# GMDN – User Guide for Manufacturers

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**GMDN**

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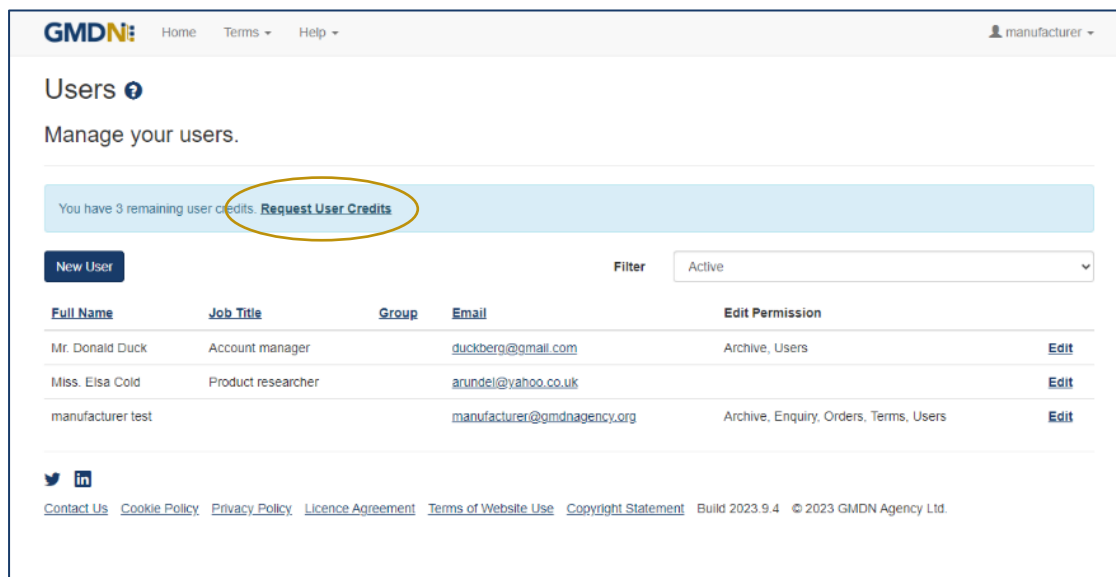
1. Login to the GMDN Database using your Username and Password.

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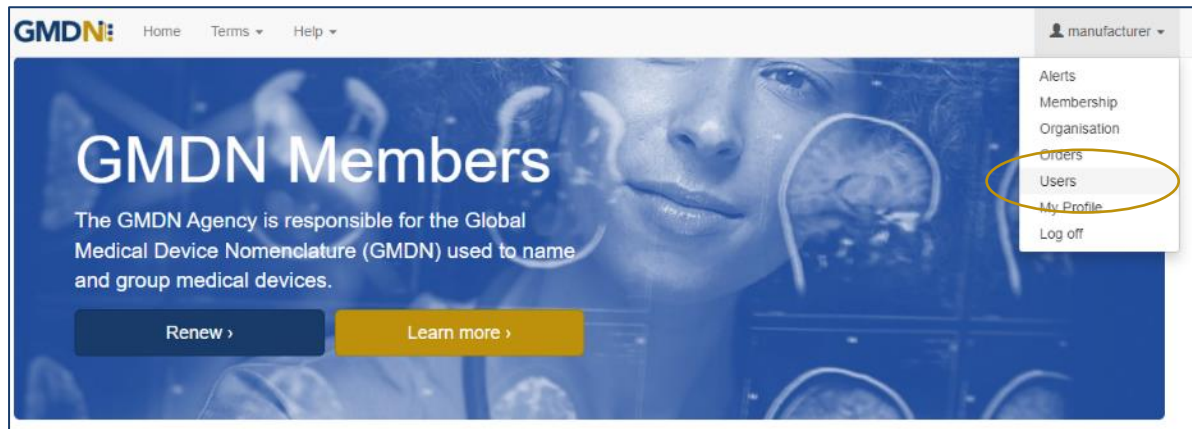


2. By clicking on *Users* the list of existing users will be listed for your account.

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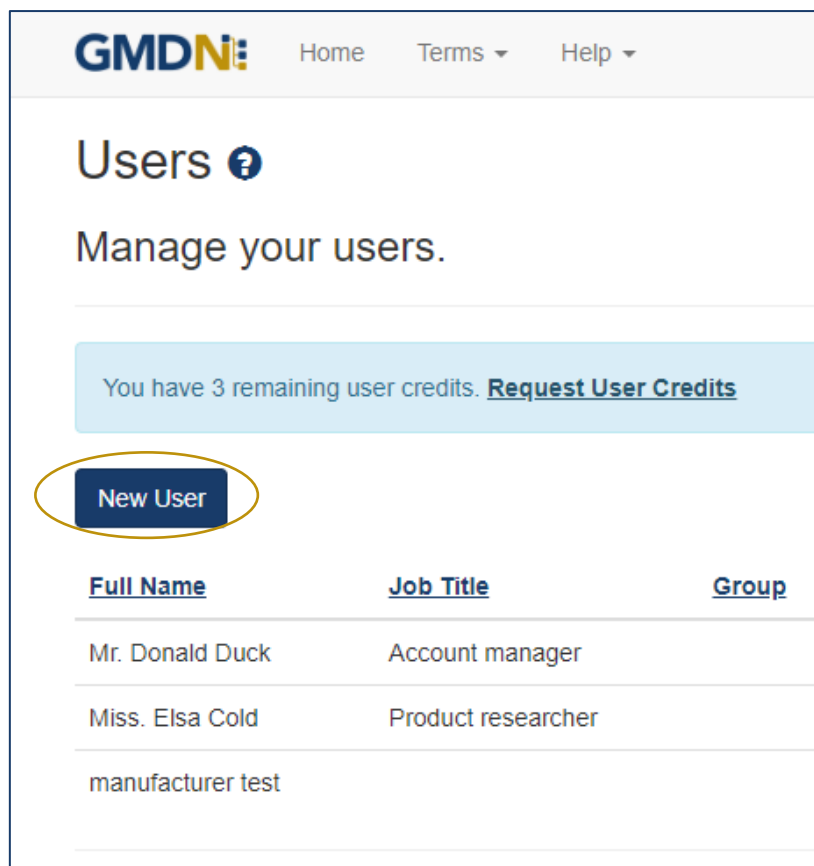
4. Each account when first activated, is provided with a certain number of user credits which are used to add more users. If you require more, they can be requested using the *Request User Credits* button.

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*.

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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.

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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.
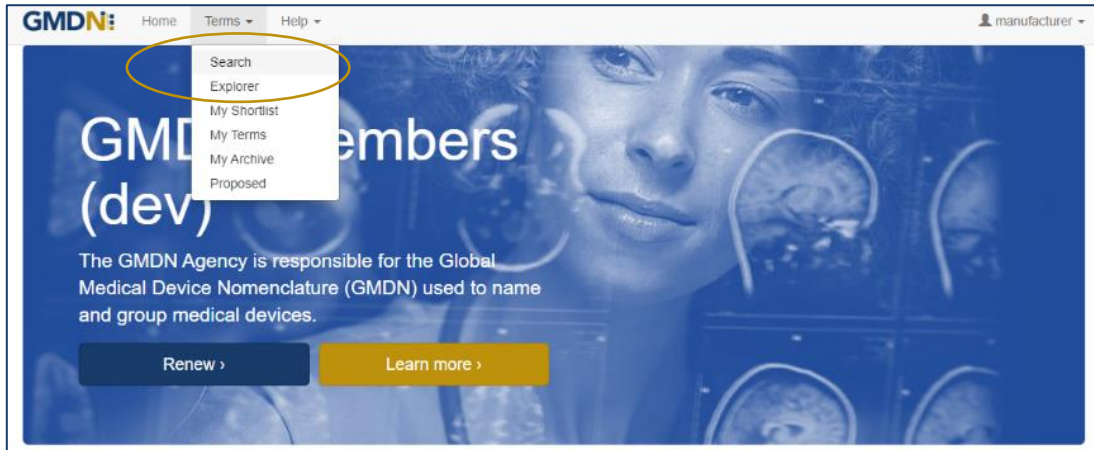


3.  In the box, type in the keyword(s) for the medical device you are looking for.



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.

4. The *Advanced* tab provides additional filters to narrow the search by Term Modification Date and searching in specific user locations, such as the *My Terms* list.

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.
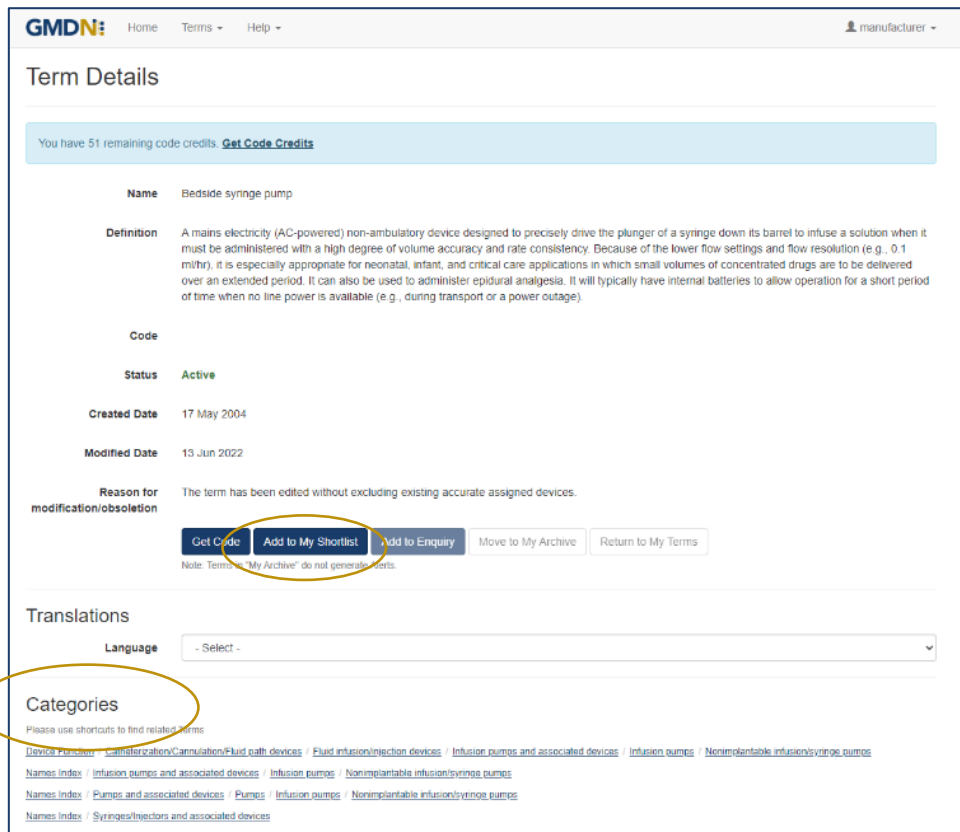


One of the advance features of the *Term Details* view is the use of *Categories*. This uses the new GMDN *Explorer* to view all the Terms that are related by linking it to other GMDN Terms with similar characteristics. More information can be found in the 'Explorer Step-By-Step Guide'.

6. To see the 5-digit GMDN Code, you must use your Code Credits. You can do this by clicking the *Get Code* button. Note: New Memberships will have an allocated Code credit starter allowance.

At any point, you can click on *Add to My Shortlist.* You can review Terms added to *My Shortlist* for transfer to *My Terms* by selecting *My Shortlist* on the dropdown menu under *Terms* at the top of the webpage.

If the Term is already in *My Shortlist*, the button will become *green*. If the Term is already in *My Terms,* the GMDN Code will appear.

Note: The Term Code won't be revealed until the member opens *My Shortlist* and confirms the purchase by clicking on the *Get* or *Get All* button. This will use one or more Codes credits.

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7. A list of GMDN Terms in *My Shortlist* will be displayed to review.

Terms can be selected or removed individually or as a group.
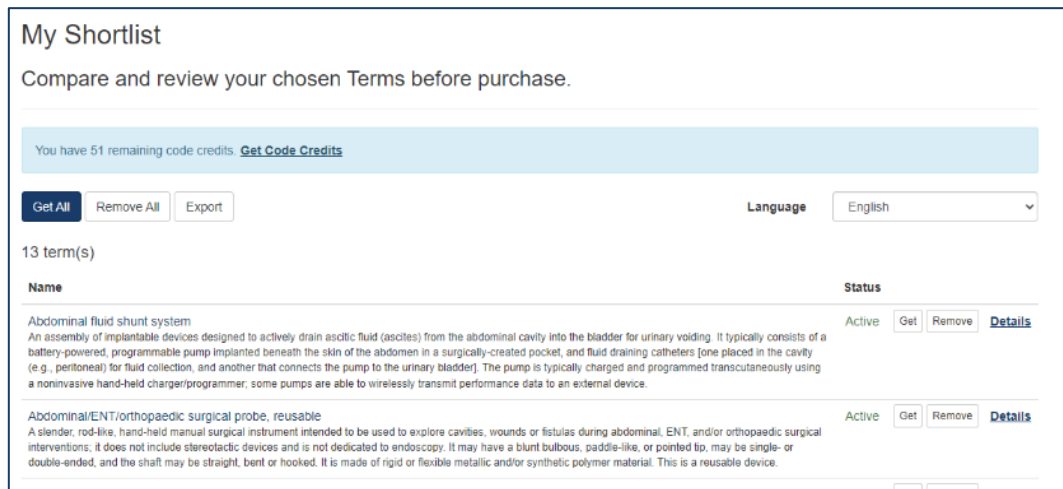


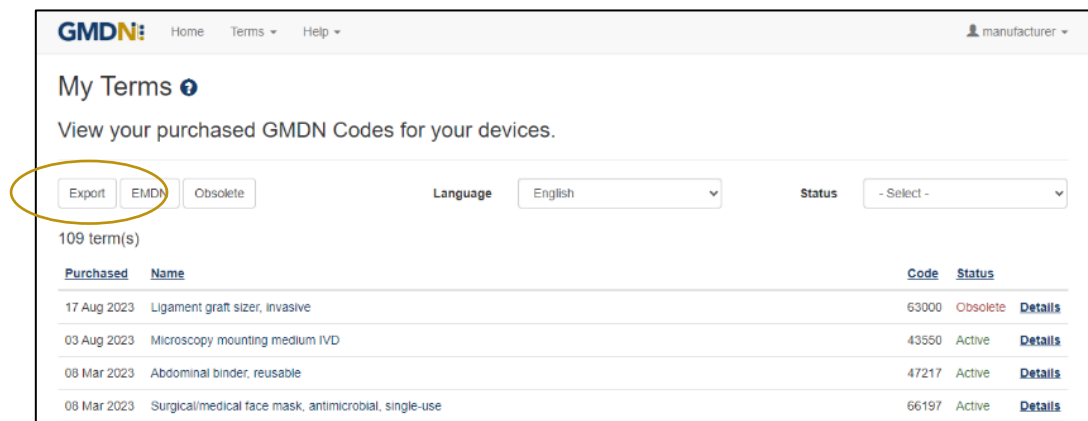8. Terms that you have purchased will be stored in the *My Terms* list (in the *Terms* dropdown menu) and the Codes are also displayed. This is your organisation's collection of GMDN Terms and the GMDN Agency monitors this list for you and informs you if a change in the status of any Term occurs.



This list of Terms the *My Terms* list can also be exported from the website in a convenient XML format file. This file format allows the data to be imported into most popular applications, such as a spreadsheet.

The list can also be filtered and sorted by several different fields, useful if you have a long list of Terms.

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9. If you are no longer using a GMDN Term for your product, you can remove it from your *My Terms* list by moving to *My Archive*. The *My Archive* list is found in the *Terms* menu. A Term can be un-archived and returned to the *My Terms* list at any time. It will then continue to be monitored by the GMDN Agency.

If you search for a GMDN Term and it is already in your *My Archive* the GMDN Code will be displayed with a strikethrough, as seen in the example below.

### 3. GMDN Website - Explorer – Step-by-Step Guide

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.
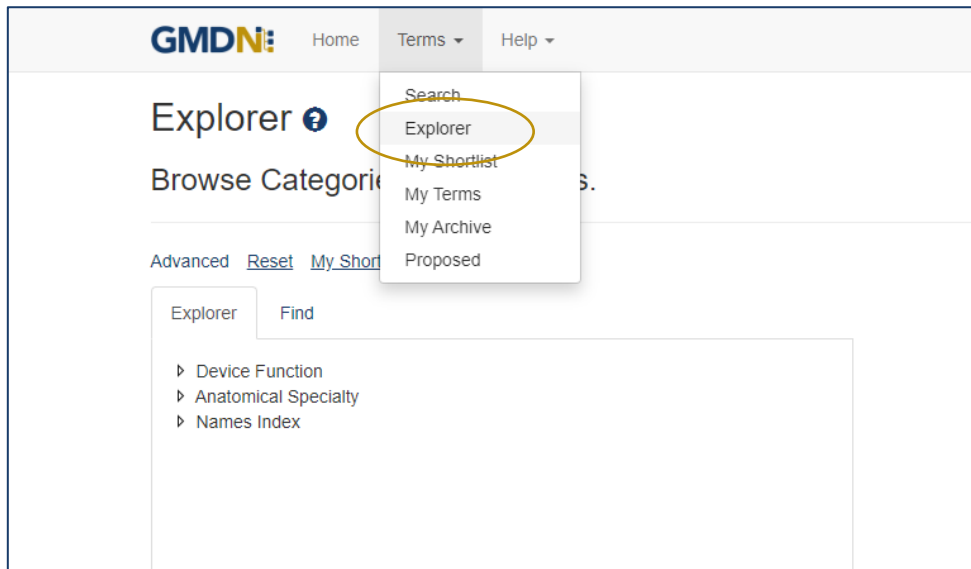


3. The choice of language can be selected using the *Advanced* tab, but the translation button will need to be used to update the hierarchy tables of groups.
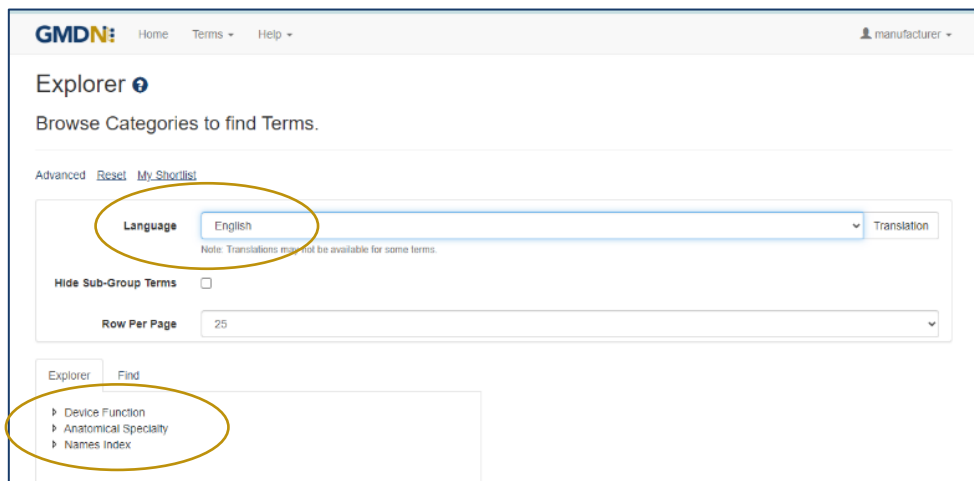


The *Explorer* uses three sets of groups, those related to the device function (for example – Anaesthesia or Cardiology) those related to Anatomical Speciality (for example – Cardiovascular or Neurological) as well as a Names Index. The structure of the hierarchy is revealed by clicking on the arrows.
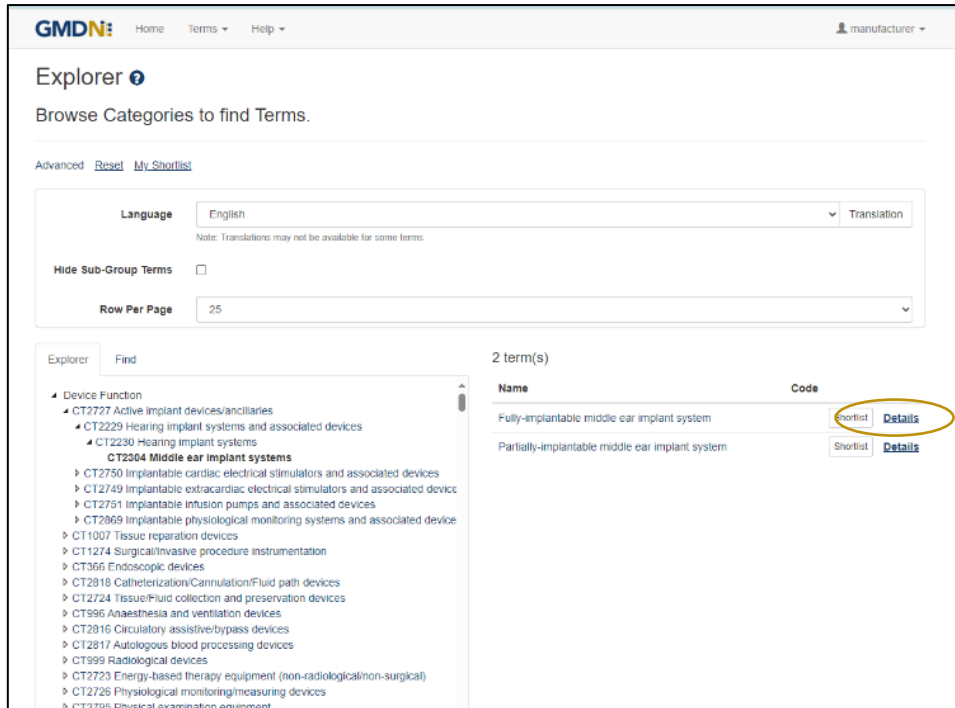
4. The list of GMDN Terms in each Explorer group is revealed by clicking on it. The Term Definition is revealed by clicking on the Term Name. By clicking in the *Details* link, you can see more information belonging to that Term, including a translation of the text, if available.
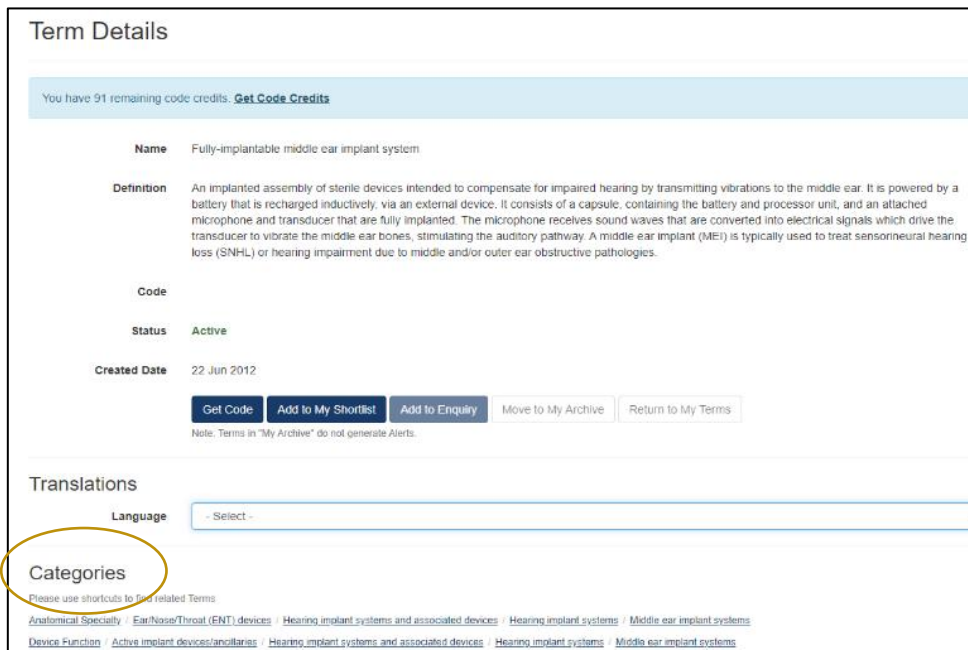


One of the advance features of the *Term Details* view is the use of *Categories*. This uses the new GMDN *Explorer* to view all the Terms that are related by linking it to other GMDN Terms with similar characteristics.

5. To see the 5-digit GMDN Codes, you must use your Code credits. Note: New Memberships will have an allocated Code credit starter pack to allow this.

At any point, you can click on *Add to My Shortlist* and review Terms to transfer to *My Terms* found in the *Terms* drop down menu.

If the Term is already in *My Shortlist*, the *Add to My Shortlist* button will become inactive.

If the Term is already in *My Terms,* the GMDN Code will appear.

**Note:** The GMDN Code won't be revealed until the member opens *My Shortlist* and confirms the purchase by clicking on the individual *Get* button or *Get All* button. This will use one or more Code credits.

6. A list of GMDN Terms in *My Shortlist* will be displayed to review. Terms can be selected or removed individually or as a group.
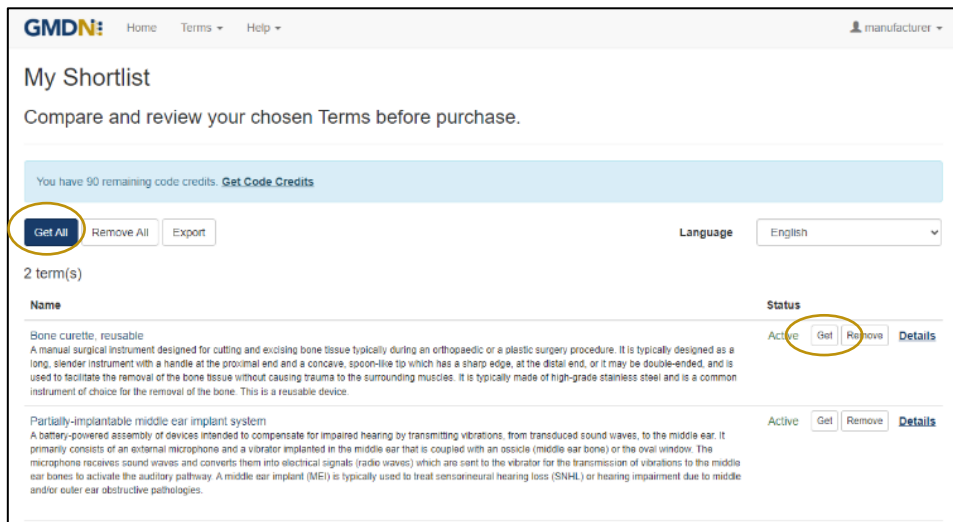


7. Terms that you have purchased will be stored in the *My Terms* list (in the *Terms* menu) and the Codes are also displayed. This is your organisation's collection of GMDN Terms and the GMDN Agency monitors this list for you and informs you when a change in the status of any Term occurs.
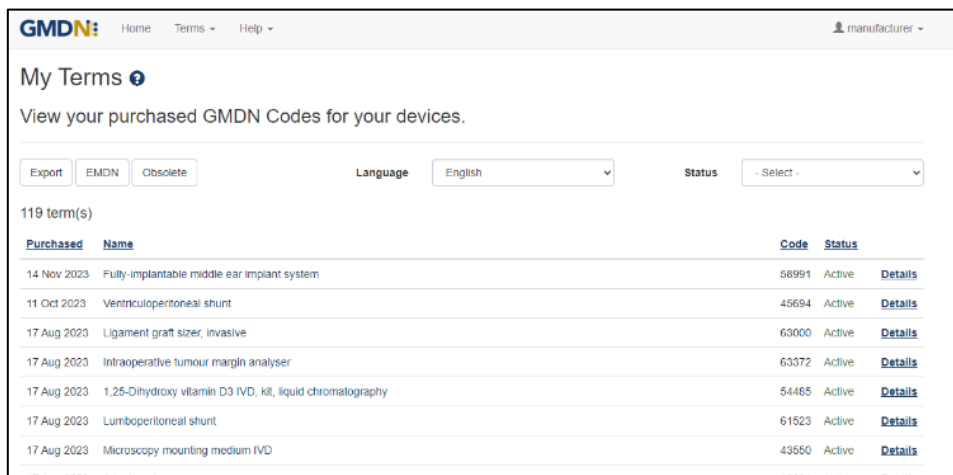
This list of Terms can also be exported from the website in a convenient XML format file. This file format allows the data to be imported into most popular applications, such as a spreadsheet.

The list can also be filtered and sorted by several different fields, which is particularly useful if you have a long list of Terms.

8. If you are no longer using a GMDN Term for your product, you can remove it from your *My Terms* list by moving to *My Archive*. The *My Archive* list is found in the *Terms* drop down menu. A Term and be un-archived and returned to the *My Terms* list at any time. It will then continue to be monitored by the GMDN Agency.

## 4. GMDN Website – My Terms - Exporting GMDN Data into a Spreadsheet

This is a Step-by-Step Guide for Exporting the GMDN Term data 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 *My Terms* page is found in the dropdown list in the *Terms* menu at the top of the webpage.
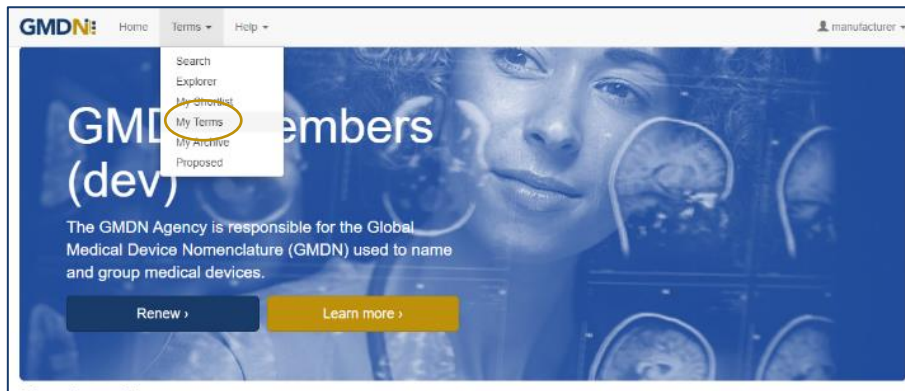


2. By clicking on *My Terms* the list of purchased GMDN Terms is displayed for your account.
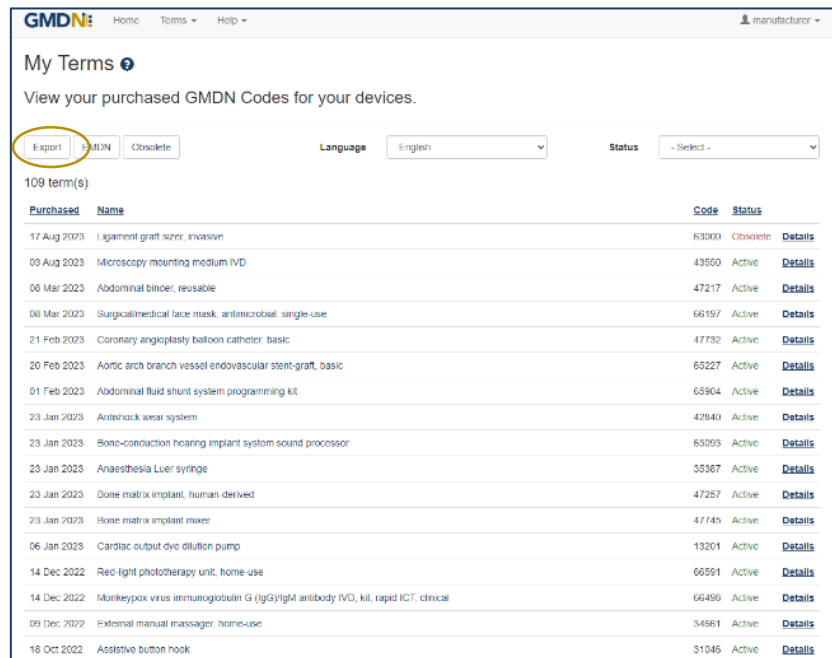


3. Click on *Export* and the list of Terms will be saved to the default location on your device (usually the 'Downloads' folder) in the XML format. The XML format has been chosen because it is compatible with the GMDN Database and is easily converted and imported into all software packages for further analysis.

4. To import the data into an Excel Spreadsheet. Start Excel with a Blank Workbook. Click *File* and *Open* and locate and select the XML file you downloaded. Click *Open* and Excel will display the following dialogue box



Click *OK*. Another dialogue box may be displayed. Click *OK*.
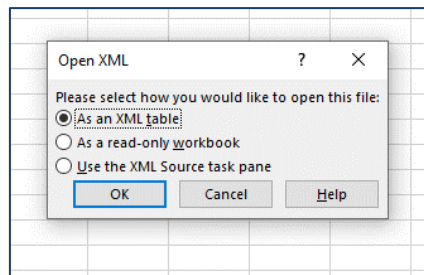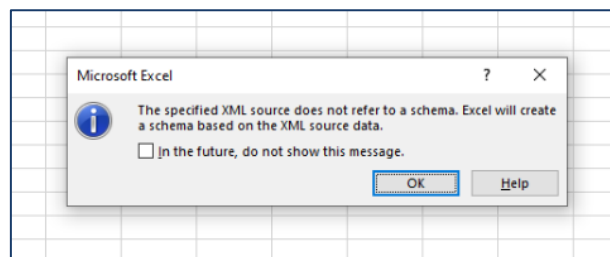


6. The data will be imported into the Worksheet.



The column names are defined in the tables below:

| Column name | Description |
| --- | --- |
| *copyright* | Copyright statement |
| *title* | My Terms |
| *Membership number* | Your GMDN membership number |
| *Lang* | Language chosen for export |
| *date* | The date the file was exported |
| *count* | The number of Terms in the spreadsheet |
| *TermName* | GMDN Term Name |
| *TermDefinition* | GMDN Term Definition |
| *TermCode* | GMDN Term Code |
| *TermStatus* | Active / Obsolete |
| *TermIsIVD* | Non-IVD / IVD flag |
| *createdDate* | The date the Term was first published |
| *obsoleteDate* | The date the Term was made obsolete |
| *purchaseDate* | The date the Term was purchased by the customer |
| *modifiedDate* | The date the Term was last modified |

### 5.   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.
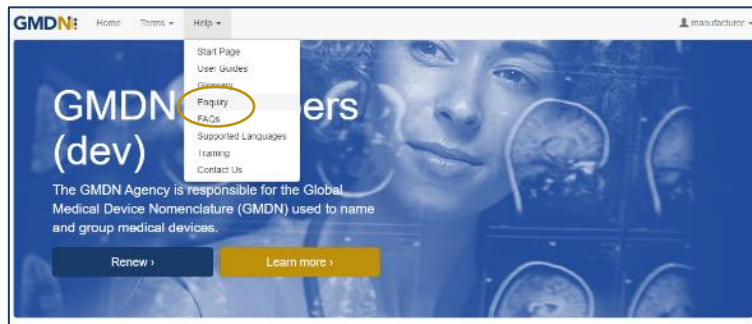


3. The *Enquiry* screen displays all the previous enquiries submitted from the same account. A filter is available to list all enquires by a specific user applicant. This page is also used to monitor progress on all outstanding enquires.
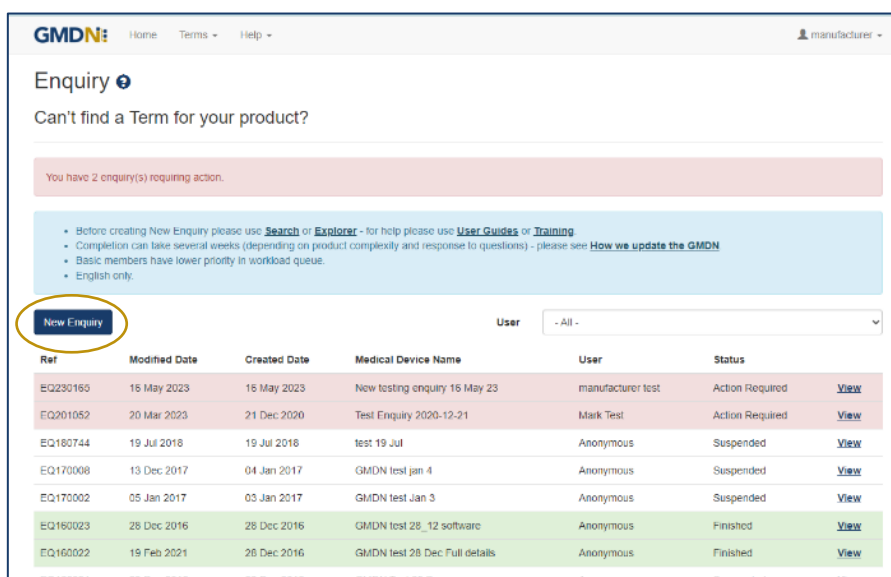


4.  Click on *New Enquiry* to start filling in product details.

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.



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.

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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## 6. GMDN Website – Managing Obsolete Terms – Step-by-Step Guide

This is a Step-by-Step Guide to help with managing obsolete GMDN Terms using the GMDN website.
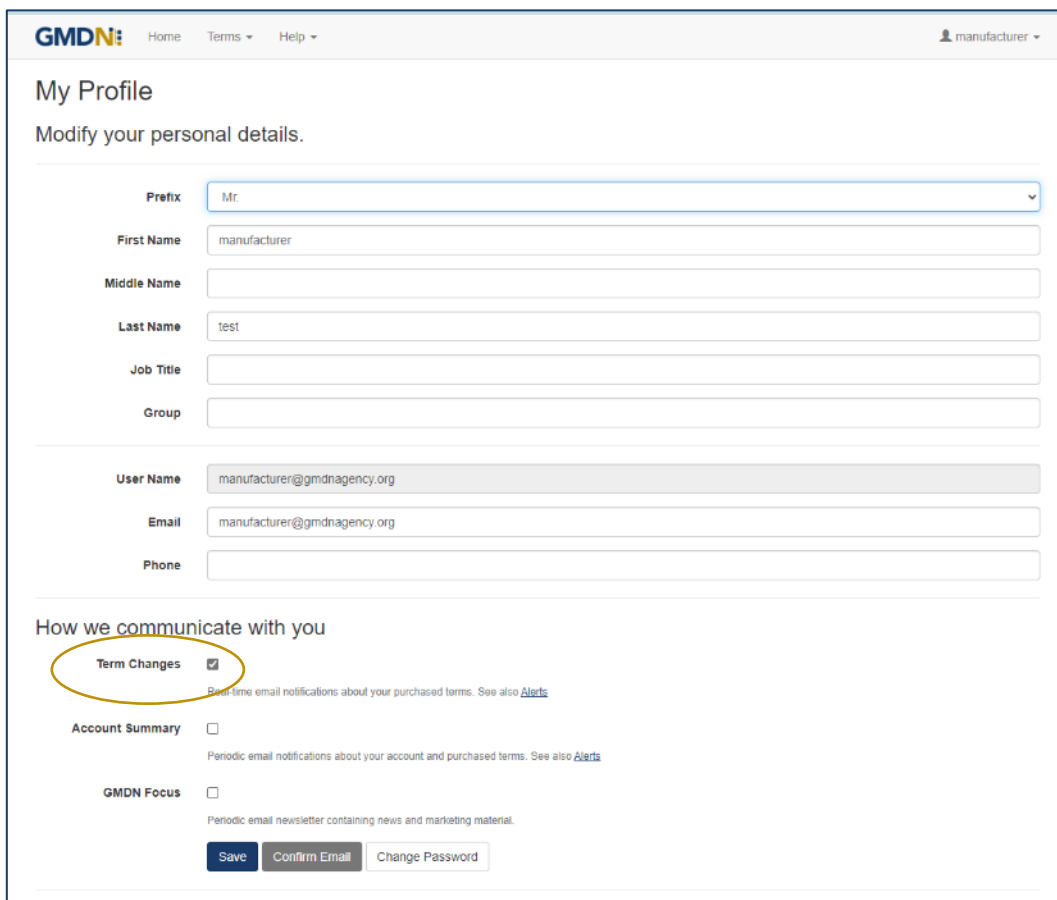
You will only receive notification of Term being made obsolete if that Term is currently listed in your *My Terms* list.

If one of the GMDN Terms you have been using is made obsolete you can verify this by one of these three methods:

- Email notification
- Alerts
- My Terms List

**Email notification**

The email notification will be sent to all users that are eligible and have the *Term Changes* box ticked in their *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).

An email in the format below will be provided.

Dear GMDN Member,

A GMDN Term in your My Terms list has been made obsolete. Please find an alternative by reviewing the Terms in the Explorer groups linked to the obsoleted Term.
Additional notifications can be found in Alerts

**Obsolete** - 10 Dec 2018 - Fistula hook (46769)

Regards
GMDN Agency
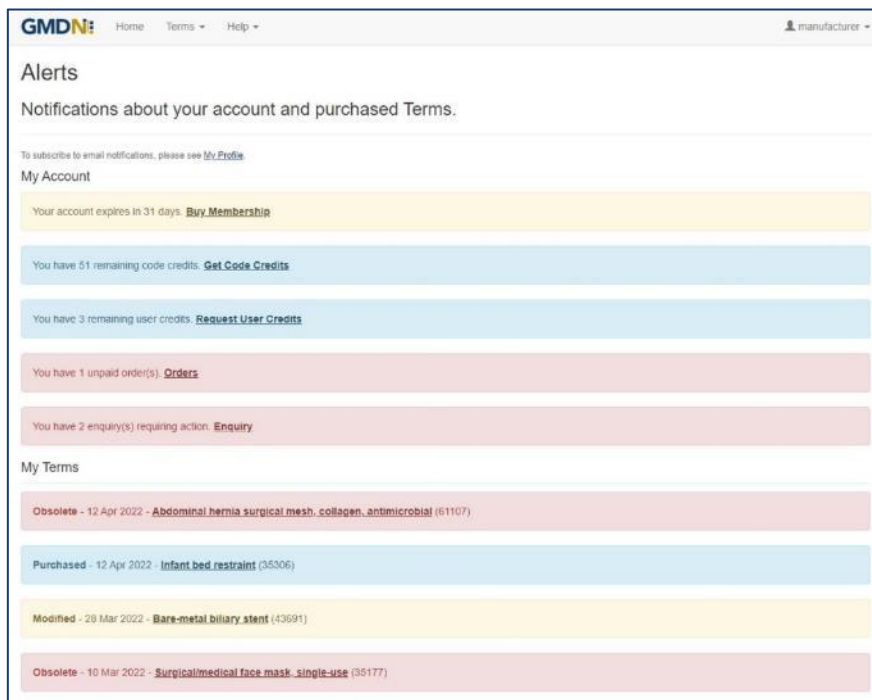
This is an automated message sent by GMDN Agency, please do not reply.
To unsubscribe, please update My Profile

## Alerts

*Alerts* are found in the Account dropdown menu at the top right of the webpage (with the person icon).
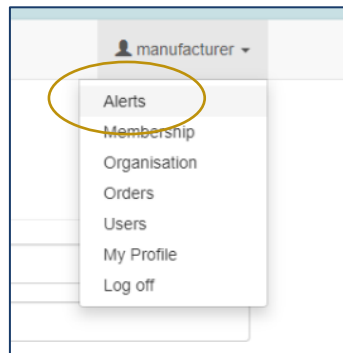


*Alerts* will always display any Terms in your *My Terms* list that have been made obsolete, unless and until they are moved from the *My Terms* list to the *My Archive* list.

## My Terms List

The *My Terms* list provide a list of all Terms that are monitored. The *My Terms* list can be found on the Terms dropdown menu at the top of the page.
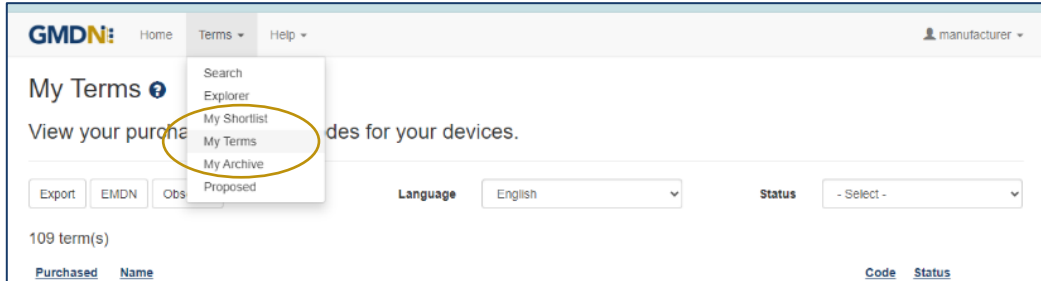


The *My Terms* list can be sorted by purchase date, Term name, GMDN Code and status. The below example has been filtered by Obsolete status.
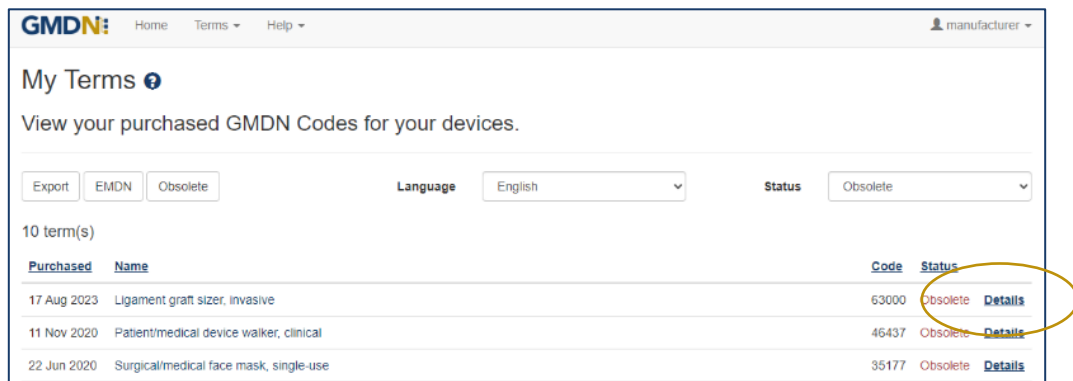


By clicking on *Details*, you will be taken to the Obsolete Term details page where you will find the list of suggested Alternative Term(s) at the bottom of the page
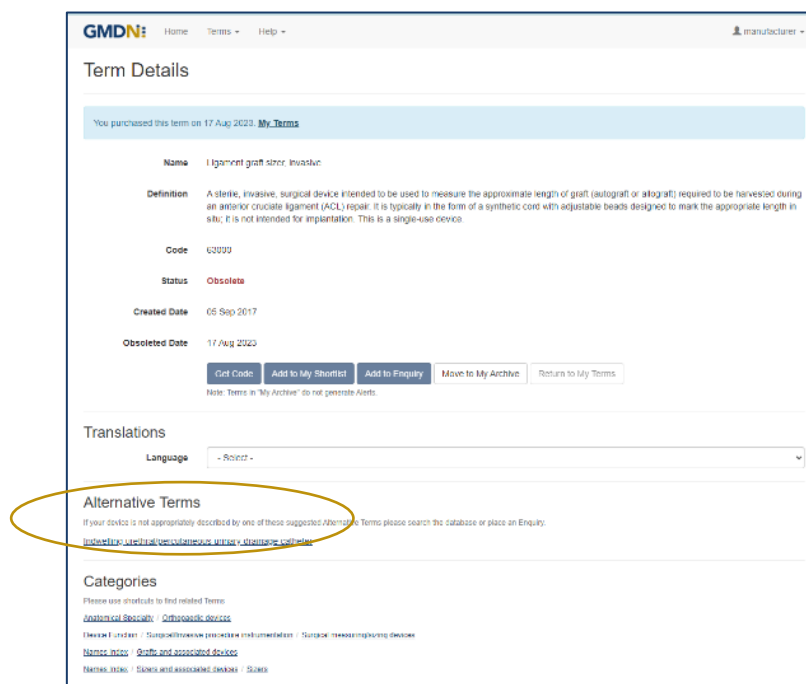
*Categories* at the bottom of the page can also be used to find Alternative Terms via the hierarchical categorisation tool



By clicking on a Category, it will open *Explorer* which provides a listing of all similar devices. The list of alternative Terms and their definitions are displayed.



Please add the appropriate Alternative Term(s) to your account.

When the Alternative Term has been selected and added to the *My Terms* list the obsolete Term can be moved to the *My Archive*. Click on the Term *Details* to do this.



An export file with the Obsolete and Alternative Terms is also available for download – please click on the Obsolete button on the My Terms page



**Note:** The appropriate Term may not always be found using the Categories link. You may need to initiate a fresh search using alternative wording. The GMDN Agency makes every effort to ensure that Terms that are made obsolete have an existing suitable Term available as a replacement, but if you have any difficulty in finding a suitable replacement please send us an Enquiry.

The replacement Term will need to be sent to your customers that have previously used the obsolete Term to update their records.

![GMDN logo]

**7. GMDN Agency - Membership Renewal Process (paid for 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). You can also renew your membership via the *Renew* button on the home page.
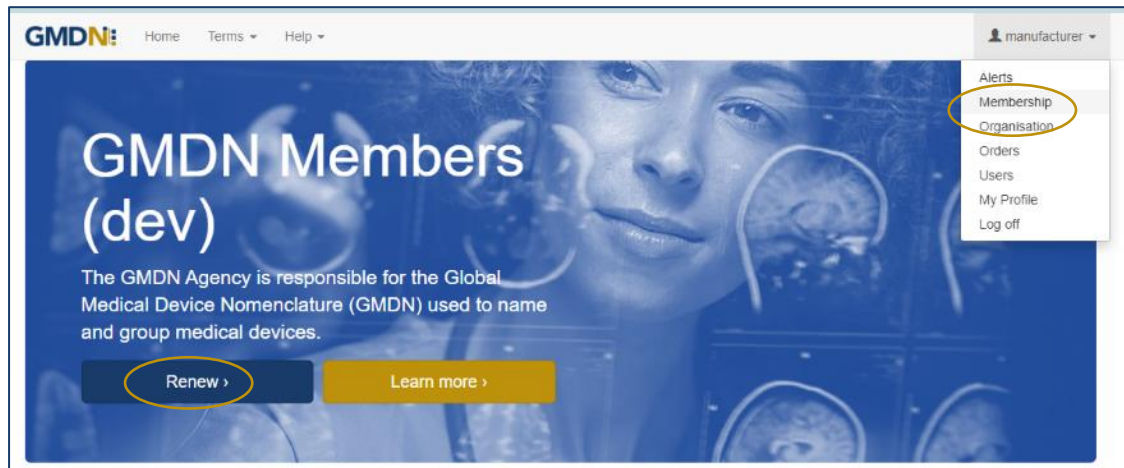


2. If you click on the *Membership* link, it will take you to your *Membership* page.
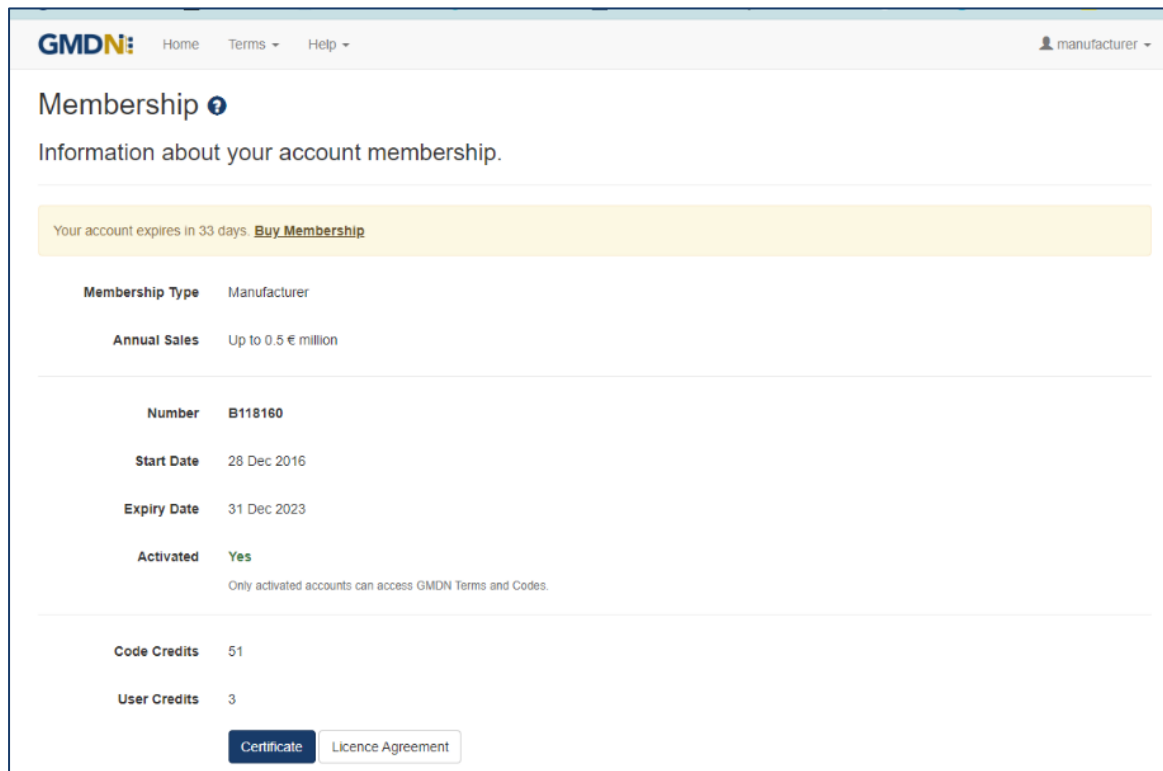
3. Membership can be renewed up to 3 months before it is due to expire and when available will be visible as a *Buy Membership* link on your *Membership* page.
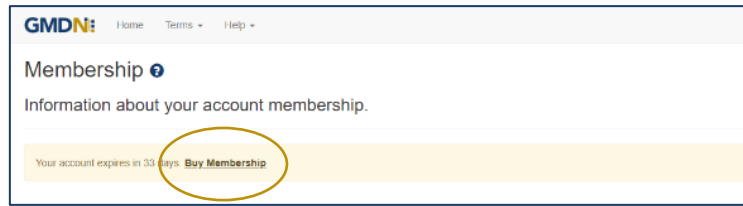


4. When the user clicks the *Buy Membership* button, the *Membership Renewal* screen will be displayed.

Note: If you are a Manufacturer you will need to select your relevant membership level based on your *Annual Sales* in $ (USD).

You can choose which currency to pay in from $ (USD), € (EUR) or £ (GBP). The default currency is £ (GBP).

Options for selecting payment method include *Credit Card* and *Invoice* as well as an option for a *Quote* if you need to raise a Purchase Order. A *Quote* can be converted to an Invoice at any time in the future. Once your payment method is selected click on the blue Next button.
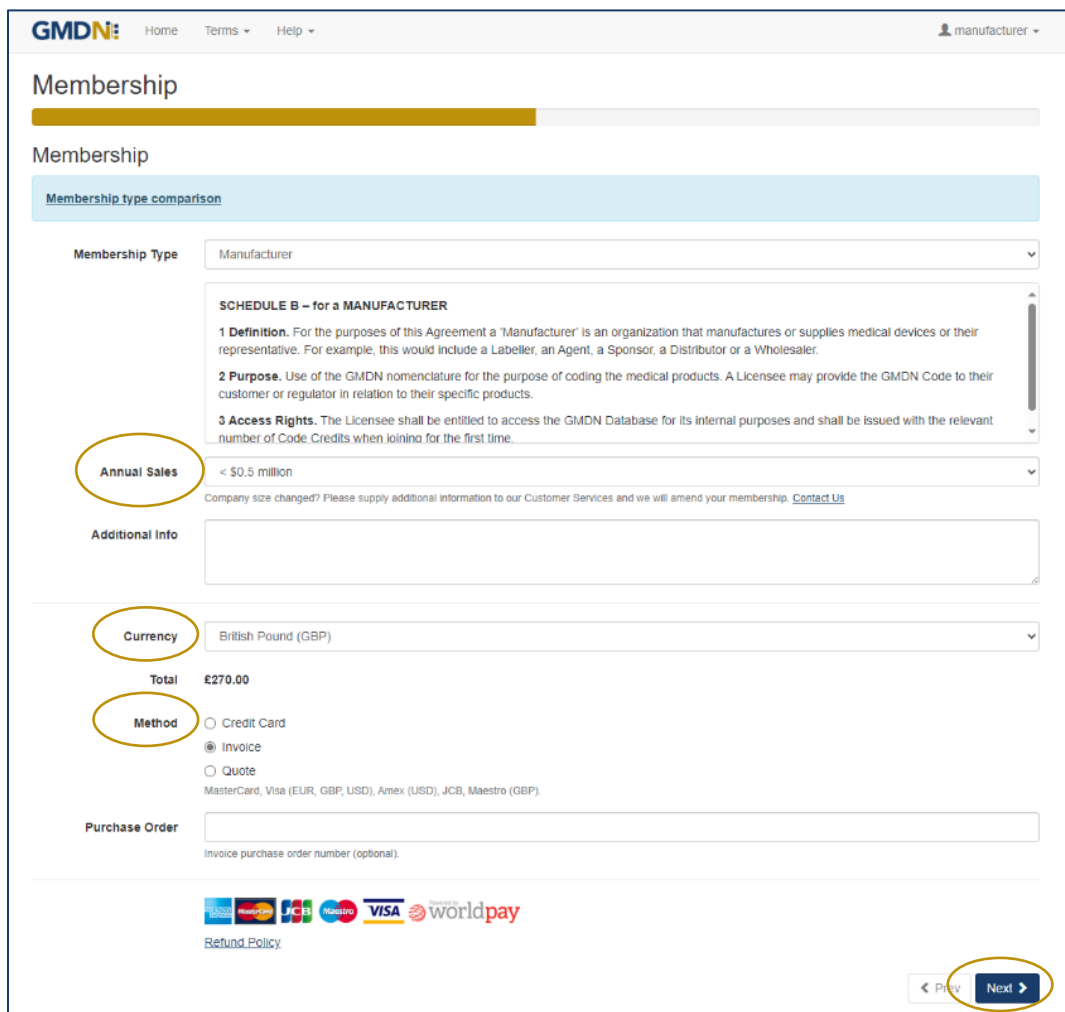
5. At the next screen you must tick the 'I Accept These Terms & Conditions' box and click on the blue Finish button.
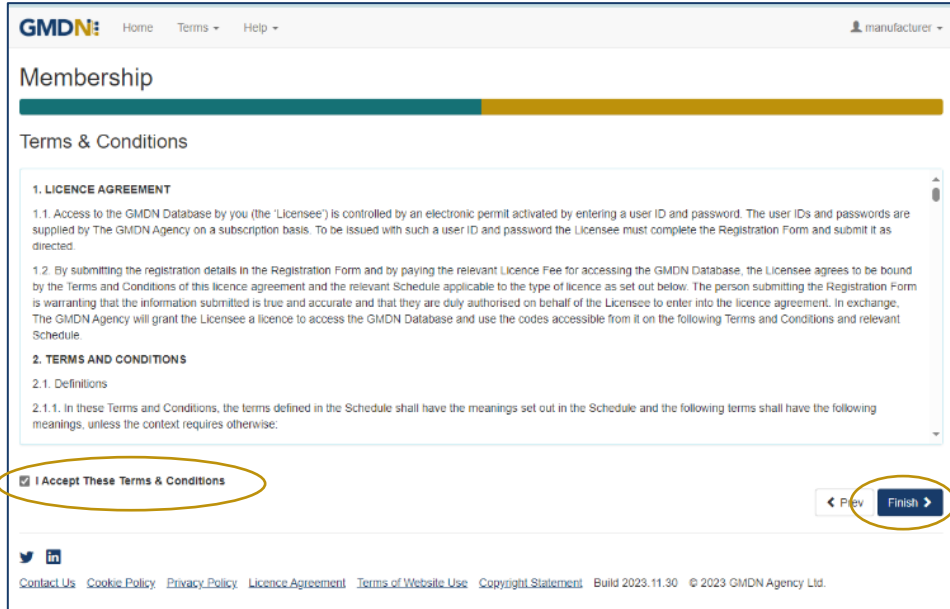


6. If an *Invoice* or *Quote* was requested it will automatically appear in the user's computer default 'Downloads' folder or you can download directly from the page.
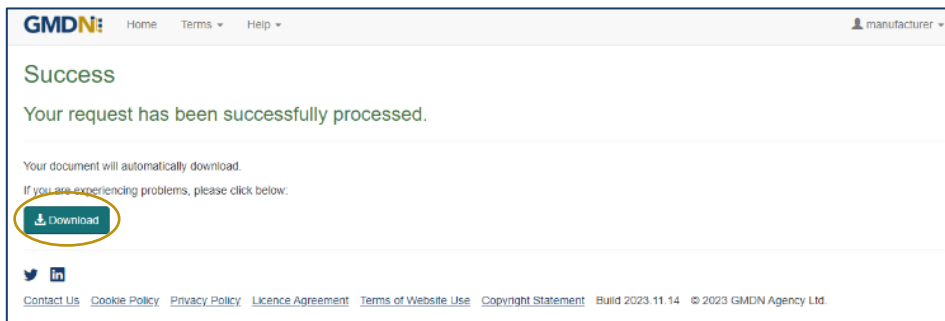


7. For reference the order history on your account renewals can be seen in the *Orders* folder and is found in the Account dropdown menu at the top right of the webapge (with the person icon).
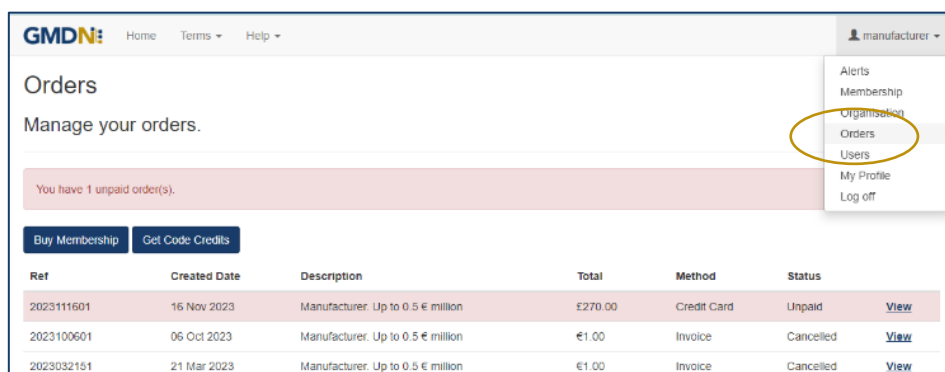
8. If a *Credit Card* payment option was selected the user will be redirected to our secure payment area and *Credit Card* details entered.

*Credit Card* payment options are now MasterCard & Visa for $ (USD), € (EUR) or £ (GBP) currencies and American Express $ (USD) only.
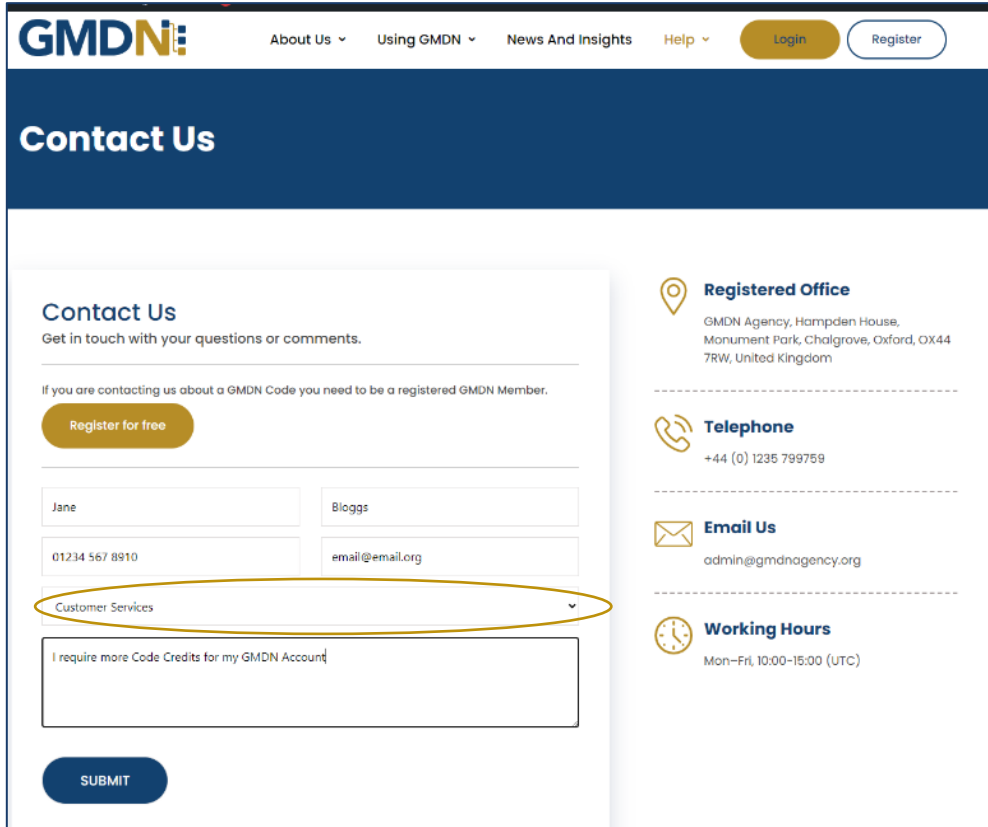


9. The user will be returned to the GMDN Website after the payment has been accepted and will be able to confirm the order has been paid by looking in the *Orders* page.
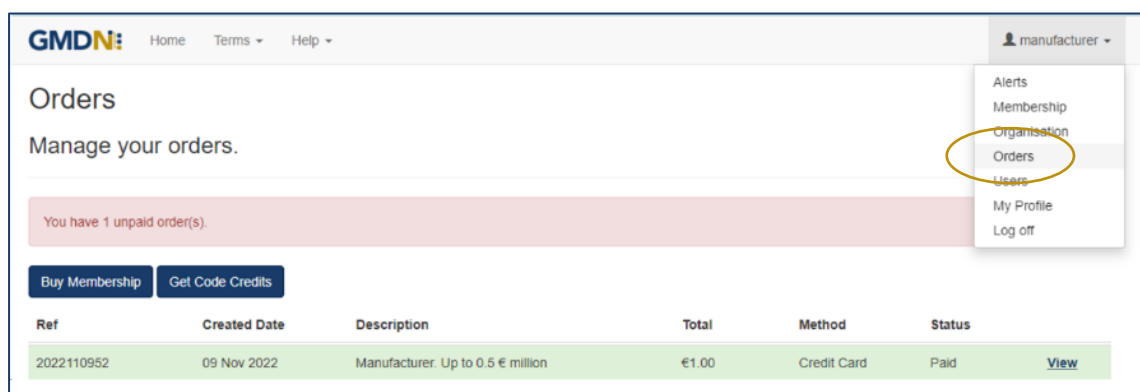


10. The user can obtain a payment receipt using the *View* button and clicking on *Receipt*.

**GMDN**

11. If you run out of Code Credits you can click on *Get Code Credits* at any time from either the *Orders* page or the *Alerts* page or in *My Shortlist* on the *Terms* dropdown menu on the site header.

This will direct you to complete a contact us form. Please select *Customer Services* on the dropdown menu and our Customer Services Team will contact you to discuss options.

# GMDN

## 8. GMDN Website – Manufacturers Code of Good Practice

The GMDN Agency has created this Code of Good Practice for Manufacturers that use the GMDN. We believe that Manufacturers that adopt our Code of Good Practice and embed it within their organisation will see improvements in their experience and use of the GMDN.

The Code of Good Practice is designed to help Manufacturers correctly assign Terms so that their products are included on procurement lists where considerations are made based on the GMDN.

```
                                                    ┌──────────────┐
                                                    │  New Device  │
                                                    └──────┬───────┘
                                                           │
  ┌──────────────┐      ╱Is the╲          No    ┌──────────▼────────┐      ┌──────────────┐
  │ GMDN Agency  │─────▶ GMDN   ╲─────────────▶ │ Start GMDN        │◀─────│ GMDN Agency  │
  │ Notifies of  │     ╱ Term    ╲               │ Assignment/       │      │ Notifies of  │
  │ Term edit    │     ╲ assignment╱             │ Reassignment      │      │ Term         │
  └──────────────┘     ╲ correct  ╱              └──────────┬────────┘      │ Obsoletion   │
                        ╲────────╱                          │               └──────────────┘
  ┌──────────────┐          │                               │
  │ GMDN Term    │          │                    ┌──────────▼────────┐
  │ assignment   │          │                    │ Search GMDN       │
  │ queried by   │          │                    │ Database          │
  │ stakeholder  │          │                    │ www.gmdnagency.org│
  │ (Regulator,  │          │                    └──────────┬────────┘
  │ group        │          │                               │
  │ purchasing   │      Yes │                    ╱Have you ╲  No   ┌──────────────┐
  │ org, GMDN    │          │                   ╱ found a  ╲─────▶ │ Submit online│
  │ Agency       │          │                   ╲ suitable ╱       │ Enquiry to   │
  └──────────────┘          │                   ╲ GMDN Term╱       │ GMDN Agency  │
  ┌──────────────┐          │                    ╲────────╱        └──────┬───────┘
  │ Internal     │          │                        │ Yes                │
  │ review of    │          │                        │                    │
  │ GMDN         │          │     ┌──────────────┐    │          ┌─────────▼──────┐
  │ Assignment   │          │     │ No immediate │    │          │ Communicate    │
  │ due          │          └────▶│ actions. Set │    │          │ with GMDN      │
  └──────────────┘                │ date for     │◀───┤◀─────────│ Agency until   │
                                  │ follow-up    │    │          │ Term agreed    │
                                  │ review of    │ ┌──▼───────────────┐ └──────────┘
                                  │ GMDN         │ │ Assign GMDN Term │
                                  │ assignment   │ │ to Device Master │
                                  └──────────────┘ │ Data record      │
                                                   └────────┬─────────┘
                                                            │
                                                   ┌────────▼─────────┐
                                                   │ Submit Device    │
                                                   │ Master Data to   │
                                                   │ UDI Database     │
                                                   └────────┬─────────┘
                                                            │
                                                   ┌────────▼─────────┐
                                                   │ Public access to │
                                                   │ Device Master    │
                                                   │ Data             │
                                                   └──────────────────┘
```

**GMDN**

## Manufacturers Code of Good Practice Guidance

- **Have a global approach to nomenclature in your organisation**

We encourage manufacturers to promote the best practice proposed in this guidance within their organisation and ensure proper management of their GMDN data with a documented quality management process. We have provided a 'model' GMDN Standard Operating Procedure (SOP) which you can adapt to meet your specific needs.

- **Have only one GMDN account for your organisation**

A single GMDN account will help the organisation to manage the Terms to which they assign to their devices. This includes having a central account for updates on Term changes (For example, new, amended, and obsoleted Terms).
Within each account, the organisation can have different individual users and allocate each user the permissions relevant to their responsibility.

- **Identify who has overall responsibility for GMDN in your organisation**

The GMDN promotes the idea of setting account permissions relevant to individual users needs and responsibilities, users with the 'User' permission have responsibility for setting permissions for other users in their organisation and therefore should have the knowledge about the different permissions available. Further guidance on setting user permission is available in our User Guides.

- **Set user permissions and notification actions**

The first registered user will, by default, have all the permissions available to them when their account is setup. They will also be able to set up additional users for individuals within their organisation and assign permissions to them. Each user can also set their own notifications preferences, which provide a channel of communication about Term changes and news from the GMDN Agency.

- **Send us Enquiries in good time**

Our enquiry process is based on priority, with those from paid memberships always having top priority than those submitted from basic membership accounts. We always encourage all manufacturers to submit their enquiries in plenty of time. The GMDN is a dynamic database and at times, a new Term will affect other existing Terms, which may have to be reviewed alongside the development of the new Term. This can make the process lengthier than expected. That is why we suggest you submit your enquiries at the earliest possible opportunity.

- **Encourage staff to do training on GMDN and promote good practice**

We have training materials our website which we encourage our members to explore, to ensure you have a good understanding of the GMDN and get the most out of the data. The first registered user should complete the GMDN training and encourage others within their organisation who will be using the website to do the same. In addition to the on-line resources, we also offer bespoke training remotely (via Teams, Zoom) or in-person, to teams within organisations, trade associations and regulators. Please contact us for more information.

![GMDN logo]

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

Manufacturers and their input form the backbone of our database and it is paramount that we maintain good communication channels. Whenever there are changes to Terms you may be subscribed to, a 'notification' that is sent out via e-mail to alert you. We encourage that you 'opt-in' to these notifications and check they don't end up in your 'spam' or 'junk' folder.

We also 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.