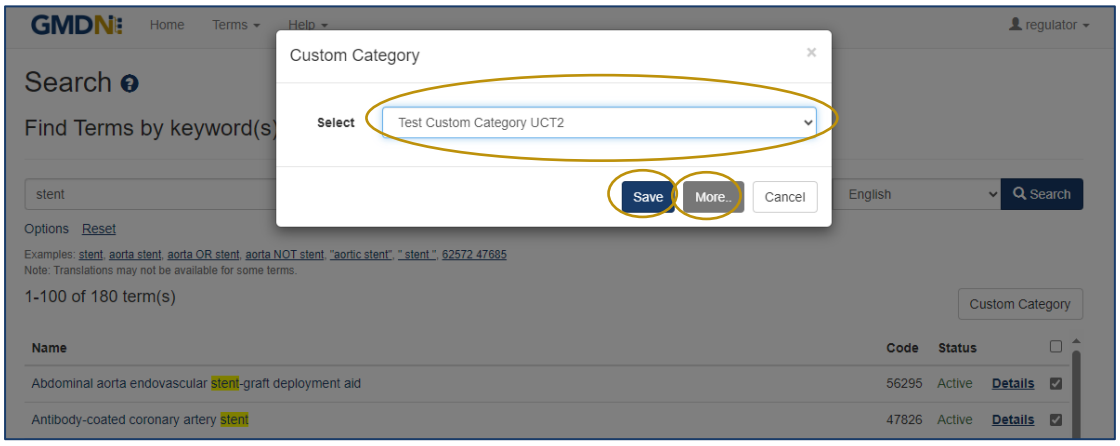


7. Using the dropdown menu on the pop-up box select which Custom Category or Categories you would like the Terms to be added to and click the *Save* button. Alternatively, you can click the *More* button.



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.

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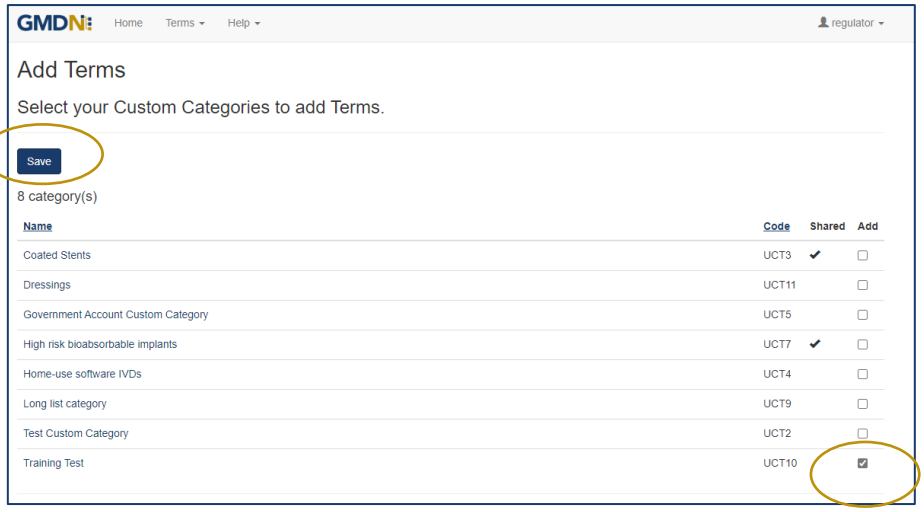
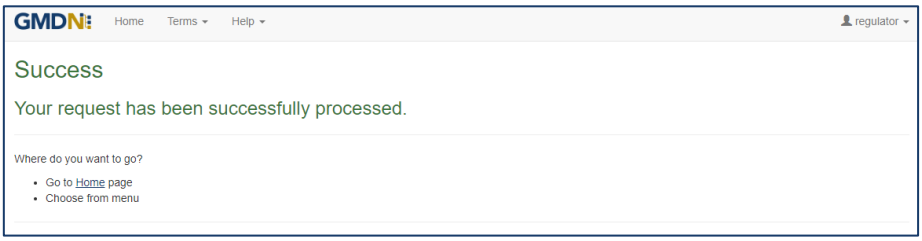
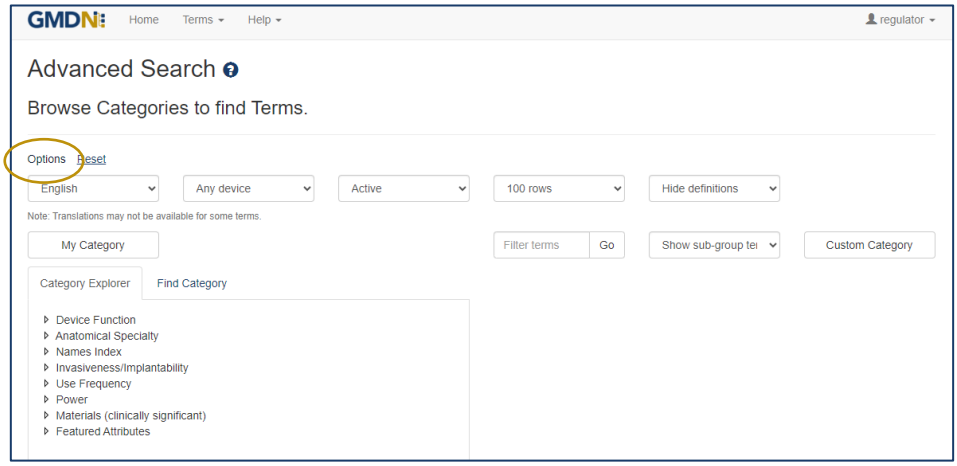


9. When the *Save* button is pressed the GMDN Terms will be added to the Custom Category.



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.



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.

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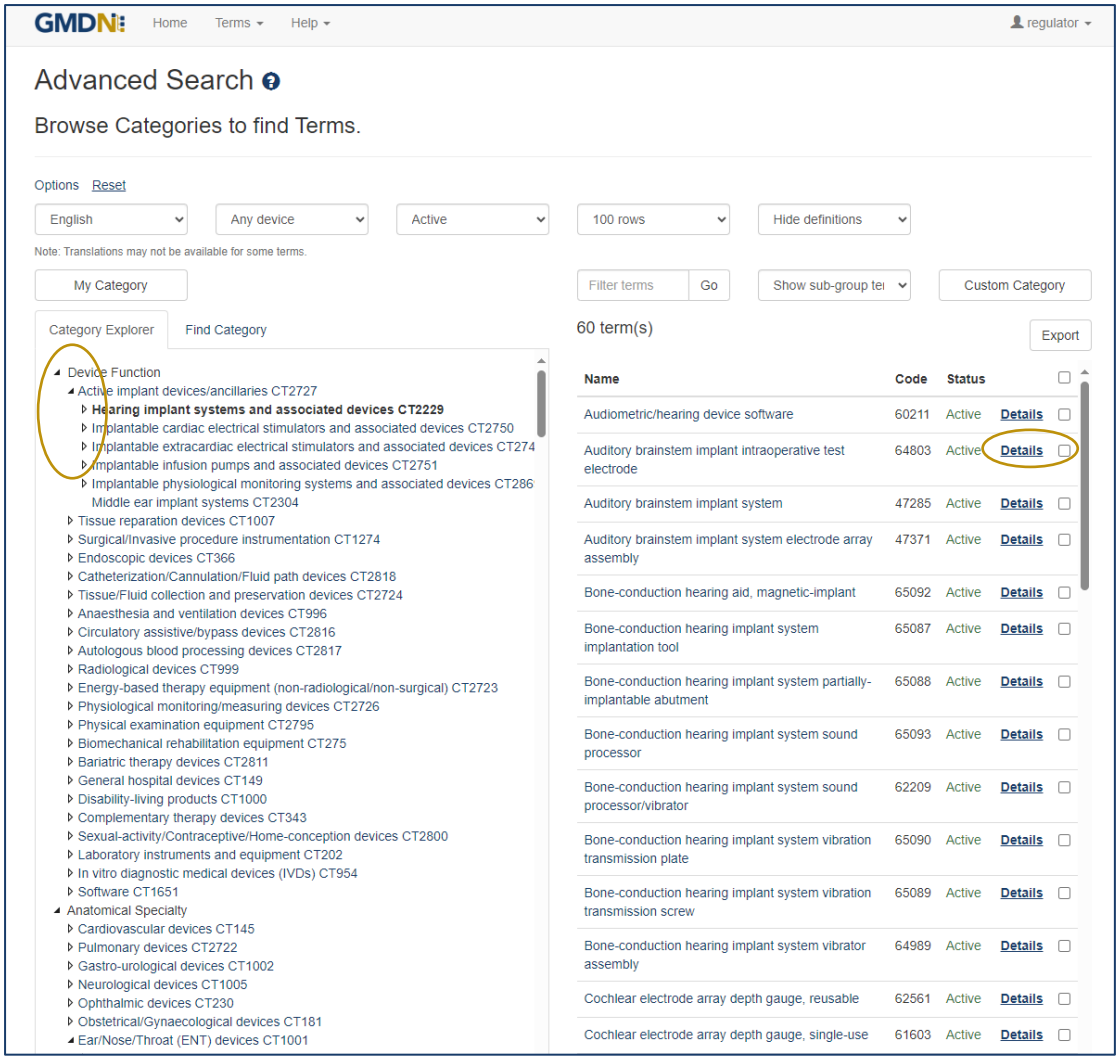

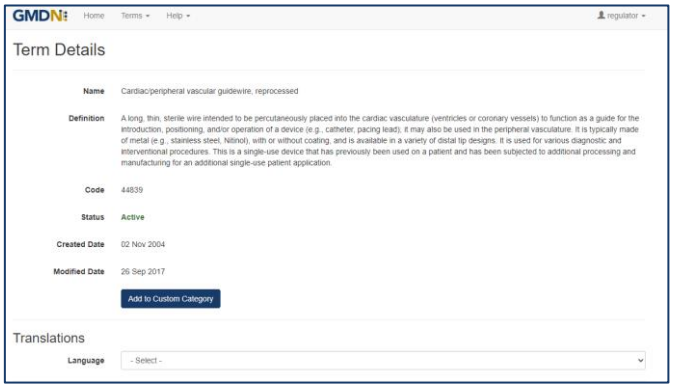

12. To add GMDN Terms to your Custom Category, click the check box next to Details and then click the Custom Category button. If you click the check box at the top this will *select all* the GMDN Terms on that page.

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.

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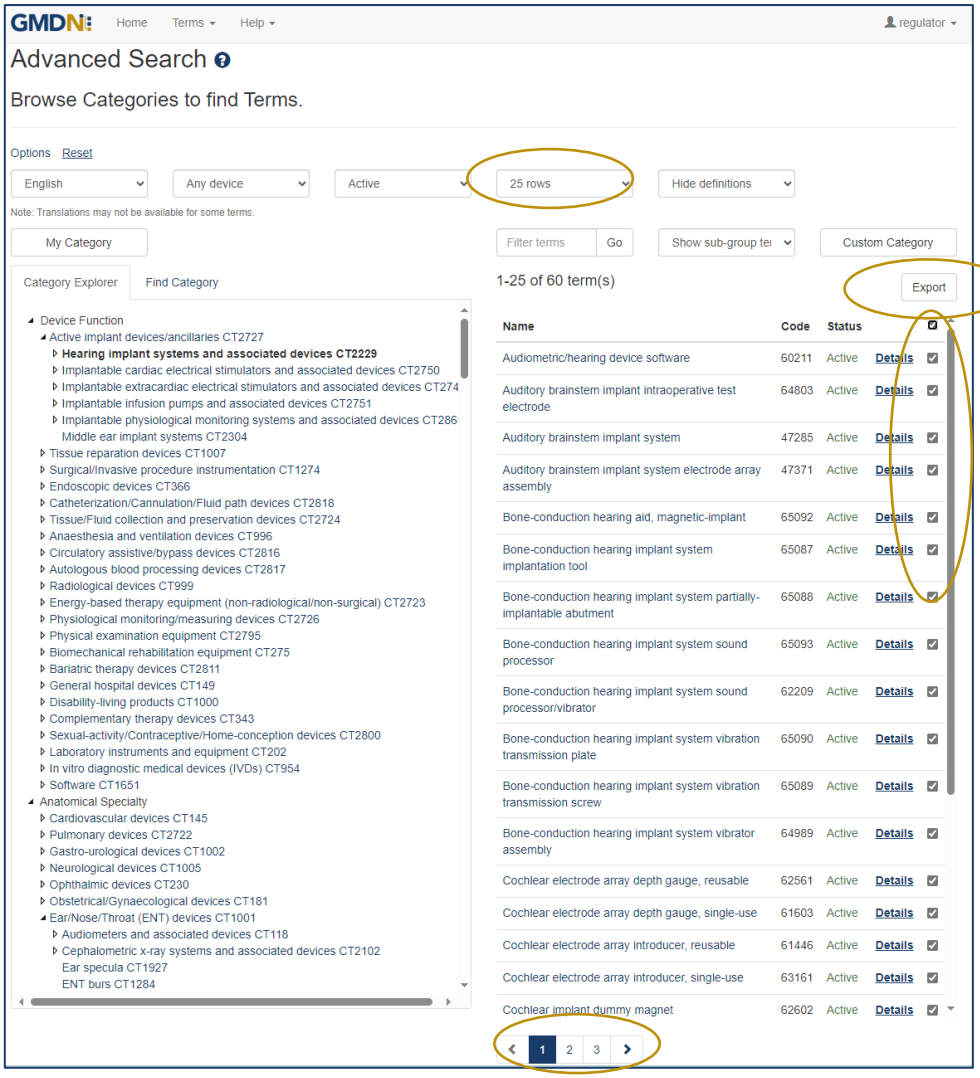
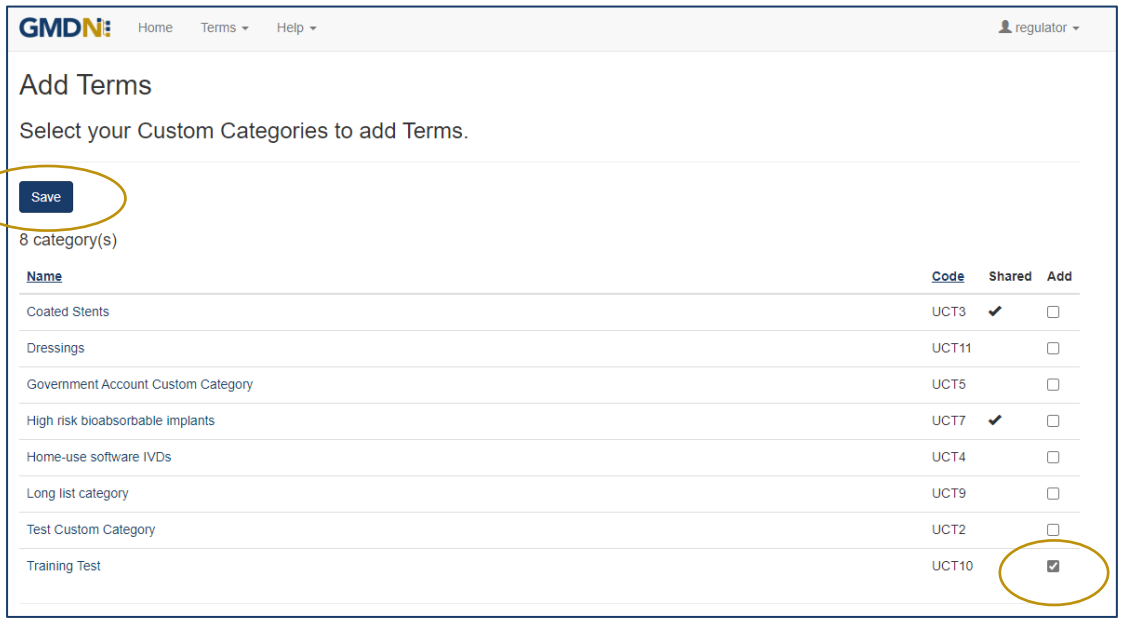


13. Then select which Custom Category or Categories you would like the Terms to be added to and select the *Save* button. The GMDN Terms will now be added to the Custom Category.



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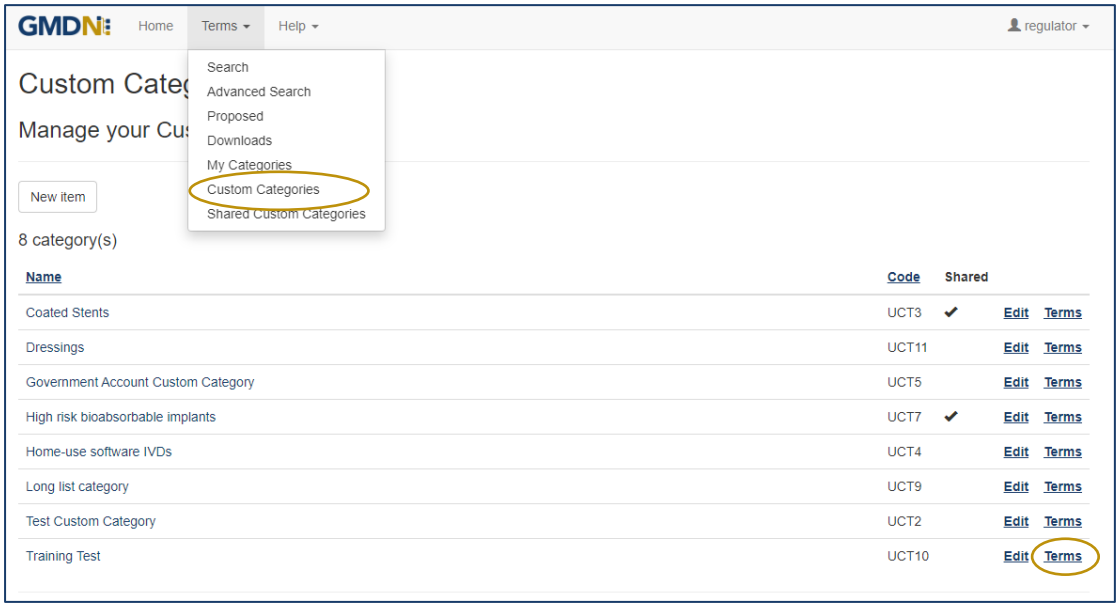
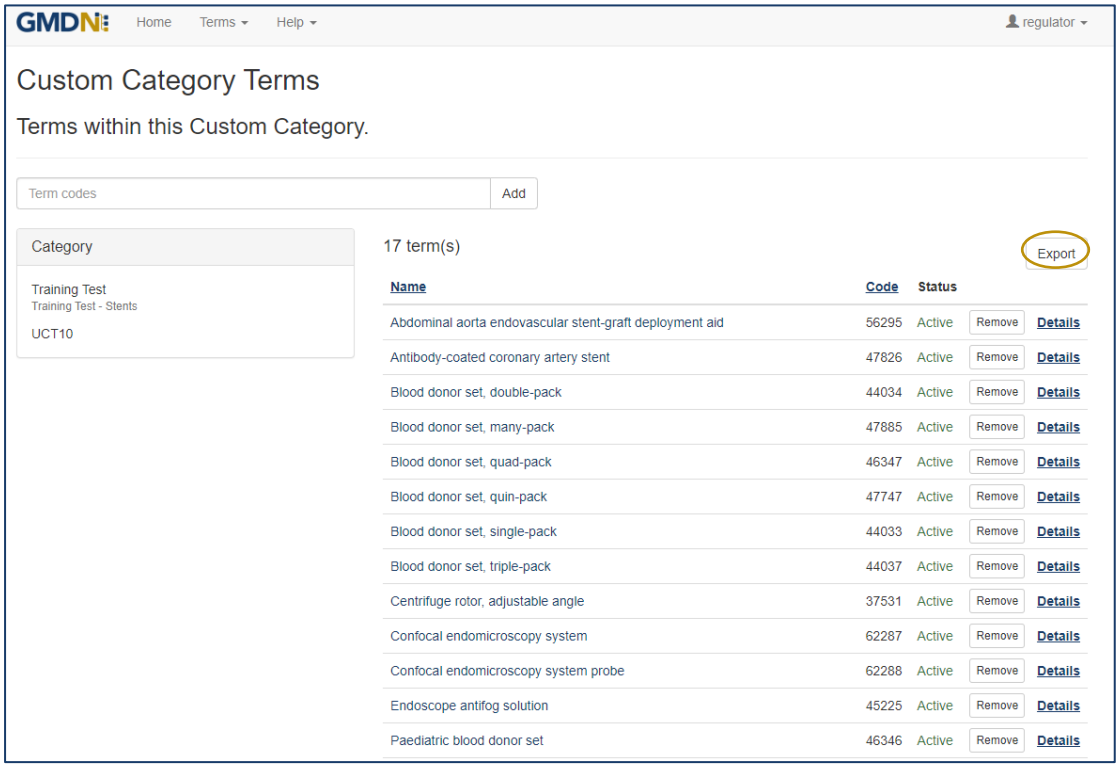
14. How to export data from your Custom Category. First select Custom Categories from the Terms dropdown menu on the page header. Then select the Terms button from the Custom Category you are wanting to export.



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.



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

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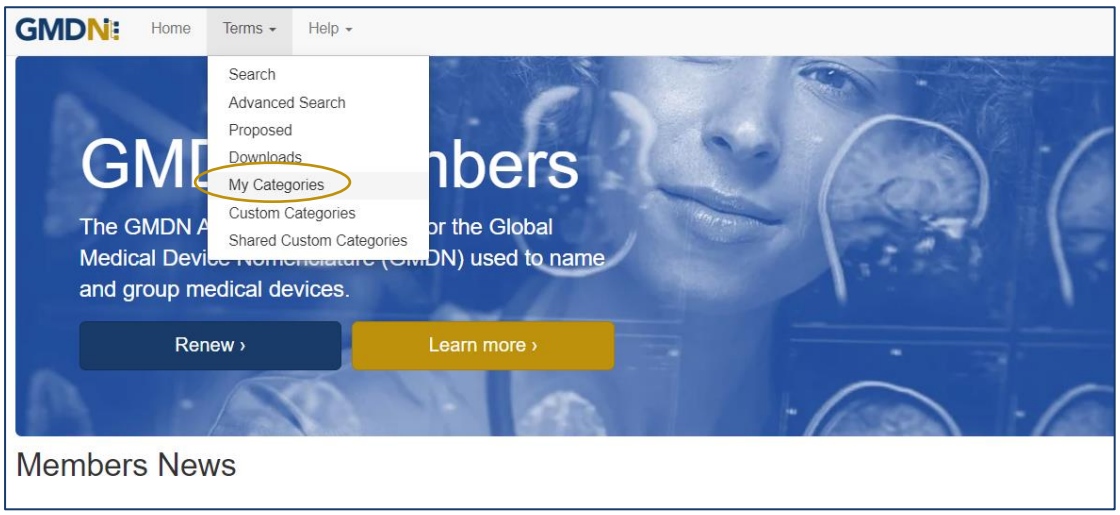
5. GMDN – My Categories – Step-by-Step Guide

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.

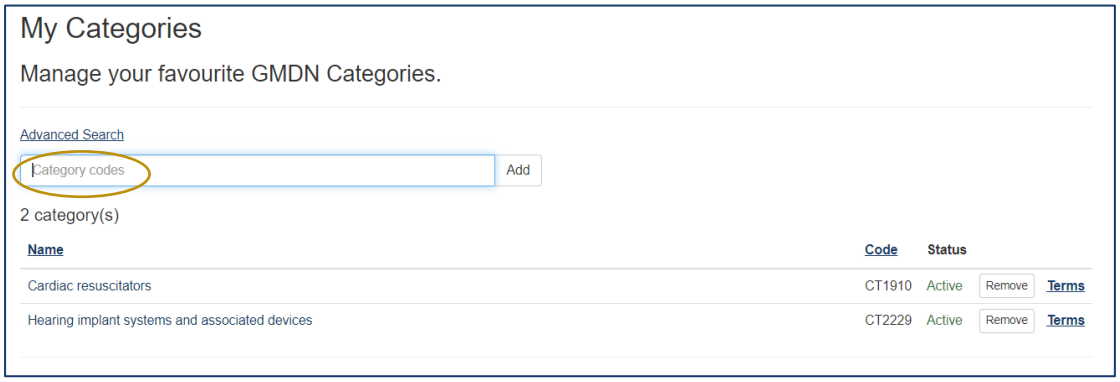
1. Login to the GMDN Database using your Username and Password.

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*.



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.

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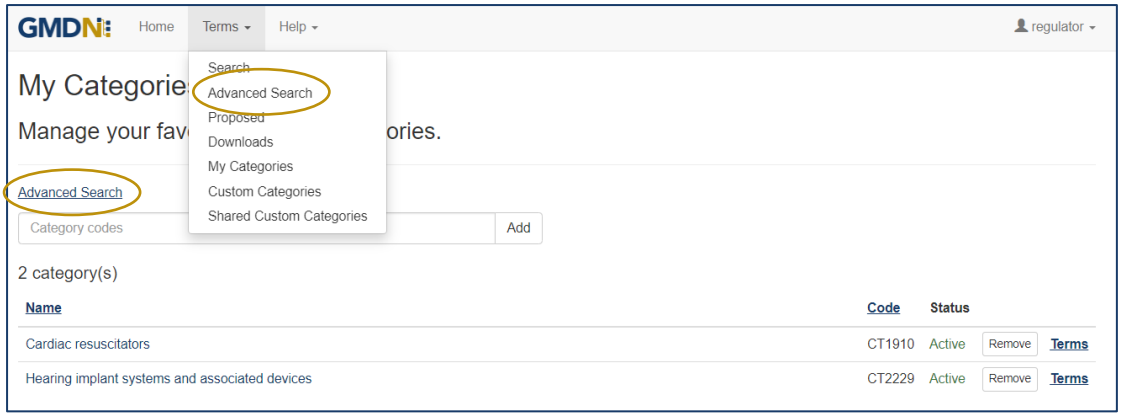
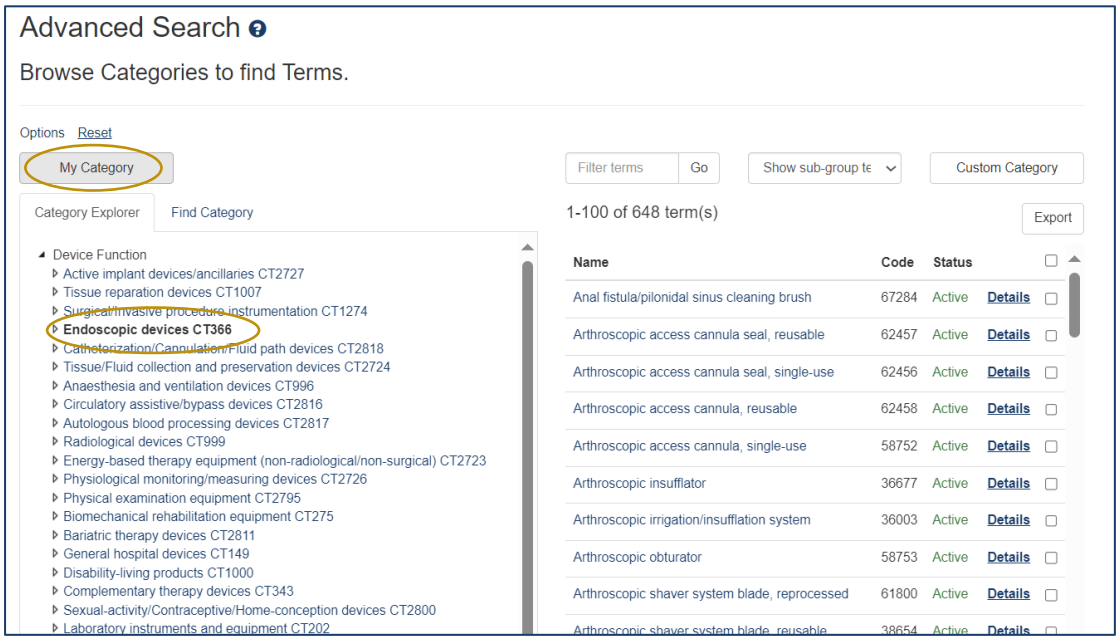
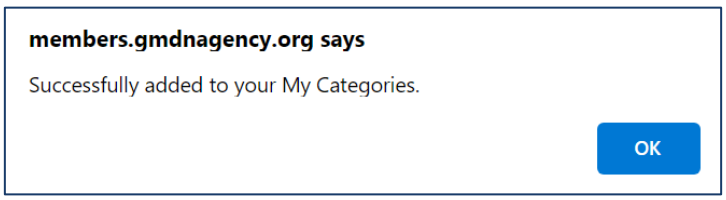


4. On the Advanced Search page use the *Category Explorer* to select the Category that you would like to add, when a GMDN Category is selected it will become bold. Then click on the *My Category* button.

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



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



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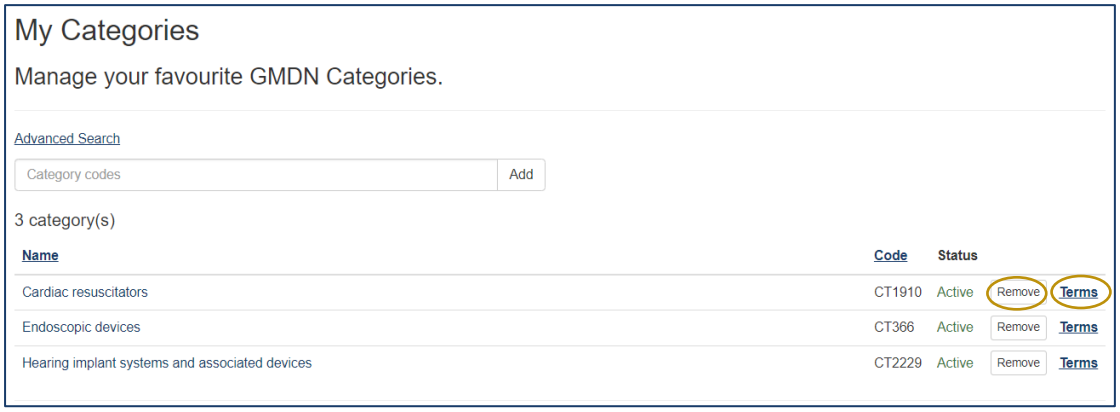
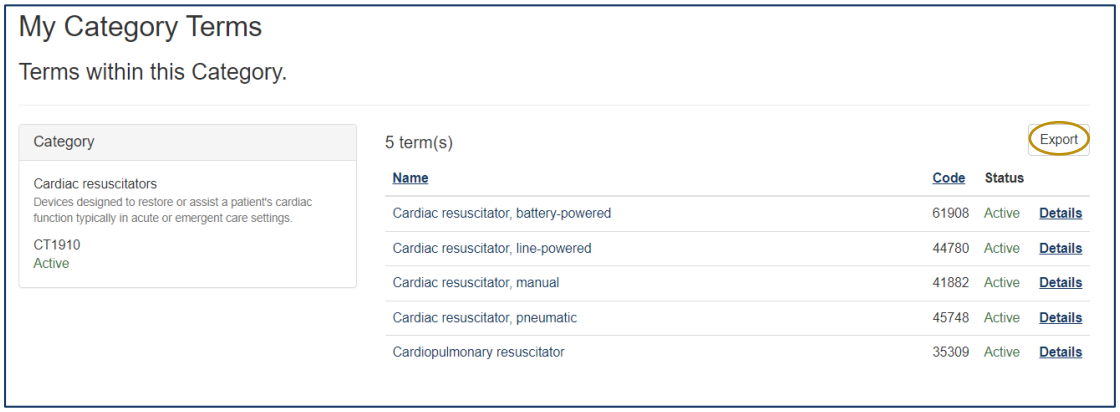
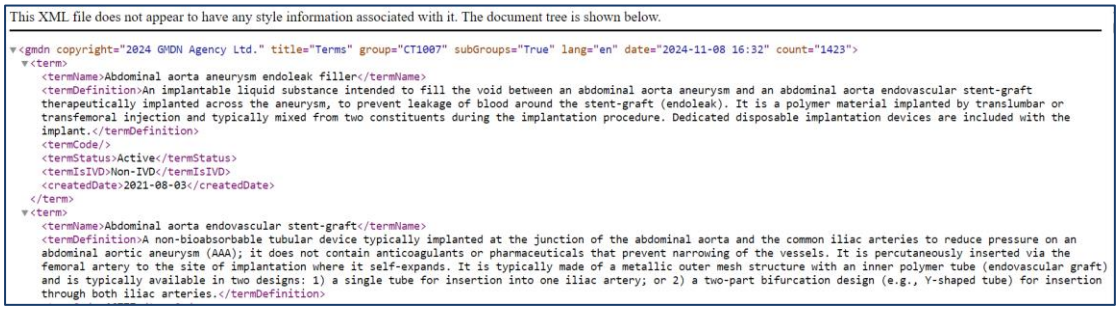
6. On the My Categories page you can view the GMDN Terms within your selected GMDN Categories by selecting the *Terms* button. You can also remove any GMDN Category from your list if you no longer require it by using the *Remove* button.



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





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.

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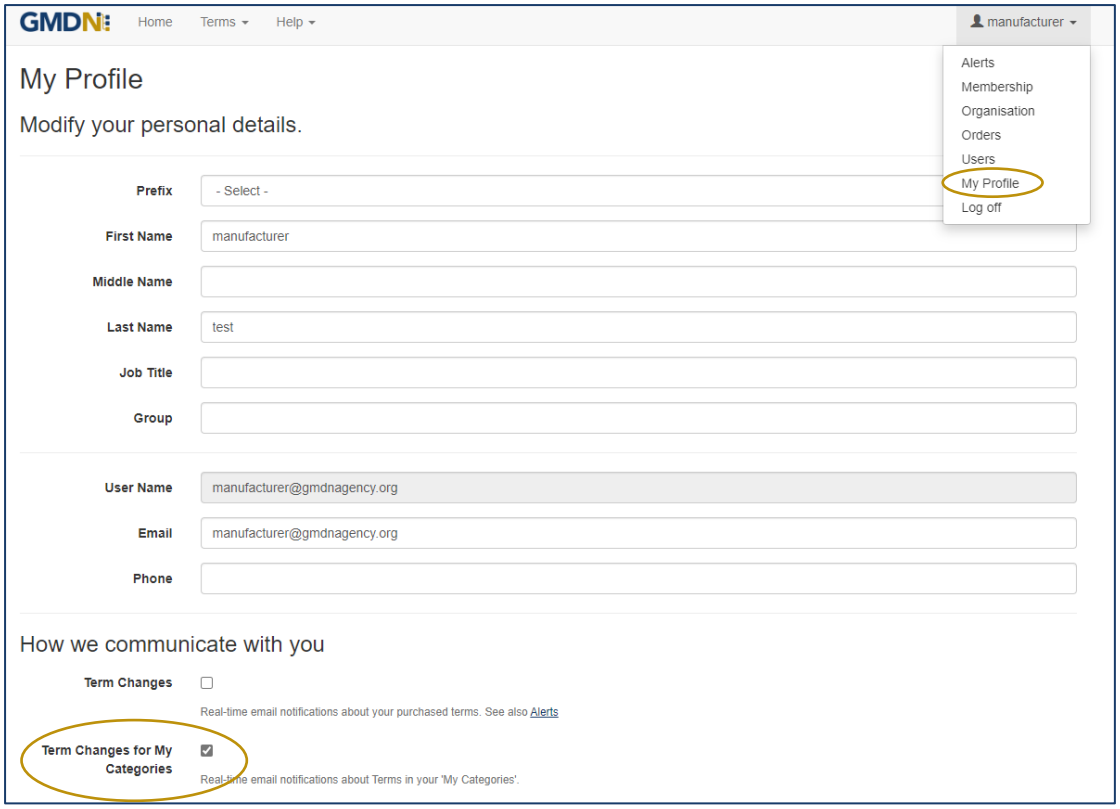

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6. GMDN Website - Enquiry – Step-by-Step Guide

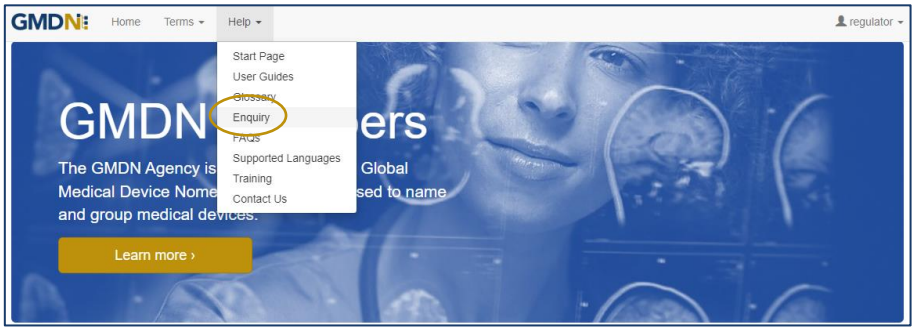
This is a Step-by-Step Guide for submitting an Enquiry for new or modified GMDN Codes using the GMDN website.

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:

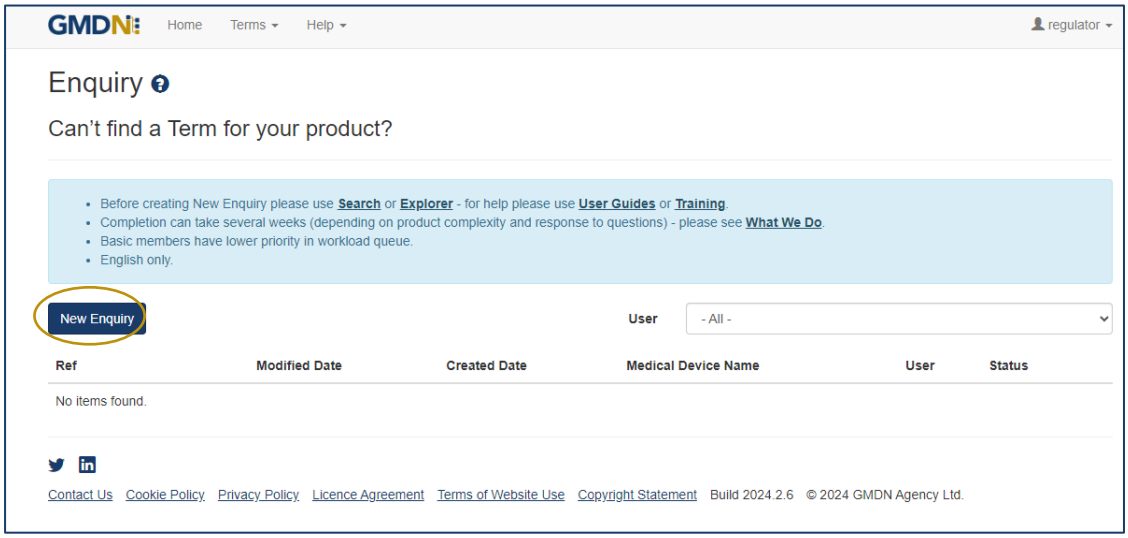
a. The GMDN Agency identifies an existing GMDN Term.
b. An existing GMDN Term is modified to include the new product's characteristics.
c. A new GMDN Term is created.

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.



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

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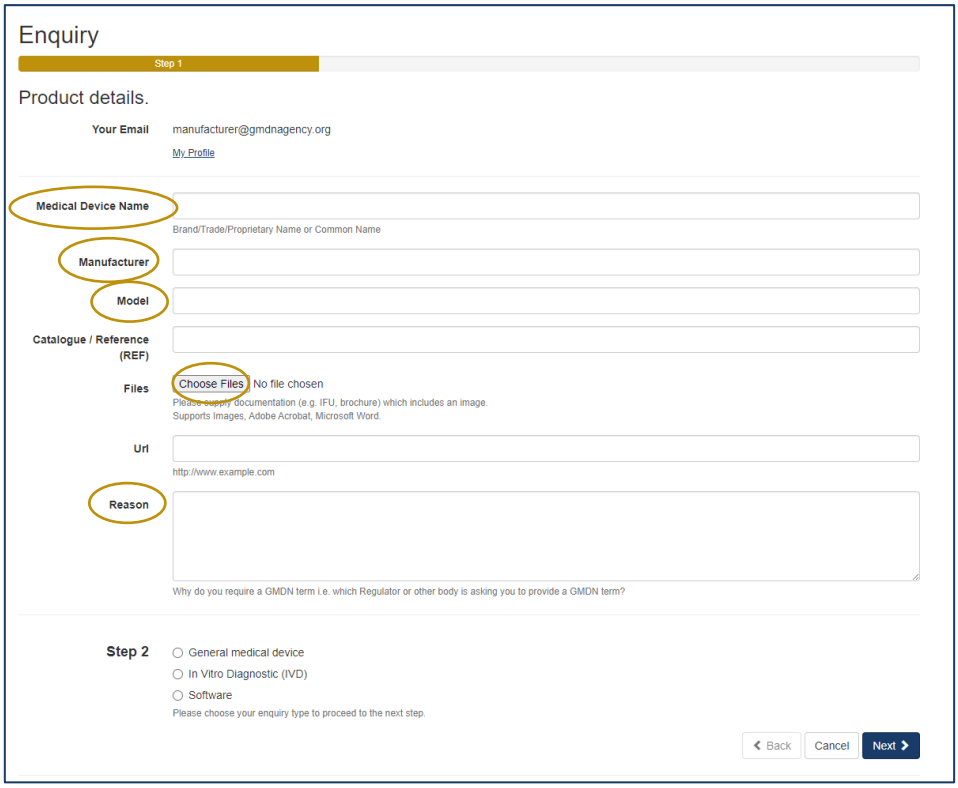
All information provided to the GMDN Agency is confidential to us and is subject to current Data Protection Law. For more information, please see our *Privacy Policy*, found in the footer of all webpages.



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

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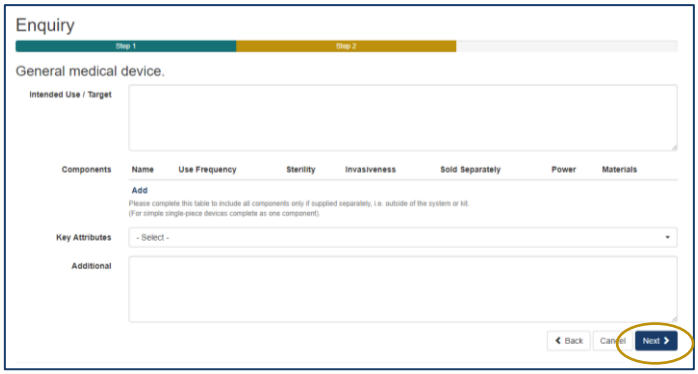
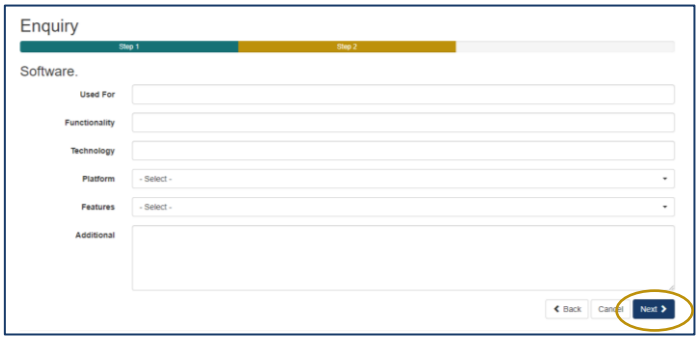
a. ***General medical device*** is for products that are to be used as a medical device only and will ask questions related to that specific technology. Once you have completed the form click next.



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.



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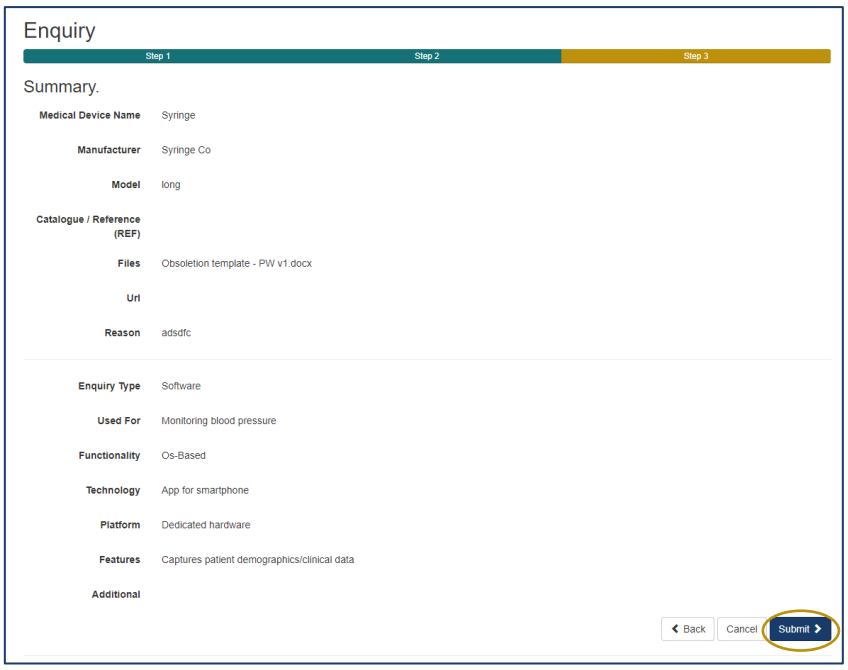
6. The *Summary* page is used to provide a final check on the product details prior to submission. Review the summary and when happy with it press submit.



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.

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7. GMDN Website – Downloading the GMDN Data Set

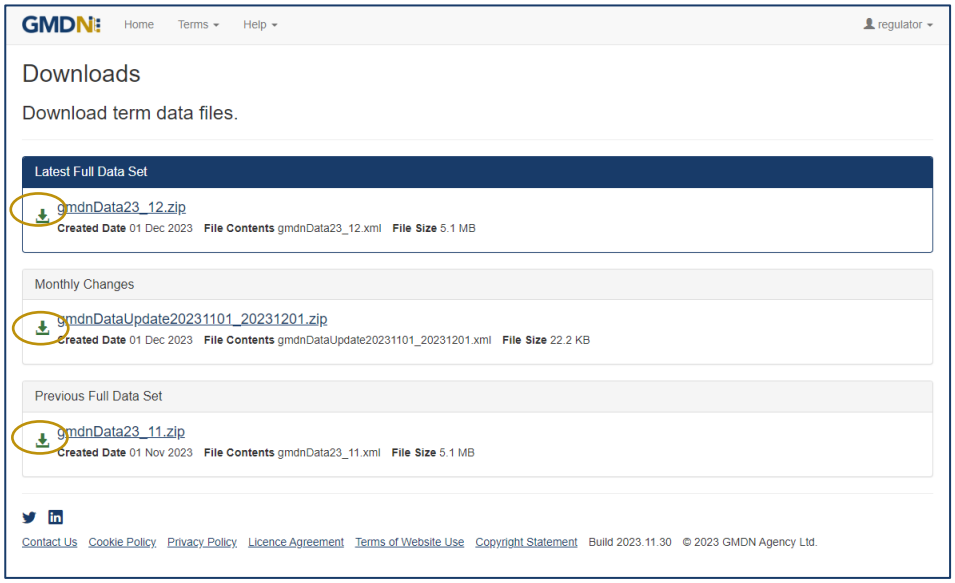
This is a Step-by-Step Guide for Exporting the GMDN Database and importing into a spreadsheet such as Excel.

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 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.

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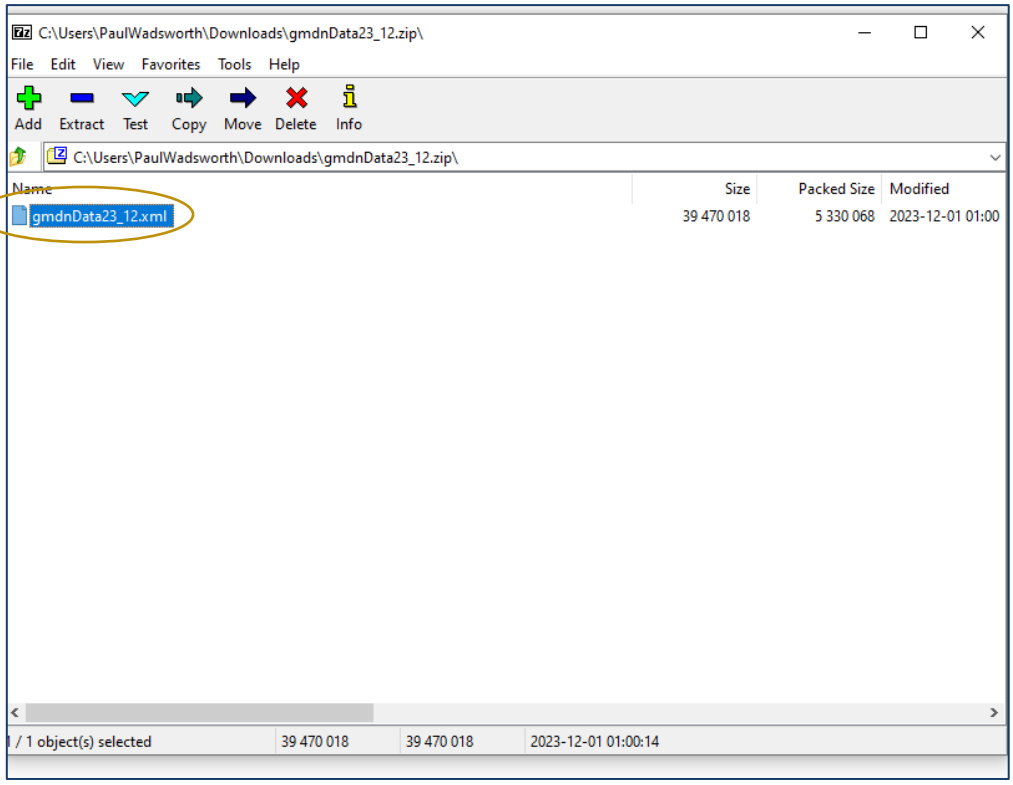

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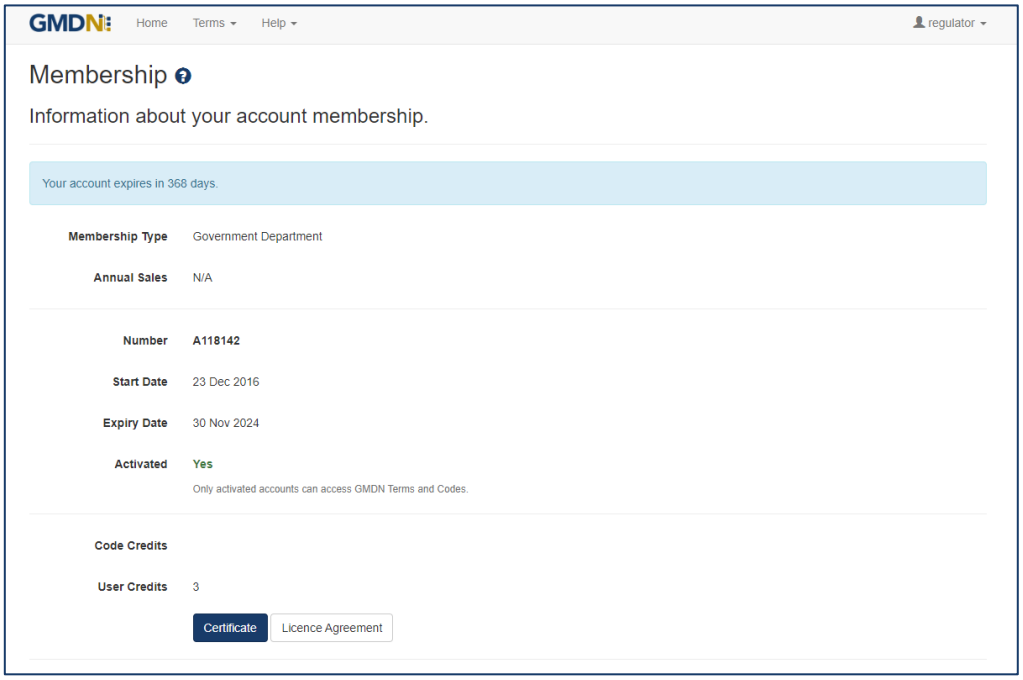
8. GMDN Agency - Membership Renewal Process (free membership access)

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.



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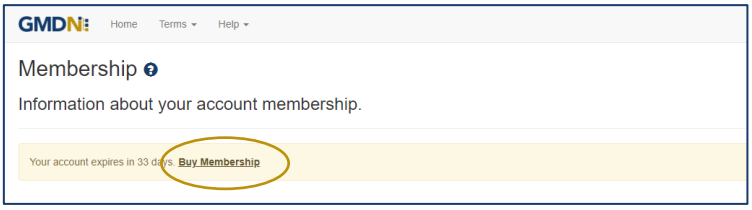
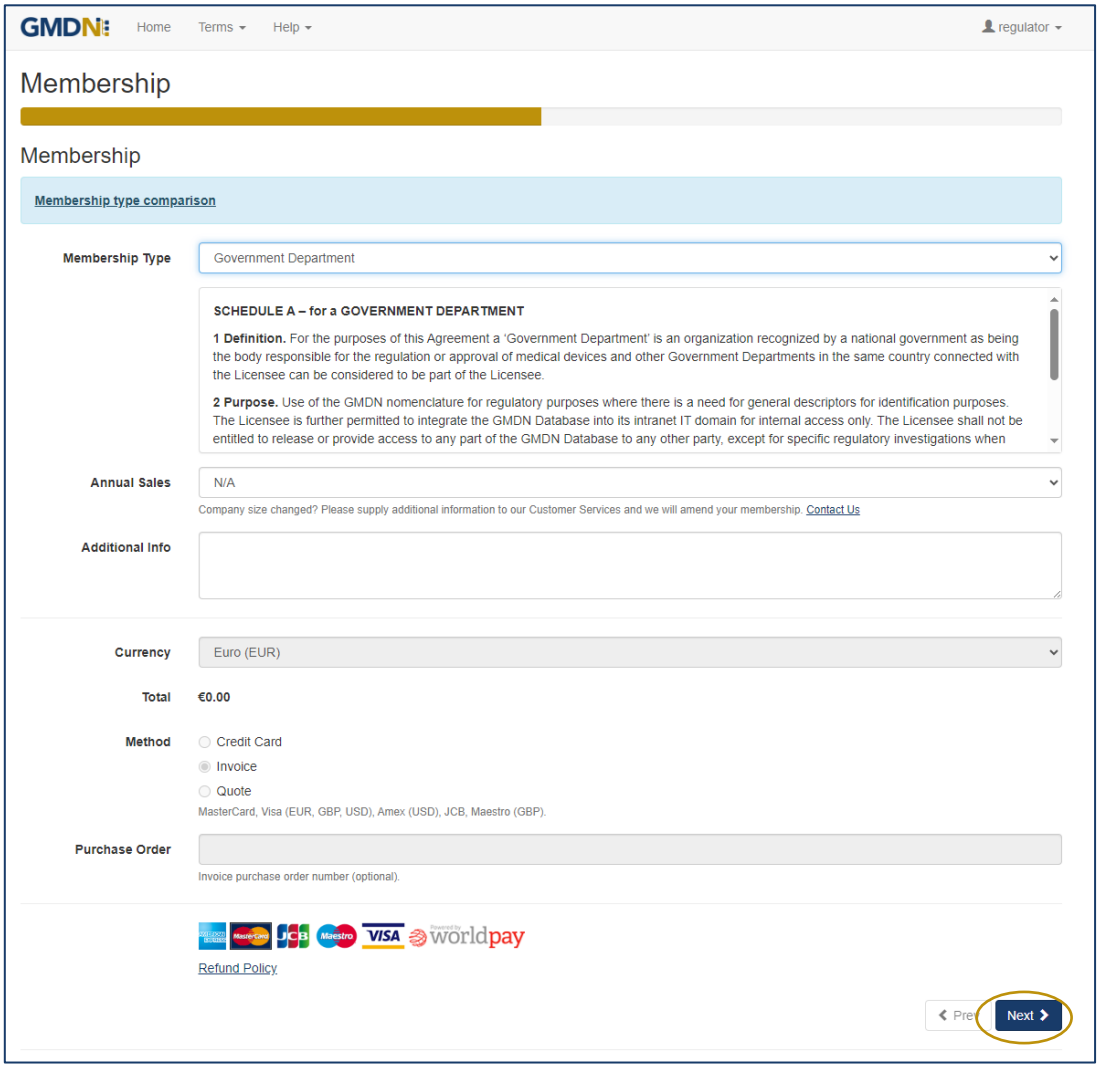
3. Membership can be renewed up to 3 months before it is due to expire and when available will be visible as a *Buy Membership* link on your *Membership* page.



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*.



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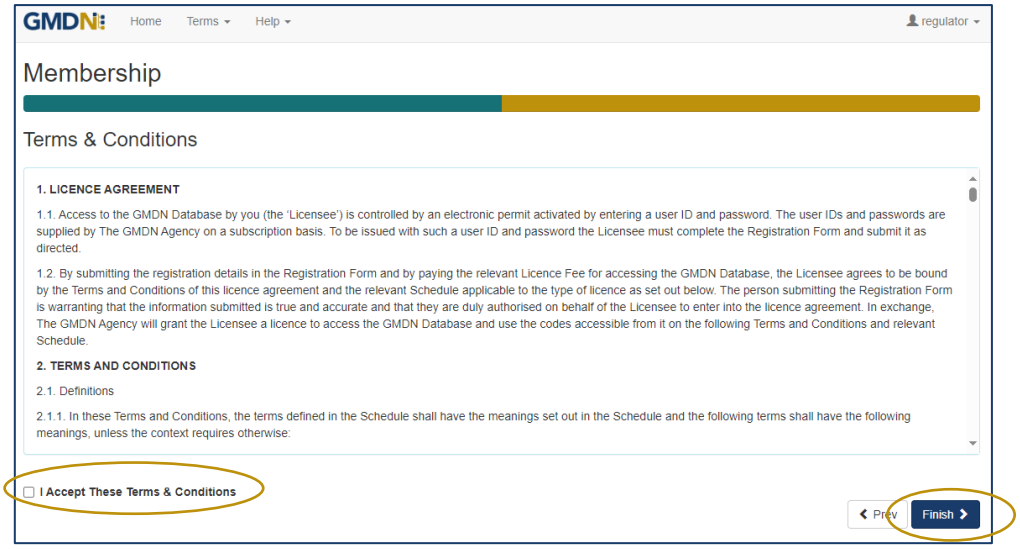
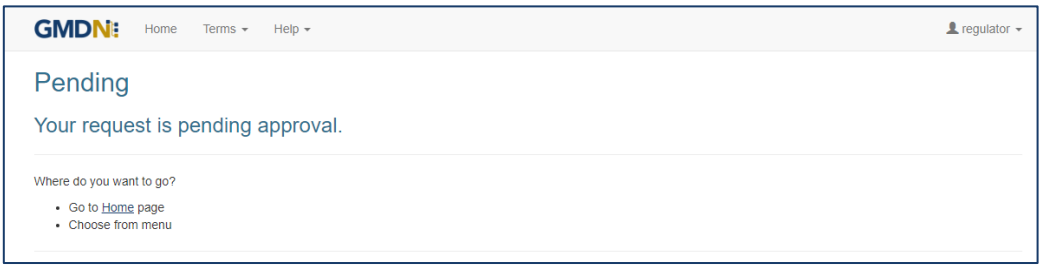
5. Next *Terms & Conditions* need to be accepted. Then click the blue *Finish* button.



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 webapge (with the person icon).

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

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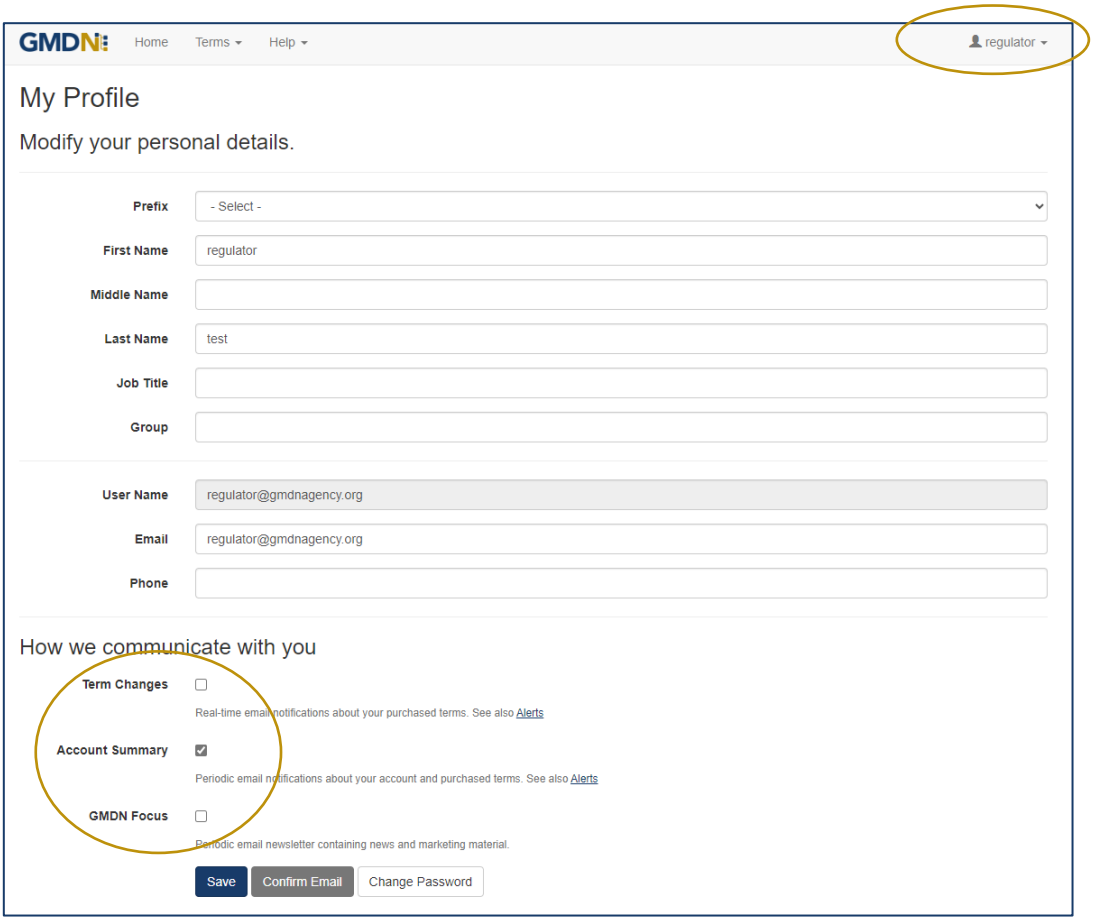
9. Stay in touch with the GMDN Agency

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).



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.

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