# Contents – Device Registration Reference Guide

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Logging in

Access MHRA Agency Services.

Read and Agree to Cookie Policy

Before accessing MHRA Agency Services, you will need to agree to our Cookie Policy. Please read the Cookie Policy and only use MHRA Agency services if you agree.

1. When you have read the Cookie Policy click the 'I Agree' button.
Username and Password

Once your Account request has been accepted by MHRA, you will be sent a username (usually firstname.lastname), a temporary password and a link to the system. Please log in for the first time on a Laptop or PC not a mobile or tablet. If you have not received the email, please check your Junk/Spam folder. You will be asked to change the password to one of your choosing.

1. On the log in page, enter the details sent to you by email (it is preferable for you to copy and paste your details into the boxes provided).

2. Click the Log in button.

New Users > Change temporary password

1. Copy and paste the temporary password (long password with multiple characters) sent to you via email into the old password box.

2. Enter a password of your choice into the new password and confirmation boxes.

3. Click on Submit. You will be able to use the password you entered from now on.
Forgot password > resets

1. On the log in page, click the Forgotten your password link.
2. Enter your username (usually firstname.lastname – not your email address).
3. Click the Send email button. Please ensure your email address is always kept up to date on the Contacts Tab, see Editing Contacts in the Account Management Reference Guide.

You will be sent an email containing a link. Please check your Junk/Spam folder. Click on the link and follow the instructions to change your password. Please do this on a Laptop/PC not a mobile/tablet.
MHRA Agency Services

Enter Service

This service allows you to submit registrations for devices (GMDN Code or Term) and products (model or version detail). You can also update your registrations, add importers, link them to registered manufacturers and order Certificates of Free sale, if required. If you are a UK Responsible Person (UKRP) or an Authorised Representative (in Northern Ireland only) you can add represented manufacturers and devices, update their details and manage device registrations on behalf of your represented manufacturers.

1. On the Landing (home) page click the Enter button under Device Registrations and Certificates of Free Sale for medical devices.
Organisations

1. This organisation is the one that the account was setup for. Click on the manufacturer name to register or manage devices that you manufacture.

2. Note that the organisation in this example is ‘Not registered’. If the status is ‘Not Registered’ this will remain the case if this organisation is acting purely as a UK Responsible Person (UKRP) in the UK or an Authorised Representative (in Northern Ireland) and has not registered devices of their own.

3. The UK Responsible Person (UKRP) of a non UK manufacturer or an Authorised Representative (in Northern Ireland) of a manufacturer based outside the UK or EU may click this button to ‘Add New Manufacturers’. This button is to be used when you are ready to make device registrations on behalf of another organisation.

4. If either your organisation or an organisation that you represent as a UK Responsible Person (UKRP) or Authorised Representative (in Northern Ireland) imports medical devices into the UK, you must use this link to Add New Importer details.

5. UK Responsible Persons (UKRP) in the UK or Authorised Representatives (in Northern Ireland) who have added represented organisations will see them in the Manufacturers you represent table.

6. UK Responsible Persons (UKRP) in the UK or Authorised Representatives (in Northern Ireland) who have added Importers will see them in the List of Importers table.
Determine if your account is migrated or re-registered

Some accounts have been migrated from our old system and some organisations who held account/s on our old system/s have been asked to re-register.

You need to determine if your account was migrated or re-registered as the information that you see in your account may differ.

To determine the migration/re-registration status of your account please:

7. Review the summary page after clicking on the manufacturer name.

8. If the Created Date is before 01 July 2018, your account has been migrated.

If the Created Date is between 01 July 2018 and 23 July 2019 your account is either a new account for an organisation not previously registered with MHRA or a previously registered account where the organisation name and/or address was different to your original MHRA registration in our old system.

If the Created Date is on or after 29 July 2019 your account has been re-registered or is a new account for an organisation not previously registered with MHRA.
Registering new devices

1. **Click** on the name of the *manufacturer* of the device as appropriate, this may be your organisation or your represented organisation.

**Please note:**
- Devices must always be added to the organisation who is the **legal manufacturer** of the device.
- Check that the manufacturer information is correct (see [Updating Registrations](#)).
2. **Click** the **Devices** tab to **review** devices and status.

**Please note** that GMDN Codes will only be displayed if you entered the GMDN Code when adding your device, otherwise only the GMDN Term will be displayed.

3. **Click** the **Show Filters** link to search for specific devices.

4. **Click** the **Add Devices** link to add new devices.

**Please note** that if you need to manage devices e.g. add new product to an existing device or link a new Conformity Assessment Certificate/Self-certification conformity declaration, please refer to the **Manage registered devices** section.

If you need to update devices or products for example add data to fields you did not complete at time of registration, or update obsolete GMDN Code or Term, please refer to the **Update registered devices and products** section.
Add devices using GMDN

1. **Select** the appropriate **device type** for the medical device to be registered.

2. Entering an appropriate word(s) into the ‘GMDN Code/Term’ text box will give you a shortlist of GMDN Terms to choose from. Entering more words into the box will reduce the shortlist.

   GMDN Members may **enter** a GMDN Code into this box. Please note The GMDN Agency provides a free enquiry service if you are in doubt about the correct GMDN Term to select for your device.

3. **Click** on a **Term name** to make your selection. You must pick a GMDN Term from the list.

4. If you are unsure of a term’s definition you can select the View all GMDN Terms and definitions. You will be presented with a list of terms which you are able to refine by typing keywords into the text box.

5. Once you have found the appropriate term, you can **Hide GMDN Terms and definitions** to allow you to continue completing the page.
6. Answer all the **mandatory questions** that appear after you have selected the appropriate GMDN Code or Term. These will differ depending on the **device type** you have selected.

**Please note** Failure to declare compliance the correct directive or regulations that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

<table>
<thead>
<tr>
<th>Declare devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What type of device is it?</strong></td>
</tr>
<tr>
<td>- General Medical Device</td>
</tr>
<tr>
<td>- In Vitro Diagnostic Device</td>
</tr>
<tr>
<td>- Active Implantable Device (Directive 90/385/EEC only)</td>
</tr>
<tr>
<td>- System or Procedure Pack</td>
</tr>
<tr>
<td><strong>GMDN Code/Term</strong></td>
</tr>
<tr>
<td>Cartoon knife</td>
</tr>
</tbody>
</table>

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7. **Click** either the Continue button to proceed to the next page or the Save & Exit button to save and exit and resume application at any stage before submitting to MHRA.

8. You can **Delete Application** at any stage before submitting to MHRA.
Upload Self-certification conformity declarations

1. If your device does not require a Conformity Assessment certificate issued by a UK Approved Body or EU Notified Body, you must upload a Self-certification conformity declaration. The document required will depend on the device type and Directive/Regulation your device complies with as follows:

- **Declaration of Conformity** – Class I medical devices and General IVDs that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed, not a re-usable surgical instrument. Find out more about [Declaration of Conformity / EU regulations](#).

- **Custom-Made Statement** – All custom-made devices. Find out more about [Custom made statement](#).

- **Declaration for all system or procedure packs and assemblers** – to UK MDR 2002 Regulation 14 (Article 12 of Directive 93/42/EEC) or Article 22 of EU Regulation 2017/745. Find out more about [UK MDR 2002 Regulation 14 / EU regulations](#).


**Please note** for each custom-made device (GMDN Code or Term), that does not require a Conformity Assessment certificate, you need to upload a Custom-made Statement.

Details of the content of this statement can be found in the relevant directive/regulation that applies to your device:

- UK Medical Devices Regulations 2002 S.I. No. 618, as amended
- Annex VIII of Medical Devices Directive 93/42/EEC
- Annex 6 of Active Implantable Medical Devices Directive 90/385/EEC
- Annex XIII of Medical Devices Regulation (EU) 2017/745

**Please note** that the statement that you upload to our system must not contain any patient identifiers e.g. patient name, NHS or hospital number etc. as this would contravene the General Data Protection Regulation (GDPR).

However, the statement you provide to the patient/clinician with the device, does need to include the patient name. Please refer to our online guidance on statements at [https://www.gov.uk/government/publications/custom-made-medical-devices](https://www.gov.uk/government/publications/custom-made-medical-devices).
2. **Click** the *Upload* button and select the relevant *Self-certification conformity declaration* file stored on your system.

3. **Select** the *Conformity assessment* that your device complies with from the dropdown.

4. **Add** a *Document Reference* of your choice. This must not contain any special characters other than hyphen (-) or underscore (_). Otherwise, the document will not upload. You will be able to search devices by reference when managing your devices.

5. **Click** the *Upload Document* button to confirm details. Repeat the process to add more documents. You can select from these as you add more devices (GMDN).

6. **Click** the *Continue* button to proceed to the next page or the *Save & Exit* button to save and exit and resume application.
Select from existing Self-certification conformity declarations

1. If you have already uploaded documents previously, from the Select from existing Self-certification conformity declaration area ensure that the correct document is selected. Tick the check box to the left of the filename to select the document.

   Please note if you have just uploaded a Self-certification conformity declaration it will automatically be selected.

2. Click the ‘Continue’ button.
Upload Conformity Assessment Certificates (if applicable)

1. **Click** the Upload button and select the Certificate issued by a UK Approved Body or EU Notified Body, stored on your system.

2. **Select** the correct Certificate Type from the dropdown menu.
   - **Enter** the correct Certificate Expiry date.
   - **Add** the Certificate reference. This must not contain any special characters other than hyphen (-) or underscore (_) otherwise the document will not upload. You will be able to search devices by reference when managing your devices.
   - **Select** the correct UK Approved Body/EU Notified Body designation type

3. **Select** the correct UK Approved or EU Notified Body from the list. If it does not appear on the list, click Other and **Search** using key words to find the correct one.

4. **Click** the Upload Certificate button to confirm details.

5. A table will appear on the page showing the uploaded Certificate, this will be pre-selected. Repeat the process to upload more Certificates as necessary for the device. As you upload more certificates, they will appear in the table for you to select from when you next add devices

6. You can **filter** by Certificate Status of All, Active and Expired.
7. **Click** the **Continue** button to proceed to next page or the **Save & Exit** button to save and exit and resume application.

**Please note** if you have selected an expired certificate or if any expired certificates are still linked to a device the **Continue** button will not be enabled. Unlink expired Certificates and upload new ones or link device to an active certificate.

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**Select from existing Conformity Assessment Certificates**

1. From the **Select from existing certificates** area ensure that the correct **Certificate** is selected. Select the **Certificate** by **ticking** the check box to the left of the certificate filename.

2. You can **filter** by **Certificate Status** of All, Active and Expired.

3. **Click** the ‘**Continue**’ button or follow the **Upload Conformity Assessment Certificate** instructions to add another certificate.

**Please note** if you have selected an expired certificate or if any expired certificates are still linked to a device the **Continue** button will not be enabled. Unlink expired Certificates and upload new ones or link device to an active certificate.
Adding products individually

1. **Enter** the product details – this is the version or model detail. Answer all the mandatory questions that appear. These will differ depending on the device type you have selected. At least one product must be added per device group (GMDN Term).

   **Please note** The GMDN Term is the device group, not the product.

   Product information follows guidelines set by the [International Medical Device Regulators Forum](https://www.imdrg.org) in their document [Common Data Elements for Medical Device Identification](https://www.imdrg.org/documentation/)

2. **Certificates of Free Sale (CFS) customers, please note:**
   - **only** the product information you enter in the Medical Device Name, Model/Version and Catalogue/Reference fields will appear on the CFS certificate or schedule.
3. Once you have answered all the mandatory questions click on the Add Product button – if you don’t your data won’t be saved. We recommend that you also populate all optional fields where possible.

4. The Product preview table will appear with limited details. To add more products individually go to the top of the page and repeat the process.

5. Once you have added all your products, click the continue button to proceed.

Removing products individually

1. If you wish to remove a product you have just added, Click on the red X next to the Product Status in the Product Preview table at the bottom of the screen.

Please note you must add at least one product to enable the Continue button
Add products in bulk – product template

You can add multiple products (model or version detail) for a device using the product template.

1. **Read** the instructions and **click** the link to Download our product template. The template contains macros.

   - Download the product template always download a new template to ensure you have the latest version.
   - Enable editing and/or content on the template.
   - Populate the template with your product information.
   - Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
   - Ensure ‘ready to validate’ message appears on the template.
   - Click to validate.
   - Ensure all fields are correct in the template.

2. The Excel sheet contains macros, so you need to **Enable Editing** on the Excel sheet.
3. **Enable Content** before you can complete and save the template on your system.

4. **Key points to note when completing template:**
   - You need to use a separate template for each device (GMDN Code or Term).
   - The templates are different and depend on the device type. Only use the correct template for the device type.
   - One row per product when completing product template.
   - Note the maximum characters for each field.
   - Where dropdown options exist, select from the dropdown – do not paste data into these fields.
   - Do not make any changes to the layout of the template otherwise it won’t upload.
   - A maximum of 1000 products can be added to the template. If you have more than 1000 products for a single GMDN, upload 1000, create separate templates for the remainder and upload in separate applications. There is currently no fee to add products.
   - Use the “Paste Values” option in Excel if you need to copy product information from another spreadsheet into the bulk upload template. If you don’t, the template may not upload to the system.
   - **We can only accept information about your products if they are entered one by one in the system or by using the bulk upload template.**
   - You must complete all the mandatory fields until the red box at the top of the template turns orange and states **'Ready to Validate'.** We recommend that you also populate all optional fields where possible.
   - **Certificates of Free Sale (CFS) customers, please note:**
     - only the product information you enter in the first three columns of the template (Medical Device Name, Model/Version and Catalogue/Reference) will appear on the CFS certificate or schedule.
Please note that uploading a template will clear all products previously added in this application. You can however add products one by one to the list of products uploaded by template in this application. Products uploaded in bulk will append to products previously accepted by MHRA.

5. Ensure that the red warning red box at the top of the template has turned orange and states ‘Ready to Validate.’

6. **Click to Validate**

   **General Medical Device Product Details**

   ![Image of Ready to Validate]

   5. Ready to validate

   6. Click to validate

7. If validation fails a warning message will appear and the cells with excess characters will be highlighted in blue.

   **General Medical Device Product Details**

   ![Image of Warning]

   7. Warning

   Text in cells highlighted in blue exceeds maximum character length. Refer to maximum length in column headers.
8. **Locate** the cells highlighted in blue on the template and amend the text.

![Cell Highlighted](image)

9. **Click to Validate** again.

   ![Click to Validate](image)

10. If the validation passes the ‘**Ready for uploading to MHRA**’ message appears – **click OK**

    ![Ready for Upload](image)

11. The ‘**Ready for Upload**’ message appears in the green box. **Save** the document.

    ![Ready for Upload](image)
12. **Upload** the completed template on the Product screen. **Click** the Upload button and select the completed template from your system.

13. **Click** the Confirm bulk upload and preview products button.
14. The products will be visible in the Preview table.

15. If you wish to remove any of the bulk uploaded products individually, click on the red X to remove.

Please note you can add additional Products individually after using the bulk upload, but not before as the bulk upload will overwrite any previously entered devices in this application. See Adding products individually.

16. If the products do not preview correctly, (you can only see limited fields here), or if you have uploaded the wrong document or you see an error message indicating you have uploaded an incorrect or invalid template:

   a) Hover over the document reference until the X appears and click the X to remove the products you have just uploaded.

   b) Make any changes required in the bulk upload template and upload it again.

17. Once you have successfully uploaded and previewed the product information click the Continue button to move to the next page, or BACK to the conformity document screen.
Adding System or Procedure Packs (SPP)

1. Enter the GMDN Code if you know it or search using multiple words. Most System or Procedure Packs (SPP) can often be found by searching GMDN Code/Term box with the word 'Kit'.

2. Answer the mandatory questions on the page.

3. Click the Continue button, this will not be enabled until you have answered all mandatory questions.
You will be taken to either the Upload Conformity Assessment Certificate page or the Self-certification conformity declaration page depending on the details you have added at Declare Devices stage (GMDN Code or Term level).

4. Once you have uploaded or linked to an existing document Enter the product details, this is the version or model detail. See Adding products individually.

- You need to add a minimum of one product (model or version) per SPP (GMDN Term).
- There is no bulk product upload function for SPPs.

5. Click the link to Download our content list template, complete and save the template on your system.

- One row per product.
- At least 2 products (contents) must be entered otherwise the template will not upload.
- We do not need the GMDN Code or Term for each of the listed contents.
- You do not need to register the contents by individual GMDN Term unless you actually manufacture these devices.
- You need to use a separate contents list template for each product (Medical Device name and Model etc).

Please note if you have multiple products covered by a single GMDN and these include a combination of similar products please upload one SPP content list for that product that covers all possible contents of the individual trays (products) under the GMDN plus the wording 'Contents may vary but are available on request' on the last line of the contents template. See example below.
6. **Upload** the completed template. **Click** the **Upload** button and select the saved template from your system.

![Upload Button]

7. **Click** the **Add Product** button – if you don’t your product won’t be saved.

8. **Preview** the product/s you have added in the **Preview table**.

![Preview Table]

9. If you wish to remove the products **click** the **Back** button and then the **Continue** button on the **Conformity Assessment Certificate or Declaration of Conformity** page and **add** the products again.

10. **Click** the **continue** button to proceed to the final **Review page**.
Review information prior to making payment

Please review all information prior to making payment. Once payment has been made applications are non-refundable. See our Terms and Conditions.

1. **Click** the chevrons to view and check that the information is correct. The Review page has separate links to view:

2. **Device Details**
   Only the fields you have populated will appear on the review screen e.g. if you have not entered Basic UDI DI or Clinical Investigation details there will be no information here. **Please note** Making any changes at GMDN Term or Code level in an application will result in the product information being removed and you will need to add product again, either individually or in bulk.

3. **Conformity Assessment Certificates/Self-certification Conformity Declarations**
   These can be changed before submitting application.

4. **Products**
   Products can be added or removed before submitting application. Follow the Adding products individually, Adding products in bulk and Removing products individually instructions.
5. Click the Add Another Device button if required. You can add up to 100 devices (GMDN Term) in a single application with a cumulative maximum of 20,000 products (version or model).

Please note if you have more than 1000 products for a single GMDN Term, upload 1000 then create separate templates for the remainder and upload in separate applications after the original application has been completed by MHRA. There is currently no fee to add additional products to a registered device. Please follow the Manage Registered Devices instructions to do this once your application to register the device (GMDN) has been completed and the device is registered.

<table>
<thead>
<tr>
<th>Add New Devices - TEMP20210716103807</th>
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<tbody>
<tr>
<td><strong>Review</strong></td>
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<tr>
<td><strong>Devices</strong></td>
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<tr>
<td><strong>Lens nuclear manipulator</strong></td>
</tr>
<tr>
<td><strong>Device Details</strong></td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
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<tr>
<td><strong>Device</strong></td>
</tr>
<tr>
<td><strong>Manufacturer registration number</strong></td>
</tr>
<tr>
<td><strong>Custom made?</strong></td>
</tr>
<tr>
<td><strong>No</strong></td>
</tr>
<tr>
<td><strong>Method of Sterilisation</strong></td>
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<tr>
<td><strong>Radiation, Gamma or Electron Beam</strong></td>
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<tr>
<td><strong>Risk classification</strong></td>
</tr>
<tr>
<td><strong>Class II</strong></td>
</tr>
<tr>
<td><strong>Resealable surgical instruments?</strong></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>Regenerated single-use device?</strong></td>
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<tr>
<td><strong>No</strong></td>
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<tr>
<td><strong>Applies to?</strong></td>
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<tr>
<td><strong>No</strong></td>
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<tr>
<td><strong>Implementer/Producer</strong></td>
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<tr>
<td><strong>No</strong></td>
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<tr>
<td><strong>Applies to?</strong></td>
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<tr>
<td><strong>No</strong></td>
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<tr>
<td><strong>Add another device</strong></td>
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<tr>
<td><strong>Yes</strong></td>
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<tr>
<td><strong>Create separate templates</strong></td>
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<tr>
<td><strong>Yes</strong></td>
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<tr>
<td><strong>Add to original application</strong></td>
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<tr>
<td><strong>Yes</strong></td>
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5. You are about to register a new device on behalf of a manufacturer or an assembler of systems and/or procedure packs. Before applying, you agree to the requirements set out in the UK Medical Devices Regulation, which states that such individual devices must be made from the appropriate essential material in conformity with the essential safety and performance requirements, as applicable, of the relevant medical devices legislation, including the availability of technical and clinical data for such devices. Devices requiring conformity assessments to be carried out by a CE-approved body must also provide a valid CE mark certificate. There are also additional legal requirements which must be met, including those which cover aspects of systems and procedure packs specifically should ensure they meet before marketing such products.

6. Please read and understand the requirements and terms and conditions. Once you have done so, tick the ‘I have read and agree to the terms and conditions’ check box.

7. Click the ‘Continue’ button to proceed to payment.
Making Payments

1. Choose billing address.

   **Please Note** see Managing Shipping, Billing, Manufacturing Site addresses in the MHRA Account Management Reference Guide.

2. Choose payment method by clicking on either worldpay or the BACS/CHAPS button.
Paying with worldpay

1. Click on the Pay with worldpay button.

2. A confirmation message will appear. Select the Yes button if you wish to proceed.

3. Click the link to be directed to the worldpay site.

Please proceed to pay with worldpay (opens in new window). Come back to ‘Complete application’ once payment is processed.

Please click here to be directed to the Workpay site.

After clicking the link and paying through Workpay, please close this window.
4. **Select** the payment method.

5. Enter payment details and **click** the **Make payment** button.
6. **Click** the **Submit Application** button. If you do not click this button (and your payment was successful) the TEMP application will remain in the **Applications Tab** and you will need to wait at least **24 hours** for the application to be auto-submitted to MHRA. Please ensure that you click **Submit Application** to avoid unnecessary issues and delays.

7. A **confirmation** screen will appear. **Click** the **Close** button.

8. **Please note** if you do not click the **Close** button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been auto-submitted. **Click** on the **OK** button.

9. **Click** on the **Applications Tab** to see your submitted application.
10. You will receive a confirmation email from Worldpay.

**Please note** MHRA does not issue tax receipts. The worldpay transaction email and the confirmation of registration email are the only documents you will receive in relation to payment for your registration.

![Transaction Confirmation]

11. You will also receive a confirmation email from MHRA.

12. **Close** the separate window that was opened when you were directed to the Worldpay site.

![Complete payment for TEMP20190510151123]

*Please click here to be directed to the Worldpay site.*

After clicking the link and paying through Worldpay, please close this window.
Pay by BACS/CHAPS

1. **Click** on the **click here** link to download a **proforma** invoice if you need an invoice to enable your accounting department to process payment of our device registration statutory fee.

2. **Click** the **BACS/CHAPS** button and make your **BACS/CHAPS** payment using the MHRA account details.

   **Please note** you must quote the ‘Reference number’

   You are able to **Save and Exit** your application and resume completion at a later time (See **Save and Exit: Resume Applications**).

3. Once payment is made **upload** your **proof of payment**.

4. **Submit** application.

![Pay by BACS/CHAPS steps](image-url)
Complete Application

5. Note the Application reference number.

![Application complete page](image)

6. Select the Close button.

7. Please note if you do not click the Close button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been auto-submitted. Click on the OK button.

![Application complete page with error](image)

8. Click on the Applications tab to see the progress of your application.
Application received email

You will receive a confirmation email informing you that your application has been submitted.

We’ve received your New device application on 01 January 2021.

Application reference number: 2021012701184461

Manufacturer name(s)
MHRA Test Sole Manufacturer

We will check the information you’ve given us and will send you an email within the next 5 days to let you know if your request has been accepted or rejected. If you haven’t received a reply from us within 5 days please check your junk mail folder.

Access your [MHRA account](#).

Remember: do not share your account details and keep them safe. MHRA won’t accept responsibility for any unauthorised access to your account.

Yours sincerely,

Device registrations service

Within 6 working days from submission you should receive an email confirming the outcome of the application. Some devices may be registered, some may be rejected.

In the meantime, you can check the status of your application in the Applications Tab.
Registration Complete

1. You will receive a confirmation email confirming the outcome of your application.

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 01 January 2021, has been reviewed:

Application reference: 2021012701184461

Manufacturer organisation: MHRA Test Sale Manufacturer
Address: 10 South Colonnade
10th Floor Area 57
Canary Wharf
London E14 4PU
United Kingdom

Manufacturer registration status: Registered

Device(s):

<table>
<thead>
<tr>
<th>GMDCN-term</th>
<th>Status</th>
<th>MHRA-comment</th>
</tr>
</thead>
</table>
| Scavenging anaesthesia face mask | Registered | \n
Please note this email confirmation does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- company/organisation information e.g. name and address
- additional devices (GMDCN-code or term)

2. The manufacturer will now have a Registration Status of Registered.

Device Registration & Certificates of Free Sale

Your Organisation

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Country</th>
<th>Devices (Products)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHRA Test</td>
<td>10 South Colonnade, London, E14 4PU</td>
<td>United Kingdom</td>
<td>20 (11060)</td>
</tr>
</tbody>
</table>

Key
- Registered
- Not Registered
- Unregistered

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the Applications list.
Updating Registrations

Editing organisation details

See the Edit Organisation section in the Account Management Reference Guide for instructions on how to update organisation name/s and/or address/s and upload new Letters of Designation – registration fees will apply.

Adding new devices

See steps for Add device using GMDN.

Export devices data to Excel file

1. Select the organisation (Legal Entity) for the devices/s you want to export to Excel.

2. Click on Export Devices Data to Excel File link.
3. **Click** on Download Data to Excel File link.

4. The Excel dialogue box will open. **Open** or save the file as required.

   **Please note** the maximum number of characters for an organisation name in the file name is 25 therefore you may not see the full name but can also identify the organisation by the account number that is also included in the file name.

5. The Excel dialogue box will open. Open or save the file as required. You will need to **Enable Editing** to save the file.
Using filters to search for devices and products

Filter options are available to enable searches for specific devices and products. These can be found on the Devices screen, Products screen and Manage Devices screen. You can use multiple filters to refine your search.

1. When devices have been deleted, they will no longer appear in the table when you search for specific devices, you must filter for them by using the Device Registration status filter and selecting option No Longer Registered.

2. The Reason for Deletion will be displayed. Devices may have been deleted by MHRA, for example due to non-compliance or incorrect data provided. You will receive email confirmation when MHRA deletes a device from your account including the reason for deletion.

Please note reason for deletion will only appear for devices deleted after 21 August 2021.
3. To view when device was deleted and by whom, **click** on the GMDN Term of the deleted device.

<table>
<thead>
<tr>
<th>Status</th>
<th>GMDN Code</th>
<th>Term Name</th>
<th>Device Type</th>
<th>Reason For Deletion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>41349</td>
<td>Allergen-specific immunoglobulin E (IgE) antibody IVD, control</td>
<td>In Vitro Diagnostic Device - IVD General</td>
<td>Entered in error</td>
</tr>
<tr>
<td></td>
<td>30000196</td>
<td>Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)</td>
<td>In Vitro Diagnostic Device - IVD General</td>
<td></td>
</tr>
</tbody>
</table>

4. The device details will appear and the deletion history will be displayed under **Device History**.

**Please note** Device History will only be populated for devices deleted after 21 August 2021.
Manage registered devices

Please use the Manage Devices function to:
• manage (upload, link and unlink) Conformity Assessment Certificates and Self-certification conformity declarations
• add or remove products (model or version)
• delete devices (GMDN) and all linked products
• there is currently no fee to do this

Please note you cannot update obsolete GMDN or other device details e.g. Substances, Clinical Investigations etc. or products e.g. populate fields you did not complete at registrations stage from this screen – please see Update registered devices and products.

1. Go to Agency services > Enter Device Registrations and Certificates of Free Sale for medical devices.

2. Select the manufacturer (Legal Entity) of the devices/s you want to manage.

Device Registration & Certificates of Free Sale

Your Organisation

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Country</th>
<th>Devices (Products)</th>
<th>Registration Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHRA DEMO</td>
<td>10 South Colonnade, Canary Wharf, London, E14 4FU</td>
<td>England, United Kingdom</td>
<td>4 (9)</td>
<td></td>
</tr>
</tbody>
</table>

Key
Registered  Not Registered  Unregistered  Suspended  Rejected

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the Applications list.

Search by manufacturer name:

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Country</th>
<th>Devices (Products)</th>
<th>Relationship</th>
<th>Registration Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demo represented org Three</td>
<td>147 Bella Vista, East Side Compound, 1000 Medtech Drive, Sea View Industrial Zone, Santa Barbara, CA, 93016</td>
<td>United States</td>
<td>20 (21)</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
<tr>
<td>DEMO Represented Organisation</td>
<td>125 Street, Sea View Industrial Estate, Boston, MA, 12345</td>
<td>United States</td>
<td>3 (10)</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
<tr>
<td>DEMO Represented Organization Two</td>
<td>234 Avenue Estate, Encino, RiverDrive, 43231</td>
<td>Mexico</td>
<td>1 (1)</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
<tr>
<td>DEMO Represented Organization Three</td>
<td>69 Strand Street, Douglas, Isle Of Man, IM1 2EL</td>
<td>Isle of Man</td>
<td>0 (0)</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
</tbody>
</table>

Key
Registered  Not Registered  Unregistered  Suspended  Rejected
3. **Click** on the Manage Devices link.

4. If you have many devices, use the available filters to search for a specific device. See Using Filters to search for devices and products.
5. **Click** on the GMDN Term of the device to manage.

6. The details of the GMDN Term you have selected will open to enable you to view device details. If you want to delete the device click the Back to Manage Devices button and see the Delete Devices instructions.

---

### Manage Devices & Products for MHRA Demo

**Manage device: “Abdominal aorta endovascular stent-graft”**

- **Device type**: General Medical Device
- **Owner**: Yes
- **Regulatory Action**: Yes
- **Single use device**: Yes
- **Reprocessed single-use device**: No
- **Implantable Products?**: Yes
- **Active Products?**: No
- **Administrator/Remove medicinal Product?**: No

### Conformity Assessment Certificates

One or more certificates have already expired or will expire soon:

<table>
<thead>
<tr>
<th>Certificate</th>
<th>Reference</th>
<th>Expiry date</th>
<th>Certificate type</th>
<th>UK Approved Body/DN Notified Body</th>
<th>Conformity Assessment Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE Certificate 1</td>
<td>UKCA</td>
<td>31/01/2023</td>
<td>Full Quality Assurance (Refer to Evaluating Section 6)</td>
<td>ENI</td>
<td>UKCA - MEDICAL/GE/143/31</td>
</tr>
</tbody>
</table>

### Products (6)

<table>
<thead>
<tr>
<th>Medical Device Name [Brand/Trade/Proprietary or Common Name]</th>
<th>Model/Version</th>
<th>Catalogue/Reference (REF)</th>
<th>UDI leading Entry</th>
<th>UDI Device Identifier (UDI-ID)</th>
<th>Product Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premium-Seed A</td>
<td>&quot;A&quot;</td>
<td>5817078</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
<tr>
<td>Premium-Seed B</td>
<td>&quot;A&quot;</td>
<td>5815551</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
<tr>
<td>Premium-Seed B</td>
<td>&quot;A&quot;</td>
<td>5816667</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
<tr>
<td>Premium-Seed B</td>
<td>&quot;A&quot;</td>
<td>5816667</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
<tr>
<td>Premium-Seed B</td>
<td>&quot;A&quot;</td>
<td>5815551</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
<tr>
<td>Premium-Seed B</td>
<td>&quot;A&quot;</td>
<td>5815551</td>
<td>G01 A/SL</td>
<td>0425012748025216</td>
<td>On the GB &amp; M-market</td>
</tr>
</tbody>
</table>
Manage Conformity documents

Please note if your conformity assessment document expires this will be published on the Public access database for medical device registration (PARD). The GMDN term for your registered devices will be appended with the wording 'Conformity Assessment Certificate Expired' until the certificate has been updated. This message can remain for up to a week after you have uploaded a new certificate as PARD is usually updated on Monday.

You will receive reminder emails at 3 months, 2 months and 1 month before expiry of conformity assessment certificates. Please ensure that you act on these to avoid unnecessary status changes to your devices on the Public Access Registration Database.

You will also be unable to order Certificates of Free Sale until valid conformity assessment certificates have been uploaded and linked to all relevant devices.

7. To Add new Conformity Assessment Certificates/Self-certification conformity declarations and unlink expired ones, click the Edit Conformity Assessment Certificates or Edit Self-certification Conformity Documents button and unlink the old certificate or document.

Follow the upload Conformity Assessment Certificates and upload Self-certification conformity declarations instructions or the select from upload Conformity Assessment Certificates and select from Self-certification conformity declarations instructions.

Please note you cannot delete Conformity Assessment Certificates/Self-certification conformity declarations from the system so ensure you unlink devices from any documents that have expired or are no longer appropriate.

Once all actions are complete Click on the Apply Changes button at the bottom of the screen.
Add/remove products

8. To **Add** or **remove** products (model or version) **click** the Add/Remove product button.

<table>
<thead>
<tr>
<th>Products (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Device Name</strong></td>
</tr>
<tr>
<td>(Brand/Trade/Proprietary or Common name)</td>
</tr>
<tr>
<td>Premium Steril A</td>
</tr>
<tr>
<td>Premium Steril B</td>
</tr>
<tr>
<td>Premium Steril A</td>
</tr>
<tr>
<td>Premium Steril B</td>
</tr>
<tr>
<td>Premium Steril A</td>
</tr>
<tr>
<td>Premium Steril A</td>
</tr>
</tbody>
</table>

9. To **add** more products follow the instructions for **Adding products individually** or **Adding products in bulk**.

10. **Please note** if a product is no longer placed on the market, do not use the red X function to remove the product. Please **update** the product status to one of the ‘No longer placed on the market’ options and add the end of the distribution date – see **Update registered devices and products**.

11. To **remove** products, **click** the red X next to the product status in the Product preview table. You must always have at least one product linked to a device so if you remove the last product the Apply changes button will not be enabled and you must at least one product. If you only have one product the red X will not be present.

12. **Click** the Apply Changes button to confirm removal of the product/s. **Please note** once changes applied and application submitted you can’t reinstate the product/s. If you delete a product in error, you will need to **add** it again.
Delete device/s

13. To delete device/s, you must be on the Manage Devices and products screen. If you have opened the device details to review, click the Back to Manage Devices button to display the Manage Devices and products screen.

14. Tick the box next to Status column of the device/s you wish to delete.

Please note if you select multiple devices for deletion, they must all have the same reason for deletion. If they have different reasons you must delete the devices individually.

Please note if GMDN is obsolete you can update the GMDN to a valid Code/Term, you do not have to delete the device. See Update Registered devices and products.

15. Click the Delete Selected Devices button to remove the device/s and all underlying products of the device.

Please note You cannot manage and delete the same device in the same application. If you manage device and/or products the Delete Selected Devices button will be disabled.
16. **Select a Reason for deletion.** If device is no longer placed on the market, provide **End of Distribution date**.

**Please note** if you select multiple devices for deletion, they must all have the same reason for deletion. If they have different reasons you must delete the devices individually.

17. **Click** the **Remove Device(s)** button.

18. **A warning message** will appear, **click YES** to proceed or **NO** to cancel deletion. **Please note** once deleted you cannot reinstate the device. You will need to **add** it again and pay the fees.
19. You can **manage** multiple devices in a single application. Each time you click **Apply Changes** the device it will appear in a table at the top of the screen indicating what action has been taken. Click the red **X** in this table if you want to abandon all changes to the specific device.

20. When you are ready to submit the application, **Read** the on-screen information and terms and conditions, **click** the 'I have read and agree to the terms and conditions' box.

21. **Click** the Submit button to complete the application or the Clear All but to clear all changes made in this application.

   Please note there is no Save & Exit function on this page, so you need to either Submit your changes or Clear All and start again if you are not ready to submit.
22. After submitting, note the application number, the application will now show as in progress within the list of applications. While the application is in progress you will NOT be able to order a CFS for the device(s) or make further updates to device/s in the application, until the application is complete.

23. Click on the Close button.

23. Please note if you do not click the Close button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been auto-submitted. Click on the OK button.

You will receive email confirmation of your submitted application and the review outcome.
Update registered devices and products

Use this function if GMDN is now obsolete or device and/or products (model or version detail) need to be updated because the details have changed, or the field/s were optional, and you did not populate them at the time of registration.

Please note only certain fields can be updated. These will be enabled on the update screen to allow you to add or update data. GMDN Codes/Terms can only be updated in cases where the existing GMDN has been made obsolete. Changes made on this screen do not currently incur a fee.

If you need to update active GMDN Codes or Terms or any fields that are not enabled on the screen, you must remove the Device via the Manage Devices link. All underlying products will also be removed. You need to add the device and products again using the Add Device function to add new GMDN Code or Term, and pay the fees.

If products need to be added or removed from an existing registered device, or Conformity Assessment Certificates/Self-certification conformity declarations need to be uploaded, linked, or unlinked from existing registered devices this can be done via the Manage Devices link.

1. Go to Agency services > Enter Device Registrations and Certificates of Free Sale for medical devices.

2. Select the organisation (Legal Entity) of the devices/products you want to update.

1. [AGENCY SERVICES]

2. [DEVICE REGISTRATIONS]

Device Registration & Certificates of Free Sale

Your Organisation

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Country</th>
<th>Devices (Products)</th>
<th>Registration Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demo represented org Three</td>
<td>167 Bella Drive, East Side Compound, 1000 Meditech Drive, Sea View Industrial Zone, Santa Barbara, CA, 93065</td>
<td>United States</td>
<td>20 (2)</td>
<td>UK Responsible Person</td>
</tr>
<tr>
<td>DEMO Represented Organization</td>
<td>128 Street, Sea View Industrial Estate, Boston, MA, 12346</td>
<td>United States</td>
<td>3 (10)</td>
<td>UK Responsible Person</td>
</tr>
<tr>
<td>DEMO Represented Organization Two</td>
<td>234 Avenida Escala, Cancun, Yucatan, 43231</td>
<td>Mexico</td>
<td>1 (1)</td>
<td>UK Responsible Person</td>
</tr>
</tbody>
</table>

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the Applications list.

Search by manufacturer name: [SEARCH]
3. **Click** on the Update Registered Devices/Products Devices link (depending on your browser and zoom level settings this link may be split across two rows).

4. Use the available filters to search for a specific device.

   Please note only registered devices will be visible on the Update Registered Devices & Products screen. If the conformity assessment document has expired you must update this before you can update GMDN, device details or products. See Manage conformity documents.

5. **Click** on the GMDN Term of the device/product to update.
6. The details of the **GMDN Term** you have selected will open to enable you to:

- **Update** selected device and/or product fields if you are not updating obsolete GMDN
- **Update** obsolete GMDN and device data – you cannot update products at the same time as updating obsolete GMDN, you will need to do this in two applications – currently no fee

7. If GMDN is now **obsolete** a box will appear to enable you to either enter a valid GMDN Code if you know it, or search for a suitable GMDN Term using multiple words.

**Please note** you cannot update the GMDN and products in the same application, if you are going to update an obsolete GMDN you must do this first and submit the application and then update products once the first application is complete. If you update the products first and then attempt to update the obsolete GMDN in the same application, you will lose all the product data you entered.

---

### Update Registered Devices & Products for Organisation MHRA Demo

Only certain fields can be updated. These will be enabled on the below screen to allow you to add/remove/update data. GMDN Code/Terms can only be updated in cases where the existing GMDN has been made obsolete. Changes made on this screen do not currently incur a fee. If you need to update active GMDN Code or Terms on any fields that are not enabled below, you must remove the Device and/or product(s) via the Manage Devices link and add the device/product(s) again using the Add Device function to add new GMDN Code or Term, and pay the appropriate fees. To manage Conformity Assessment Documents or add or remove products from a registered device use the Manage Devices function.

<< Back to all "Devices & Products"

<table>
<thead>
<tr>
<th><strong>35596 - Vascular clamp, reusable</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Type</strong></td>
</tr>
<tr>
<td><strong>GMDN description</strong></td>
</tr>
<tr>
<td><strong>GMDN Code/Term</strong></td>
</tr>
<tr>
<td><strong>Directive/Regulation</strong></td>
</tr>
<tr>
<td><strong>Is custom made</strong></td>
</tr>
<tr>
<td><strong>Risk classification</strong></td>
</tr>
<tr>
<td><strong>Is sterile</strong></td>
</tr>
<tr>
<td><strong>Method of sterilisation</strong></td>
</tr>
<tr>
<td><strong>Single-use device?</strong></td>
</tr>
<tr>
<td><strong>Reprocessed single-use Device?</strong></td>
</tr>
<tr>
<td><strong>Are any of the products related to this device implantable?</strong></td>
</tr>
<tr>
<td><strong>Are any of the products related to this device active?</strong></td>
</tr>
</tbody>
</table>
8. If any other fields can be updated these will be enabled. If you need to make changes to a field that is not enabled you must delete the device and products via the Manage registered devices function and add the device again, the fee will be payable.

9. The Conformity Assessment Certificates or Self-certification conformity declarations table will also be visible for your information. You cannot make changes to documents on this screen. Please follow the Manage registered devices instructions to update documents.

10. The Product Details table will appear to enable updating product data. Click on the Medical Device Name to update the product.

Please note if you have updated an obsolete GMDN you will not be able to update products in the same application and the Medical Device Name link will not be enabled. You must update product/s in a separate application, after the obsolete GMDN application has been submitted and completed.
11. All fields that can be updated will be enabled. If you need to make changes to a field that is not enabled you must delete the products via the Manage registered devices function and add them again, there is currently no fee to add/remove products.

<table>
<thead>
<tr>
<th>Product Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Name</td>
<td>Clamp 1</td>
</tr>
<tr>
<td>Model/Version</td>
<td>T235464</td>
</tr>
<tr>
<td>Catalogue/Reference (UDI)</td>
<td>5257677777</td>
</tr>
<tr>
<td>UDI issuing Entity (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CEI ASSL</td>
</tr>
<tr>
<td></td>
<td>MEDIC</td>
</tr>
<tr>
<td></td>
<td>CECEBA</td>
</tr>
<tr>
<td></td>
<td>UDI not assigned</td>
</tr>
<tr>
<td>Product Status</td>
<td></td>
</tr>
<tr>
<td></td>
<td>On the GB &amp; N market</td>
</tr>
<tr>
<td>URL for additional information (optional)</td>
<td></td>
</tr>
<tr>
<td>Type of UDI-P (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lot or Batch Number</td>
</tr>
<tr>
<td></td>
<td>Serial Number</td>
</tr>
<tr>
<td></td>
<td>Manufacturing date</td>
</tr>
<tr>
<td></td>
<td>Expiration date</td>
</tr>
<tr>
<td></td>
<td>Software version</td>
</tr>
<tr>
<td>Does the device incorporate human cells or tissues, or their derivatives (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Does the device incorporate animal cells or tissues, or their derivatives (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Are storage/handling conditions specified in the label/instructions for use (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Quantity per package configuration (optional)</td>
<td></td>
</tr>
<tr>
<td>Need for sterilisation before use (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>What USD safety information does the labeling contain? (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Does the label/instruction for use include Critical warnings or contraindications (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Containing latex (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Clinical size applicable (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>USA DI from secondary entity (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Endocrine disruptor (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Please Select</td>
</tr>
<tr>
<td>Additional product description (optional)</td>
<td></td>
</tr>
</tbody>
</table>

12. Once all fields have been updated, click the Apply Changes button.
13. On the Review page, click the > icon to display the Updated device details. Only fields that you have updated will display here.

14. On the Review page, click the > icon to display the Updated product details. Only fields that you have updated will display here.
<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Of UDI-PI</td>
<td></td>
</tr>
<tr>
<td>Does The Device Incorporate Human Cells Or Tissues, Or Their Derivatives</td>
<td>No</td>
</tr>
<tr>
<td>Does The Device Incorporate Animal Cells Or Tissues, Or Their Derivatives</td>
<td>No</td>
</tr>
<tr>
<td>Storage/Handling Conditions Specified</td>
<td>Yes</td>
</tr>
<tr>
<td>Description Of Storage/Handling Conditions</td>
<td>See IFU</td>
</tr>
<tr>
<td>Quantity Per Package</td>
<td>10</td>
</tr>
<tr>
<td>Need For Sterilisation Before Use</td>
<td>Yes</td>
</tr>
<tr>
<td>Method of sterilisation</td>
<td>Steam</td>
</tr>
<tr>
<td>MRI Safety Information</td>
<td>MRI Unsafe</td>
</tr>
<tr>
<td>Critical Warnings or Contra-indications</td>
<td>Yes</td>
</tr>
<tr>
<td>Critical Warnings or Contra-indications</td>
<td>See IFU</td>
</tr>
<tr>
<td>Containing Latex</td>
<td>No</td>
</tr>
<tr>
<td>Clinical Size Applicable</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical Size</td>
<td>1cm</td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>UDI-0i From Secondary Entity</td>
<td></td>
</tr>
<tr>
<td>Secondary UDI</td>
<td>FA GmbH</td>
</tr>
<tr>
<td>Issuing Entity</td>
<td>6657674</td>
</tr>
<tr>
<td>Device Identifier</td>
<td></td>
</tr>
<tr>
<td>Endocrine Disruptor</td>
<td>No</td>
</tr>
<tr>
<td>Additional Product Description</td>
<td>Curved</td>
</tr>
</tbody>
</table>

15. If you have **removed** any product data, the details will be displayed here.
16. When you are ready to submit the application, **Read** the on-screen information and terms and conditions, **click** the ‘I have read and agree to the terms and conditions box’ and **click** the Submit button to complete the application.

**Please note** there is no **Save & Exit** function on this page, you need to either Submit your changes or go Back and make further changes or Cancel to abandon all changes.

If you have updated an obsolete GMDN you will receive email confirmation of your submitted application and another email confirming outcome of MHRA review. You will not receive email confirmation for updating other device and/or product fields.

18. Use the filters on the Devices tab and Product tab screens to search for updated devices and products.
Version history

Each application to update a device or product will generate a version history for the device.

1. To view the version history for a device. Search for the device using the Is device updated filter? on the Device tab.

2. Click on the GMDN Term of the updated device.
3. An **Update History** table will appear with a **version** entry for each update application submitted for the device, indicating when the device was modified and by whom.

4. **Click** on each **version** to view updates made to the device.

5. The application number and the updates made in that application will display.

6. **Click** the **Back** button to go back to the **Update History** table and view other versions.
7. To view the version history for a product, Search for the product using the Updated Products filter on the Products tab.

8. Click on the GMDN Term of the updated product.
9. **Click** on the Medical Device Name of the product

<table>
<thead>
<tr>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Device Name</strong></td>
</tr>
<tr>
<td>Clamp1</td>
</tr>
</tbody>
</table>

**Key**
- Registered
- Not Registered
- No Longer Registered
- Rejected

10. An **Update History** table will appear with a version entry for each update application submitted for the product, indicating when the product was modified and by whom.

<table>
<thead>
<tr>
<th>Update History</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version</strong></td>
</tr>
<tr>
<td>Version 3</td>
</tr>
<tr>
<td>Version 2</td>
</tr>
<tr>
<td>Version 1</td>
</tr>
</tbody>
</table>

11. **Click** on each version to view updates made to the product.

12. The application number and the updates made in that application will display.

13. **Click** the Back button to go back to the Update History table and view other versions.
Removing migrated Pseudo GMDN Terms

This section applies to Migrated customers only. Please see Determine if your account is migrated or re-registered. You will need to add all the devices you manufacture first and then remove the Pseudo GMDN Terms.

1. Click the Devices link

2. Check if you have any migrated Pseudo GMDN Terms in your list of devices – these can be identified by the following symbol:

![Diagram of the Devices list with migrated Pseudo GMDN Terms highlighted]

- Click the Devices link
- Check if you have any migrated Pseudo GMDN Terms in your list of devices – these can be identified by the following symbol:
3. **After** following all the [Add Device using GMDN](#) instructions to add all the devices you manufacturer:

4. **Select** all the Pseudo GMDN Terms migrated from our old system. You can identify these in your manage devices list by either searching for the device using filters or searching all devices that are not CFS ready by using the Is CFS ready? filter, the Remark column will indicate 'Invalid GMDN Term'.

5. **Click** the Delete Selected Devices button.

6. **Select** option Information updated/existing data no longer valid for Reason for deletion. This option will be applied to all the deleted devices.

   **Reason for deletion**
   - No longer placed on the market:
   - **Information updated/ existing data no longer valid**
   - Entered in error

7. **See** [Using filters to search for devices and products](#) to search for deleted devices.
Adding a Manufacturer (only for UKRP in UK and EU AR in NI)

1. **Click** the **Enter** button on the **Landing Page**.

2. **Click** on the **Add New Manufacturer** button.

**Please note.** Only UK Responsible Persons (of manufacturers outside the UK) or NI-based Authorised Representatives (of manufacturers outside the UK or EU) may **click** this button to ‘Add New Manufacturers’. This button is to be used when you are ready to make device registrations on behalf of a represented manufacturer.
3. Enter manufacturer details:
   - Select to confirm I wish to represent this manufacturer as UK Responsible Person or I wish to represent this organisation as an Authorised Representative (the Authorised Representative option will only appear if you are based in Northern Ireland).
   - Select up to three options to describe the organisation.
   - Complete all the mandatory fields otherwise you won’t be able to proceed.

4. Enter details of the contact at the represented organisation – please do not enter your contact details here.
5. **Upload** the Letter of Designation.

**Please note** This must be a legal contract, stating that you are the exclusive UK Responsible Person or Northern Ireland Authorised Representative, acting for the manufacturer and specifying the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contact for UKRPs can be found in our [regulatory guidance for UK Responsible Persons](#). For Authorised Representatives in Northern Ireland the requirements can be found in the [guidance for Authorised Representatives](#).

![Upload Letter of Designation](image)

6. **Enter** the Letter of Designation validity dates

**Please note** you will receive email reminders 3, 2 and 1 month prior to expiry of your Letter of designation. If you do not upload a new Letter of Designation before the expiry of the existing one, your account will be suspended until you upload a valid letter. A suspended account means you are no longer lawfully allowed to place devices on to the UK market. It is a legal requirement to hold an active registration with the UK competent authority (MHRA). It is an offence to place a non-compliant device on the UK market. Your details will also be removed from the [Public access database for medical device registration](#) (PARD). See [Uploading New Letter of Designation](#) in the Account Management Reference Guide to update Letter of Designation.

![Upload Letter of Designation](image)

7. **Click** the Continue button to go to the Add Devices page and follow the instructions as for [Registering New Devices](#) or click the Save & Exit button if you wish to save a draft application.
Adding Importers

You must add the details of all importers that import medical devices into the UK for your organisation or any of the organisations that you represent as a UK Responsible Person (of manufacturers outside the UK) or Northern Ireland-based Authorised Representative (of manufacturers outside the UK or EU).

1. **Click** the **Enter** button on the Landing Page.

2. **Click** on the **Add New Importer** button.
3. **Enter** the importer details:

   - **Select** to confirm I am associated with this organisation as UK Responsible Person and/or Manufacturer and/or Authorised Representative (the Authorised Representative option will only appear if you are based in Northern Ireland)

   - Multiple associations can be ticked e.g. if you have a dual or triple role and also use the importer for your represented manufacturers in your capacity as UKRP or Northern Ireland Authorised Representative

   - **Complete** all the mandatory fields otherwise you won’t be able to proceed.

4. **Select** from the list of Registered Manufacturers you represent. Multiple manufacturers can be selected.

   **Please note** if you have selected that you are associated with this importer as a manufacturer, your organisation will automatically be included and will not appear in the List of Registered Manufacturers.
5. **Enter** all mandatory address fields for the importer.

6. **Enter** the importer’s contact details—please do not enter **your** contact details here.

5. **Click** the **Continue** button.
6. Click the Complete Application button.

Add New Importer - TEMP202001030154509

Payment is not required for the application. Please click on complete application to finish.

7. Click the Close button.

Application complete

Your reference number
202010300115416

What happens next...

We have sent you a confirmation email and your application has been sent to an officer at MHRA.
We will contact you again within the next 2-5 working days to let you know of our decision, or to ask for more information if needed.

8. The importer will appear in the List of Importers on the Organisation page.

If you are no longer associated with an importer please see Deactivating Importers.
9. Click on the importer name in the List of Importers on the Organisation page.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Country</th>
<th>Relationship</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Big Shipping UK Limited</td>
<td>Unit 581, Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU</td>
<td>England, United Kingdom</td>
<td>UK Responsible Person; Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Demo Importer</td>
<td>Unit 765, Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU</td>
<td>England, United Kingdom</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
<tr>
<td>DEMO TWO Importer</td>
<td>344 High Street, Industrial Estate, Rochester, Kent, CT10 7BU</td>
<td>England, United Kingdom</td>
<td>UK Responsible Person</td>
<td></td>
</tr>
</tbody>
</table>

Key
- Active
- Inactive

10. The details of all Associated Manufacturers will be displayed, including your organisation if you have selected that you are associated with this importer as a manufacturer.

Please note if you or any of your represented manufacturers are no longer associated with an importer, you will need to deactivate the importer account. You can add the importer again with new associated manufacturers, if applicable. There is currently no fee to do this. Please see Deactivating Importers.
Deactivating Importers

1. **Click** on the name of the importer you want to deactivate in the List of Importers table.

   **Please note** if you need to make any changes to association between **Importer** and **Manufacturers** you must **deactivate** the importer, **add** them again and link the appropriate associated manufacturers. It is not currently possible to remove associated manufacturers from an importer record.

2. **Click** on the **Deactivate Importer** button.
3. **Click** the Yes button to **deactivate** or the No button to cancel the action.

**Please note** once the importer has been **deactivated** you will not be able to re-activate/reinstate the record. You will need to **add** the importer again, if required.

4. The status of the importer will change to **Inactive** on the Summary page and in the List of Importers.
Save and exit: resume applications

When completing an application, you may save, exit and return to completing the application from where you left off. This creates a TEMP (draft) application.

Please note TEMP applications will be automatically deleted 90 days from creation date. Please ensure that you regularly review your TEMP applications and submit to MHRA within 90 days of creation. Once deleted TEMP applications cannot be reinstated.

1. Click the Save and Exit button (if available on the page that you are on).

2. Confirm that you want to Save and Exit.

3. A TEMP (Draft) application will be created that you can access and resume work on

4. Click the Close button.
5. Click on the Applications tab on the home page or the Applications link on the Organisation page. This will display all the applications for your organisation and all of your represented organisations (if applicable).

6. You can also click on the Applications tab within an organisation. This will only display the Applications for that organisation.
7. **Click** on the TEMP (draft) application’s **Reference** to open it. TEMP applications will be automatically deleted 90 Days from creation date. You will need to create again.

8. The application will open on the page where you clicked **Save and Exit**.

---

**Add New Devices - TEMP20210716103807**

**Review**

**Devices**

- Cartilage knife
- Lens nucleus manipulator

**ADD ANOTHER DEVICE**

You are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical devices or placing items on the market in the UK the manufacturer must provide a signed self-certification conformity declaration stating that each medical device has met the appropriate essential requirements (or general safety and performance requirements, where applicable) of the relevant medical devices legislation, including the availability of technical and clinical data for each device. Devices requiring conformity assessments to be carried out by a UK approved body/ EU notified body must provide a valid UKCA/CE certificate. There are also additional legal requirements which must be met, including those which assemblers of systems and procedure packs specifically should ensure they meet before marketing such products.

Further information on the legal requirements is available at the following links in relation to the UK Medical Devices Regulations 2022 (in the form that they exist on 1 January 2021) and also regarding the EU Medical devices and in-vitro diagnostic devices regulations.

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £160 to make the relevant changes.

**NOTE:** It is possible to select a GMDN code/item for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisation and/or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £160 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our terms and conditions.

- [ ] I have read and agree to the terms and conditions

[CONTINUE] [SAVE & EXIT] [BACK] [DELETE APPLICATION]
9. If you have multiple users on your account you will need to Click on the Accept task button in order to continue with the application or Click on the Go Back button to go back to the Applications list. All TEMP applications will be visible and accessible to all users on the account with the exception of Applications saved on the Payments page.

**Please note** if you have clicked Save and Exit on the Payments page only **you** will be able to see the TEMP application in the Applications Tab. If you want your colleagues to be able to view the application please Click the Back button to the Review page and then Click on the Save and Exit button.
Annex I – Workflow

Device Registrations Workflow

1. Register a new Manufacturer and Devices
   1a. Update Manufacturer details
      1b. Add new devices to registered manufacturer

2. Confirm Manufacturer details
3. Enter and Save Device Details
4. Add Another Device?
   Yes
   5. Add Conformity Assessment Certificate
      6. Add Declaration of Conformity or Custom-made Statement
9. Submit Application to MHRA

5. No
   7. Review
      8. Agree terms and conditions
      9. Make payment

MHRA

New Device/Product
Accept Mfr
Accept Device & Products
Approve Application
Submit Application to MHRA

New Manufacturer & Devices
Reject Mfr
Reject Devices & Products
Reject Application
End

MHRA Receive Application

If Class I sterile or measuring or Class IIa, IIb, III or non-custom AIMD, or IVD List A, List B or Self-test
If custom made or Class I or SPP non sterile or measuring or IVD general or IVD Class A
Add GMDN term/code and answer questions

Upload Proof of payment
If BACS/CHAPS

Add and Save Product Details and save Device
If SPP add contents list. If Custom AIMD add label & IFU