Medicines & Healthcare products Regulatory Agency

Device Registrations

Reference Guide

Please do not print this document. View online only to ensure you have the latest version.

Contents – Device Registration Reference Guide

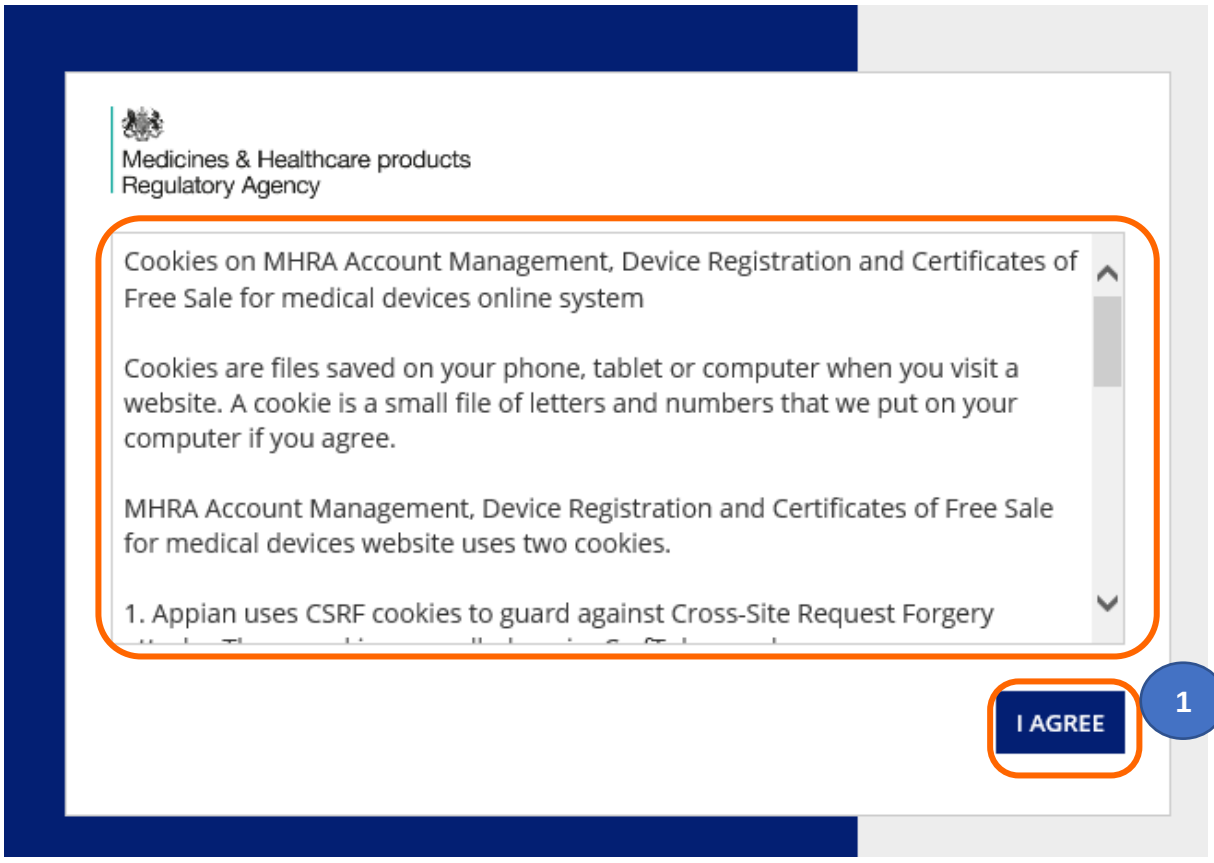
Logging in

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, two emails will be sent to the email address you entered in your account request application:

1. A welcome email with subject line **Account creation – outcome**, from email address no-reply@mhra.gov.uk with instructions on initial actions to take in the registration system

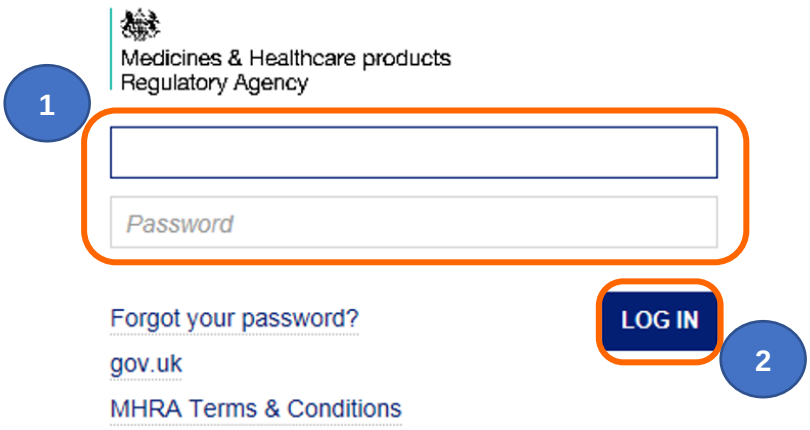
2. A separate email with subject line **MHRA Portal account creation** from email address admin@mhrabpm.appiancloud.com containing your username (usually firstname.lastname), a temporary password and a link to the system

Please log in for the first time on a laptop or PC not a mobile or tablet. If you have not received the emails, please check your Junk/Spam folder. You will be asked to change the password to one of your choosing.

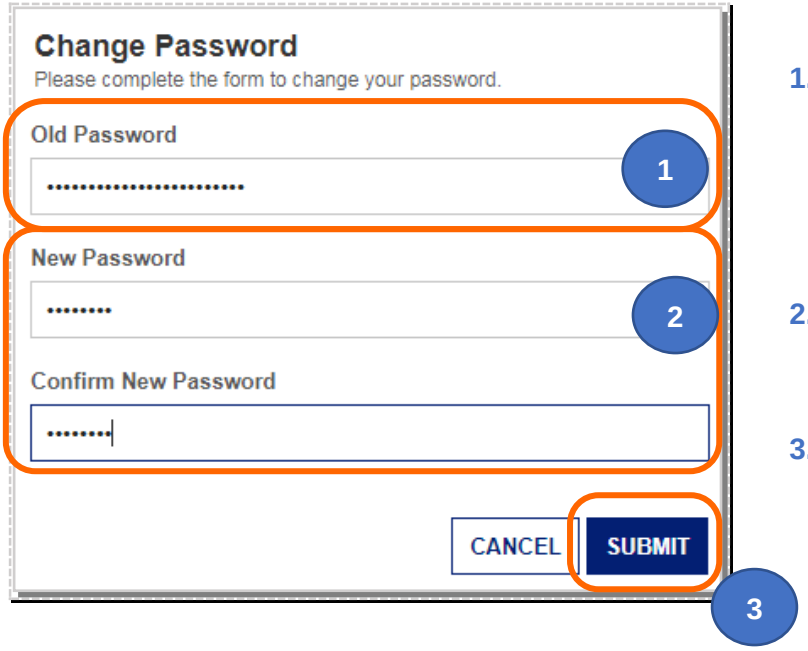
If the welcome email or the username and temporary password email have not been received this is usually due to your system blocking the originating email address. Please add the above email addresses to your **safe senders** list, usually via settings in your email system and email device.registrations@mhra.gov.uk to obtain your username and further instructions.

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

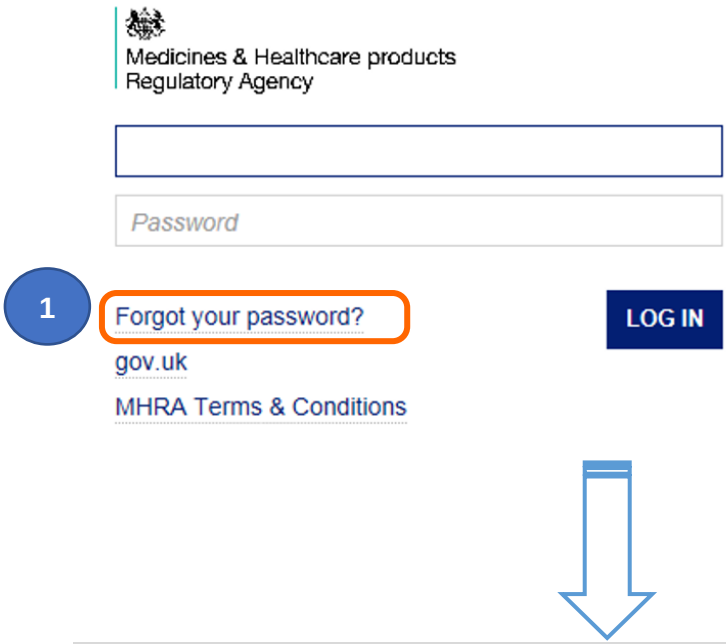


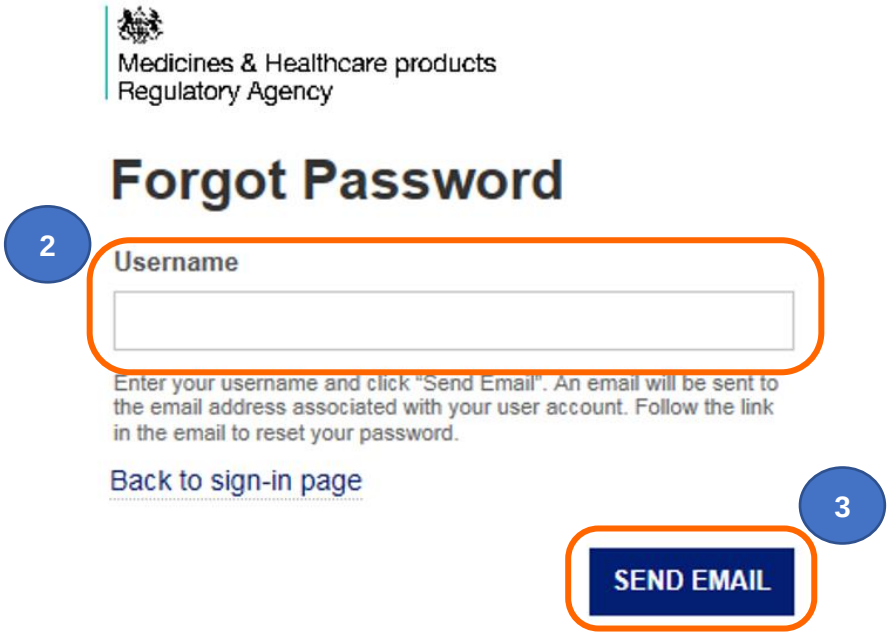
1. **Copy** and **paste** the **temporary** password (long password with multiple characters) sent to you via email into the old password box.
2. **Enter** a password of your choice into the new password and confirmation boxes.
3. **Click** on Submit.
   You will be able to use the password you entered from now on.

Forgot password > resets

1. On the log in page, **click** the Forgot 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.

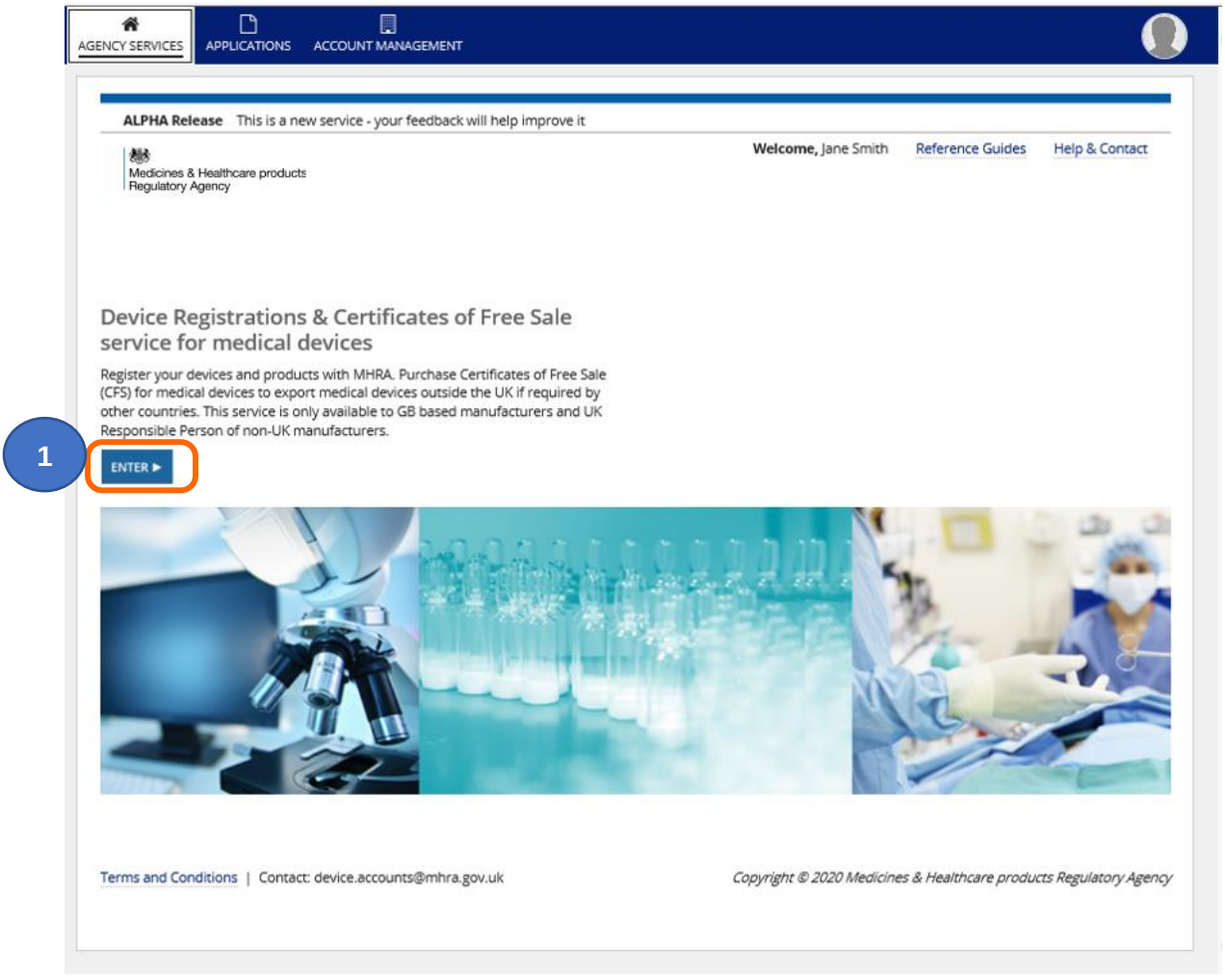



Medicines & Healthcare products
Regulatory Agency
Forgot Password
2
Username
Enter your username and click "Send Email". An email will be sent to the email address associated with your user account. Follow the link in the email to reset your password.
Back to sign-in page
3
SEND EMAIL

MHRA Agency Services

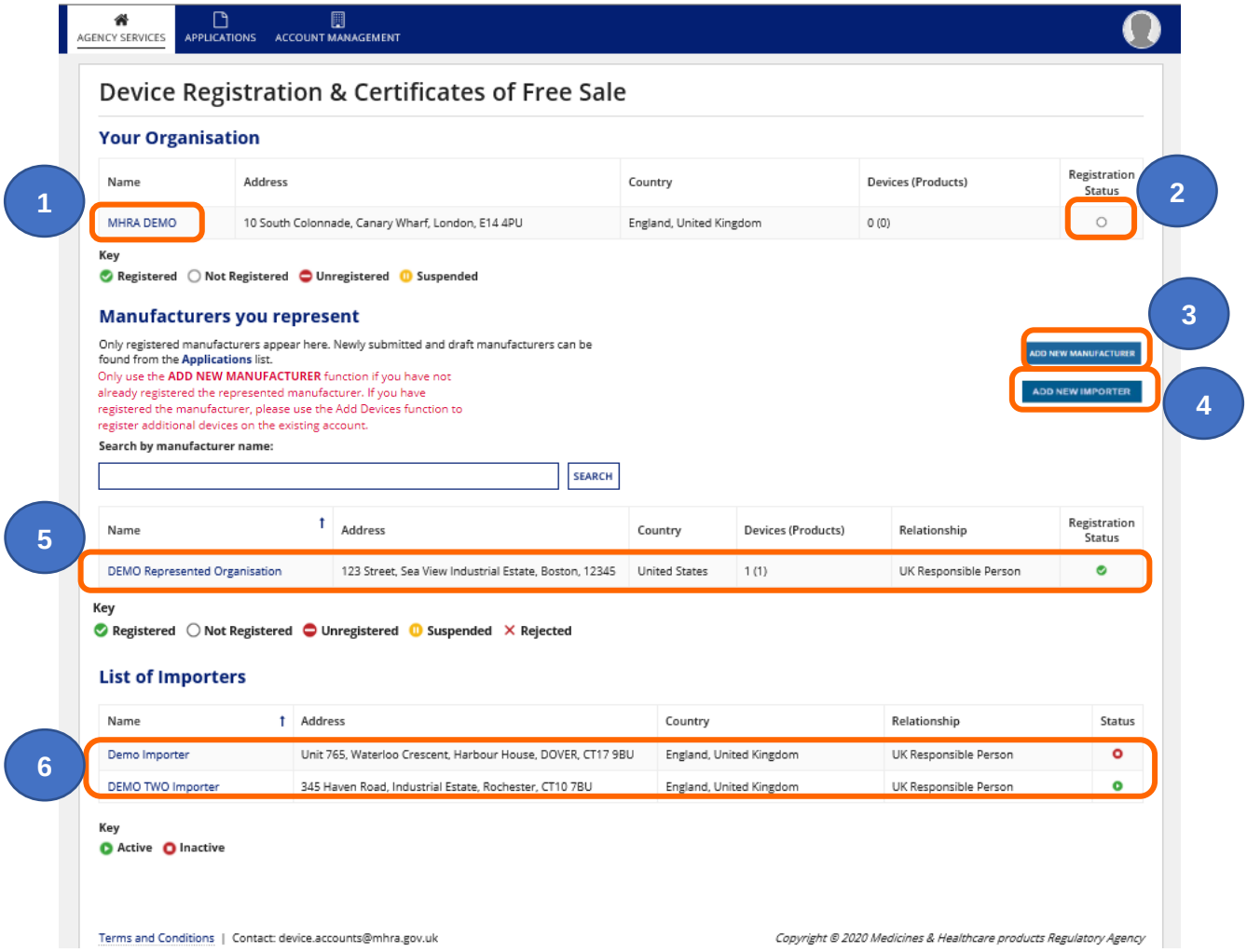
This service allows you to submit registrations for devices (GMDN® Code or Term) and products (brand or trade name, model/version, catalogue/reference, UDI DI and DI data). You can also update your registrations, add importers, link them to registered manufacturers and order Certificates of Free sale, 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.

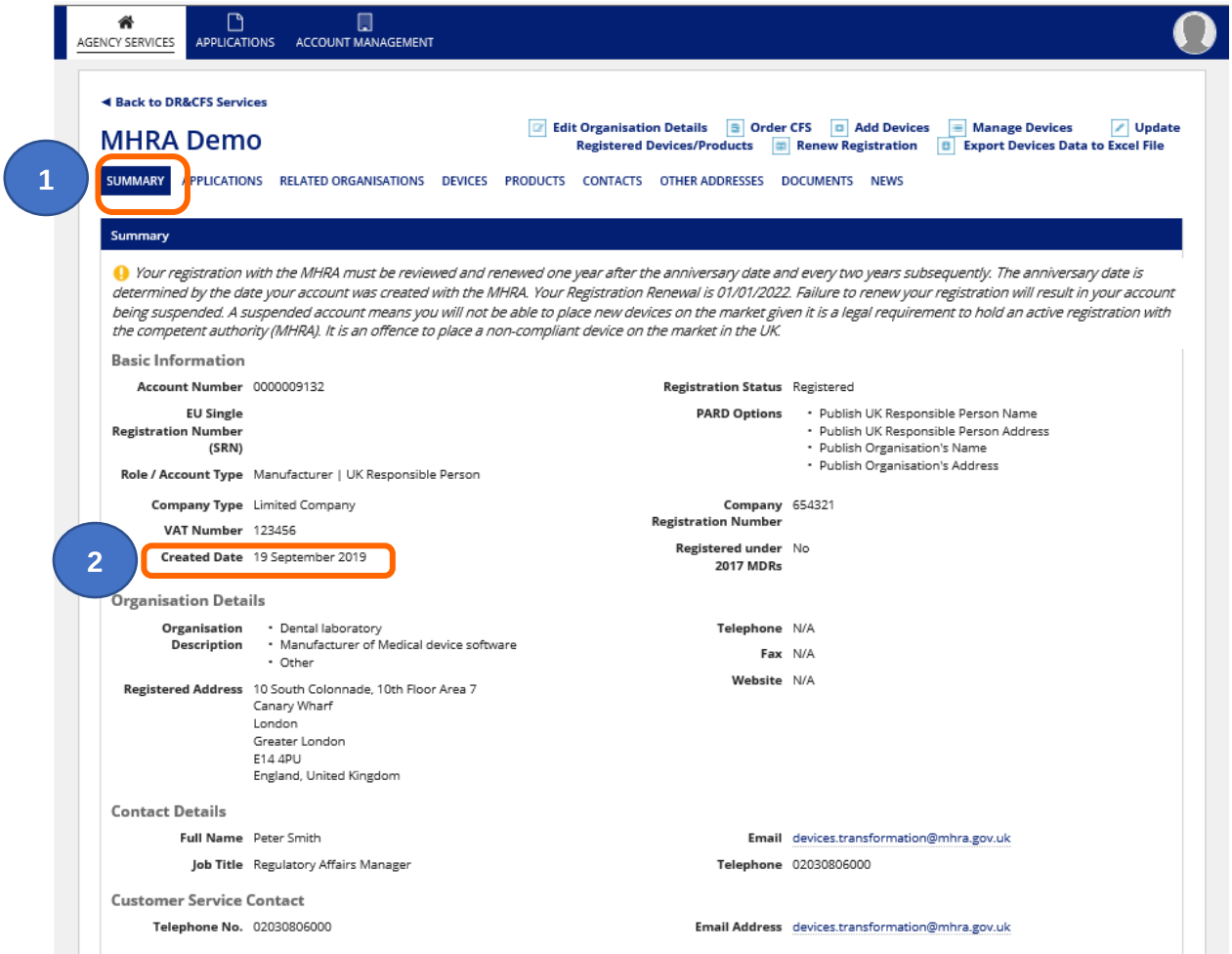
To determine the migration/re-registration status of your account please:

1. **Review** the summary page after **clicking** on the manufacturer name.

2. 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.

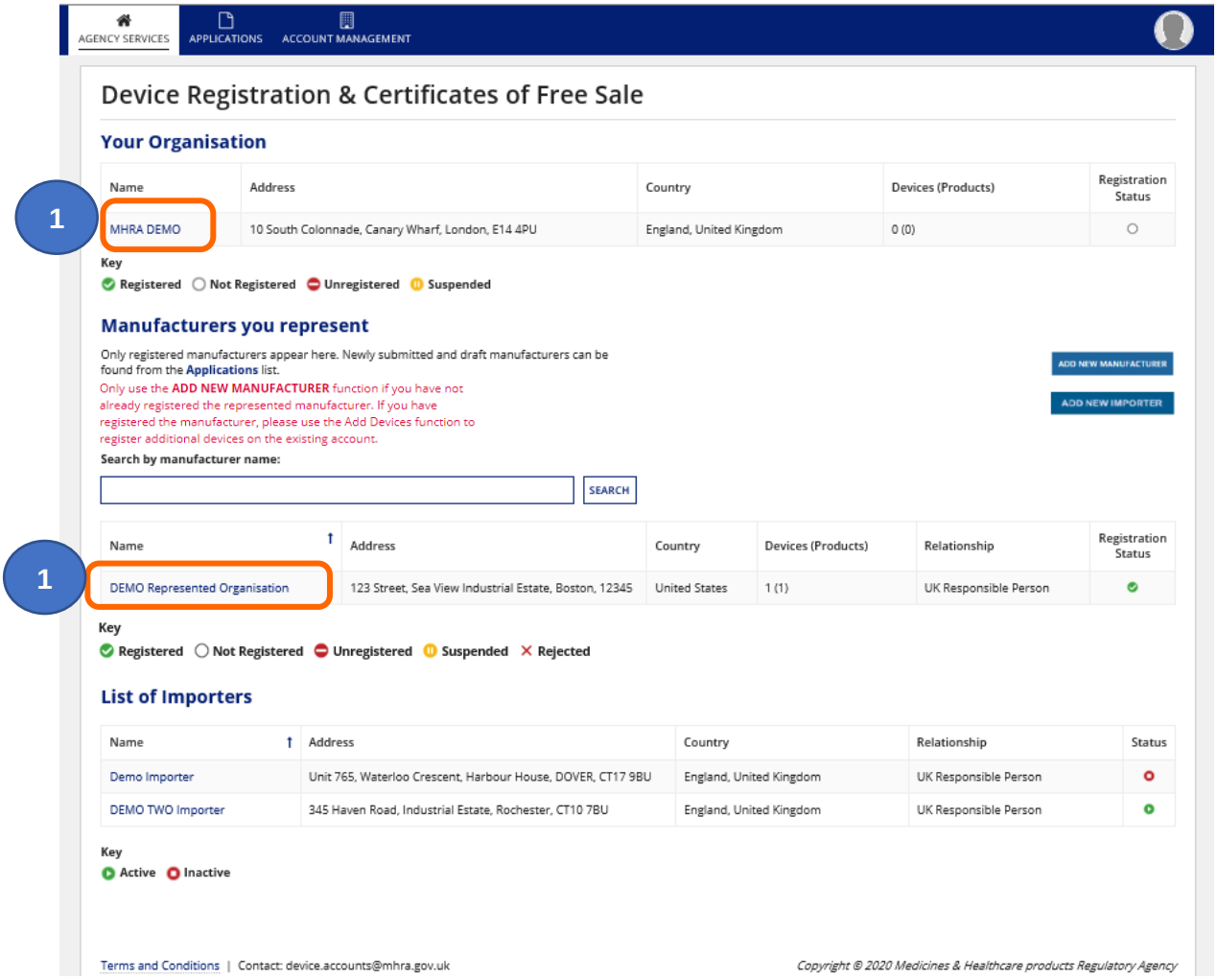


Registering new devices

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

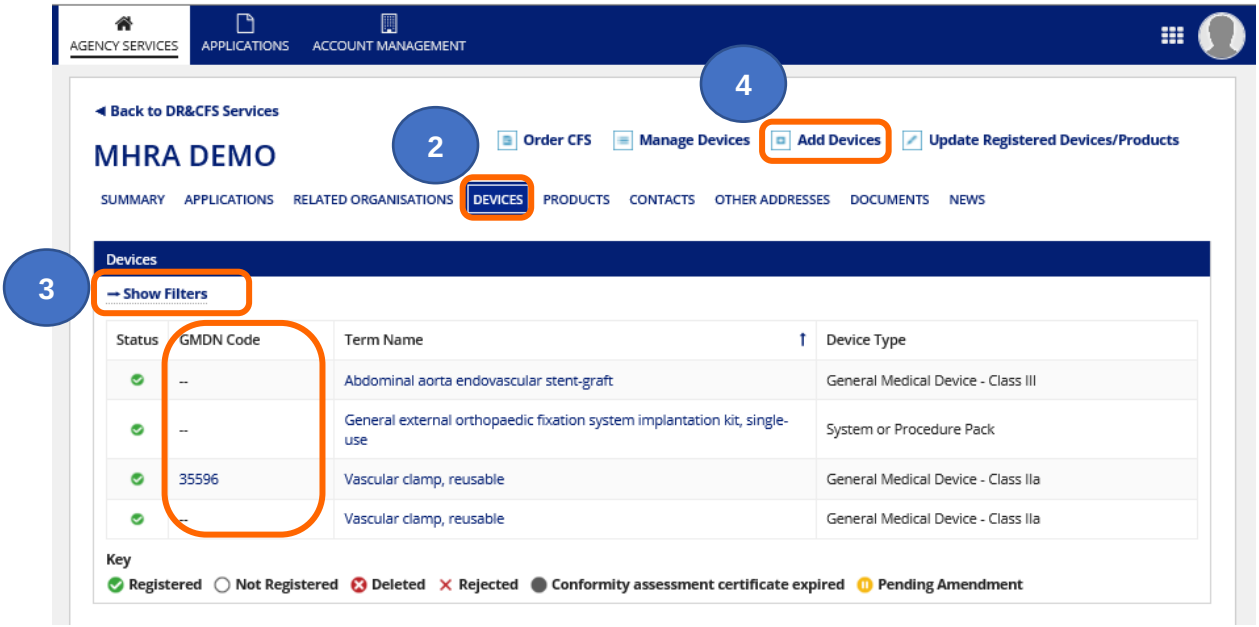
Please note:

- 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).

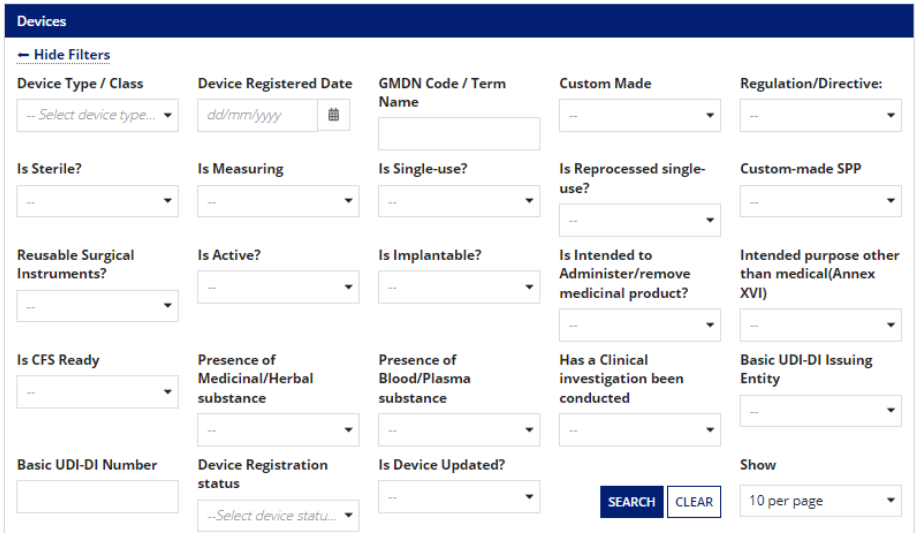


2. **Click** the Devices tab to **review** devices you have already registered and the device status.

   Please note that previously GMDN® Codes were only be displayed if you entered the GMDN® Code when adding your device. We now display both the GMDN® Code and the Term.



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.

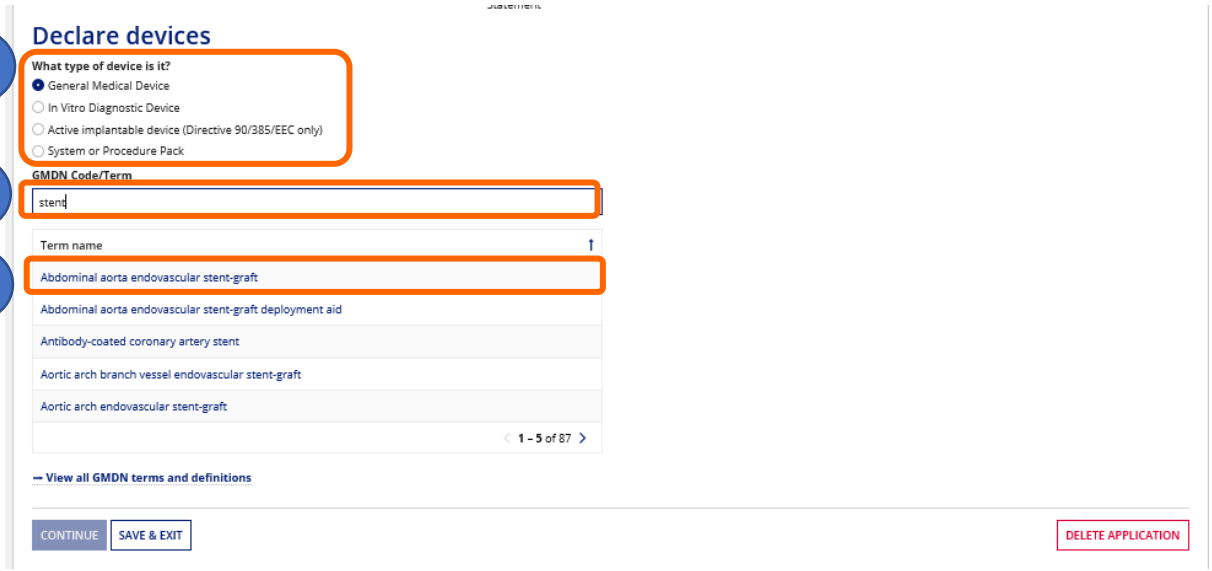
   If you need to update devices or products for example add data to fields you did not complete at time of registration, or update obsolete GMDN® Code or Term, please refer to the Update registered devices and products section.

Add devices using GMDN®

1. **Select** the appropriate device type for the medical device to be registered.
2. Entering appropriate words into the Global Medical Device Nomenclature GMDN® Code/Term text box will give you a list of GMDN® Terms to choose from. Entering more words into the box will reduce the list.

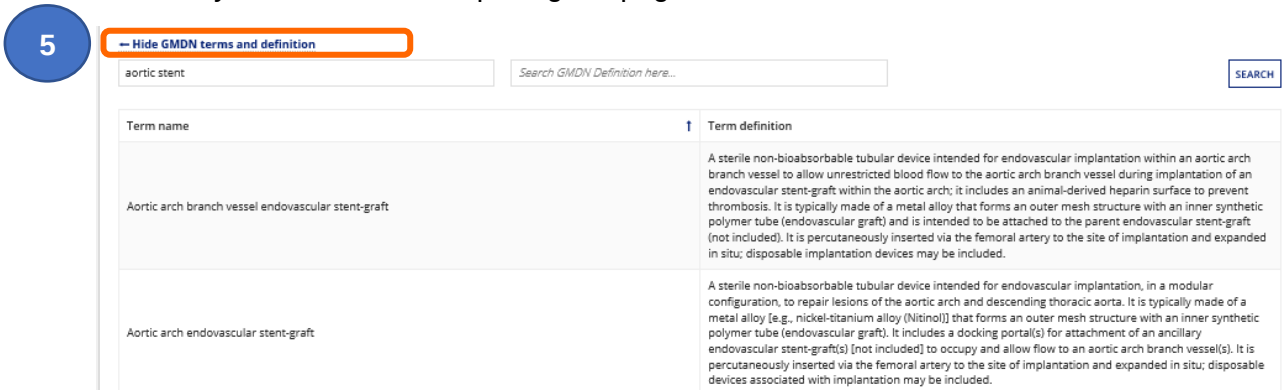
> GMDN® Members may **enter** a GMDN® Code into this box.
> Please note The GMDN Agency provides a free enquiry service if you are in doubt about the correct GMDN® Term to select for your device

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



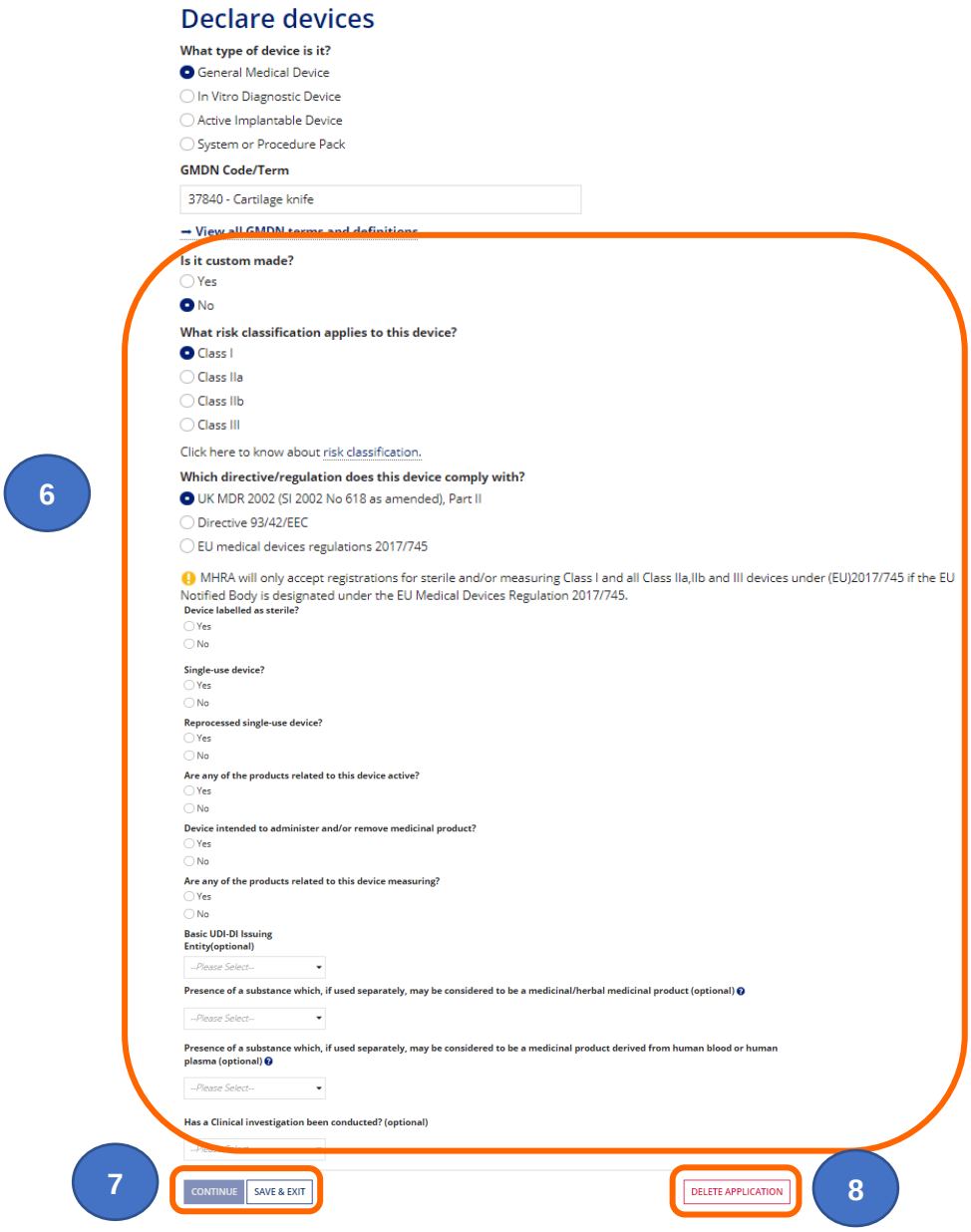
4. If you are unsure of a term's definition you can select the View all GMDN® Terms and definitions. You will be presented with a list of terms which you are able to refine by typing keywords into the text box.

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 regulation or directive that you are certified for will result in your registration becoming invalid and you will be charged a further statutory fee to make the relevant changes.



7. **Click** either the Continue button to proceed to the next page or the Save & Exit button to save and exit and resume application before submitting to MHRA. The Continue button will not be enabled until you have answered all the mandatory questions.

8. You can Delete Application at any stage before submitting to MHRA. This will delete all devices in the application.

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

   - 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, as appropriate. Find out more about UK MDR 2002 Regulation 14 / EU regulations

   - Declaration for Performance Evaluation – to UK MDR 2002 Regulation 43 Statement, Annex VIII of Directive 98/79/EC) or Part A of Annex XIII of EU regulation 2017/746, as appropriate. Find out more about Performance Evaluation / EU regulations

   Custom-Made Statement – 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. Find out more about Custom made statement and see important information below concerning legislation for custom-made devices.

   Details of the content of the custom-made statement can be found in the relevant directive/regulation that applies to your device:
   - Regulation 15 of UK Medical Devices Regulations 2002 (S.I. No. 618, as amended), Part II
   - Regulation 28 of UK Medical Devices Regulations 2002 (S.I. No. 618, as amended), Part III
   - Annex XIII of Medical Devices Regulation (EU) 2017/745

   Important information:

   GB market:
   Custom-made devices under the EU MDD (93/42/EEC) or EU AIMDD (90/385/EEC) can no longer be registered for the purposes of placing on the GB market.

   You can register your custom-made device under UK MDR Part II or Part III (which is currently consistent with EU medical devices directive requirements) for the GB market only, with a suitable accompanying custom-made statement.

Northern Ireland market:
Only custom-made devices consistent with EU MDR 2017/745 can be placed on the Northern Ireland market.

However, custom-made devices registered under the EU MDD or EU AIMDD and placed on the market in an EU member state other than Northern Ireland, prior to 26 May 2021, can still be registered with MHRA for the purposes of placing on the NI market only. The content of the custom-made statement needs to have been drawn up prior to 26 May 2021 and be consistent with:

- Annex VIII of Medical Devices Directive 93/42/EEC
- Annex 6 of Active Implantable Medical Devices Directive 90/385/EEC

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).

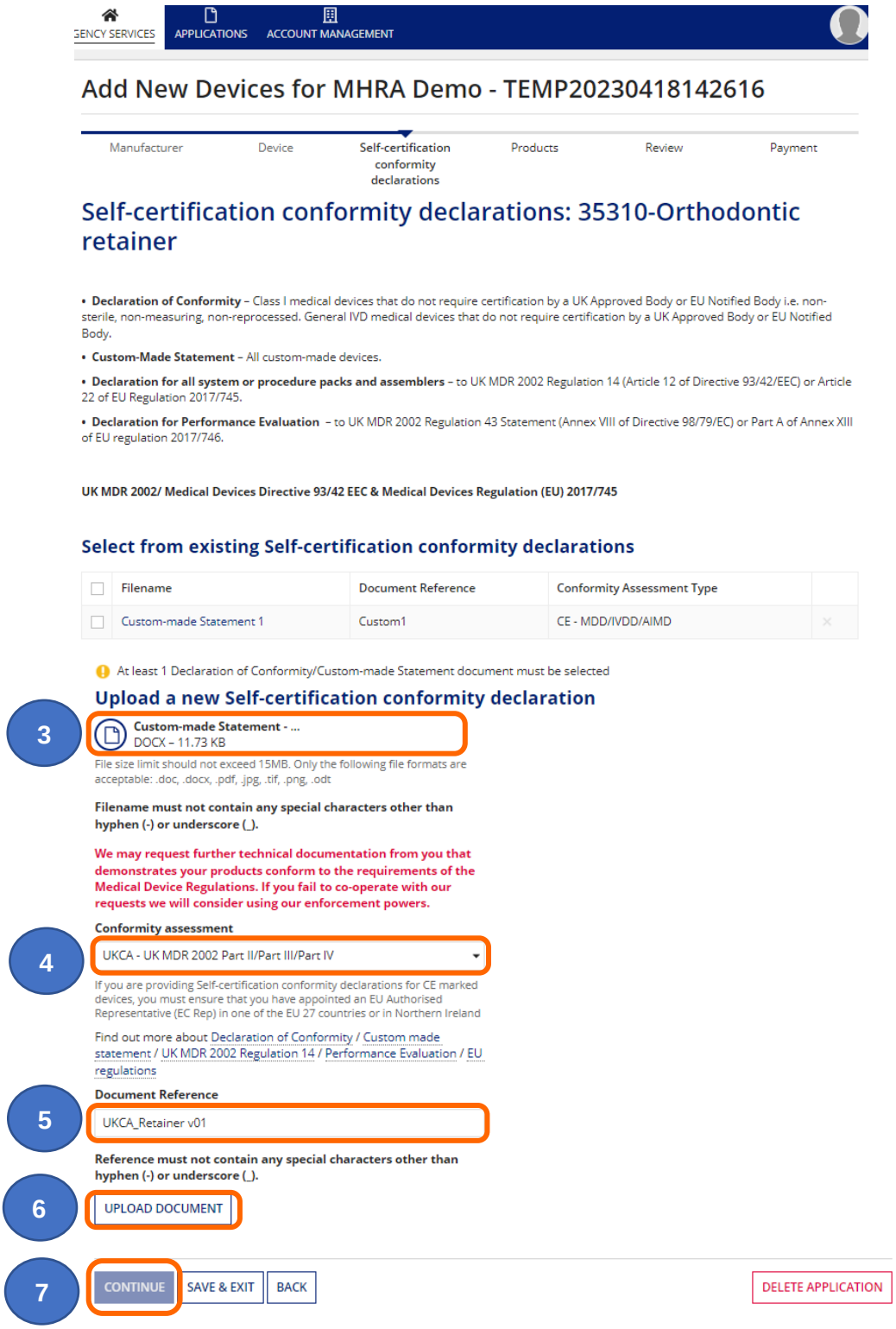
However, the statement you provide to the patient/clinician with the device, **does** need to include the patient name. Please refer to our online guidance on statements at https://www.gov.uk/government/publications/custom-made-medical-devices

2. **Important note** concerning **CE UKNI-MDR/IVDR** option.

You must **not** select the CE UKNI-MDR/IVDR option for self-certification conformity assessment type. This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

3. **Click** the Upload button and select the relevant Self-certification conformity declaration file stored on your system.



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

5. **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.

6. **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®).
7. **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

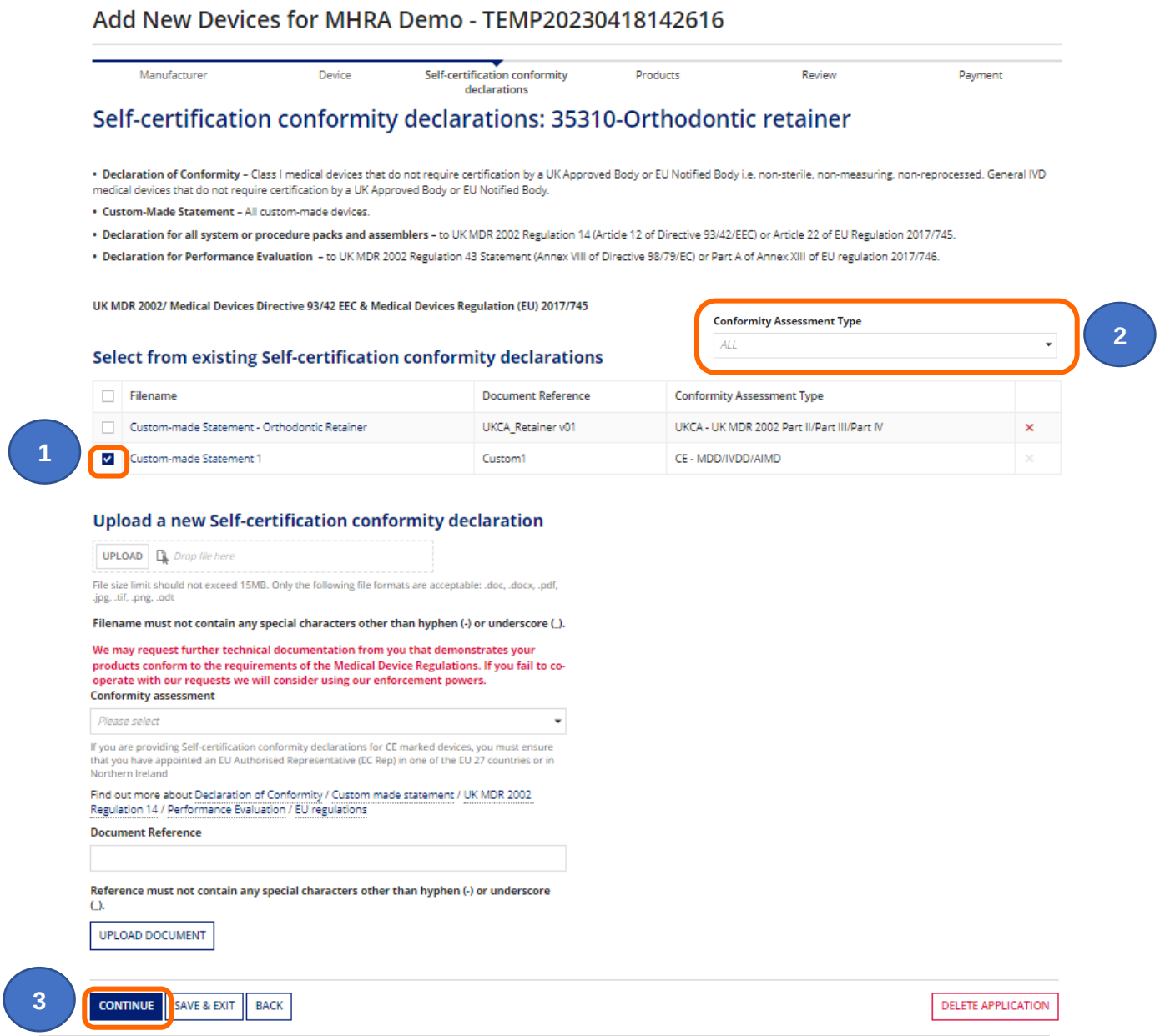
1. If you have already uploaded documents previously, from the Select from existing Self-certification conformity declaration area ensure that the correct document is selected. **Tick** the check box to the left of the filename to **select** the document.

2. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

   UKCA – MDD/IVDD/AIMD
   CE (UK NI) – MDD/AIMD/IVDD
   CE (UK NI) – MDR/IVDR

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

3. **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.

   Important note concerning **CE UKNI-MDR/IVDR** option.

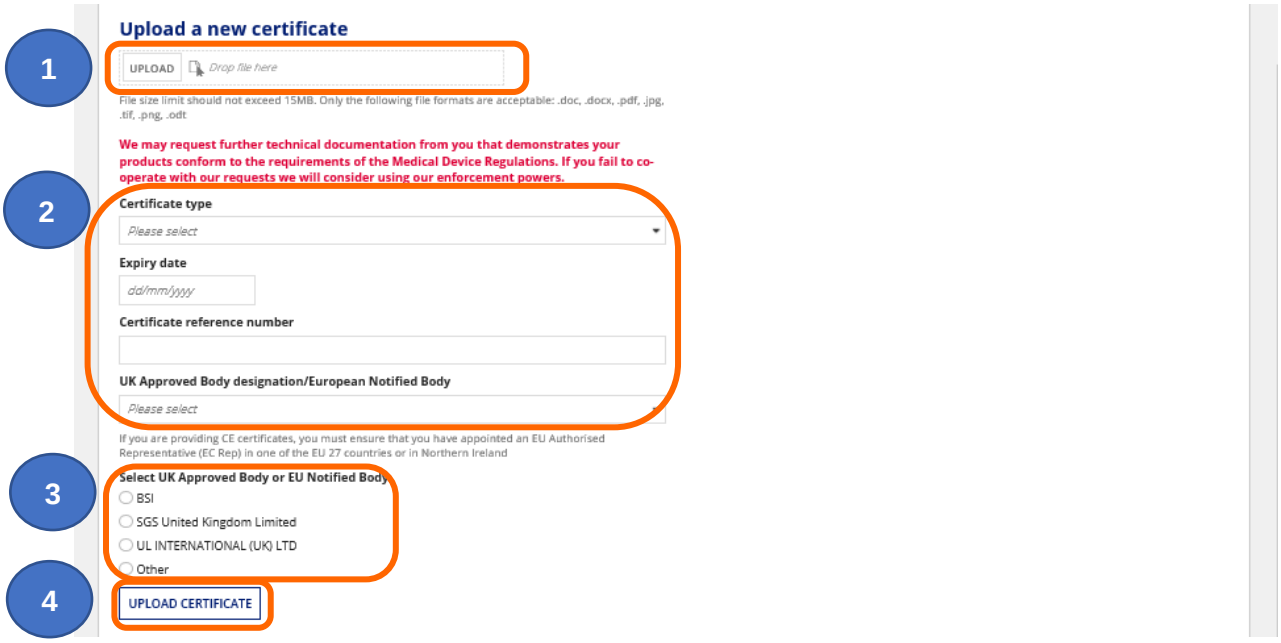
   This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

   https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

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.

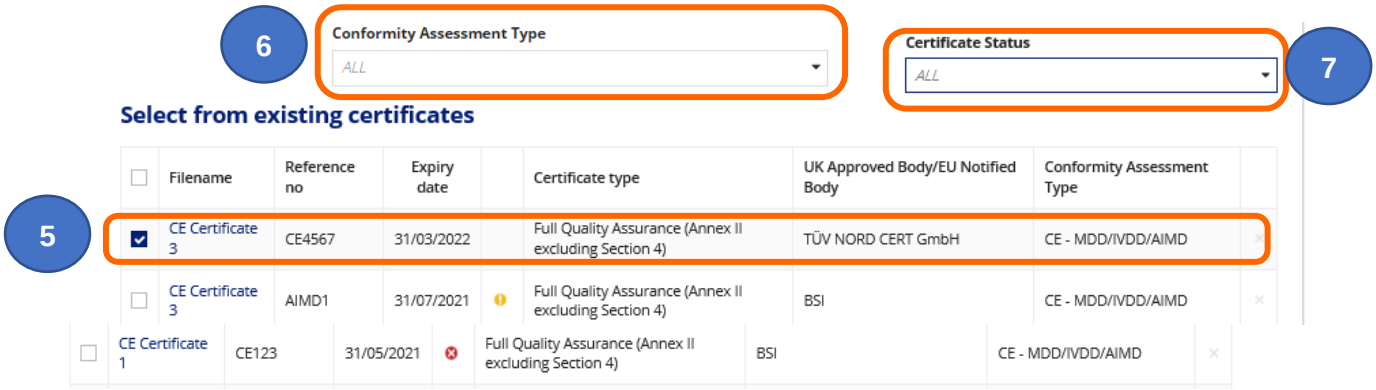


5. A table will appear on the page showing the uploaded Certificate, this will be pre-selected. Repeat the process to upload more Certificates as necessary for the device. As you upload more certificates, they will appear in the table for you to select from when you next add devices.

6. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

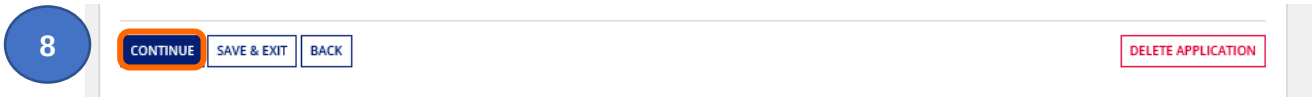
   UKCA – MDD/IVDD/AIMD
   CE (UK NI) – MDD/AIMD/IVDD
   CE (UK NI) – MDR/IVDR

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



8. **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.



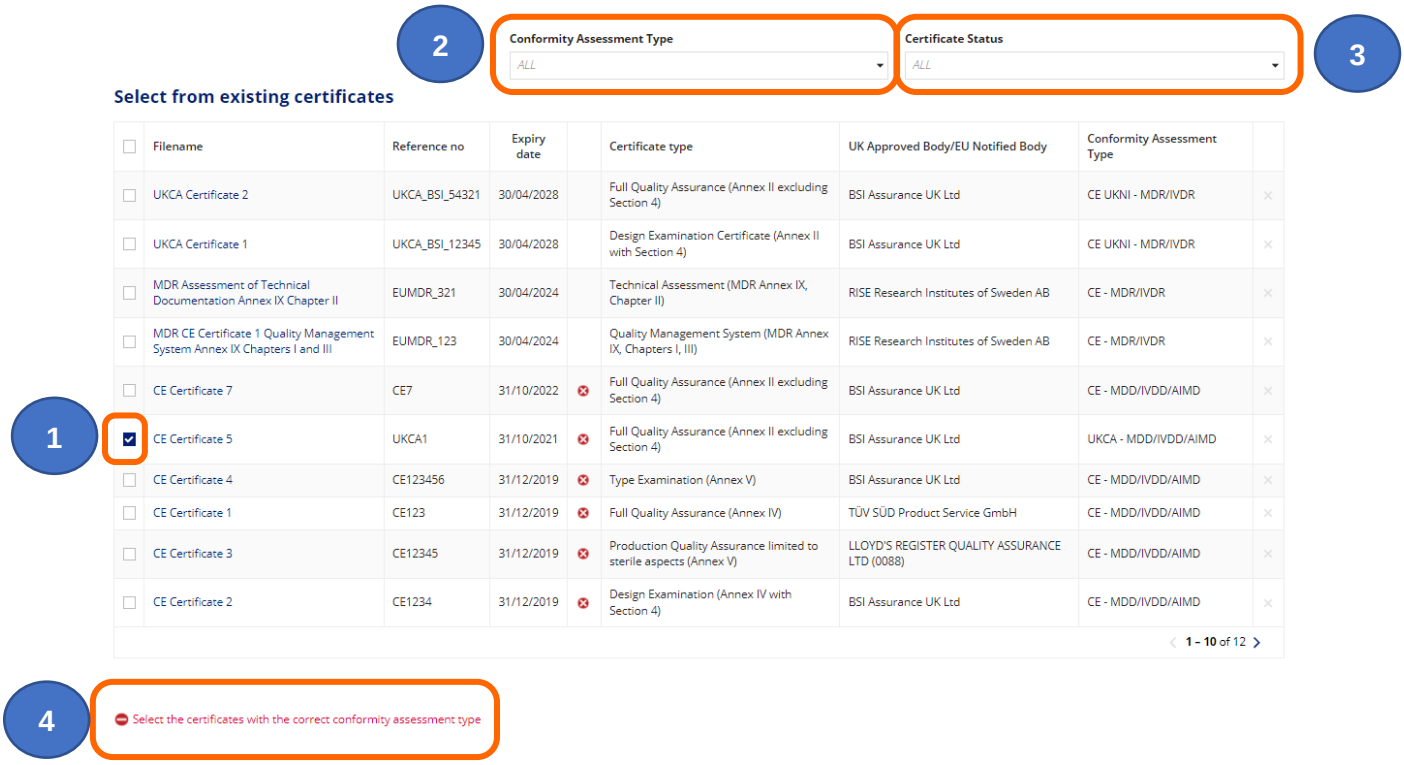
Select from existing Conformity Assessment Certificates

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 Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

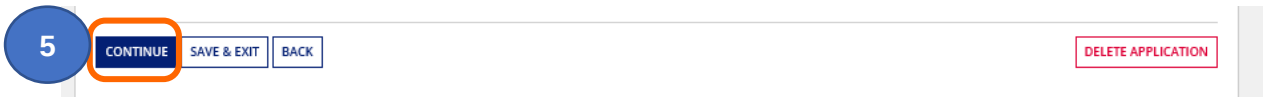
   UKCA – MDD/IVDD/AIMD
   CE (UK NI) – MDD/AIMD/IVDD
   CE (UK NI) – MDR/IVDR

3. You can filter by Certificate Status of All, Active and Expired. If you can't see the expired certificates under the 'All' filter, select 'Expired'.



4. If you have selected a certificate with incorrect Conformity Assessment Type a warning message will appear and the Continue button will not be enabled. If you have selected an expired certificate the Continue button will not be enabled .Unlink expired or incorrect Certificates and upload new ones or link device to an active/correct certificate.

5. **Click** the 'Continue' button or follow the Upload Conformity Assessment Certificate instructions to add another certificate.



Uploading expired CE certificates that are valid under EU MDR

See the latest guidance on our website, including a template to complete and upload at:

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-that-have-expiredexpiring-ce-certificates

and

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-which-are-eu-mdd-class-i-reusable-surgical-instruments-or-eu-mdd-class-i-medical-devices-upclassified-from-class-i

The guidance has intentionally not been included in this Reference Guide as this may change.

Please sign up for email updates by following the link on our webpage:

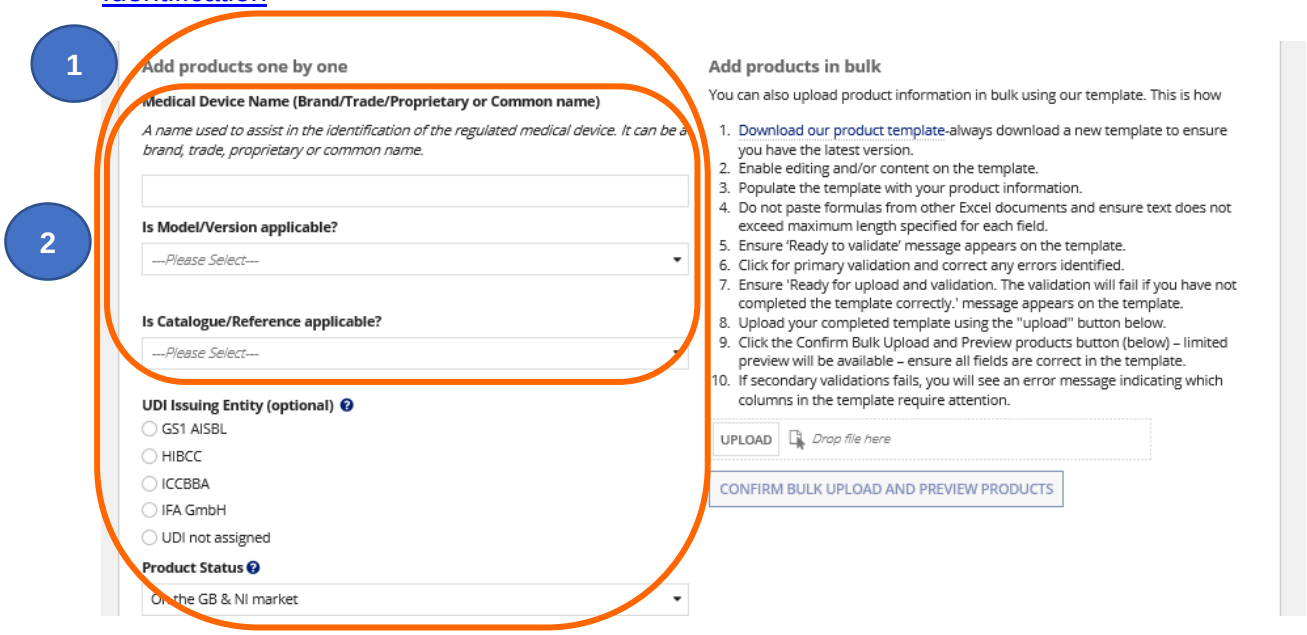
Adding products individually

1. **Add** the product details – this is the product-specific information including brand or trade name, model/version and/or catalogue/reference and UDI DI and DI data, where applicable.

   Please note:

   - Answer all the mandatory questions that appear. These will differ depending on the device type and legislation you have selected.
   - At least one product must be added per device group (GMDN® Code or Term).
   - Model/Version and Catalogue/Reference data cannot be the same. You must enter either Model/Version **or** Catalogue/Reference **or** both. You cannot select No for both fields.
   - We strongly recommend that you also populate all optional fields, where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.
   - UDI DI and DI data must be unique for each product and for each field within each product.

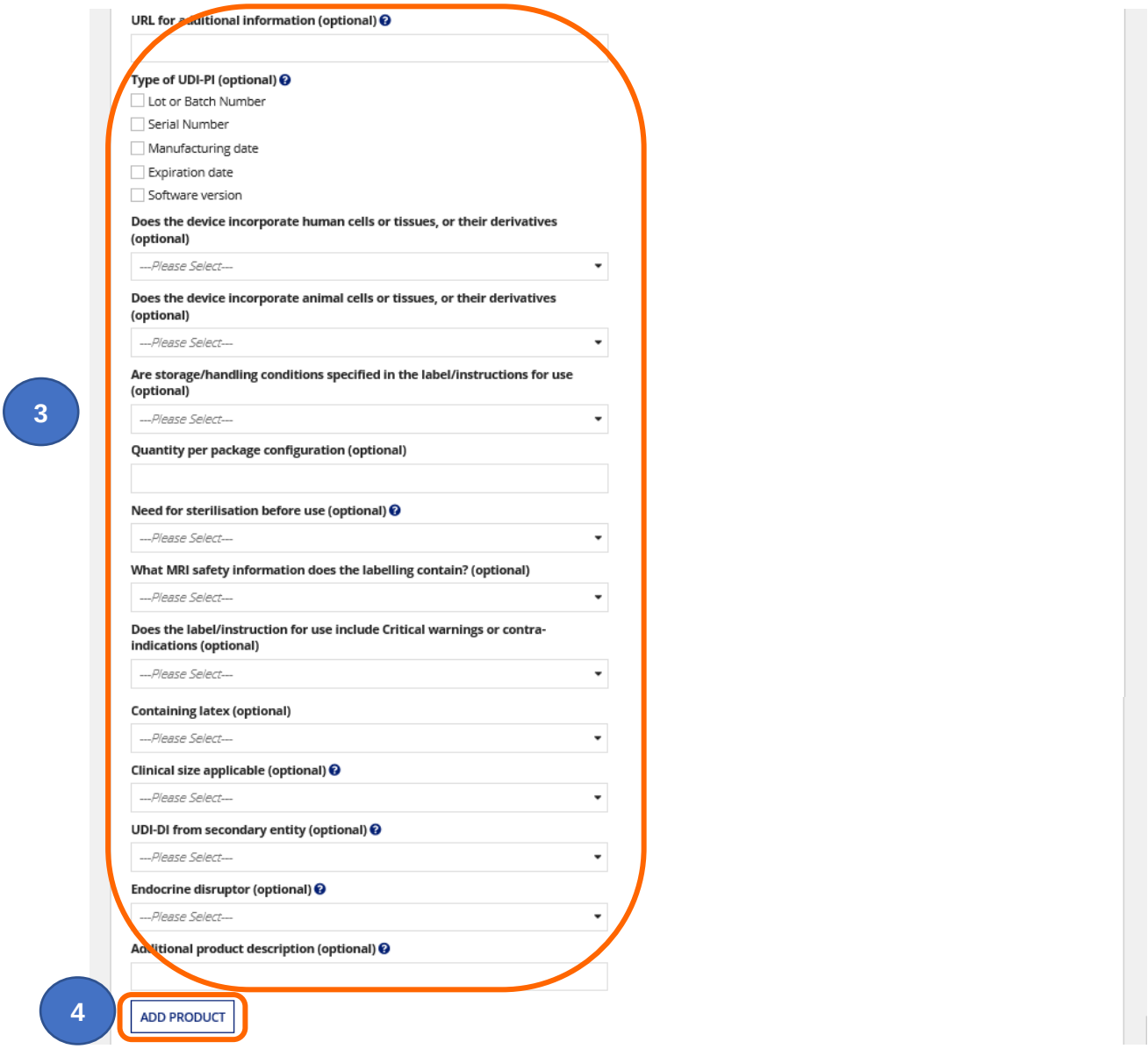
   Product information follows guidelines set by the International Medical Device Regulators Forum in their document Common Data Elements for Medical Device Identification



2. Certificates of Free Sale (CFS) customers, **please note**:

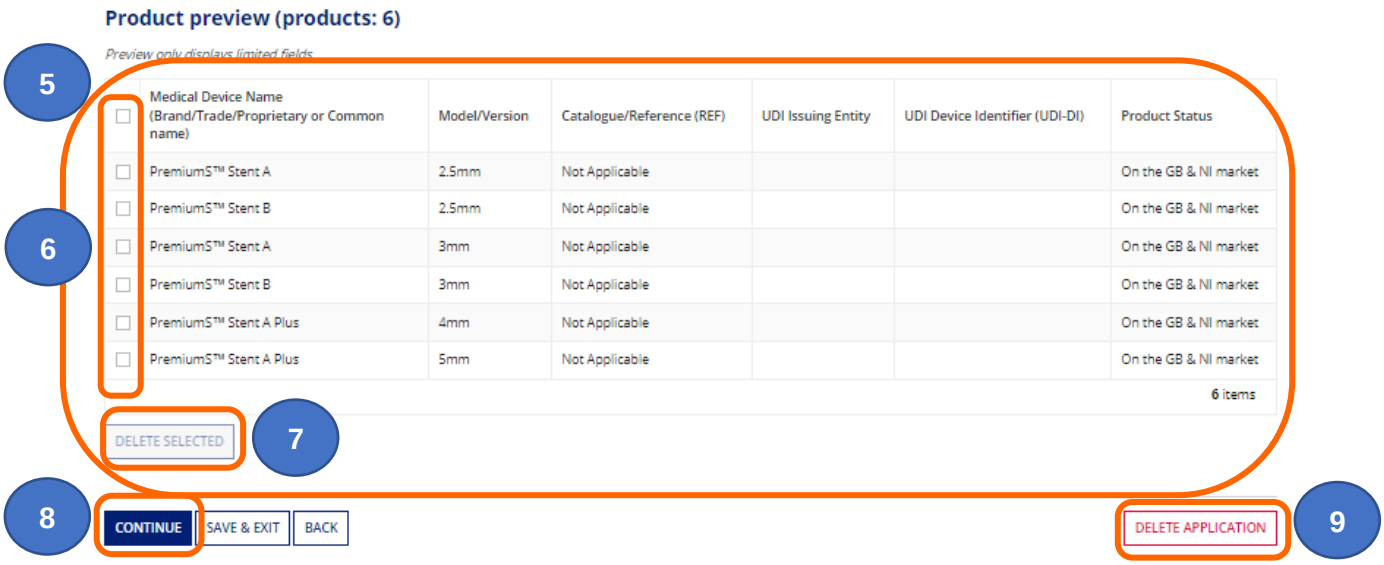
   Only the data you enter in the Medical Device Name, Model/Version, Catalogue/Reference, Basic UDI DI and Conformity Assessment Certificate Reference fields will appear on the CFS certificate or schedule.

3. Continue populating the fields on the screen. We recommend that you also populate all optional fields, where possible. This cannot be done in bulk at a later stage.



4. Once you have answered, at minimum, all the mandatory questions, **click** the Add Product button – if you don't your data won't be saved.

5. The Product preveiw table will appear at the bottom of the page with limited details. To add more products individually go to the top of the page and repeat the process. If you have many products to add, consider adding products in bulk, using a template



6. If you wish to remove a product you have just added, **tick** the box next to the Product Status in the Product Preview table at the bottom of the screen.

7. **Click** Delete Selected to remove the products.

   Please note you must add at least one product to enable the Continue button.

8. Once you have added all your products**, click** the Continue button to proceed.

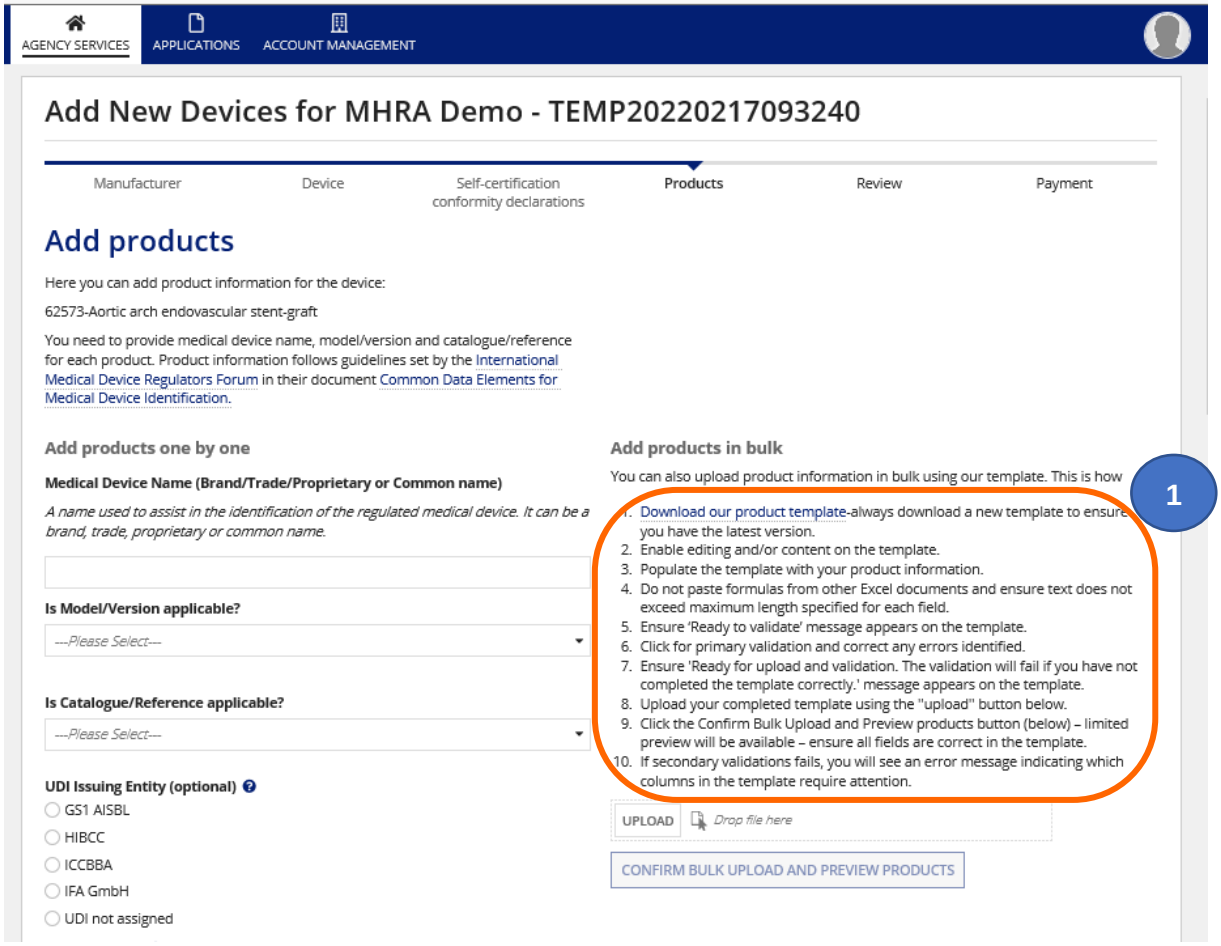
9. If you Delete Application, **all** devices in the application will be deleted.

Add products in bulk – product template

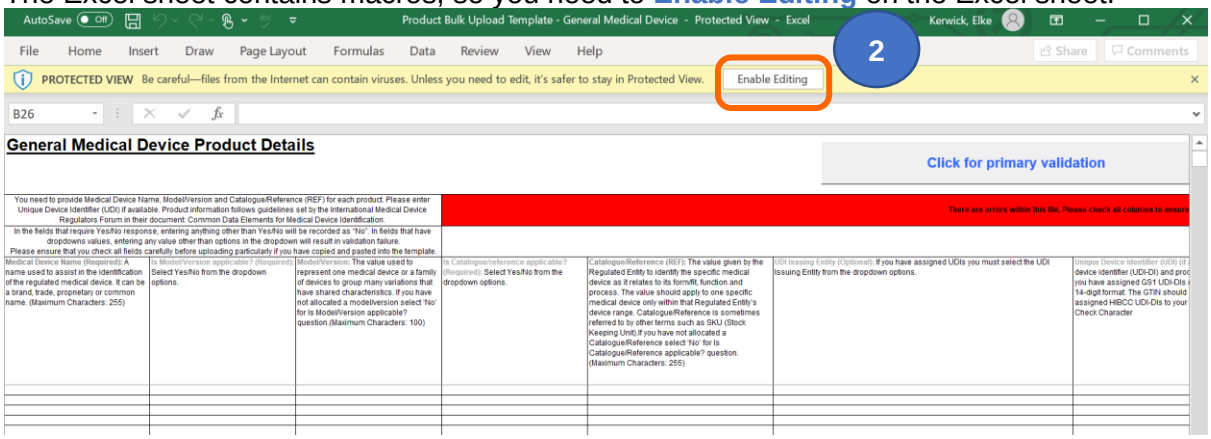
You can add multiple products (model/version detail, catalogue/reference, UDI DI and DI data etc.) for a device using the product template.

Please note that uploading a template will clear all products previously added to this GMDN® in this application. Products uploaded in bulk will append to products previously accepted by MHRA.

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

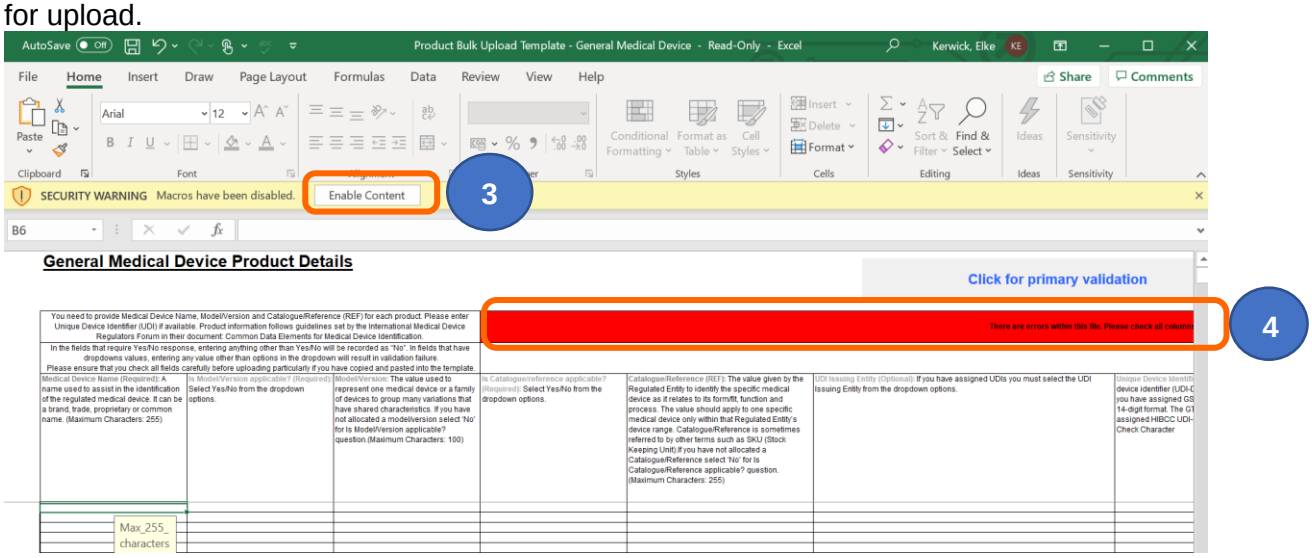


2. The Excel sheet contains macros, so you need to **Enable Editing** on the Excel sheet.



3. **Enable Content** before you complete and **save** the template on your system.

The red warning box will appear at the top of the template indicating that it is not ready for upload.



4. **Key points to note when completing template:**

The red warning box will appear at the top of the template indicating that it is not ready for upload until you have populated, at minimum, all mandatory fields. Please read the important information in the headers of each column.

- You need to use a separate template for each device (GMDN® Code or Term).
- The templates are different and depend on the device type. You must use the correct template for the device type.
- One row per product when completing product template.
- Model/Version and Catalogue/Reference data cannot be the same. You must enter either Model/Version **or** Catalogue/Reference **or** both. You cannot select No for both fields.
- We strongly recommend that you also populate all optional fields, where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.
- UDI DI and DI data must be unique for each product and for each field within each product, with the exception of Unit of Use UDI DI – see below.
- We are aware that Unit of Use UDI DI can be same across multiple products, however the bulk upload template does not curently permit this. You can omit the Unit of Use UDI DI from the template and then add the duplicated Unit of Use UDI DI by using the Update Registered Devcies and Products function. We are working to resolve this issue on the template.
- Note the maximum characters for each field.
- Where dropdown options exist, select from the dropdown – do not paste data into these fields as secondary validation will fail.

- 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 to registered devices.

- Use the "Paste Values" option in Excel if you need to copy product information from another spreadsheet into the bulk upload template.

- 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.

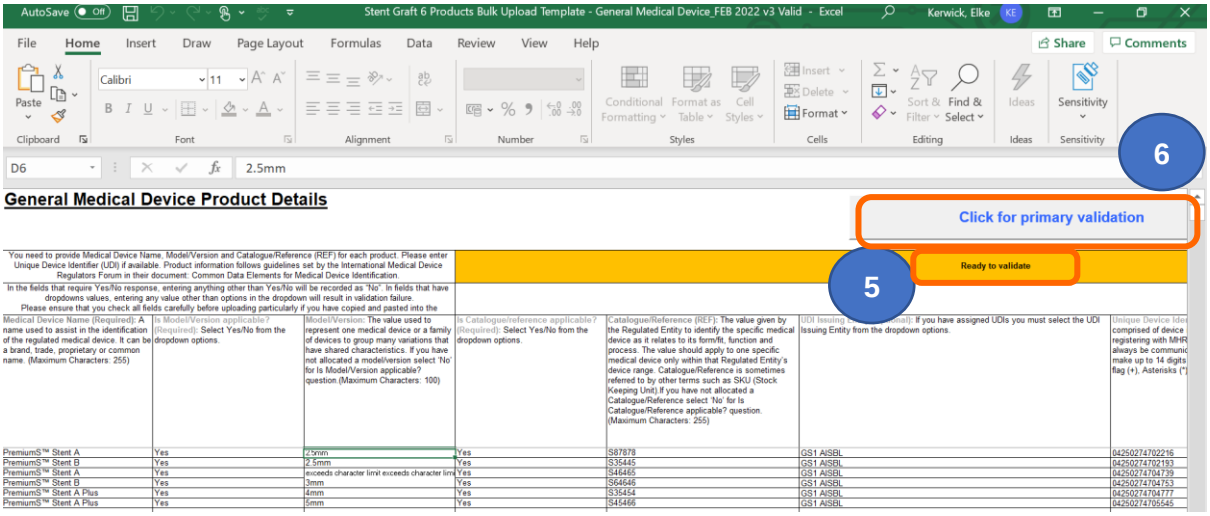
- You must complete all the mandatory fields until the red box at the top of the template turns amber and states '**Ready to Validate**.

- We strongly recommend that you also populate all optional fields where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.

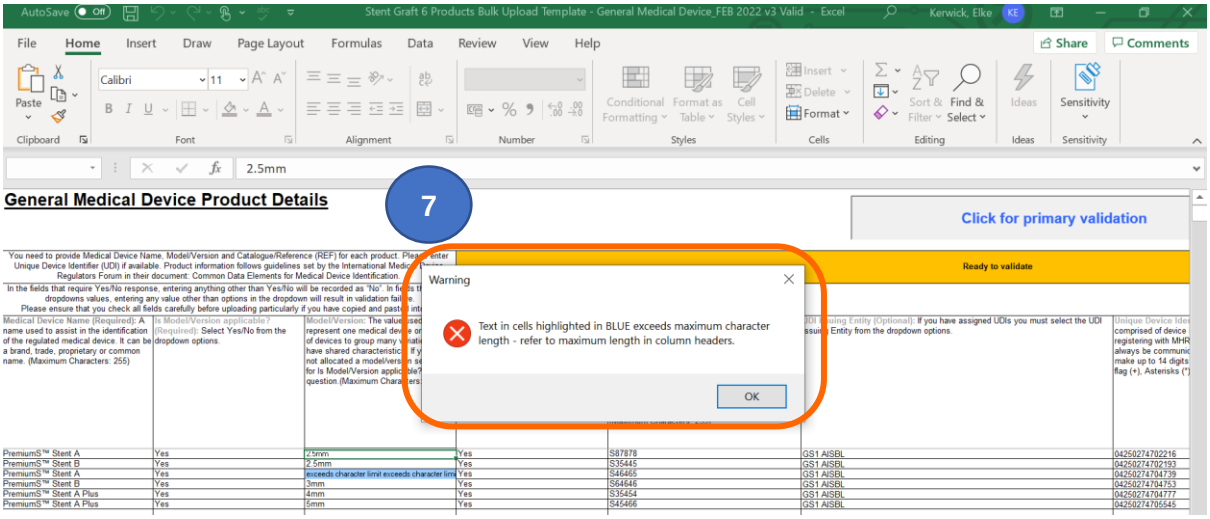
- Certificates of Free Sale (CFS) customers, **please note**:
  only the product information you enter in the first three columns of the template (Medical Device Name, Model/Version and/or Catalogue/Reference) will appear on the CFS certificate or schedule.

5. Ensure that the red warning red box at the top of the template has turned amber and states '**Ready to Validate'**.

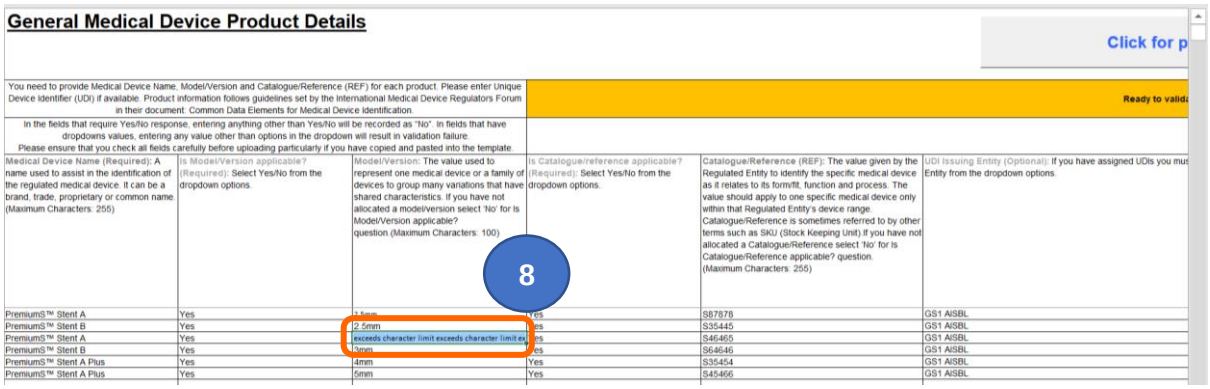
6. Click for primary validation



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

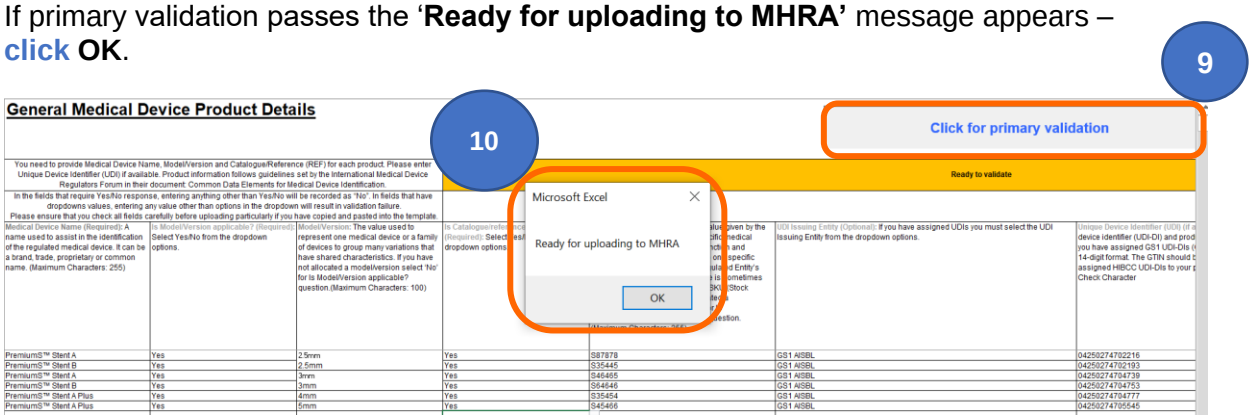


8. **Locate** the cells highlighted in blue on the template and amend the text.



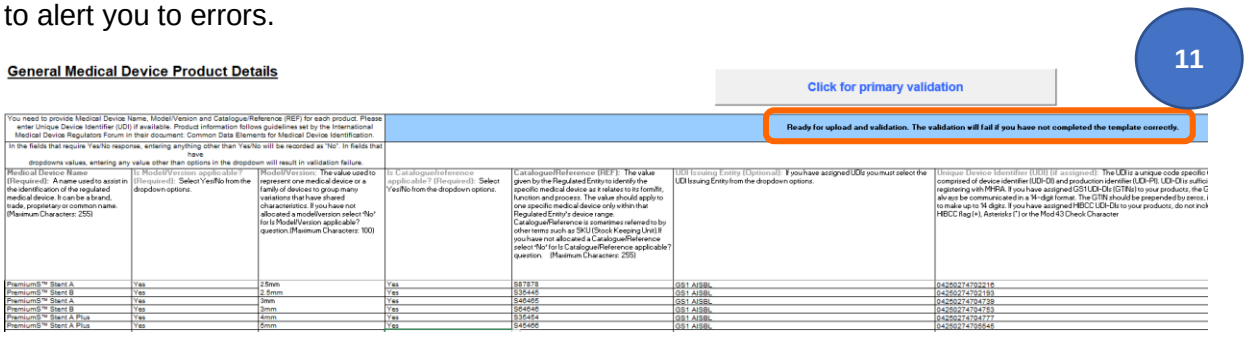
9. **Click for primary validation** again.

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

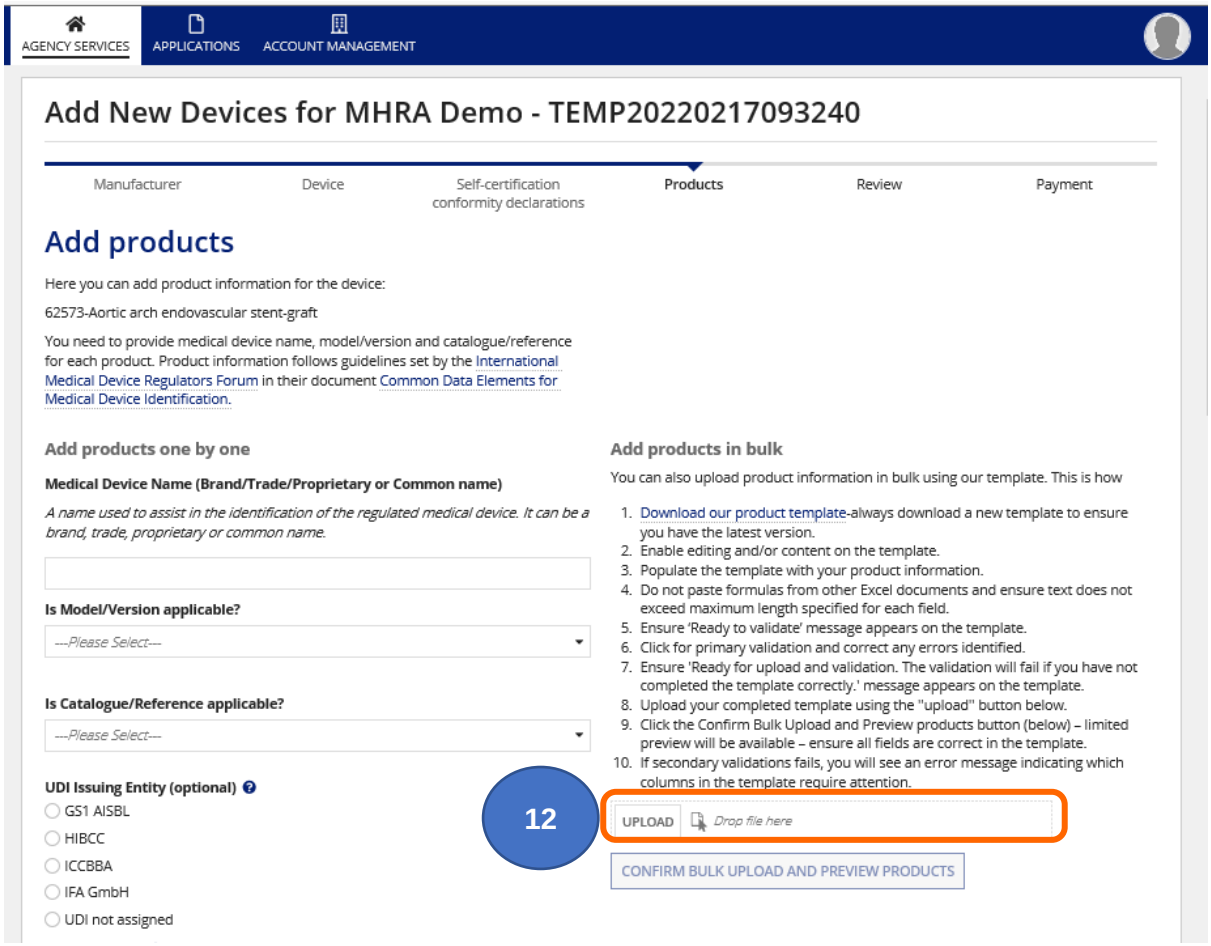


11. The '**Ready for upload and validation'** message appears in the blue box. **Save** the document. If you don't save it before uploading secondary validation will fail.

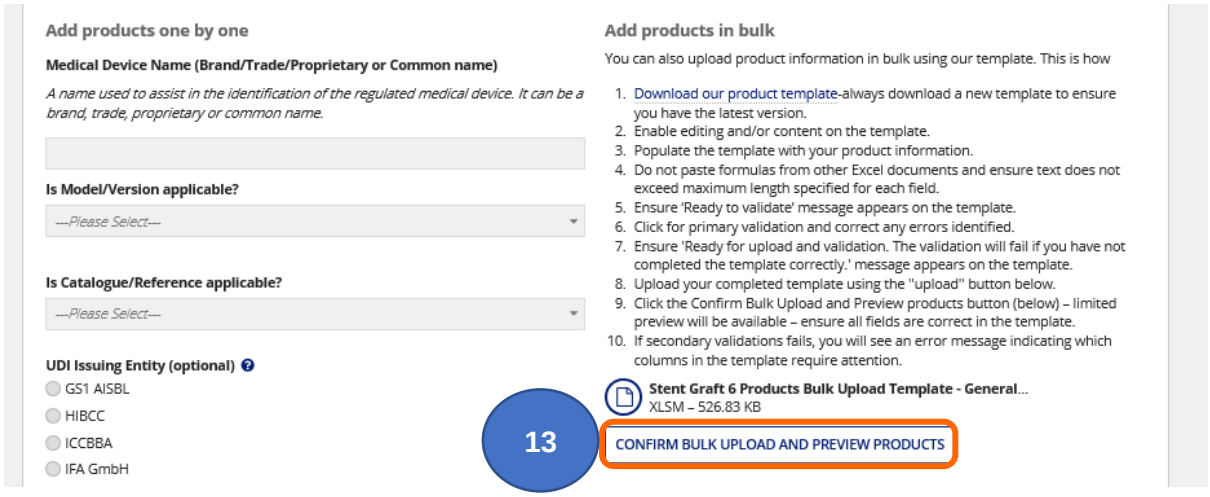
Please note that it is possible for the template to be '**Ready for upload and validation'** but still contain errors, for example if you have pasted data in dropdown fields. We can't stop this happening in Excel, so we have introduced secondary validation in the system to alert you to errors.



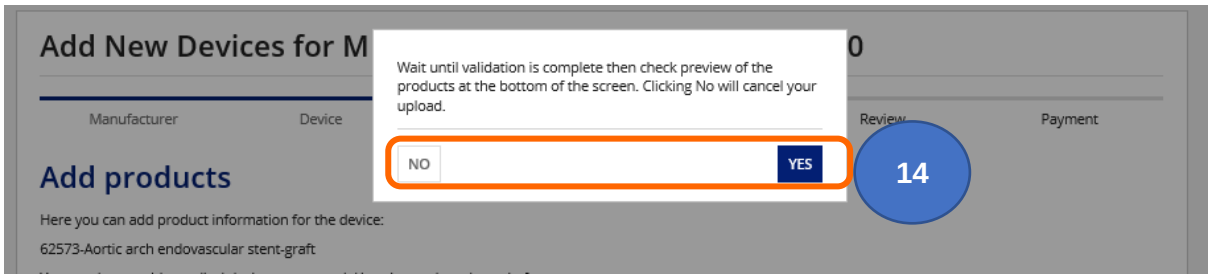
12. Upload the completed template on the Product screen. **Click** the Upload button and select the completed template from your system.



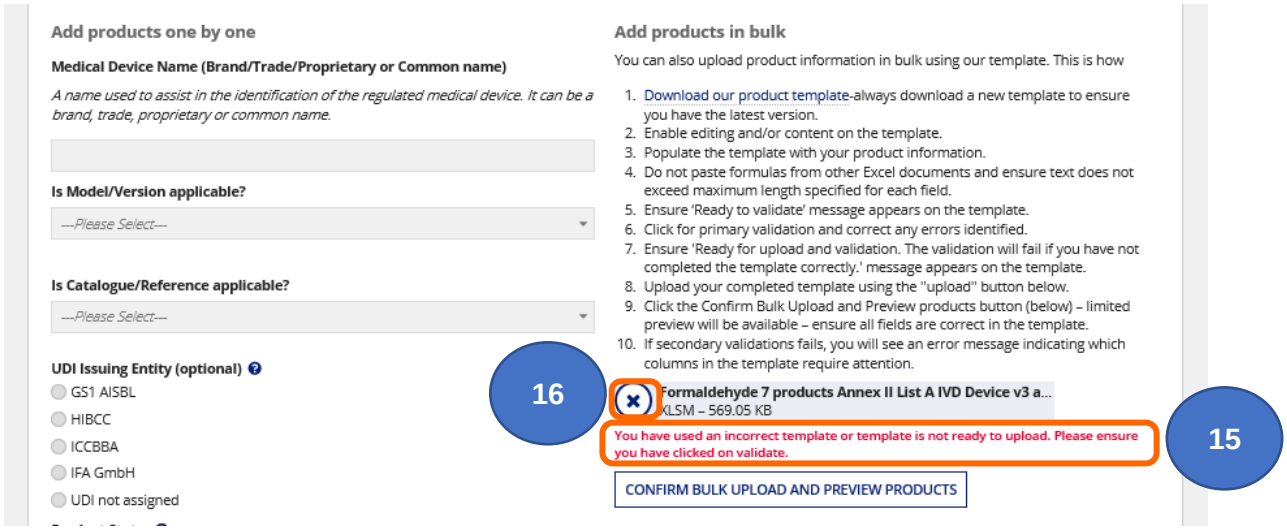
13. Click the Confirm bulk upload and preview products button.



14. The confirmation box will appear, **click** Yes to continue and wait for secondary validation to complete or No to cancel the upload.



15. If you have uploaded an incorrect template (e.g. wrong device type), invalid template (e.g. previous version), not completed all mandatory fields, not **Clicked for primary validation** or **saved** the template before uploading, you will see an error message.



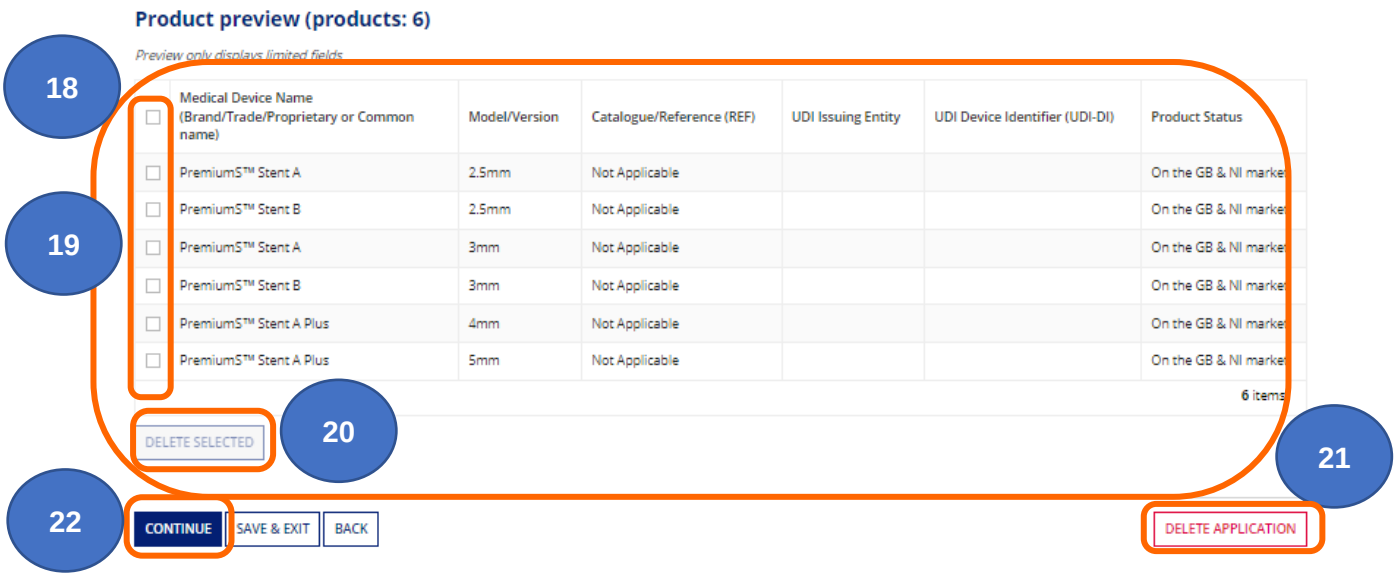
16. If the template has failed secondary validation:

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

b) Select the correct template or make any necessary amendments to the bulk upload template, **click for primary validation**, **save** it and **upload** again.

17. If the template has passed secondary validation in the system, you will see the **Validation Complete** message.

18. The products will be visible in the Preview table at the bottom of the screen.



19. If you wish to remove a product you have just added, **tick** the box next to the Product Status in the Product Preview table at the bottom of the screen.

20. Click Delete Selected to remove the products.

Please note you must add at least one product to enable the Continue button.

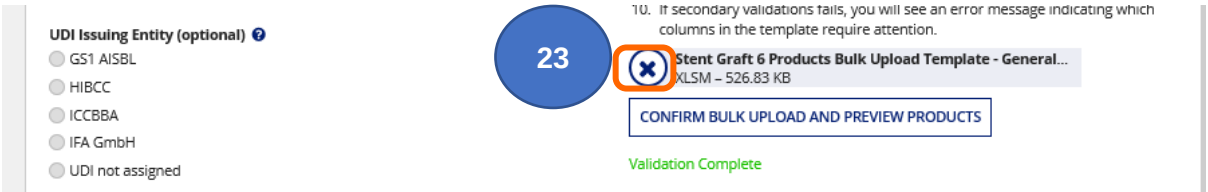
21. If you Delete Application, **all** devices in the application will be deleted.

22. Once you have added all your products**, click** the Continue button to proceed.

23. If the products do not preview correctly or you have uploaded an incorrect template:

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

b) Make any make any necessary amendments to the bulk upload template, **click for primary validation**, **save** it and **upload** again.



24. 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. Clicking the Delete Application button will delete **all** devices in the application.

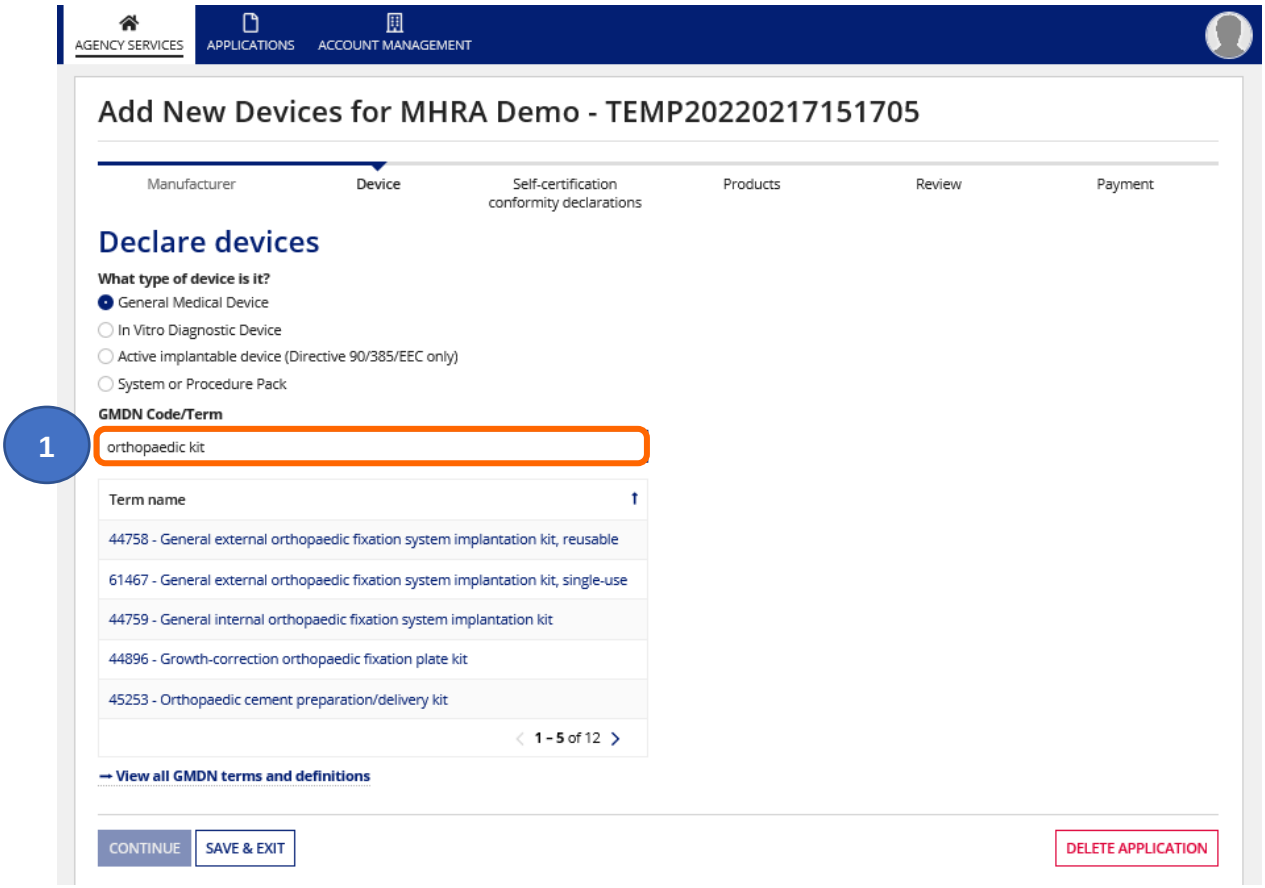
Adding System or Procedure Packs (SPP)

1. Enter the GMDN® Code if you know it or search using multiple words.

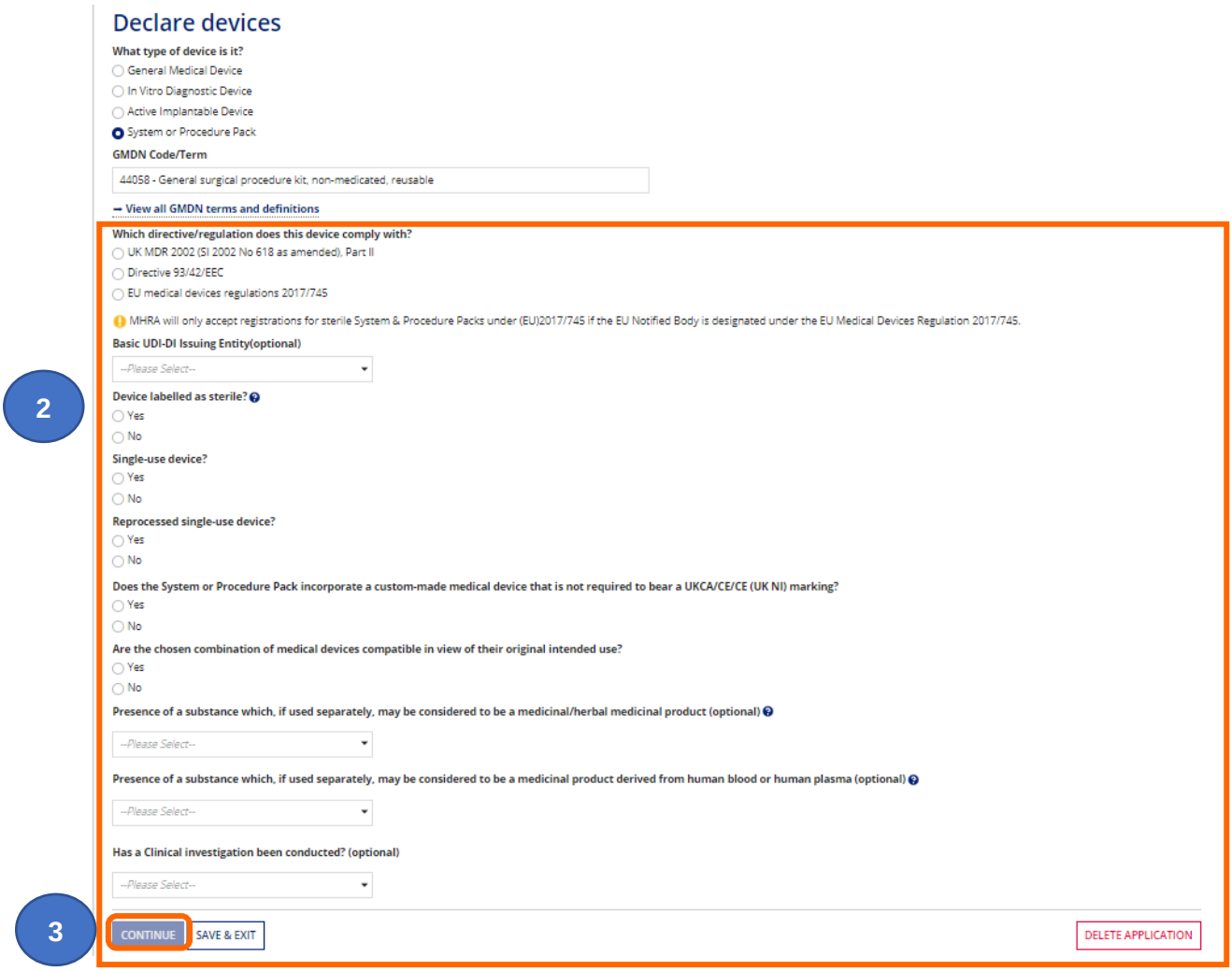
   System or Procedure Packs (SPP) Terms can often be found by **searching** GMDN® Code/Term box with the word 'Kit'.

   Assemblers should search for an appropriate term e.g. 'Spectacles', if you don't know the GMDN® Code.

   MHRA cannot advise you on which GMDN® Code or Term to select for your device.



2. **Answer** the mandatory questions on the page. We strongly recommend that you also populate all optional fields, where possible.

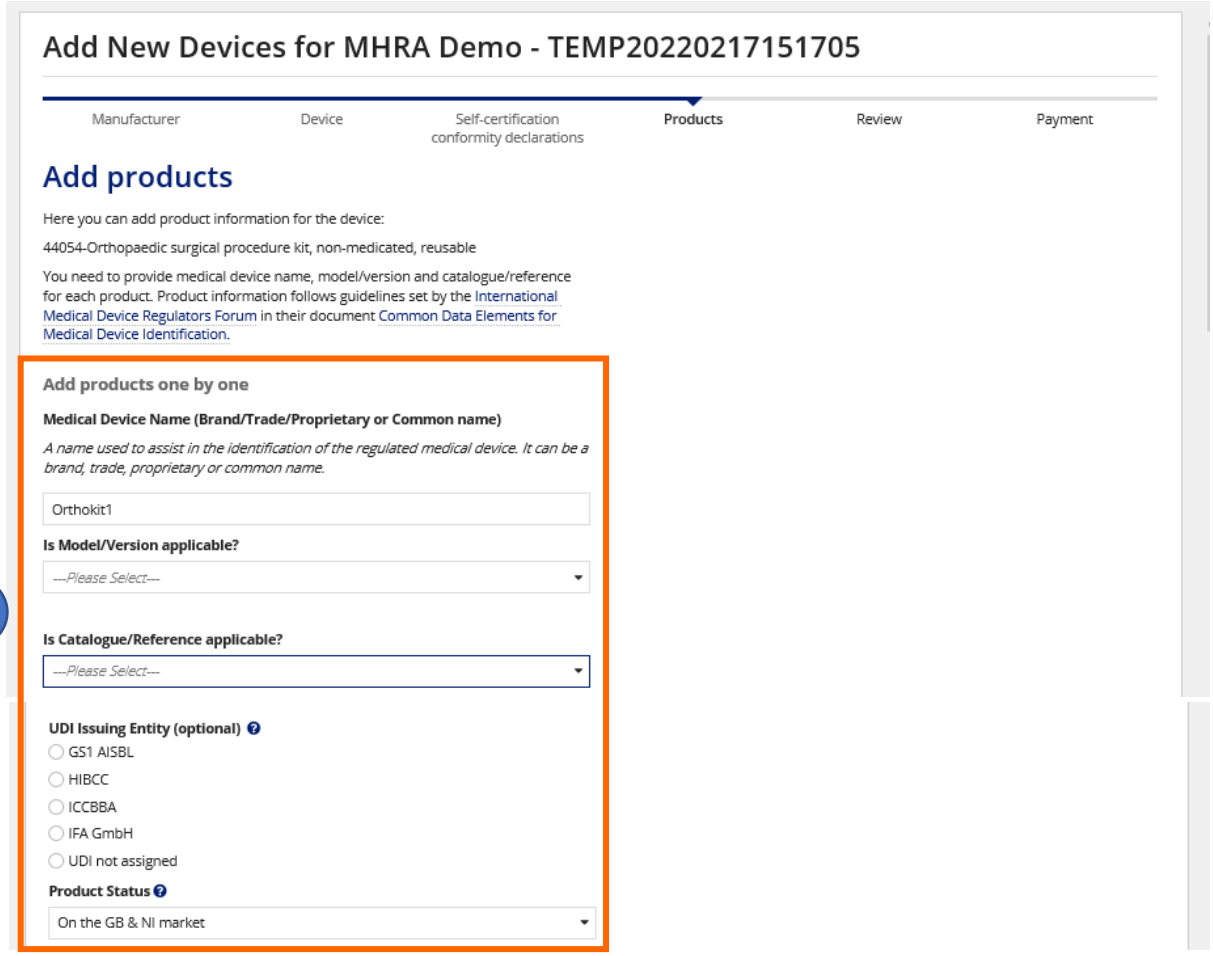


3. **Click** the Continue button, this will not be enabled until you have answered all mandatory questions.

   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).

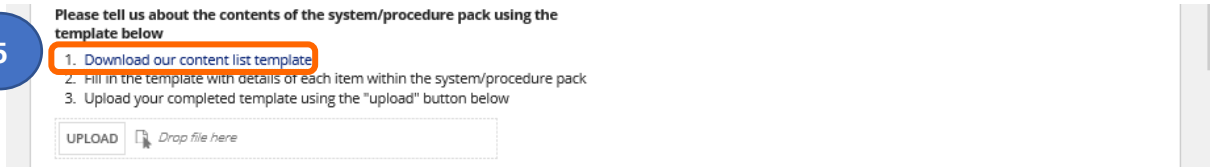
4. Once you have uploaded or linked to an existing document **Enter** the product details, this is the brand or trade name, model/version, catalogue/reference and other details.

   - You need to add a minimum of one product per SPP (GMDN® Term).
   - You must enter either a Model/Version or a Catalogue/Reference or both. Model/Version and Catalogue/Reference data cannot be the same. You cannot select No for both fields.
   - There is no bulk product upload function for SPPs.
   - Answer all the mandatory questions
   - We strongly recommend that you also populate all optional fields, where possible, as updating fields at a later stage cannot be done in bulk.



4

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



5

- One row per product.
- At least 2 products (contents) must be entered otherwise the template will not upload
- The size of the contents list file must be minimum 36KB, if it is less than this enter 'Contents may vary' in the line/s under last product until file size is 36KB.
- 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 manufacture these devices and place them individually on the UK market.
- You need to use a separate contents list template for each product (Medical Device name and Model/Version, Catalogue/reference etc.).

Please note if you have multiple products covered by a single GMDN® and these include a combination of similar products please add one product and upload one SPP content list that covers all possible contents of 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.

5

Systems and Procedure Packs Content List

You will need to provide Medical Device Name for each product within the System or Procedure Pack. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: Common Data Elements for Medical Device Identification. Model and Catalog/Reference (REF) are optional for this list.

Medical Device Name (required): A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.	**Model (optional):** The value used to represent one medical device or a family of devices to group many variations that have shared characteristics.	**Catalog/Reference (REF)(optional):** The value given by the regulated entity to identify the specific medical device as it relates to its form, fit, function and process.
ARTERY FORCEP CURVED	Model 001	SKU 001
ARTERY FORCEPS STRAIGHT 1-2 TEETH	Model 002	SKU 002
BLOCK END DISSECTING FORCEP	Model 003	SKU 003
BONE CUTTER	Model 004	SKU 004
BONE ELEVATOR	Model 005	SKU 005
BONE HOOK	Model 006	SKU 006
BONE LEVER	Model 007	SKU 007
CURETTE DOUBLE ENDED	Model 008	SKU 008
DIATHERMY DISSECTING FORCEPS	Model 009	SKU 009
DIATHERMY LEADS	Model 010	SKU 010
Contents may vary but are available on request		

6. **Upload** the completed template. **Click** the Upload button and select the saved template from your system.

6

Please tell us about the contents of the system/procedure pack using the template below

1. Download our content list template
2. Fill in the template with details of each item within the system/procedure pack
3. Upload your completed template using the "upload" button below

UPLOAD *Drop file here*

7. Continue answering all the mandatory questions. We strongly recommend that you also populate all optional fields, where possible, as updating fields at a later stage cannot be done in bulk:

7

URL for additional information (optional)

Type of UDI-PI (optional)

- Lot or Batch Number
- Serial Number
- Manufacturing date
- Expiration date
- Software version

Does the device incorporate human cells or tissues, or their derivatives (optional)

---Please Select---

Does the device incorporate animal cells or tissues, or their derivatives (optional)

---Please Select---

Are storage/handling conditions specified in the label/instructions for use (optional)

---Please Select---

Quantity per package configuration (optional)

Need for sterilisation before use (optional)

---Please Select---

What MRI safety information does the labelling contain? (optional)

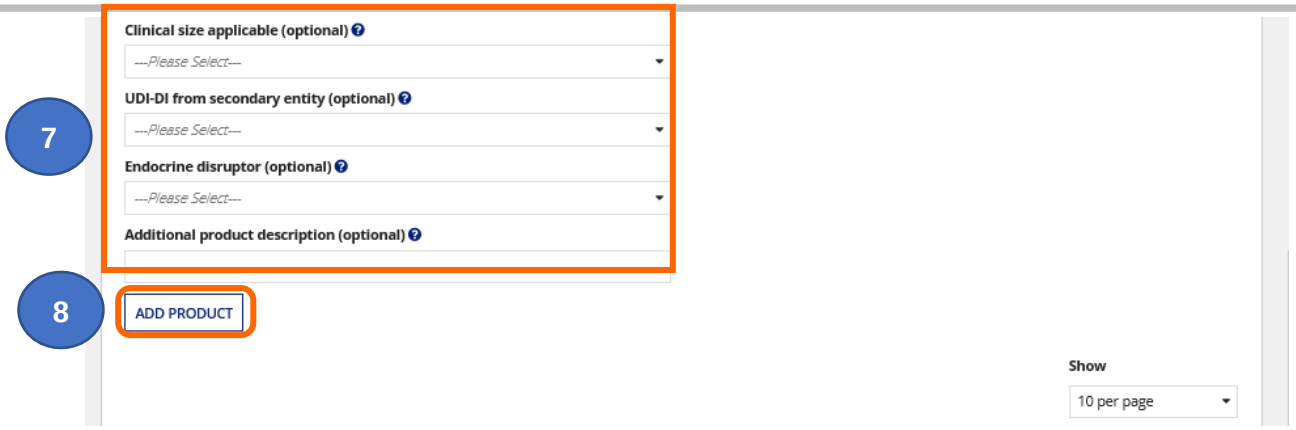
---Please Select---

Does the label/instruction for use include Critical warnings or contra-indications (optional)

---Please Select---

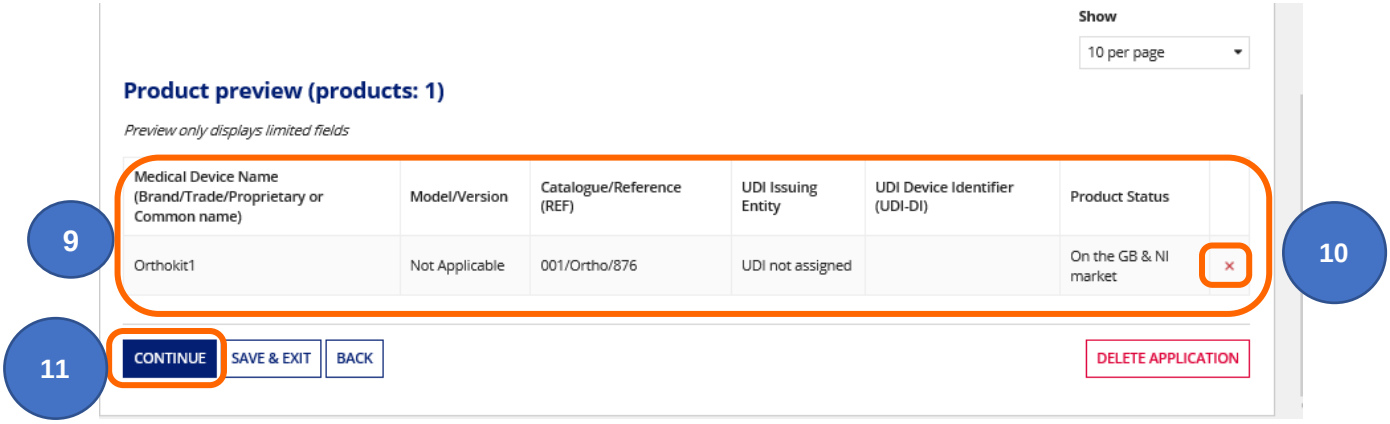
Containing latex (optional)

---Please Select---



8. **Click** the Add Product button – if you don't your product won't be saved. Repeat the process from the top of the Add Products page to add more products.

9. **Preview** the product/s you have added in the Preview table. Only limited fields display.



10. If you wish to remove any of the products **click** the red **X** to remove. The Continue button will not be enabled until you have added at least one product.

11. **Click** the Continue button to proceed to the Review page.

Review information prior to making payment

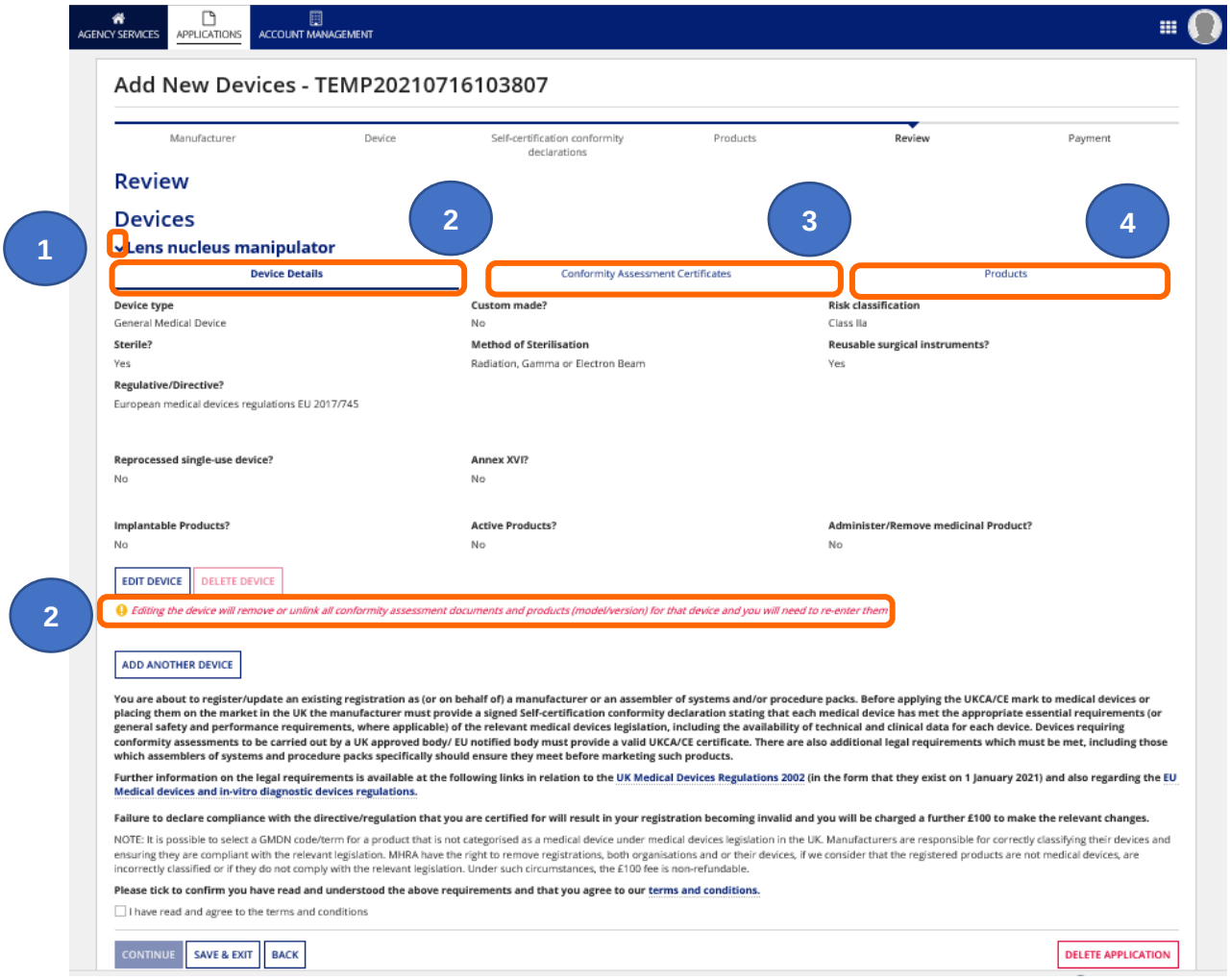
Please **review** all information prior to making payment. Once payment has been made applications are non-refundable. See our Terms and Conditions.

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. Confomity Assessment Certificates/Self-certification Conformity Declarations
   These can be amended before submitting application.

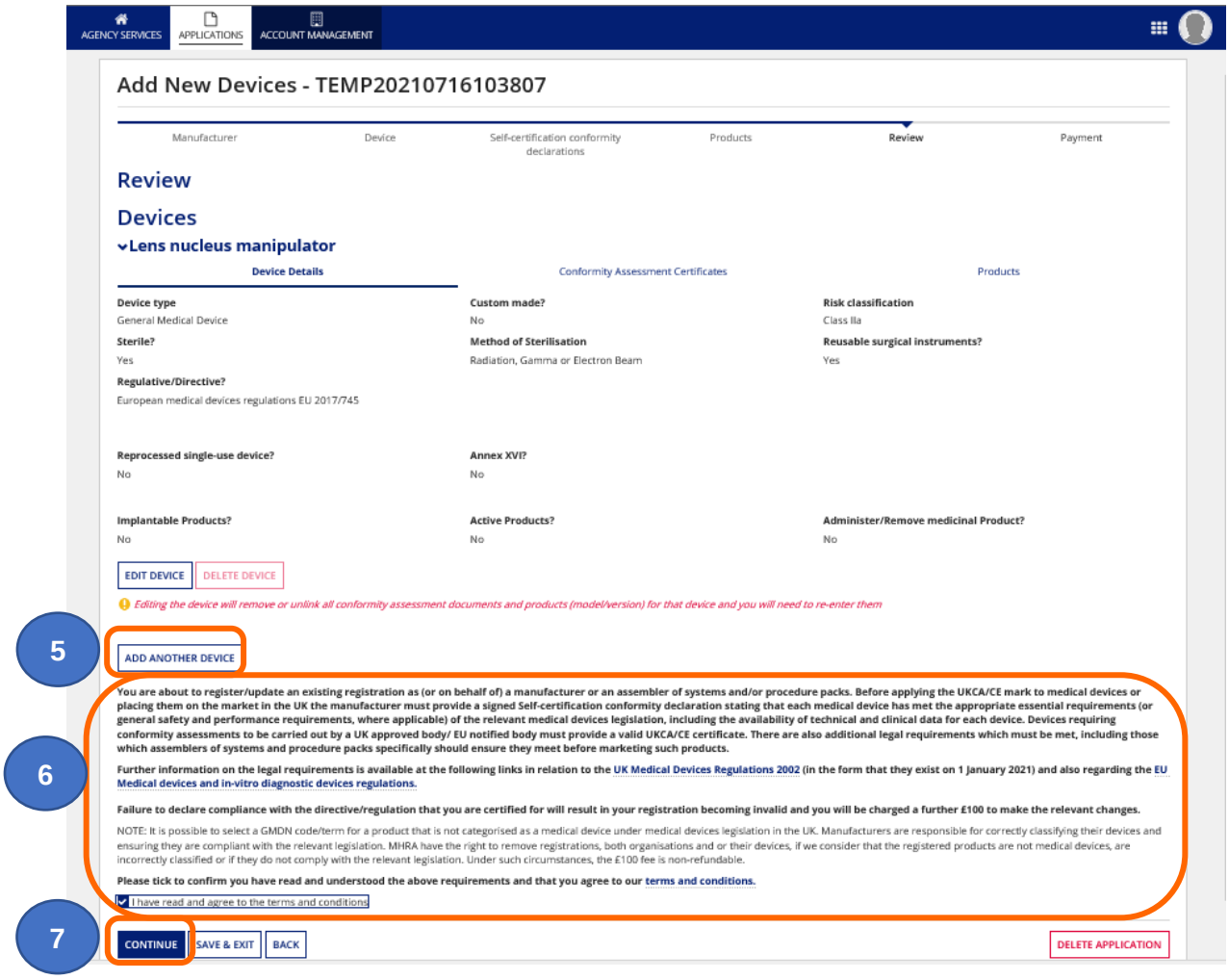
4. Products
   Products can be added or removed before submitting application. Follow the Adding products individually and Adding products in bulk instructions – these also include instructions on removing products from an application.



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 (brand or trade name, model/version and catalogue/reference details etc.).

   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 accepted 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.

   Important note: Fee in screenshot is for illustrative purposes only. Check current statutory fees on our website.



6. Please **read** 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.

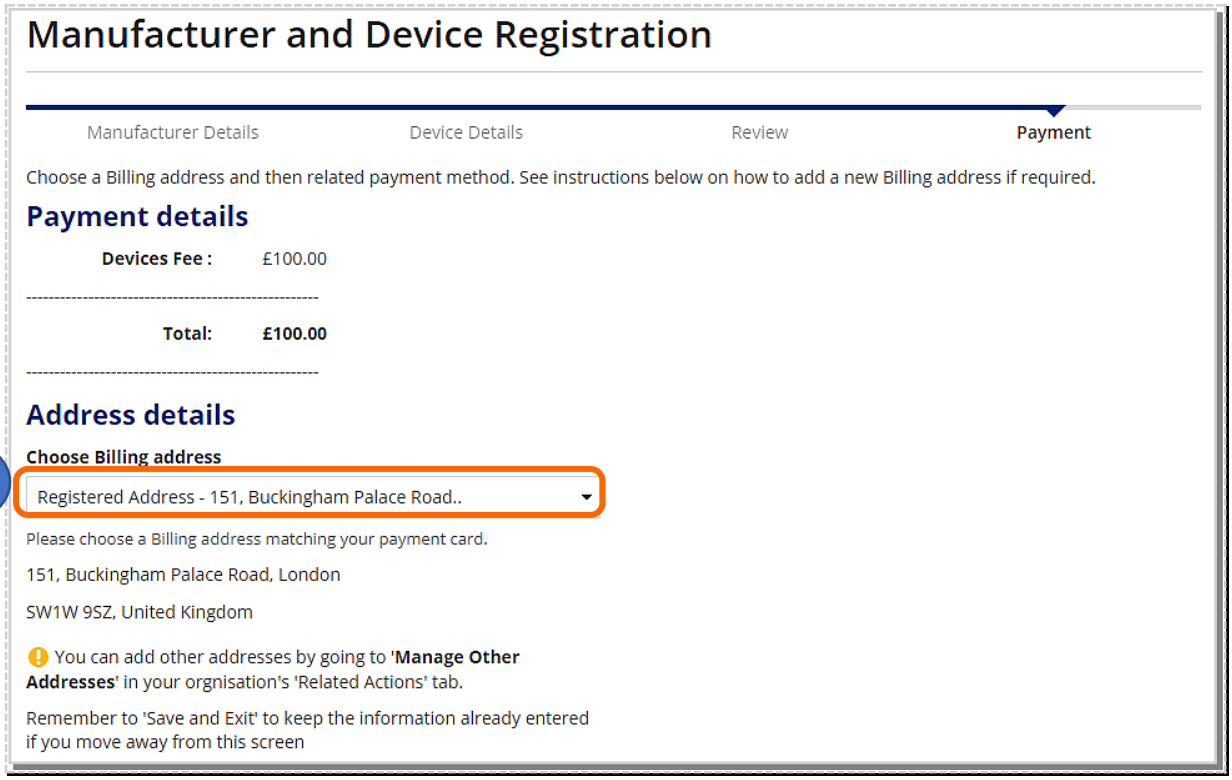
Making Payments

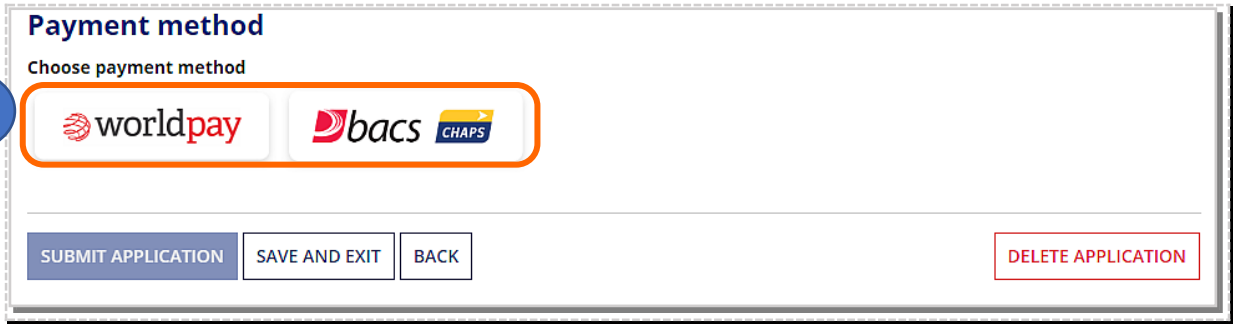
1. Choose billing address.

   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.

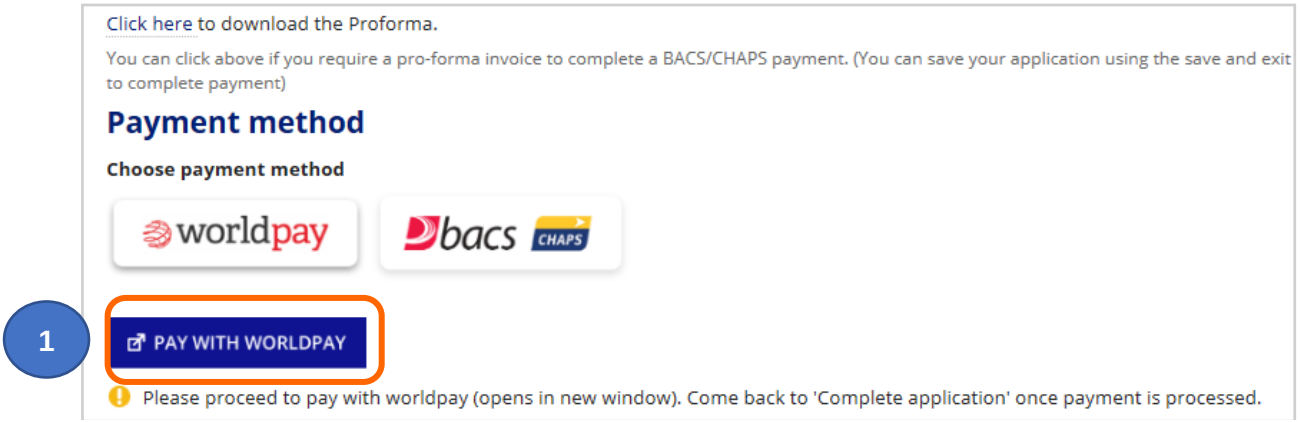
   Important note: Fee in screenshot is for illustrative purposes only. Check current statutory fees on our website.



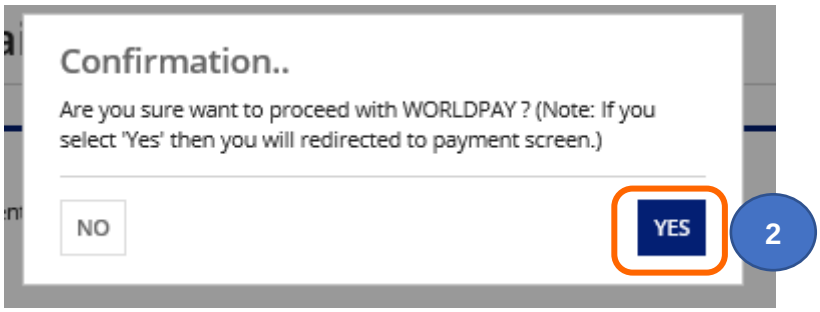


Paying with worldpay

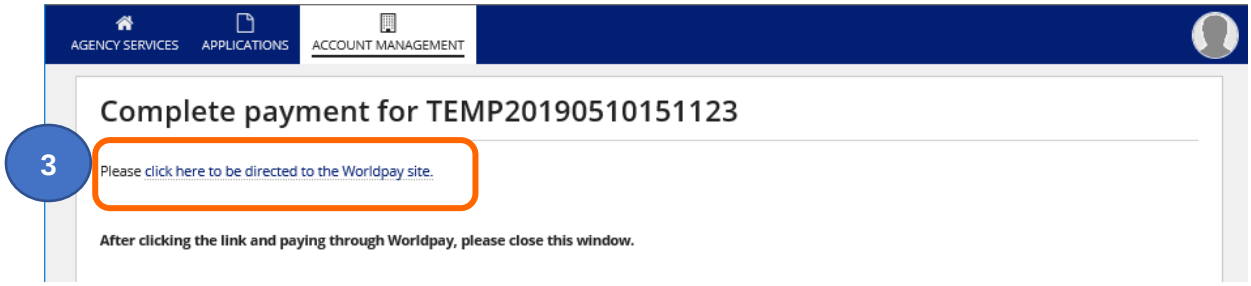
1. **Click** on the Pay with worldpay button.



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.

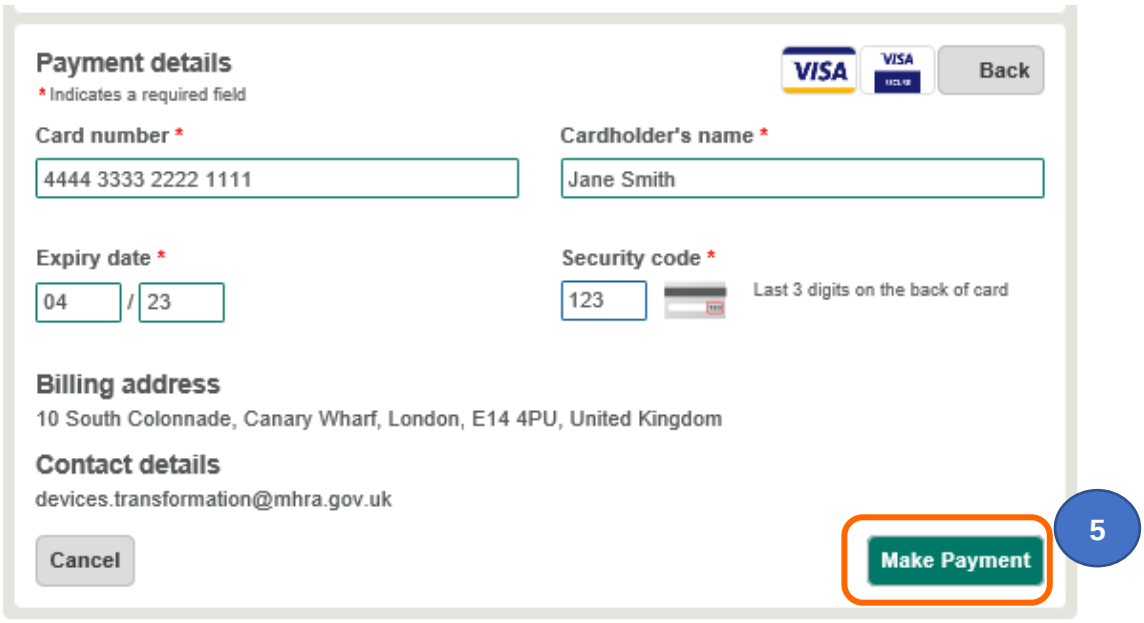


4. **Select** the payment method.

Important note: Fee in screenshot is for illustrative purposes only. Check current statutory fees on our website.

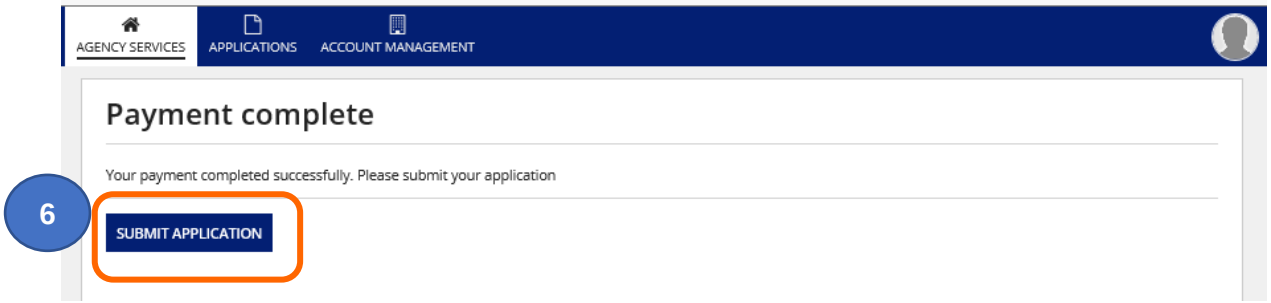
4

5. Enter payment details and **click** the Make payment button.

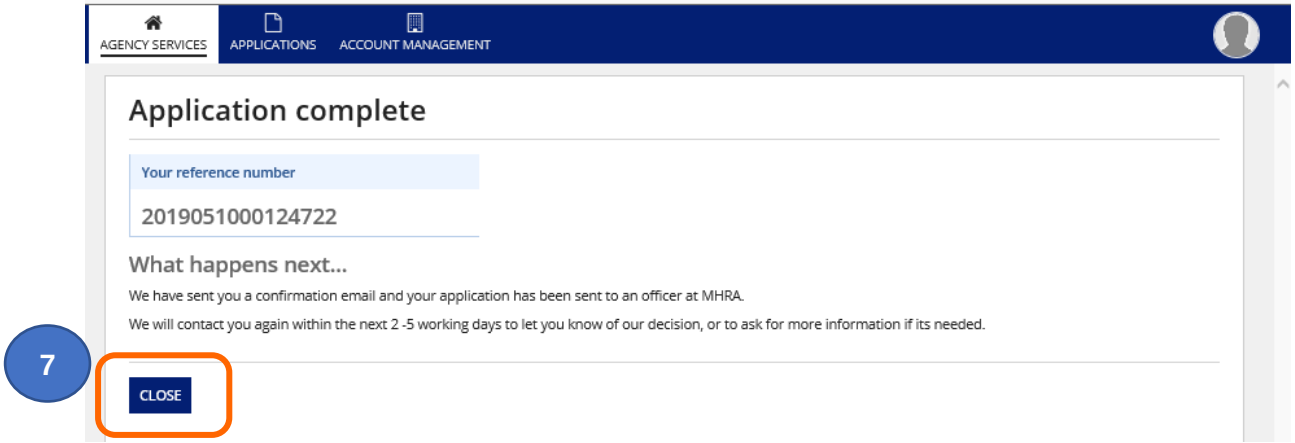


5

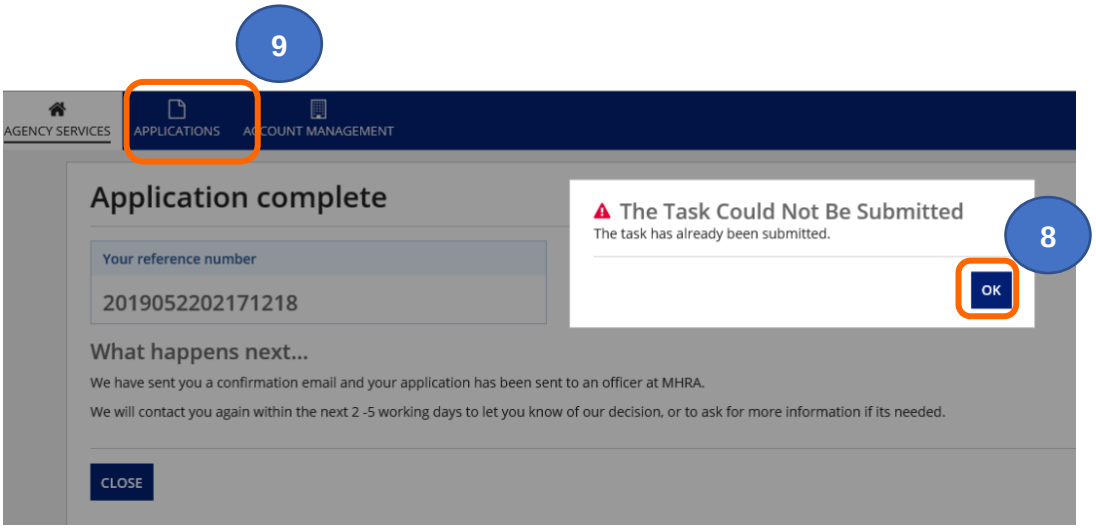
6. **Click** the Submit Aplication button. If you do not click this button (and your payment was successful) the TEMP application will remain in the Applications Tab and you will need to wait at least **24 hours** for the application to be auto-submitted to MHRA. Please ensure that you click Submit Application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

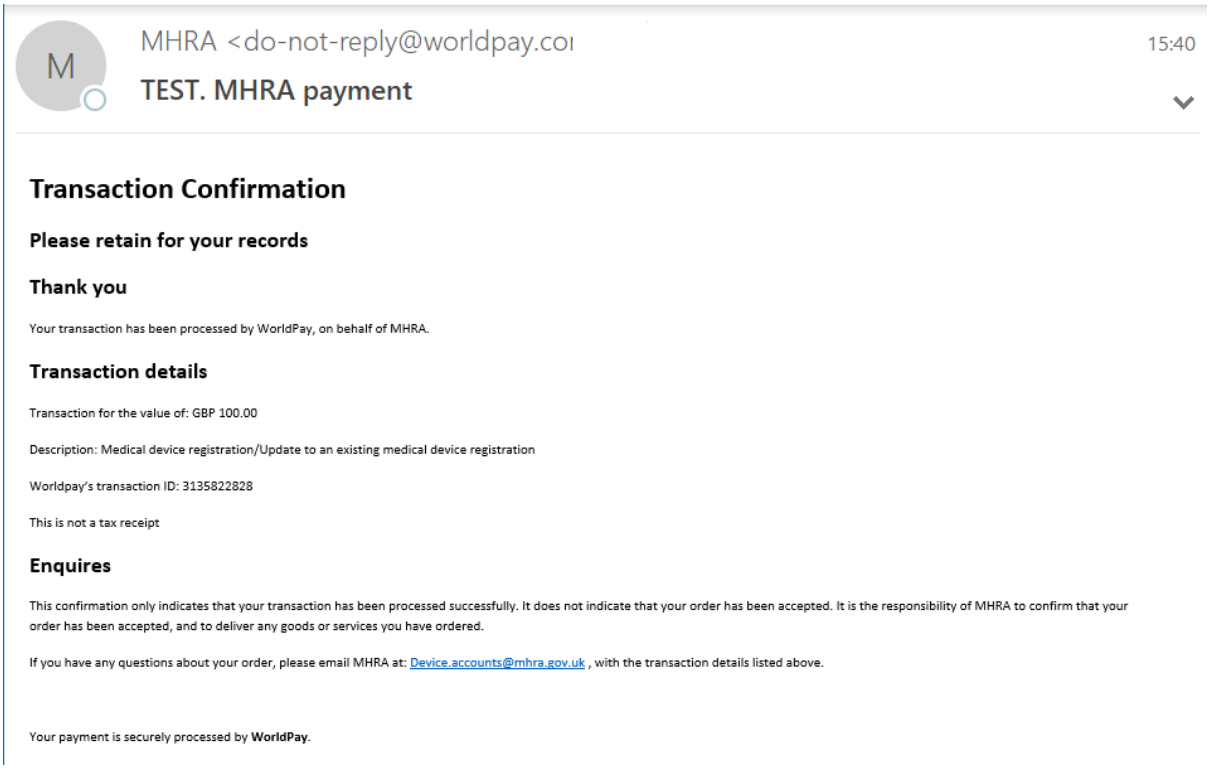


9. **Click** on the Applications Tab to see your submitted application.

10. You will receive a confirmation email from Woldpay.

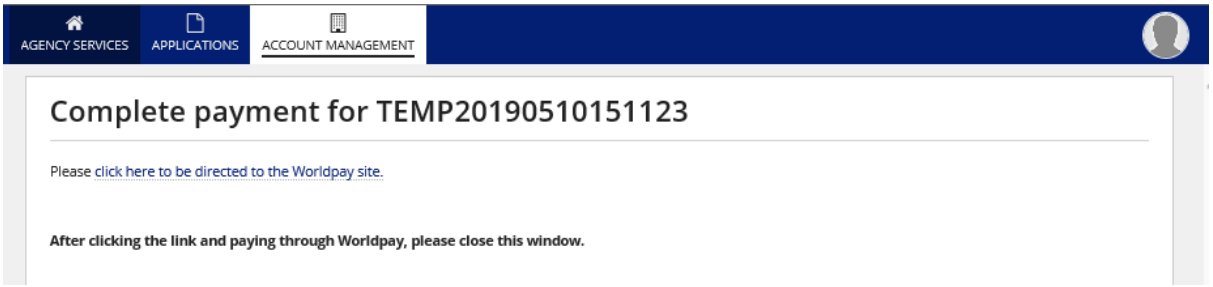
Please note MHRA does not issue tax receipts. The worldpay transaction email and the confirmation of registration email are the only documents you will receive in relation to payment for your registration.

Important note: Fee in screenshot is for illustrative purposes only. Check current statutory fees on our website.



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.



Pay by BACS/CHAPS

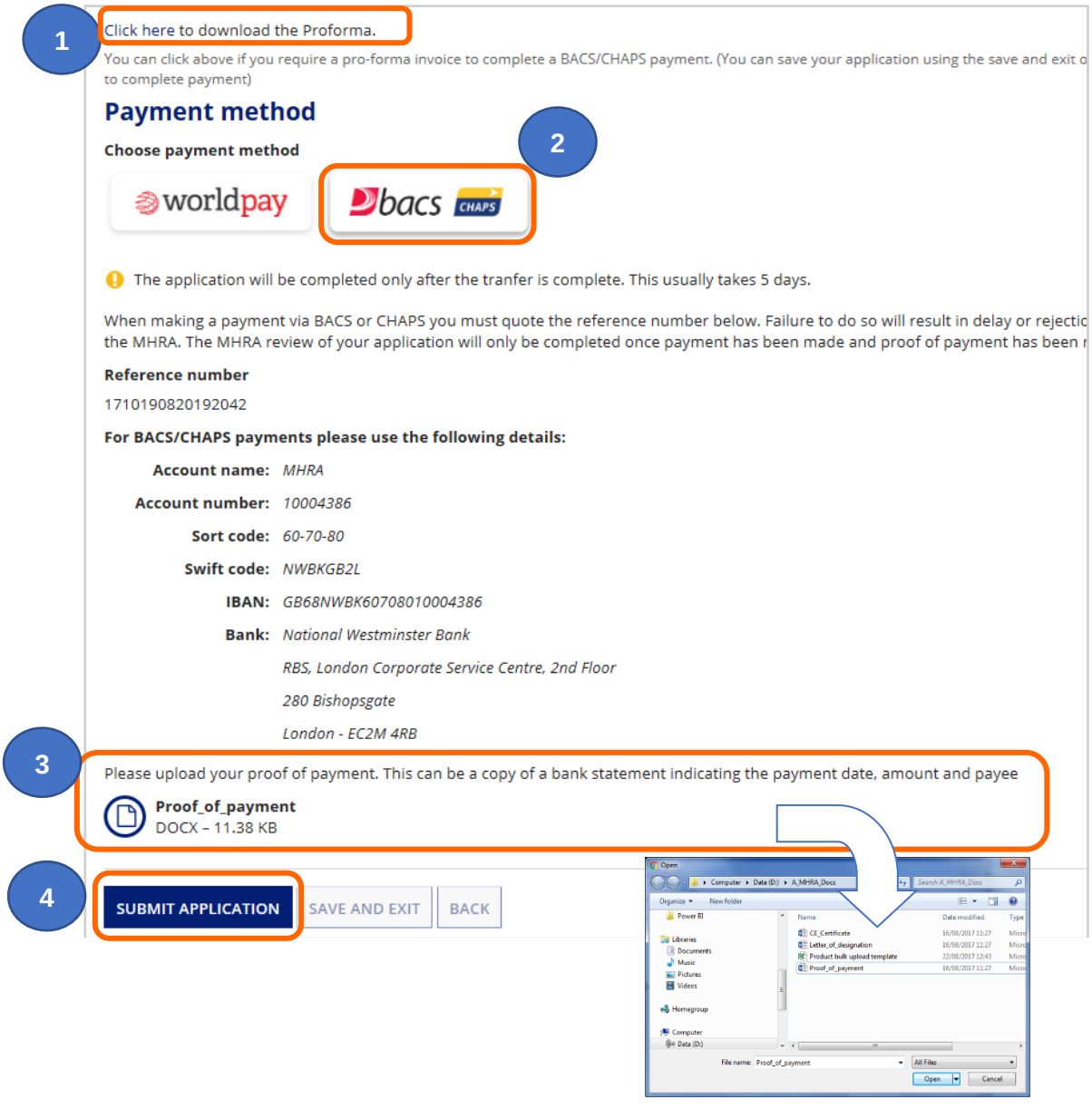
1. **Click** on the click here link to download a proforma invoice if you need an invoice to enable your accounting department to process payment of the device registration statutory fee.

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).

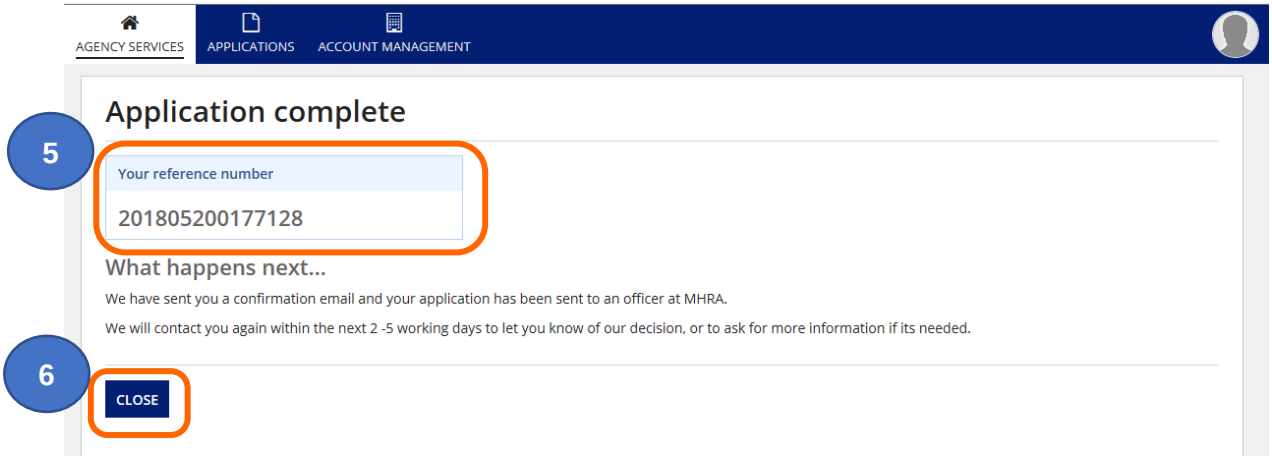
3. Once payment is made **upload** your proof of payment.

4. **Submit** application.



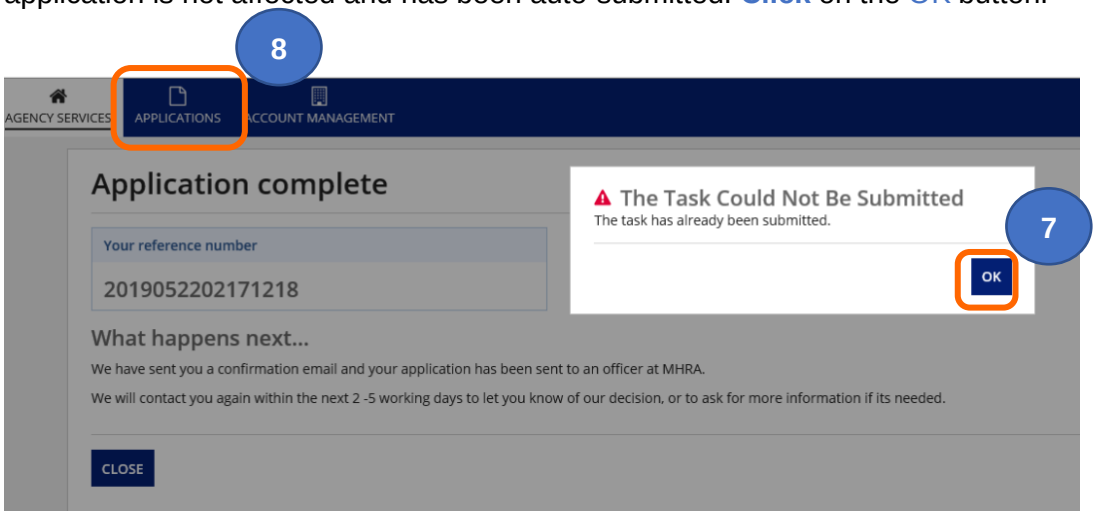
Complete Application

5. Note the Application reference number.

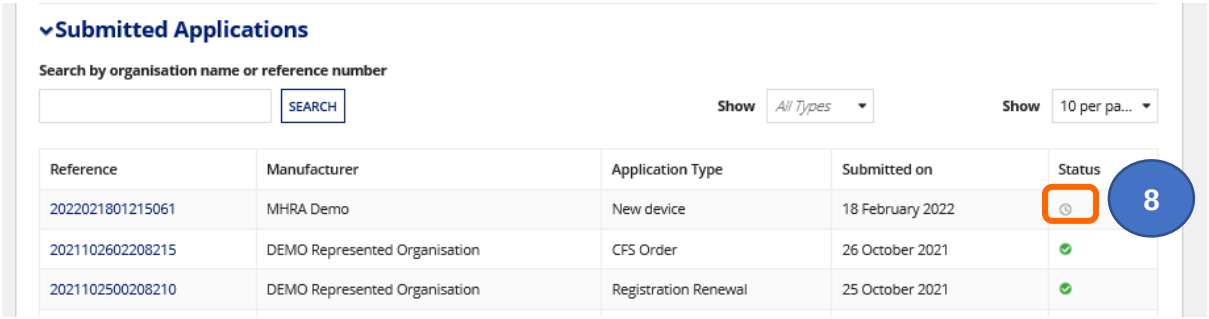


6. **Select** the Close button.

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.



8. **Click** on the Applications tab and **hover** over the status icon tab to see the progress of your submitted applicaton.



Application received email

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

We've received your New device application on 18 February 2022.

Application reference number: 2022021801215061

Manufacturer name(s)
MHRA Demo

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 .

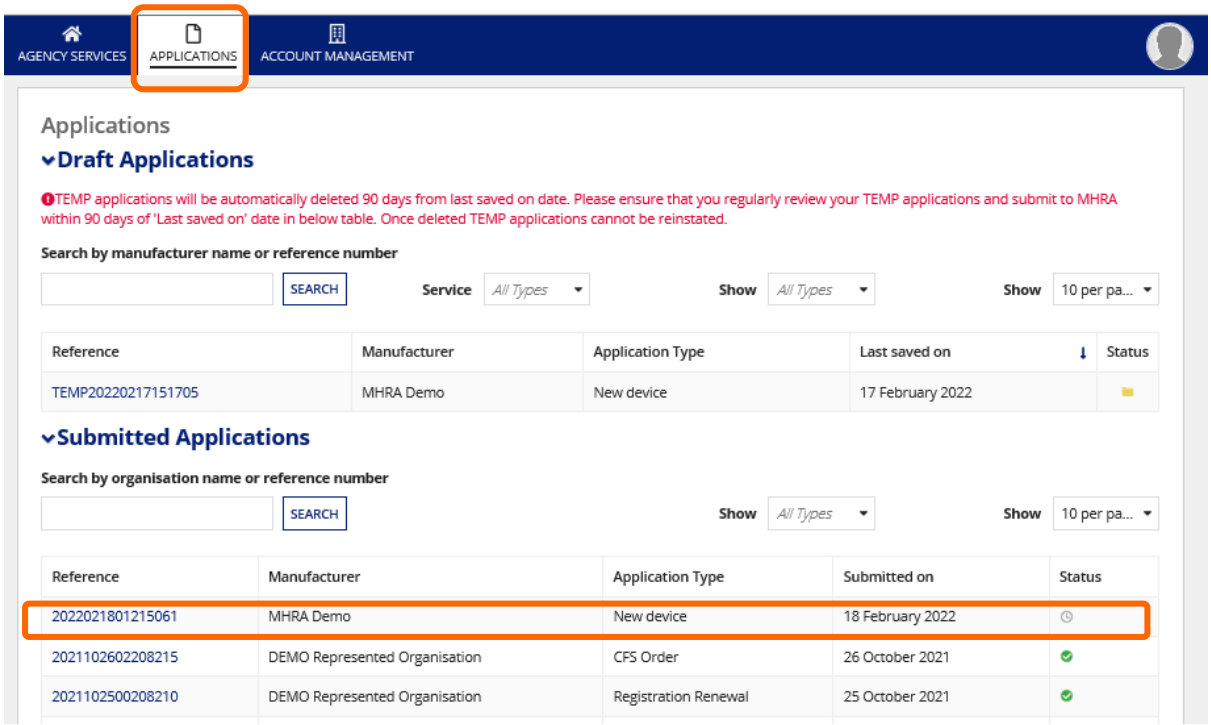
Remember: do not share your account details and keep them safe.
MHRA won't accept responsibility for any unauthorised access to your account.

Yours sincerely,

Device registrations service

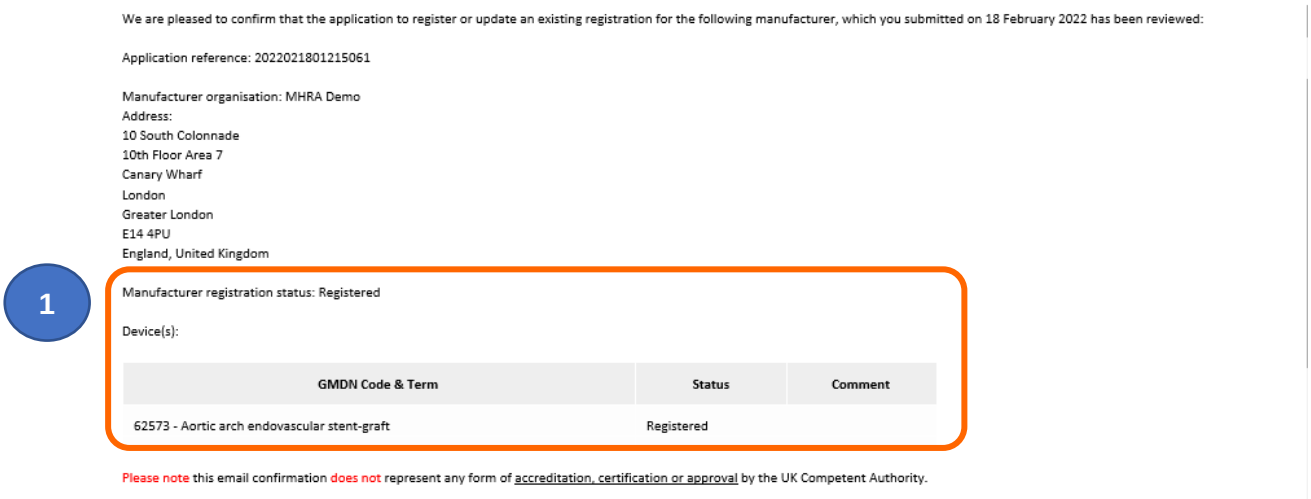
Within 5 working days from submission you should receive an email confirming the outcome of the application. Some devices may be registered, some may be rejected. This may take longer at peak times or if we require further information from you.

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



Registration Complete

1. You will receive an email with a pdf attachment confirming the outcome of your application. **Please note** a pdf will only be attached to New Device, Device Amendment/Upate and Device/Manufacturer applications. Please retain all emails and pdfs for your records.



We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 18 February 2022 has been reviewed:

Application reference: 2022021801215061

Manufacturer organisation: MHRA Demo
Address:
10 South Colonnade
10th Floor Area 7
Canary Wharf
London
Greater London
E14 4PU
England, United Kingdom

1

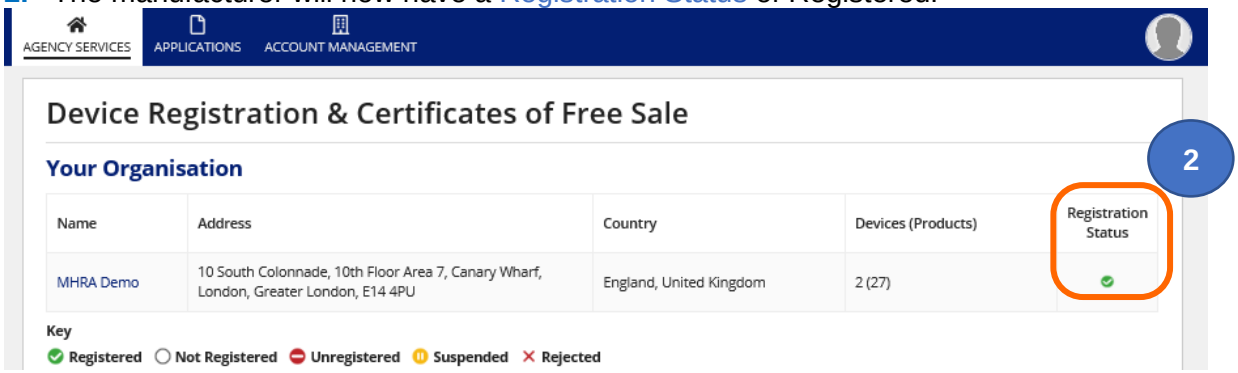
Manufacturer registration status: Registered

Device(s):

GMDN Code & Term	Status	Comment
62573 - Aortic arch endovascular stent-graft	Registered	

Please note this email confirmation does not represent any form of accreditation, certification or approval by the UK Competent Authority.

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



Public Access Registration Database (PARD)

Completed registrations will appear on the Public Access Registration Database (PARD), usually the week after completion.

In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database. These devices are not placed on the market.

If your registration account is suspended, your organisation will not appear on PARD, please see **Renew Registration** and **Uploading new Letter of Designation** in the **Account Management Reference Guide**.

If your registration is not displaying on PARD or your devices are displaying as '**Devices pending update by manufacturer'** or **'Conformity Assessment Certificate Expired'**, please access your account review your devices, and follow the Manage Registered devices instructions to take any necessary action to bring your registration up to date. Please also see Removing migrated Pseudo GMDN® Terms.

Updating Registrations

Editing organisation details

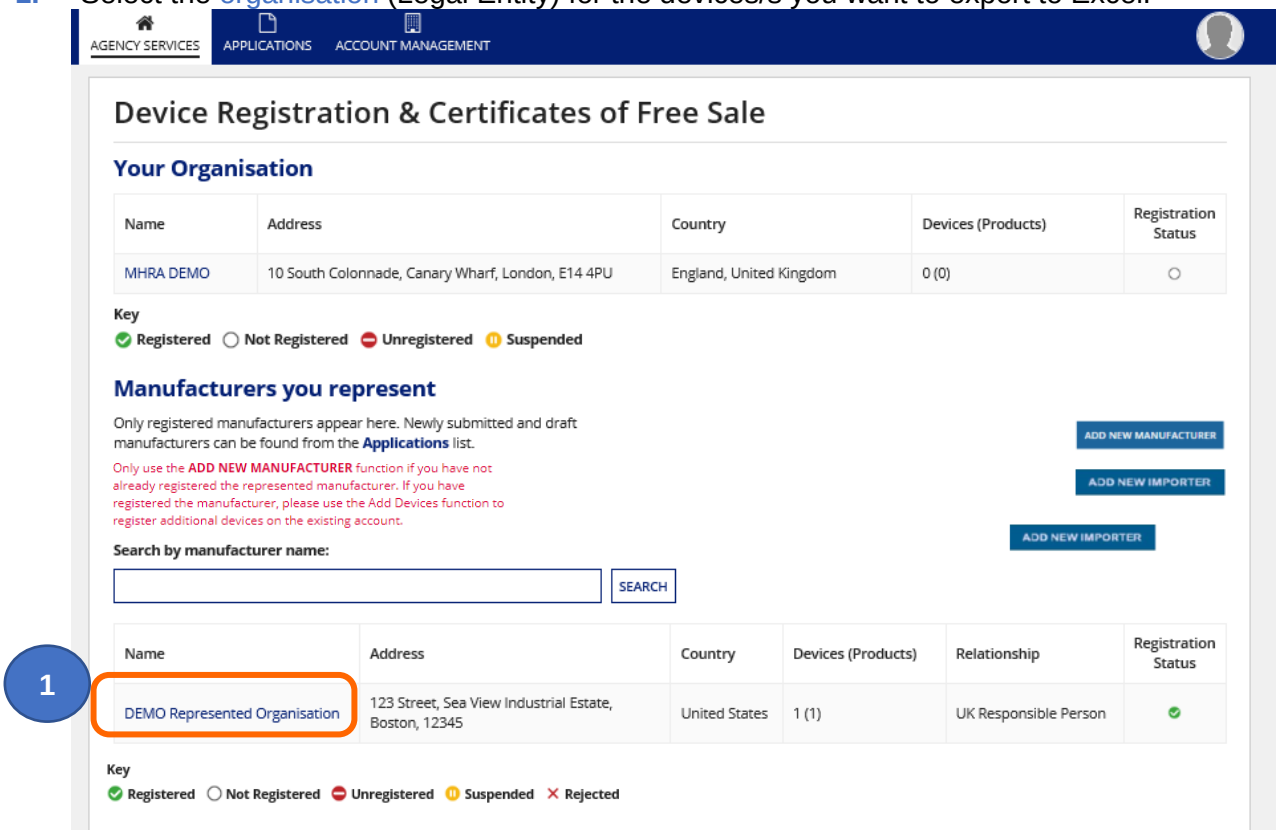
See the **Edit Organisation** section in the **Account Management Reference Guide** for instructions on how to update organisation name/s and/or address/s and upload new Letters of Designation – statutory fees will apply.

Adding new devices

See steps for Add device using GMDN®.

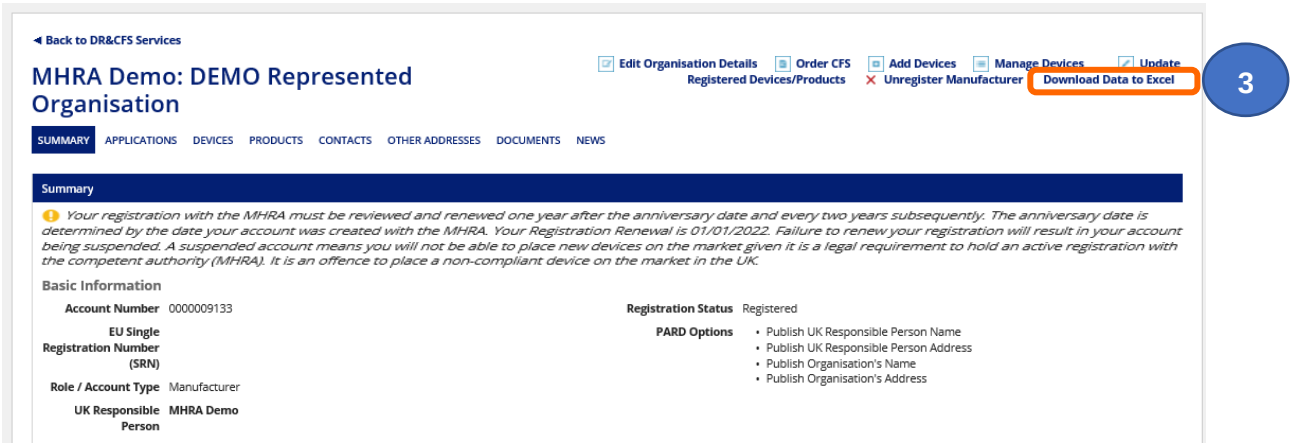
Export devices data to Excel file

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



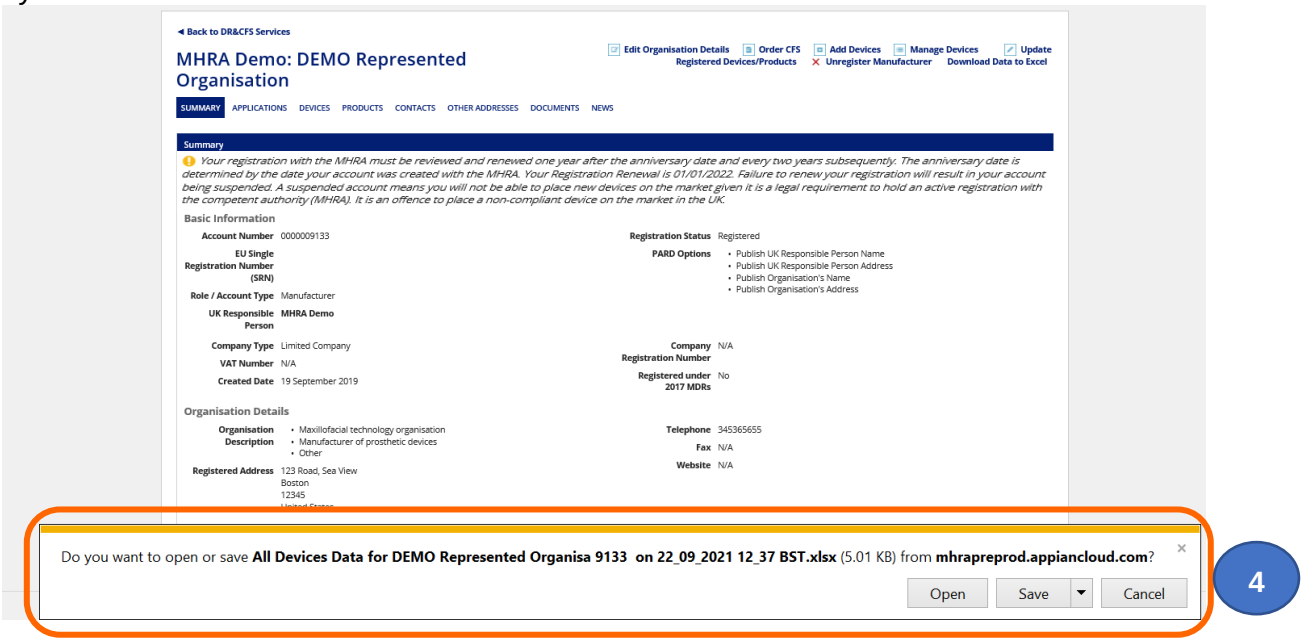
2. **Click** on Export Devices Data to Excel File link.

3. **Click** on Download Data to Excel File link.

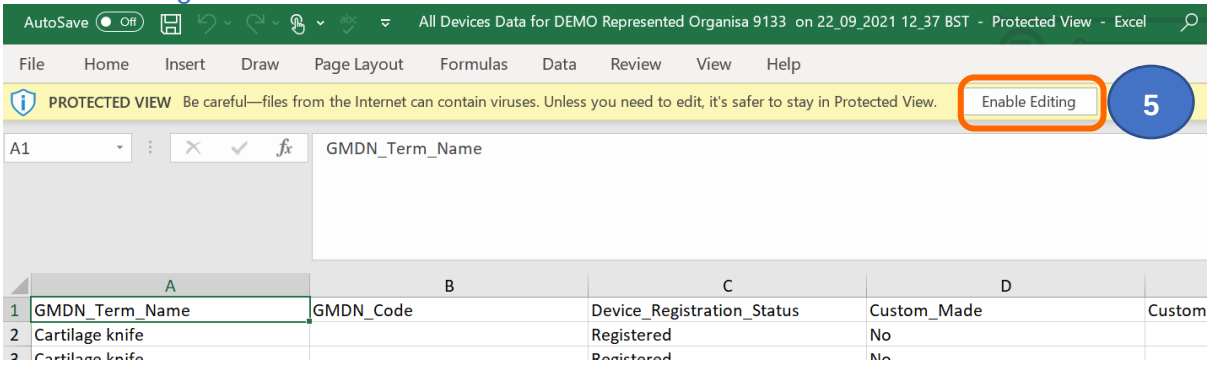


4. The Excel dialogue box will open. **Open** or save the file as required.

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.



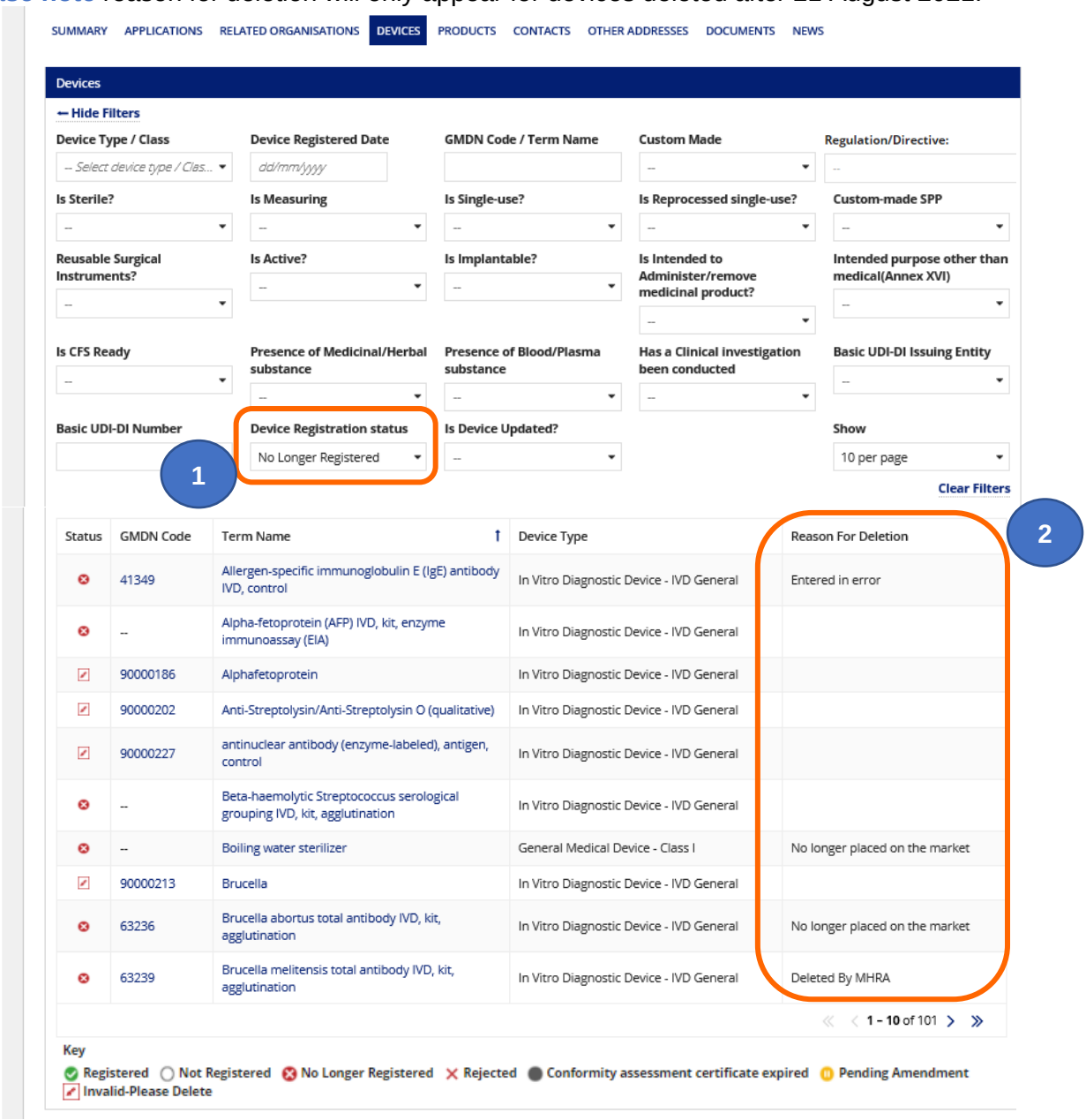
Using filters to search for devices and products

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.

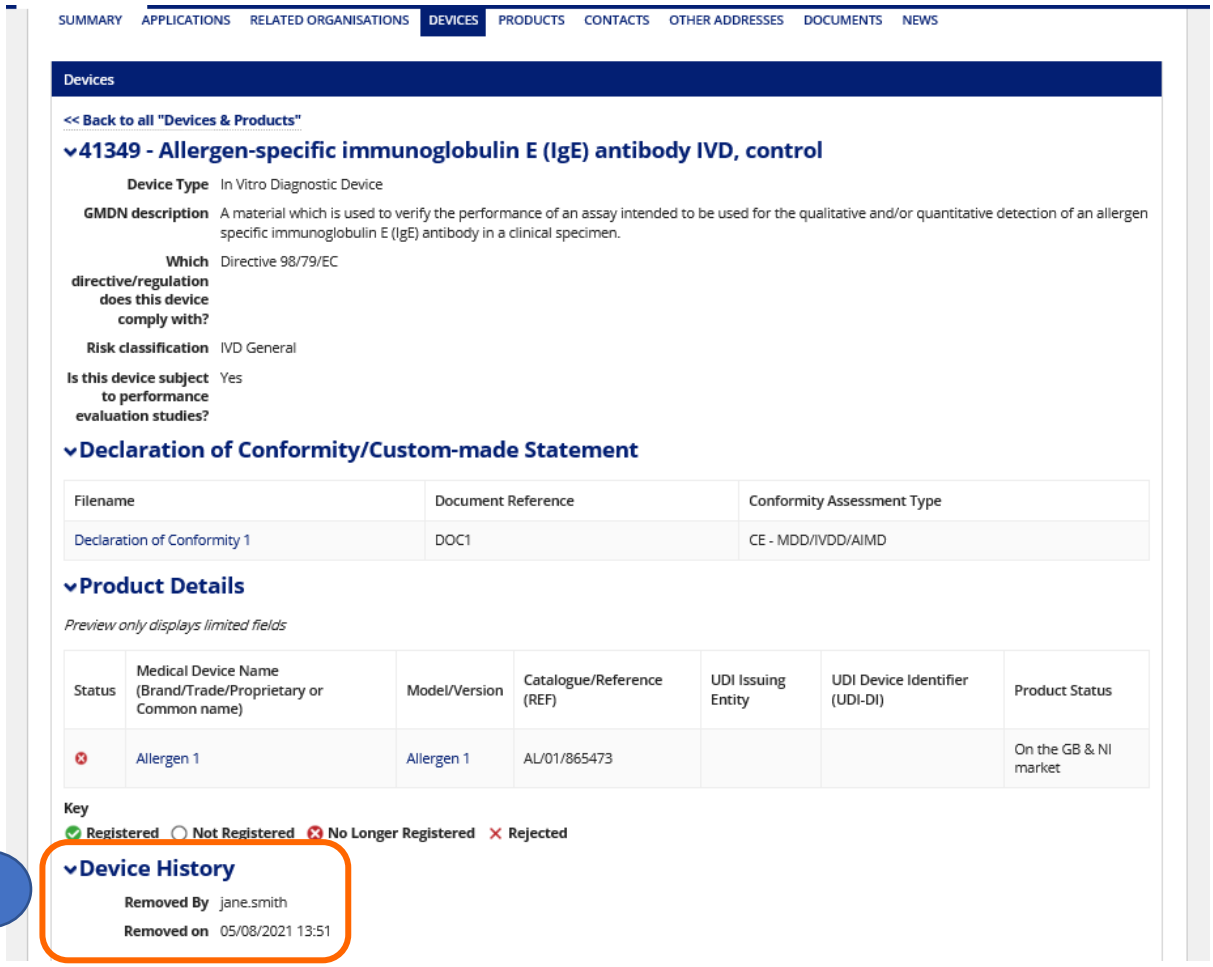
Please note reason for deletion will only appear for devices deleted after 21 August 2021.



3. To view when device was deleted and by whom, **click** on the GMDN® Term of the deleted device.

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

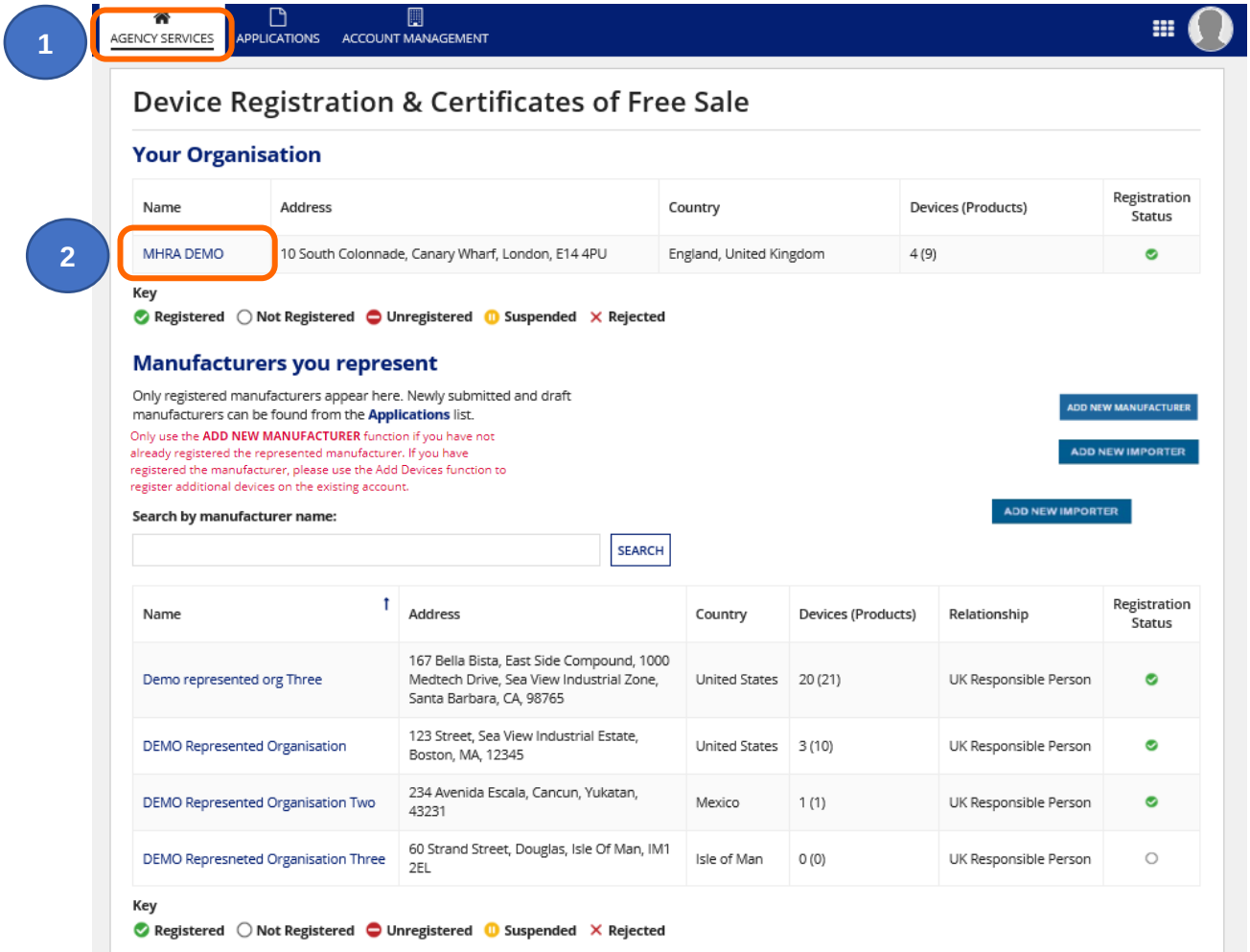
Please use the Manage Devices function to:

- **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

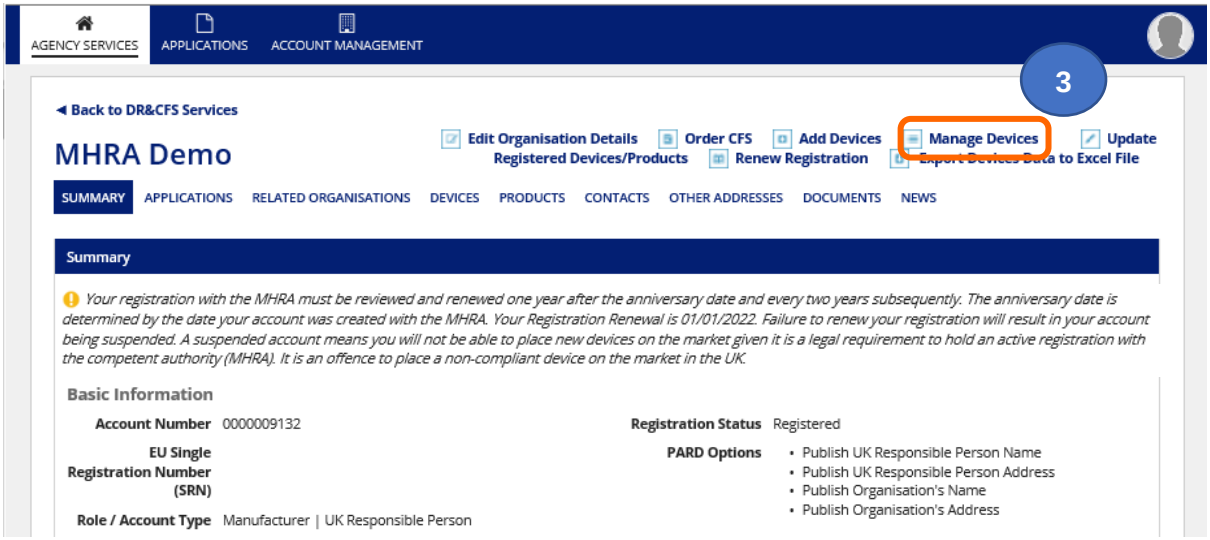
Please note you cannot update obsolete GMDN® or other device details e.g. Substances, Clinical Investigations etc. or products e.g. populate fields you did not complete at registrations stage from this screen – please see Update registered devices and products.

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

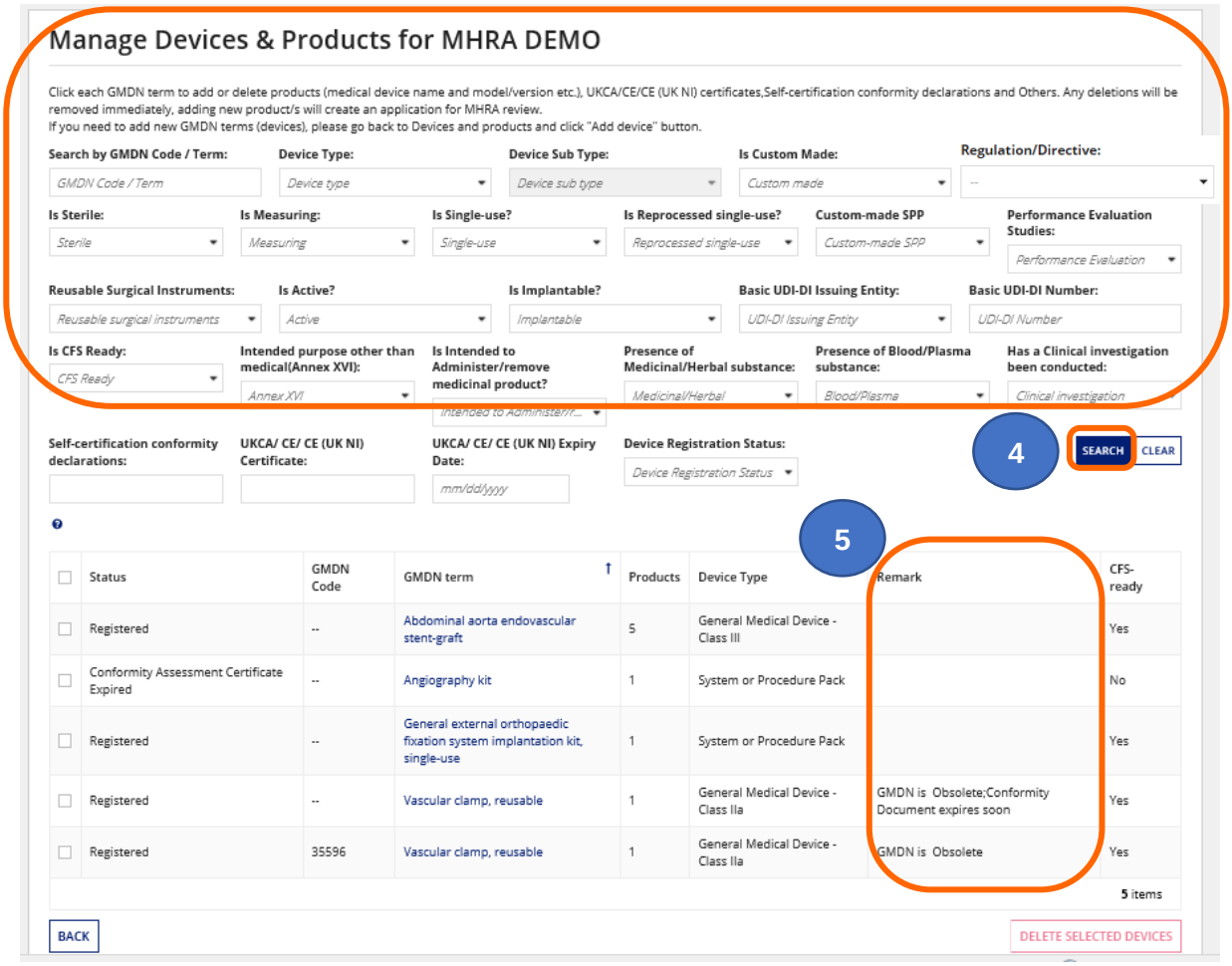
2. Select the manufacturer (Legal Entity) of the devices/s you want to manage.



3. **Click** on the Manage Devices link.

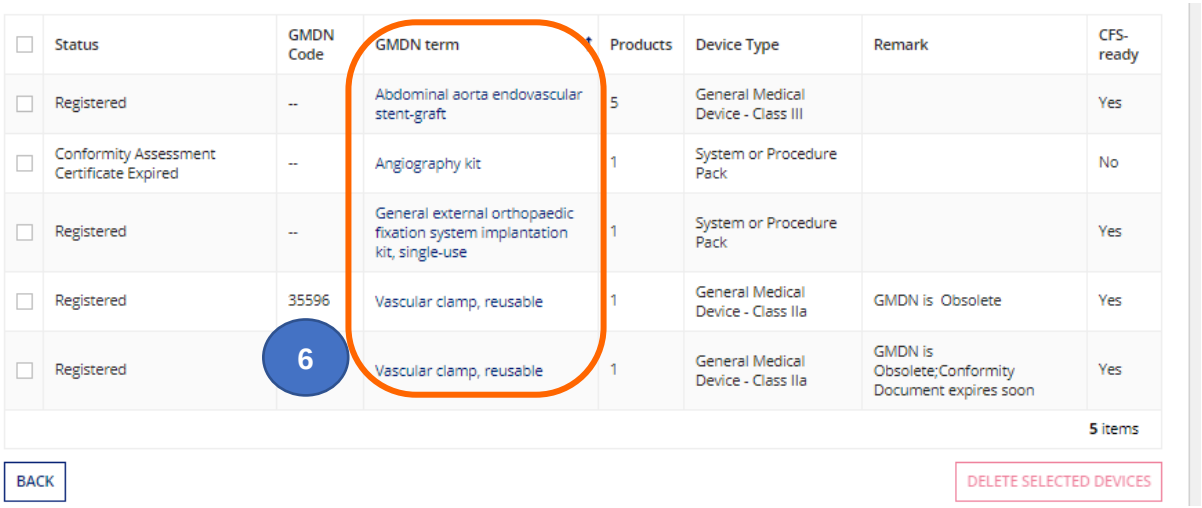


4. If you have many devices, use the available filters to **search** for a specific device. See [Using Filters to search for devices and products].

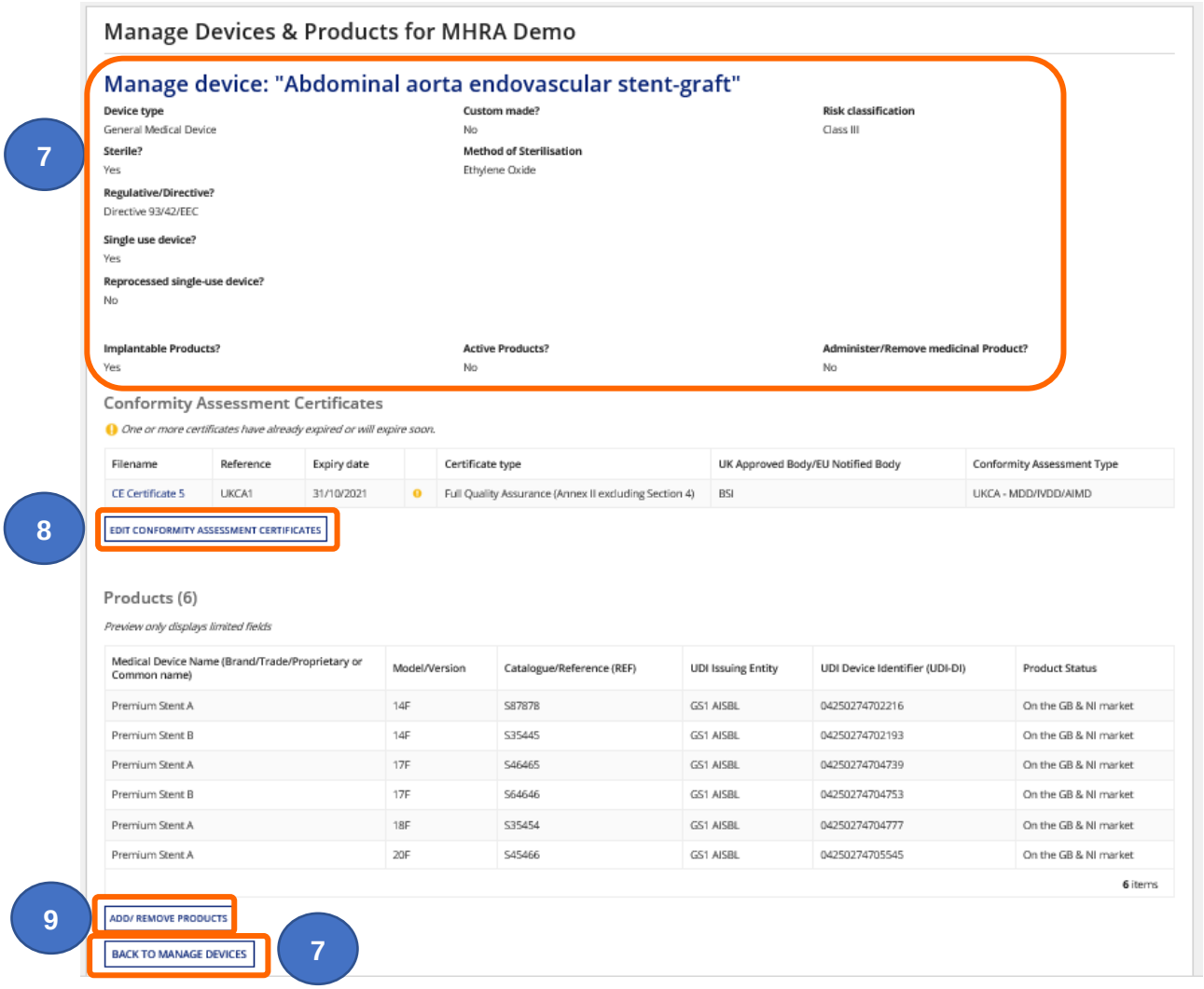


5. **Check** the Remark column for action required to bring the registration up to date.

6. **Click** on the GMDN® Term of the device to manage.



7. 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.



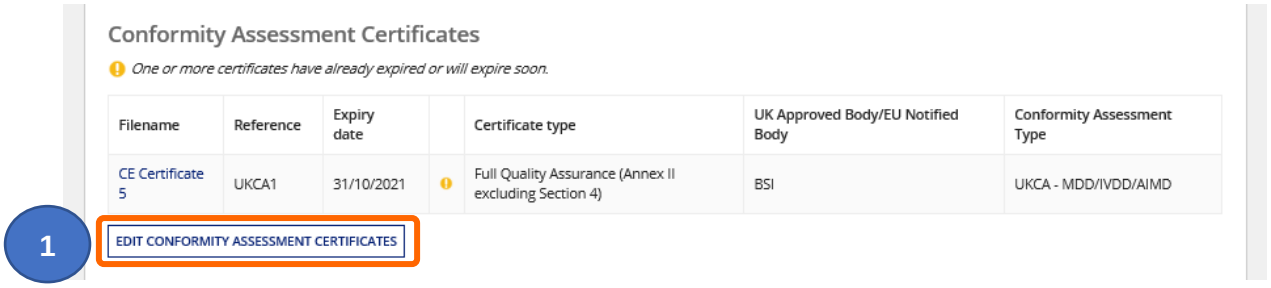
Manage Conformity documents

Please note if your conformity assessment document expires this will be published on the Public Access Registration Database (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 (PARD).

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.

1. 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, are incorrect, or are no longer appropriate.

Important note concerning **CE UKNI-MDR/IVDR** option.

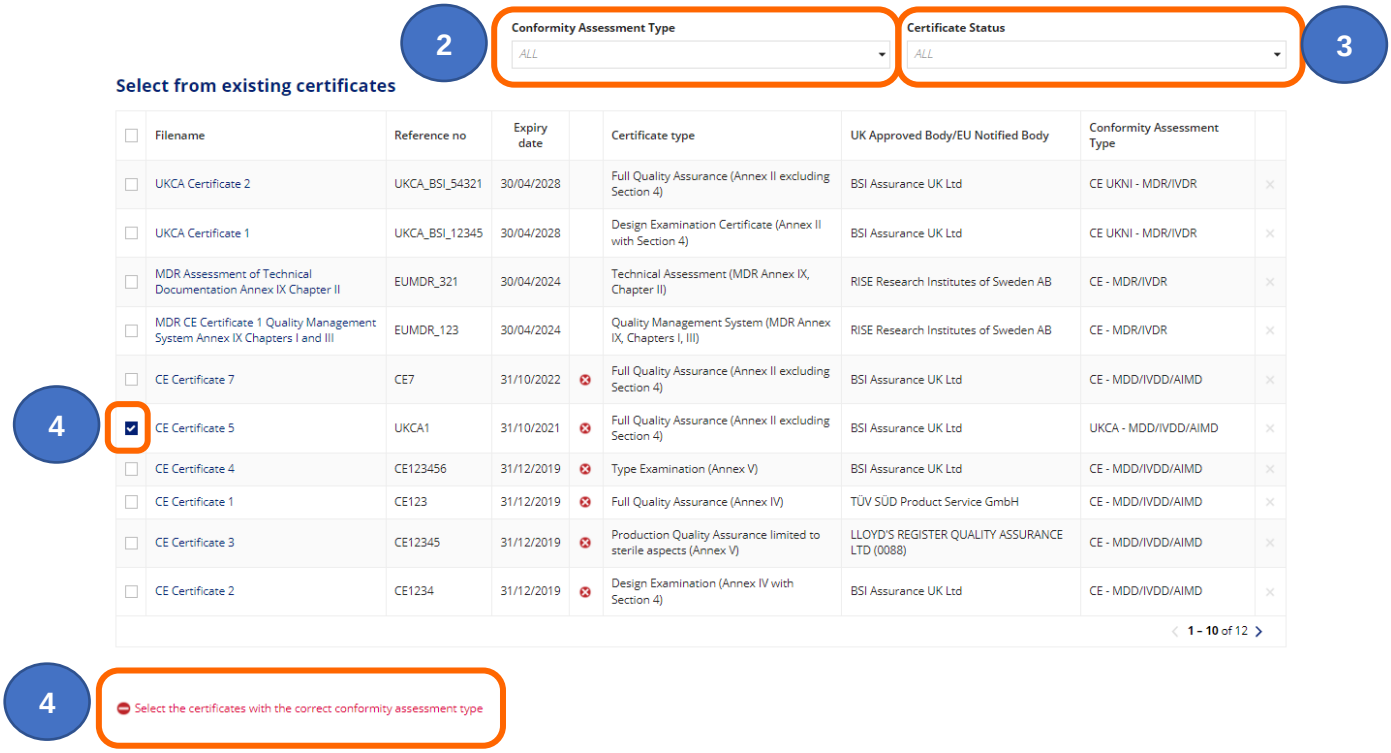
This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

2. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

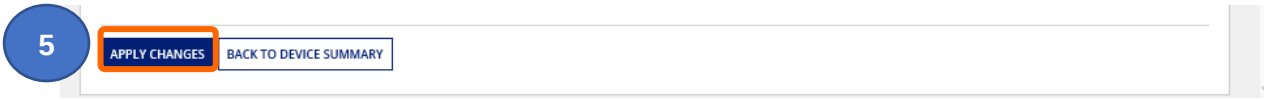
UKCA – MDD/IVDD/AIMD
CE (UK NI) – MDD/AIMD/IVDD
CE (UK NI) – MDR/IVDR

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



4. If you have selected a certificate with incorrect Conformity Assessment Type a warning message will appear and the Apply Changes button will not be enabled. If you have selected an expired certificate the Apply Changes button will not be enabled .Unlink expired or incorrect Certificates and upload new ones or link device to an active/correct certificate.

5. **Click** the 'Apply Changes button or follow the Upload Conformity Assessment Certificate instructions to add another certificate.



Managing expired CE certificates that are valid under EU MDR

See the latest guidance on our website, including a template to complete and upload at:

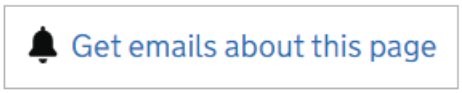
https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-that-have-expiredexpiring-ce-certificates

and

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-which-are-eu-mdd-class-i-reusable-surgical-instruments-or-eu-mdd-class-i-medical-devices-upclassified-from-class-i

The guidance has intentionally not been included in this Reference Guide as this may change.

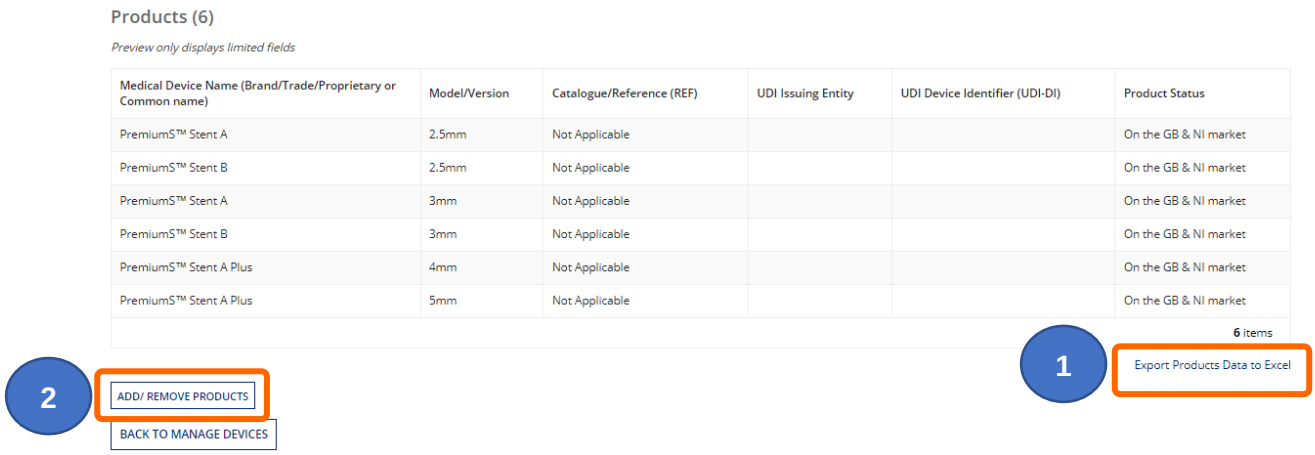
Please sign up for email updates by following the link on our webpage:



Add/remove products

1. **Click** the Export Products Data to Excel link to download all product details for review, prior to adding/removing. **Please note** once changes applied and application submitted you cannot reinstate the product/s. If you delete a product in error, you will need to **add** it again.

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



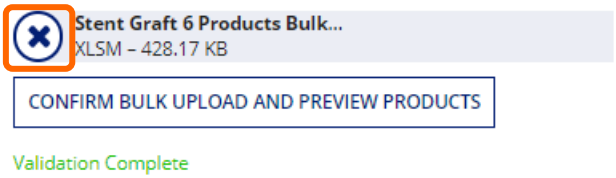
3. To **add** more products follow the instructions for Adding products individually or Adding products in bulk.

4. You can delete up to 20 products in a single application. You will be asked for a reason for deletion. The same reason will apply to all deleted products in the application. If the reasons are different, please create separate applications.

   Important note: You cannot **delete** products that you have just added in this manage devices & products application. If you attempt to, you will see an error message. This is expected system behaviour.

   To delete products you have just added or uploaded in this application, you need to either:

   Hover over the bulk upload template until the **X** appears next to the template file name and click the **X**, this will remove all the products just uploaded.

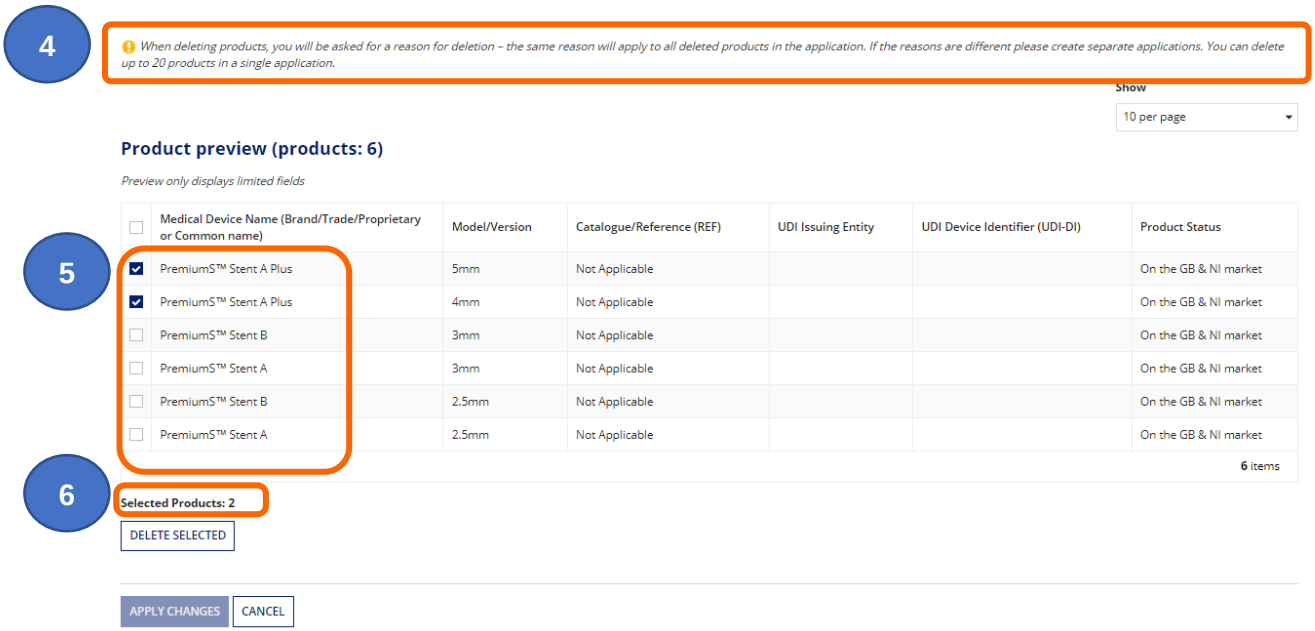


   Then **remove** the relevant products from the template and re-upload it.

   Or

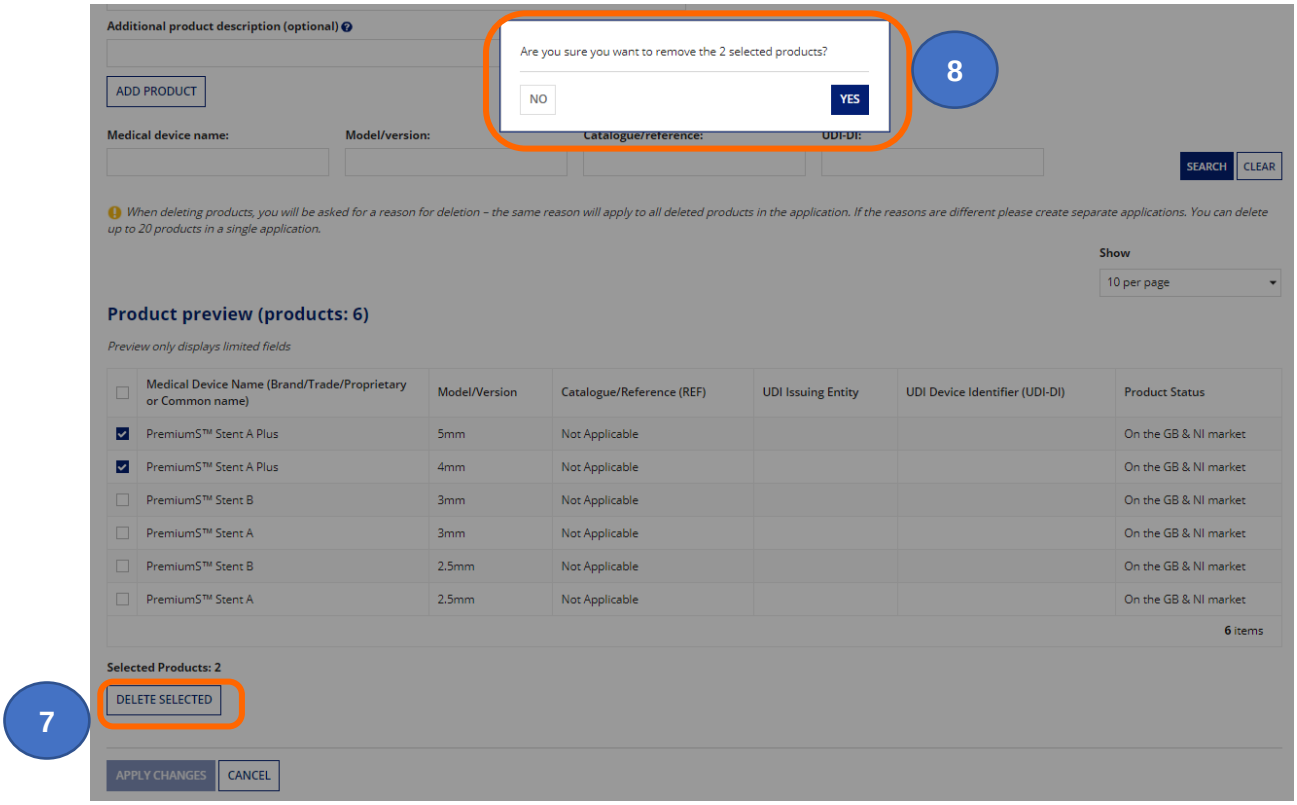
   Click the Cancel button to discard all changes in this application and start again.

5. To **remove** products previously registered, **select** the box/es next to the Medical Device Name/s in the Product preview table. You must always have at least **one** product linked to a device so if you attempt to remove the last product the Apply changes button will not be enabled.



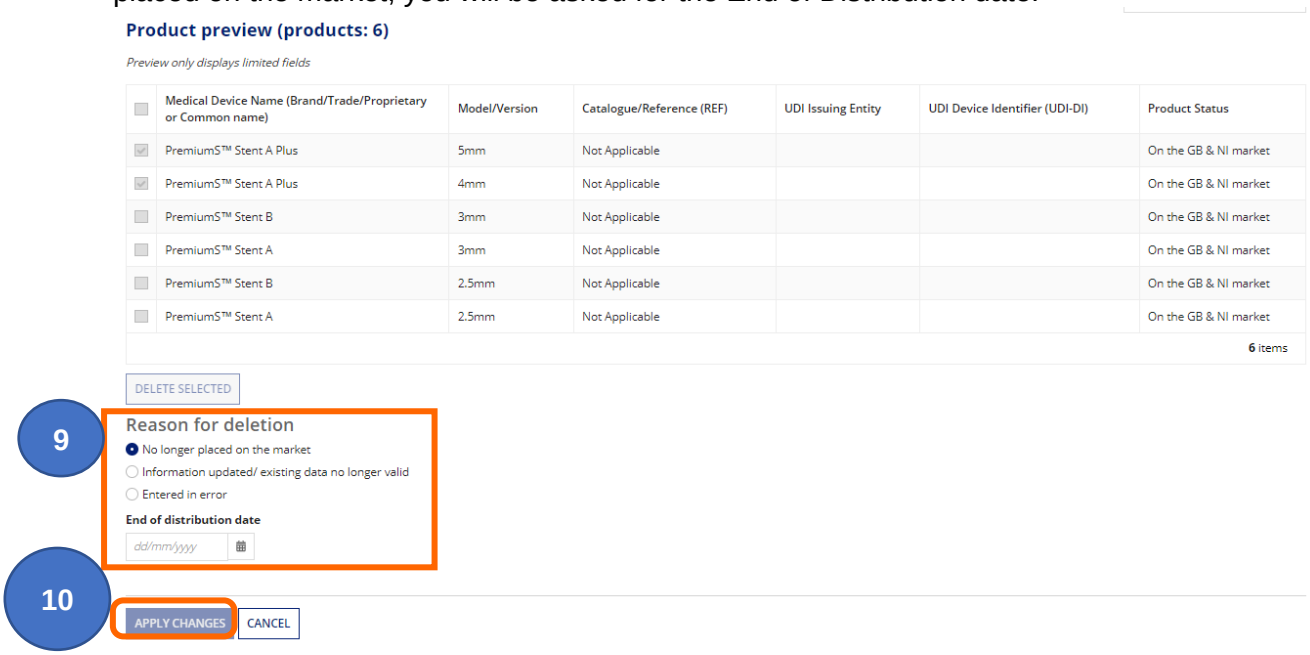
6. The number of products selected for deletion will display in the counter.

7. **Click** the Delete Selected button



8. A warning message will appear asking if you are sure you want to remove the selected products. **Click** Yes or No as appropriate.

9. If you select Yes, the Reason for Deletion options will appear. If you select No longer placed on the market, you will be asked for the End of Distribution date.

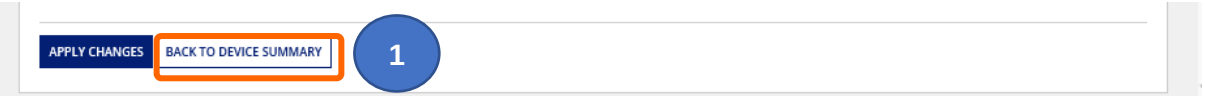


10. Click the Apply Changes button to confirm removal of the product/s.

Please note once changes applied and application submitted you cannot reinstate the product/s. If you delete a product in error, you will need to **add** it again. There is currently no fee to add products.

Delete device/s

1. 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.



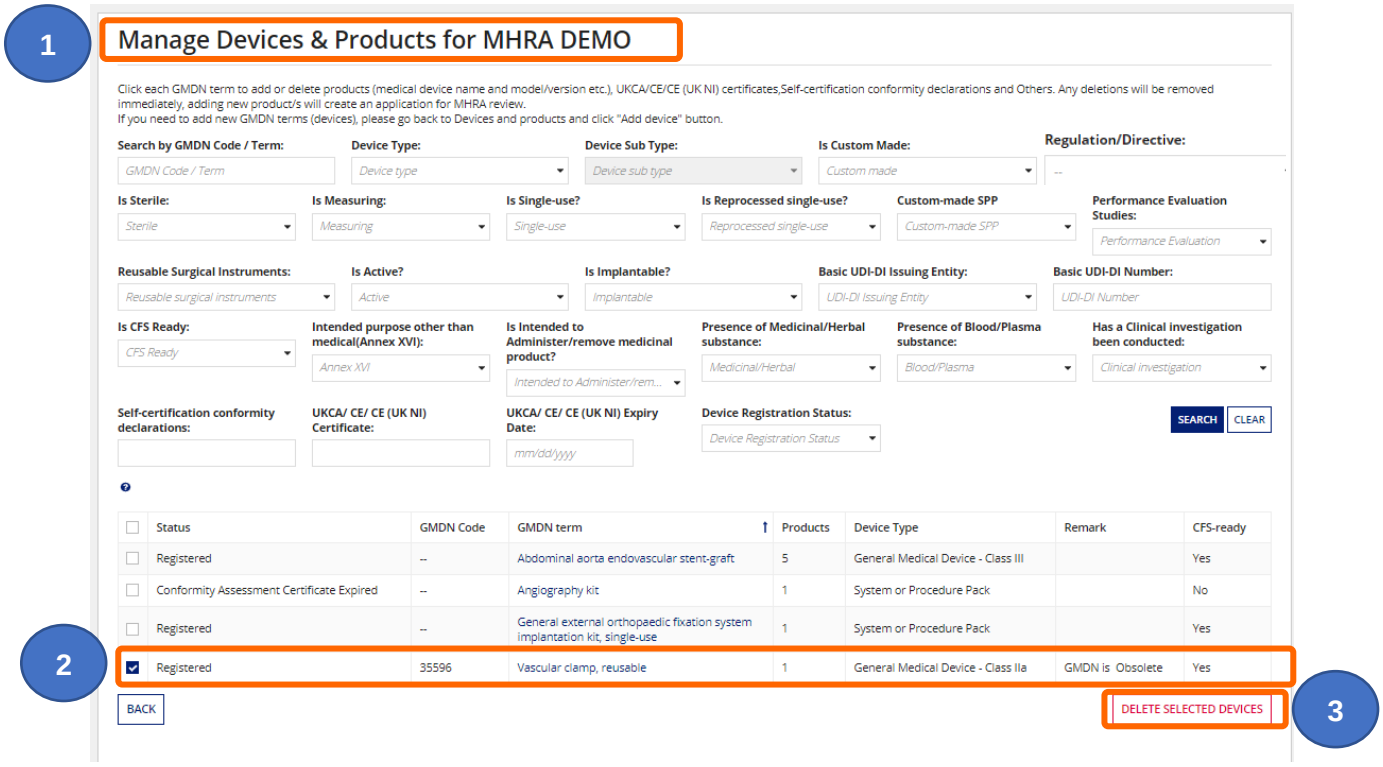
2. **Tick** the box next to Status column of the device/s your wish to delete.

   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.

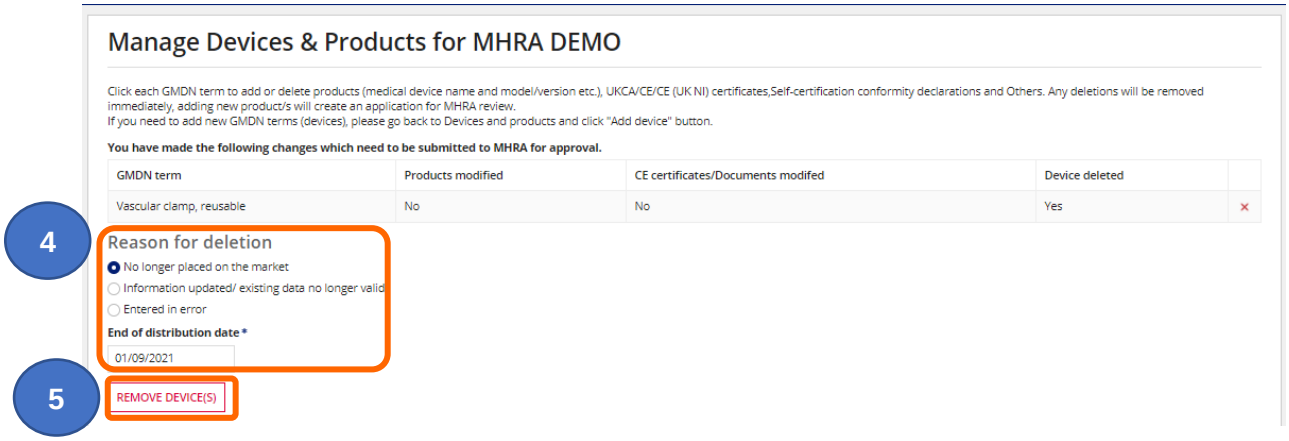
3. **Click** the Delete Selected Devices button to remove the device/s and all underlying products of the device.

   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



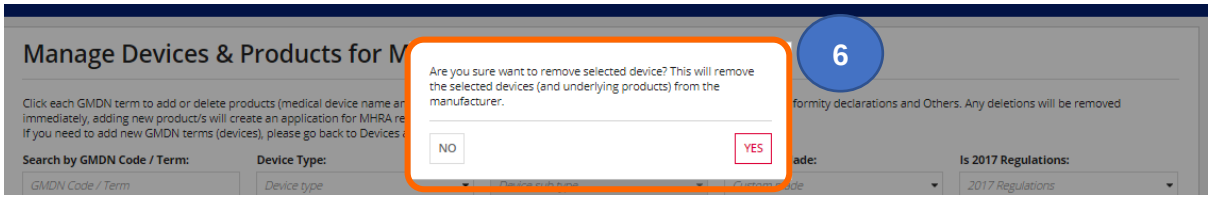
4. **Select** a Reason for deletion. If device is no longer placed on the market, provide End of Distribution date.

   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.

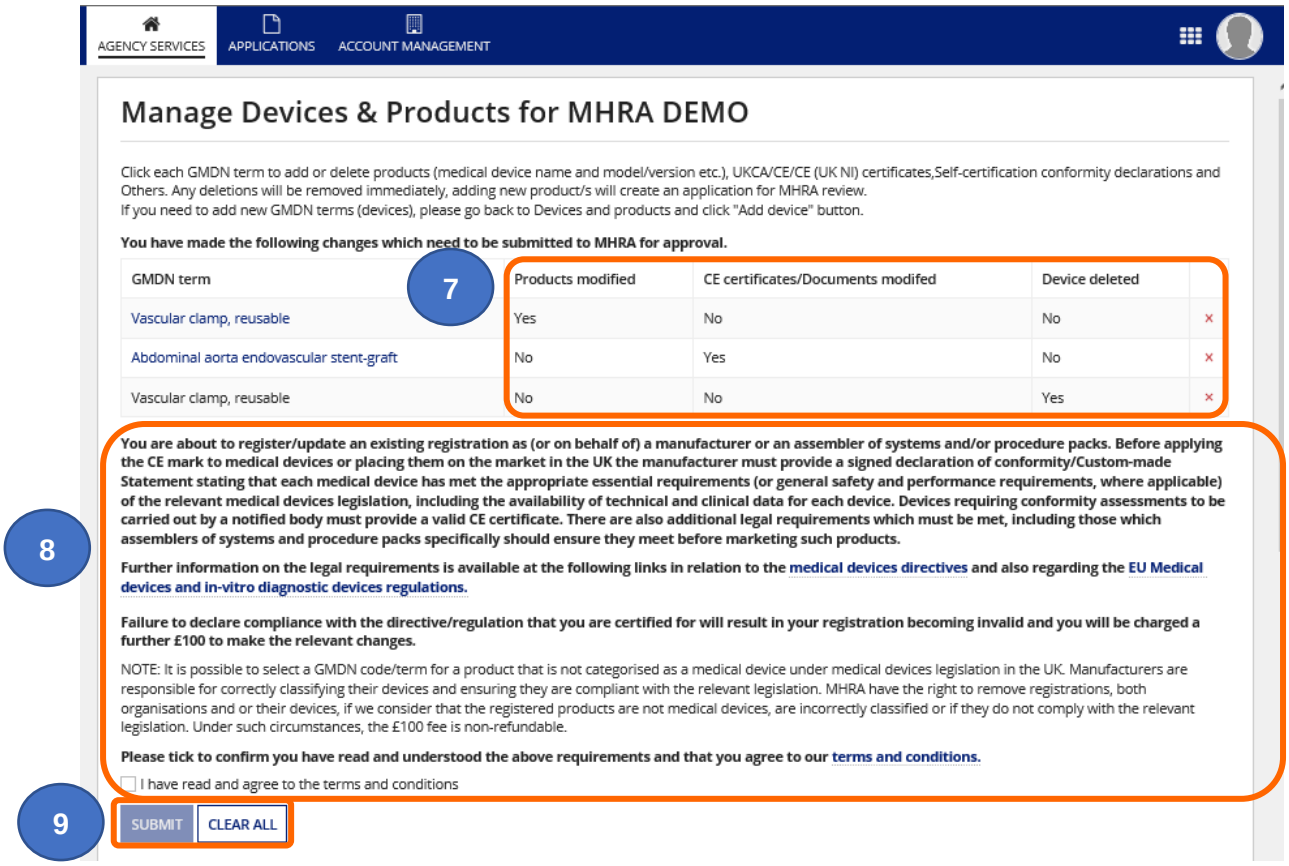


5. **Click** the Remove Device(s) button.

6. 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 statutory fee.



7. 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 <u>all changes</u> to the specific device.

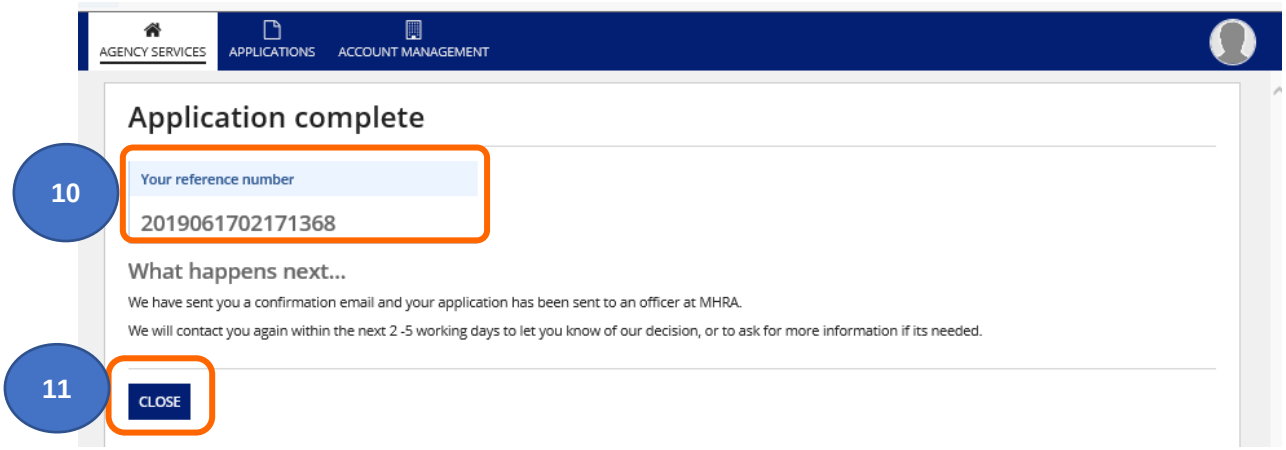


8. When you are ready to submit the application, **Read** the on-screen information and terms and conditions , **click** the **'**I have read and agree to the terms and conditions box'

9. **Click** the Submit button to complete the application or the Clear All button 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.

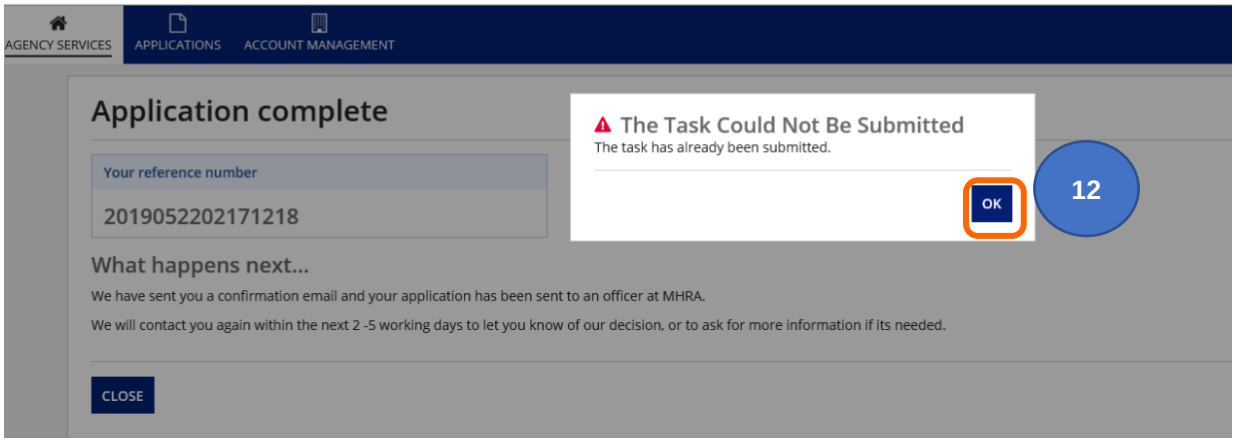
10. After submitting, note the application number, the application will now show as in progress within the list of applications. While the application is in progress you will not be able to order a CFS for the device(s) or make further updates to device/s in the application, until the application is complete.



11. **Click** on the Close button.

12. **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.

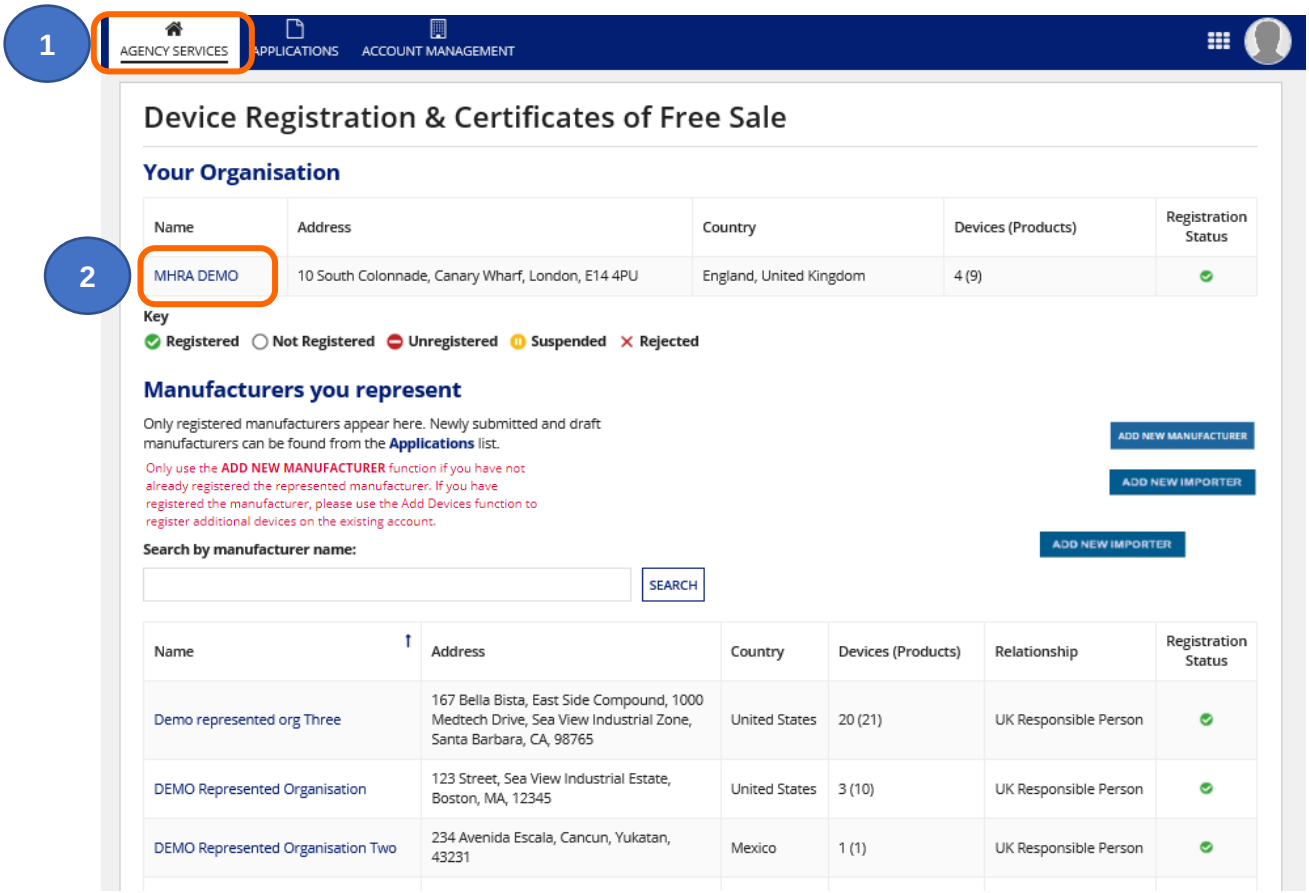
Please note only certain fields can be updated. These will be enabled on the update screen to allow you to **add** or **update** data. GMDN® Codes/Terms can only be updated in cases where the existing GMDN® has been made obsolete. Changes made on this screen do not currently incur a fee.

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 statutory fee.

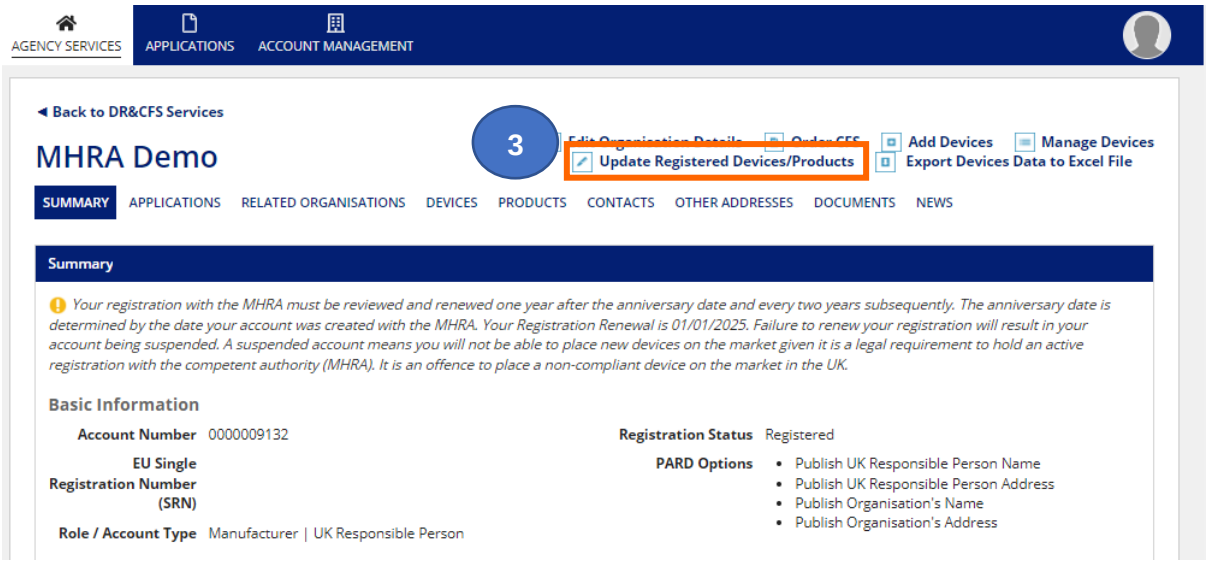
If products need to be added or removed from an existing registered device, or Conformity Assessment Certificates/Self-certification conformity declarations need to be uploaded, linked, or unlinked from existing registered devices this can be done via the Manage Devices link.

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.



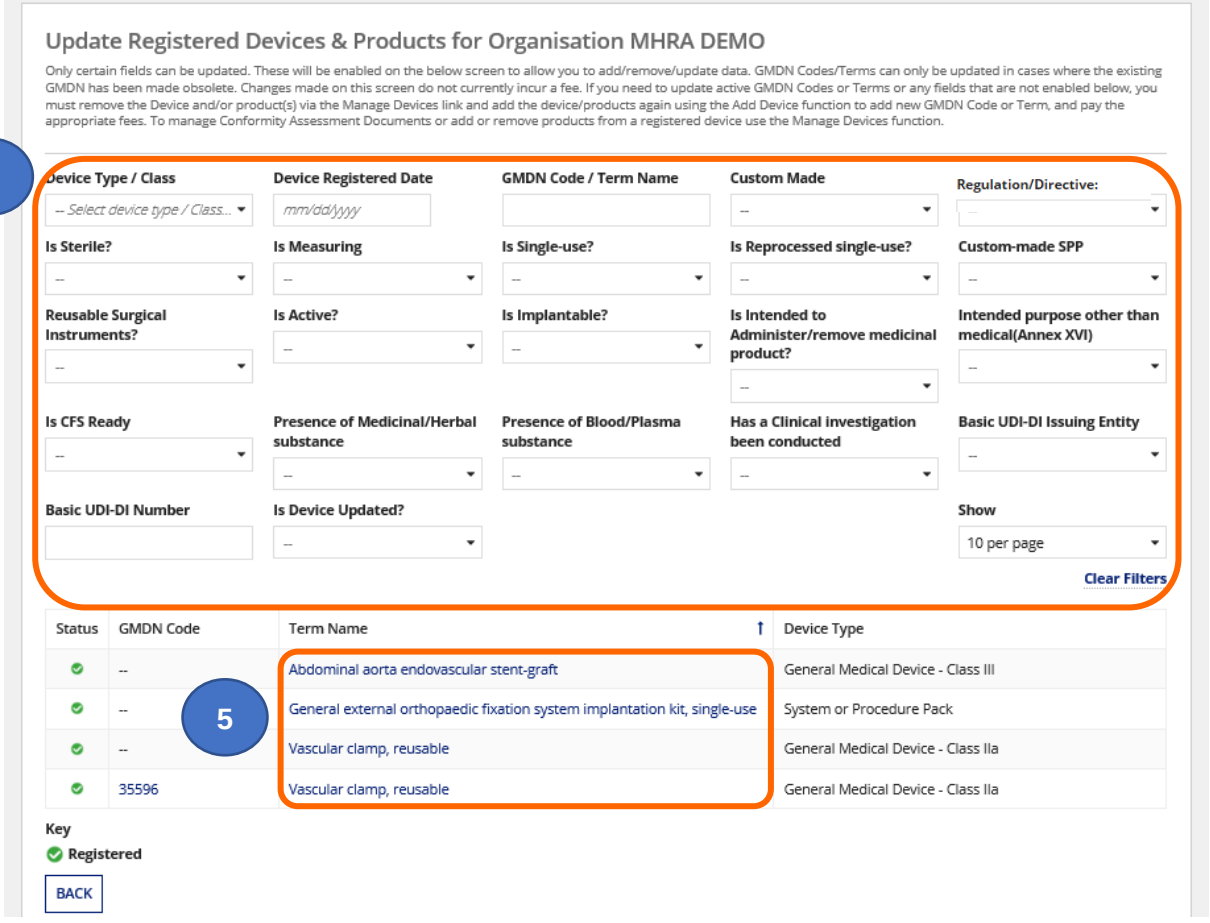
3. **Click** on the Update Registered Devices/Products Devices link on the Summary page.



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.



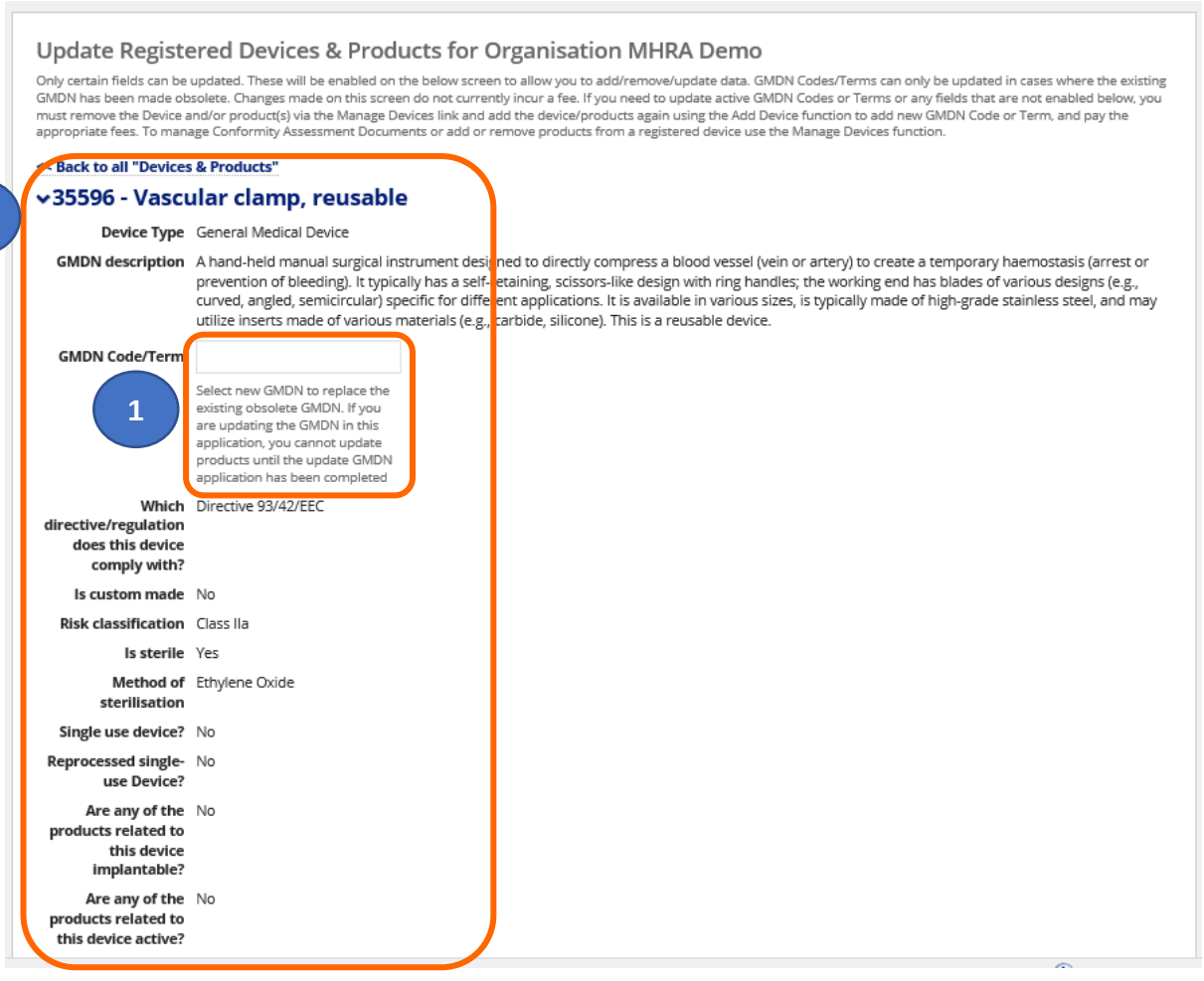
6. The details of the GMDN® Term you have selected will open to enable you to:

- **Update** 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 applies.
- **Update** selected device and/or product fields if you are not updating obsolete GMDN®

Update Obsolete GMDN

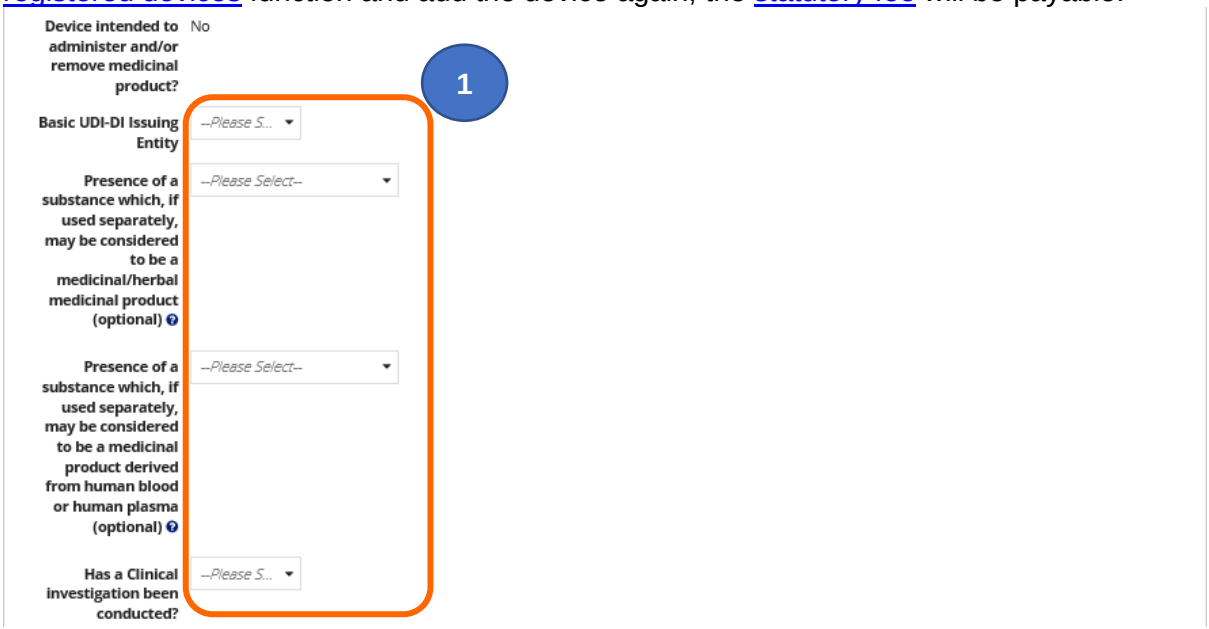
1. If GMDN® is now obsolete a box will appear to enable you to either enter a valid GMDN® Code if you know it, or search for a suitable GMDN Term using multiple words.

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.

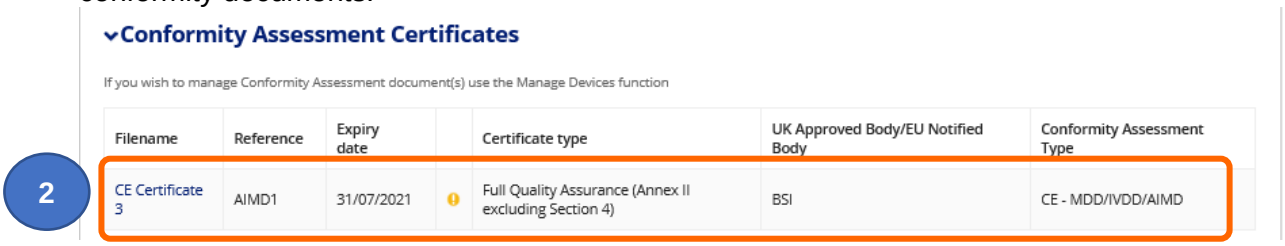


Update Device Details

1. 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 statutory fee will be payable.



2. 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 conformity documents.



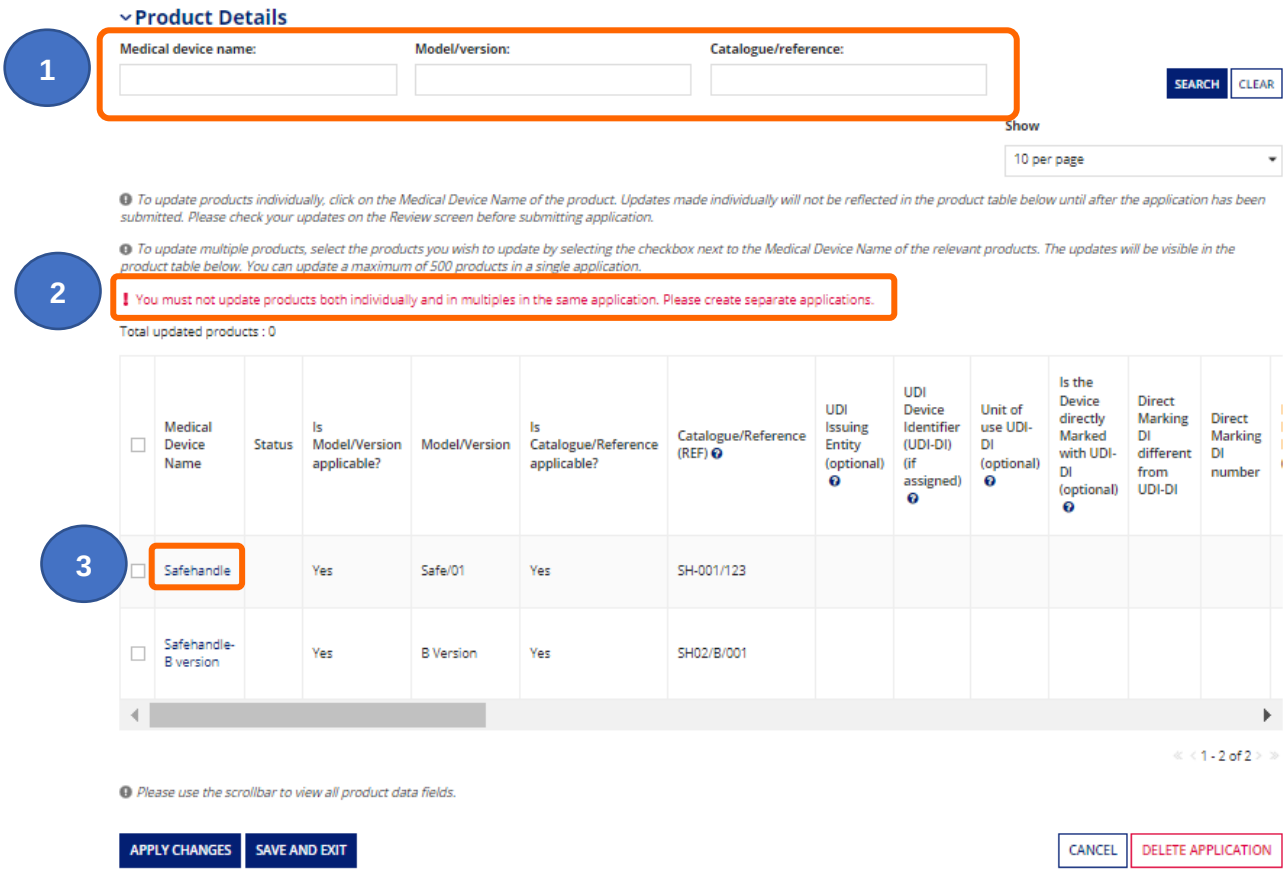
Update products individually

1. The Product Details table will appear. Use the filters to search for the product.

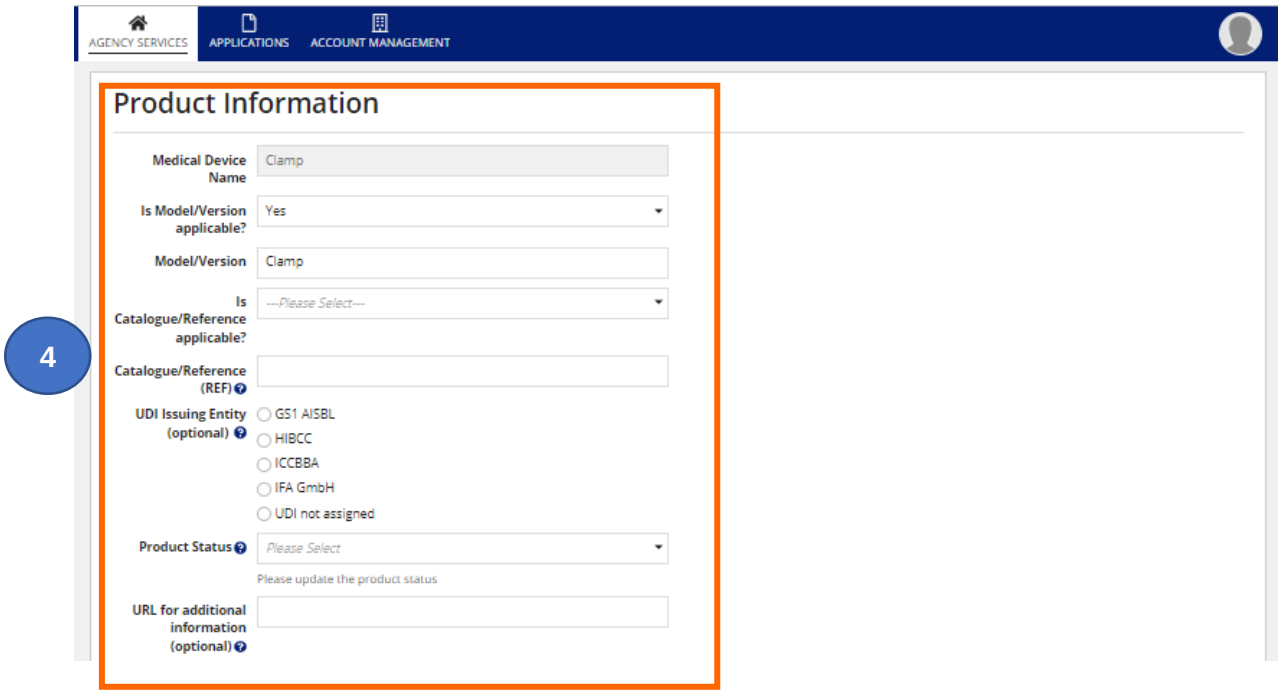
   Please note if you have updated an obsolete GMDN® you will not be able to update products in the same application and the Medical Device Name link will not be enabled. You must update product/s in a separate application, after the obsolete GMDN® application has been submitted and completed.

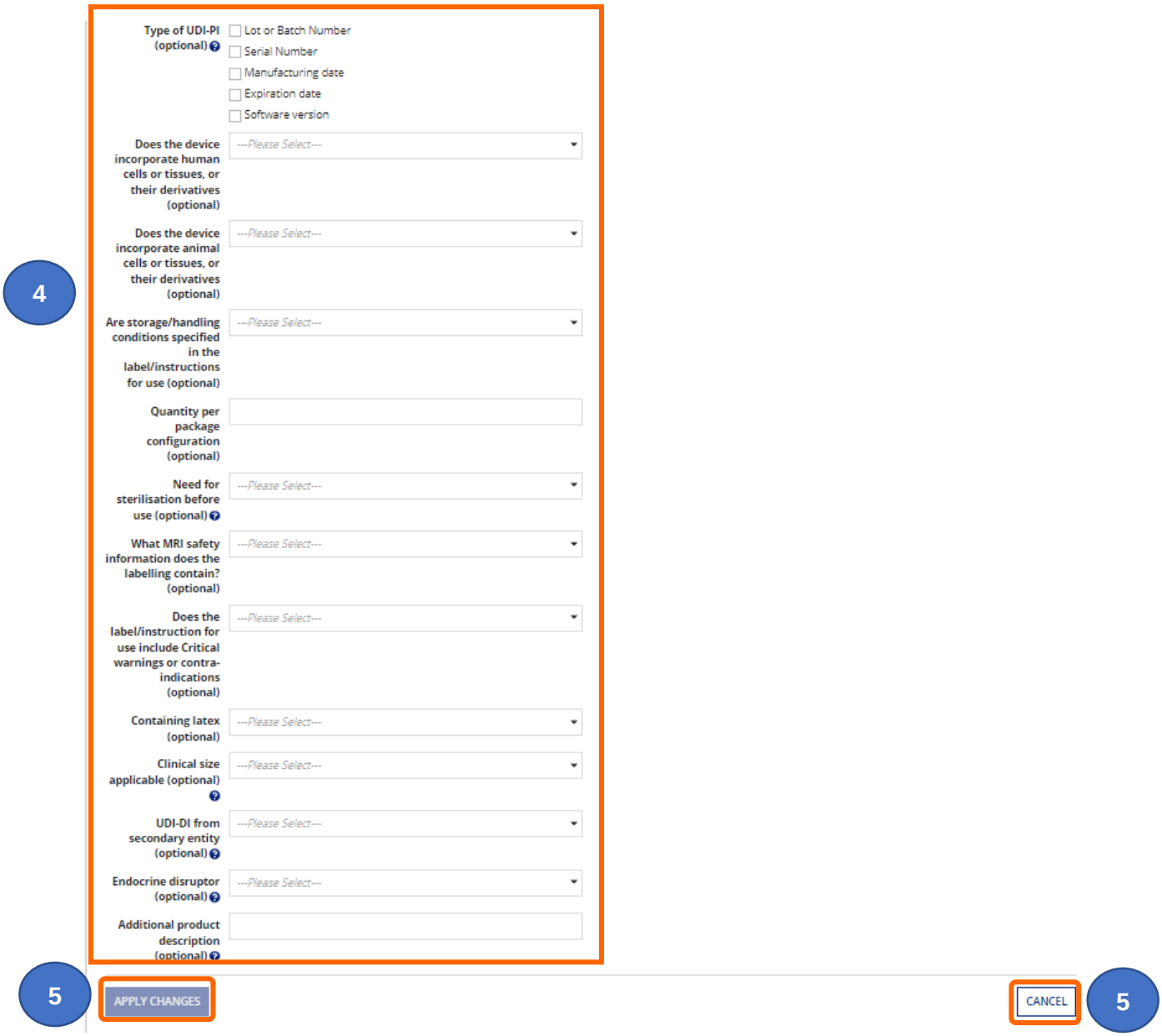
2. You can either update products individually, or update multiple products. You must **not** update products both individually and in multiples in the same application. Please create separate applications.

3. **Click** on the Medical Device Name to update the product.



4. All fields that can be updated will be **enabled**. If you need to make changes to a field that is not enabled you need to delete the products via the Manage registered devices function and add them again, there is currently no fee to add/remove products.





5. Once all fields have been updated, **click** the Apply Changes button or Cancel to discard changes.

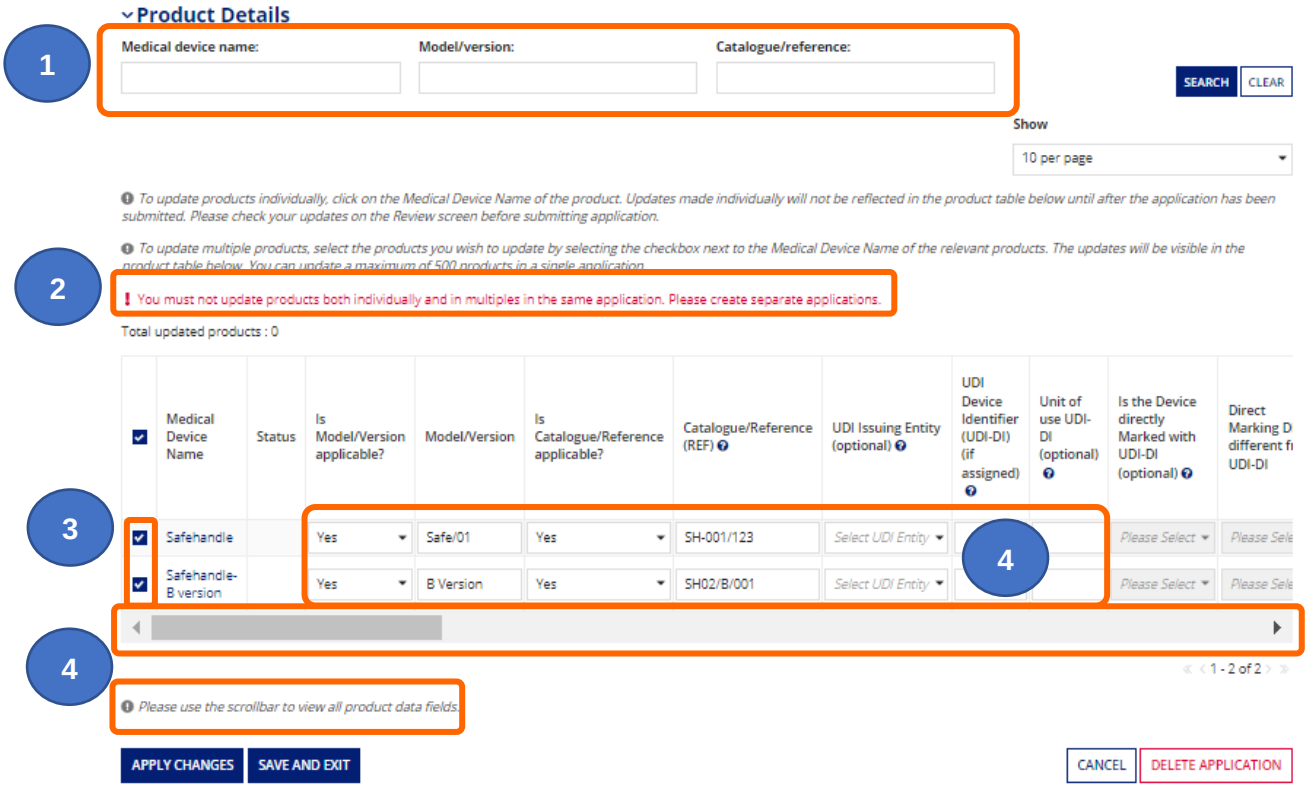
Update multiple products

1. The Product Details table will appear. Use the filters to search for products.

   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.

2. You can either update products individually, or update multiple products. You must **not** update products both individually and in multiples in the same application. Please create separate applications.

3. **Select** the tick box next to the Medical Device Names of the products you wish to update.

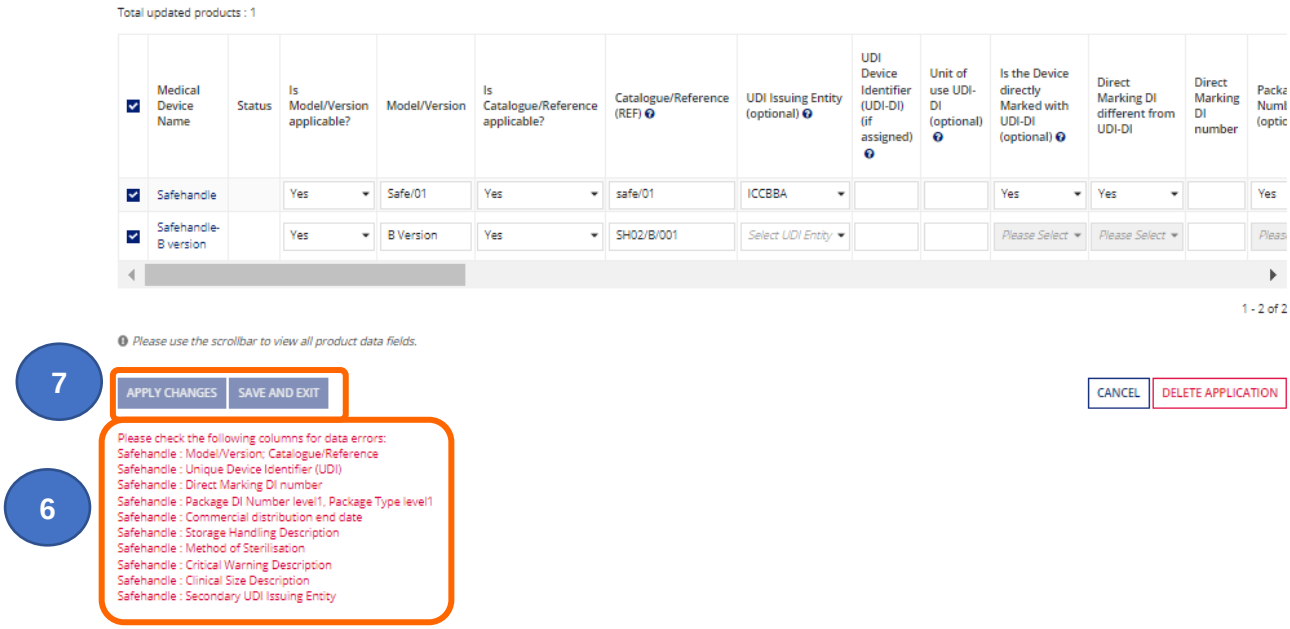


4. All fields that can be updated will be enabled.

5. Use the scrollbar to view all data fields.

Resolving data issues

6. When updating products the same validation rules apply as when adding products. If you enter invalid data, or duplicate data, or do not add data to mandatory fields you will see a warning message under the Apply Changes button with the product name and the fields that need attention.



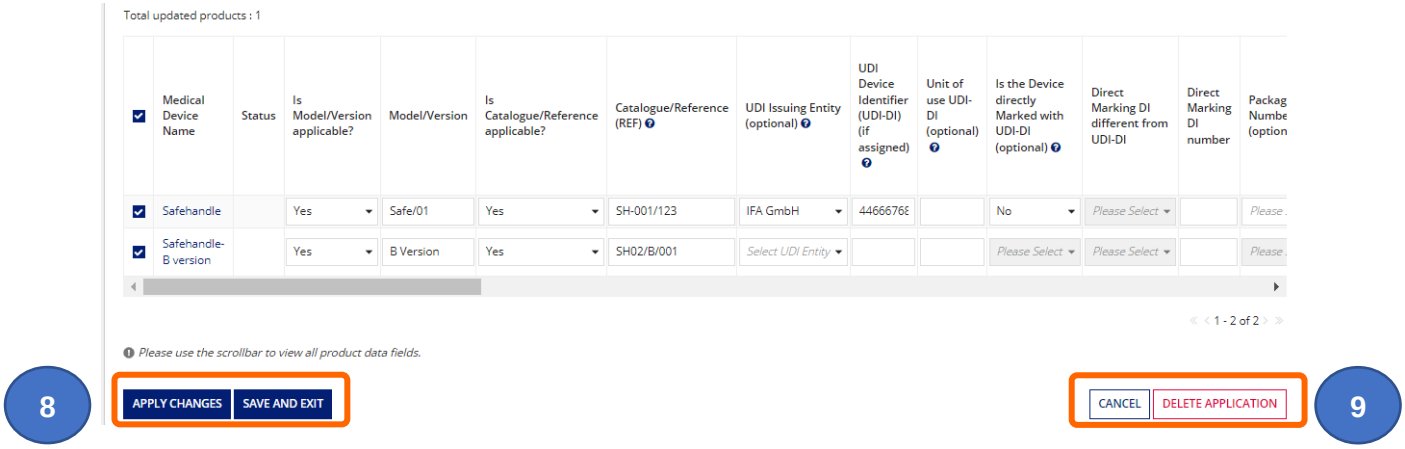
Key points to note when using the update products functions

The following are data issues that will result in errors:

- Adding duplicate data in Model/Version and Catalogue/reference field
- Selecting a UDI issuing entity and not entering a valid UDI or DI data or v.v.
- Entering invalid UDI or DI data
- Selecting product status of ‘No longer on the GB or Ni Market’ and not adding Commercial Distribution End Date
- Selecting Yes for storage handling and not entering a description or v.v.
- Selecting Yes for Method of sterilisation and not entering method or v.v.
- Selecting Yes for Critical Warning and not entering description or v.v.
- Selecting Yes for Clinical Size and not entering size or v.v.
- Selecting yes for Secondary UDI entity and not entering valid UDI DI data or v.v.

7. The Apply Changes and Save and Exit buttons will not be enabled until you have resolved all data issues.

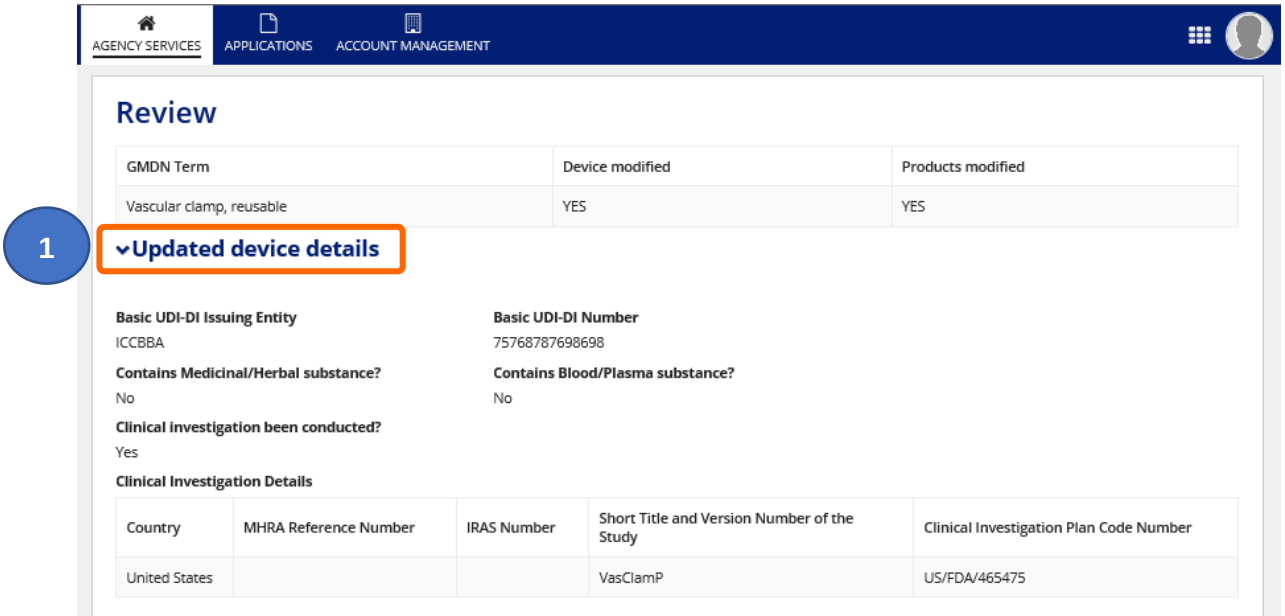
8. Once you have completed updating products, and resolved any data issues, the Apply Changes and Save and Exit buttons will be enabled.



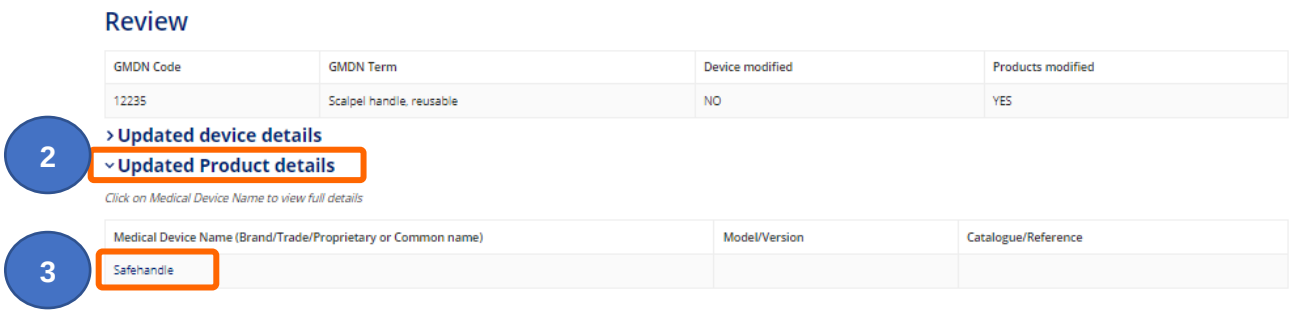
9. **Click** Cancel to discard the changes just made or Delete Application to delete all changes to all products that have not yet been submitted.

Review updated devices and products

1. On the Review page, click the **>** icon to display the Updated device details. Only fields that you have updated will display here.

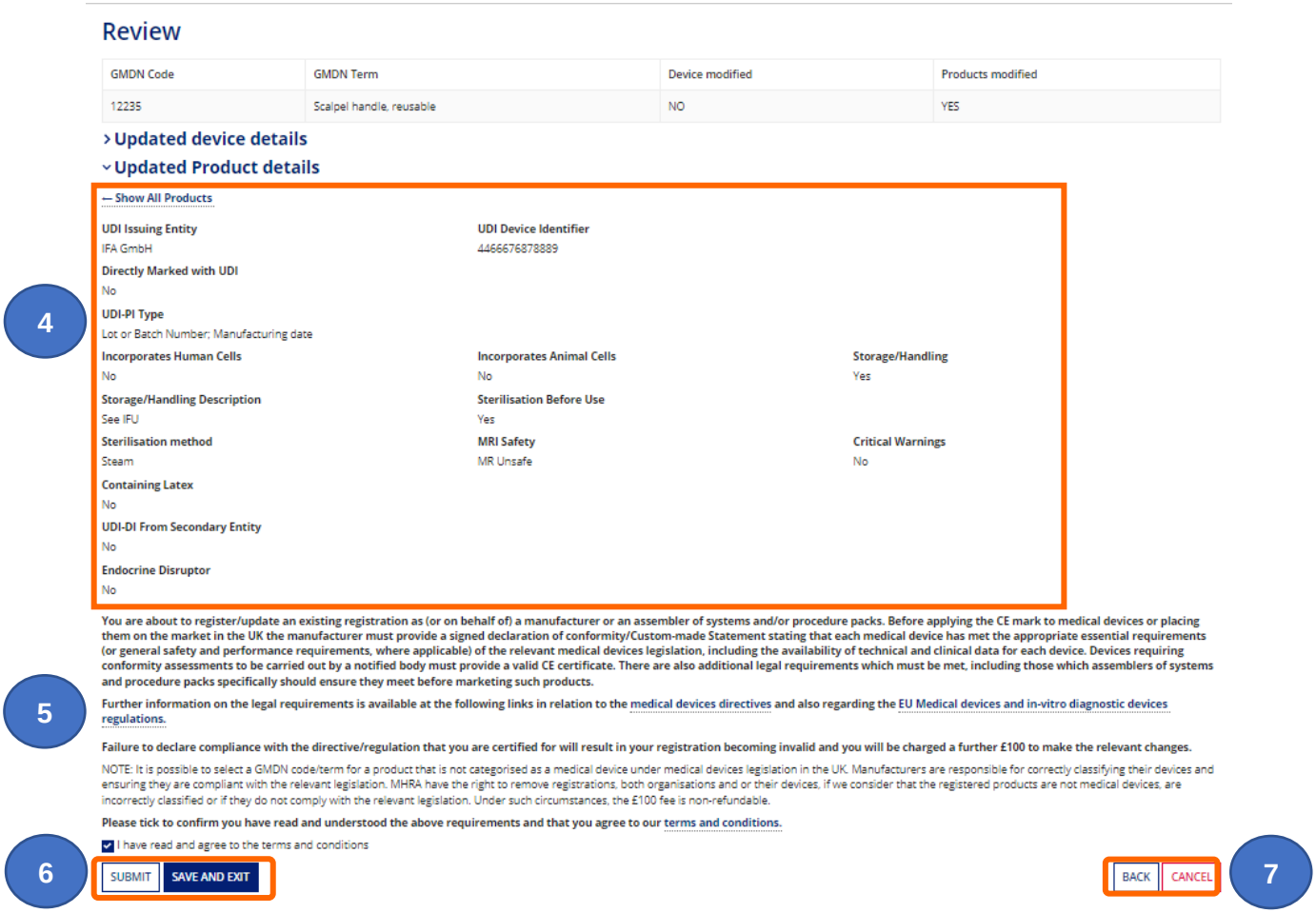


2. On the Review page, click the **>** icon to display the Updated product details.



3. **Click** on the Medical Device Name to view the updates.

4. Only fields that you have updated will display here.

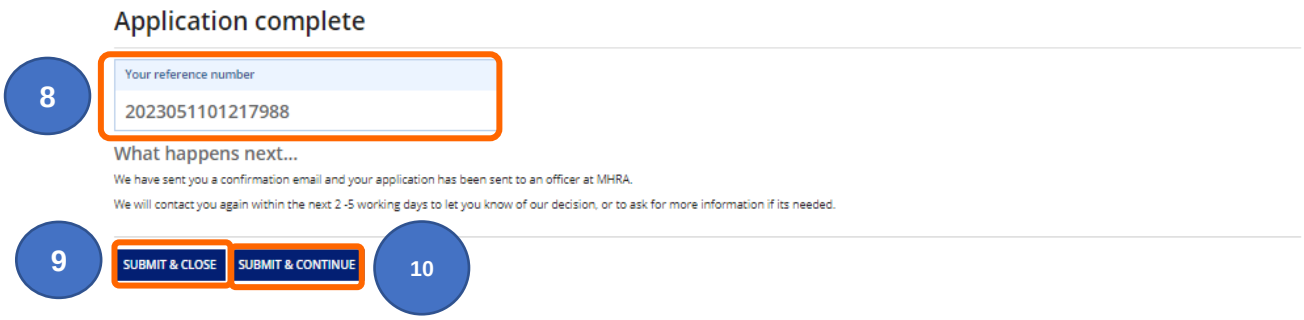


5. **Read** the important information and **agree** to our terms and conditions.

6. **Click** the Submit button to apply the changes, or **click** the Save and Exit button to save a TEMP (draft) application.

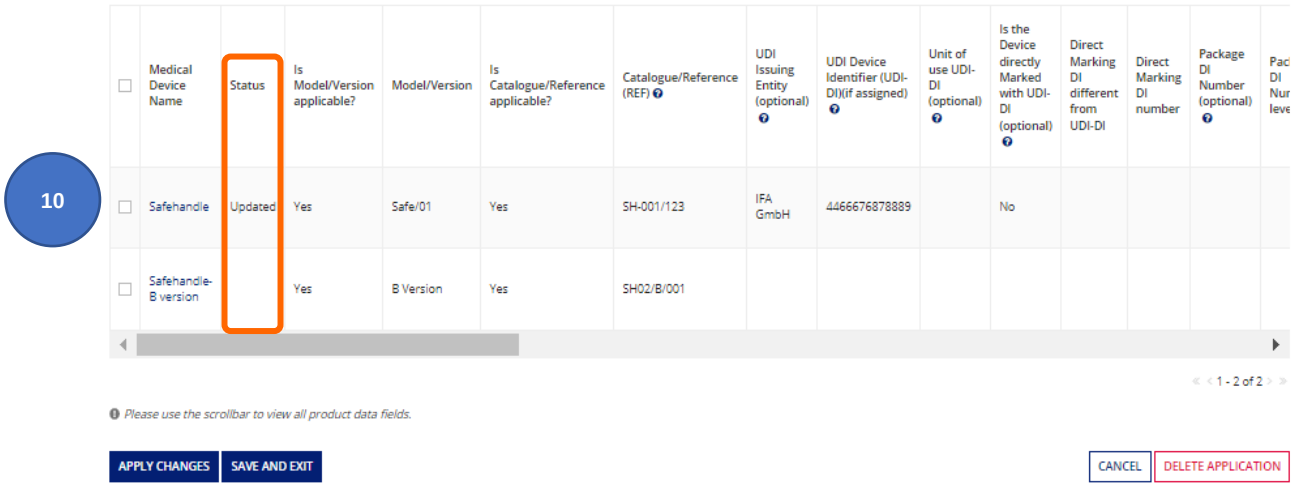
7. **Click** the Back button to go back and continue updating, or **click** the Cancel button to cancel **all** updates in the application.

8. If you **click** Submit, the changes will be applied and a reference number will be generated.



9. You will be given two options for your next action. Submit & Close will end the transaction.

10. Submit & Continue will take you back to the screen with the products that you previously selected for update but have not finished updating. The status column indicates which products have been updated.



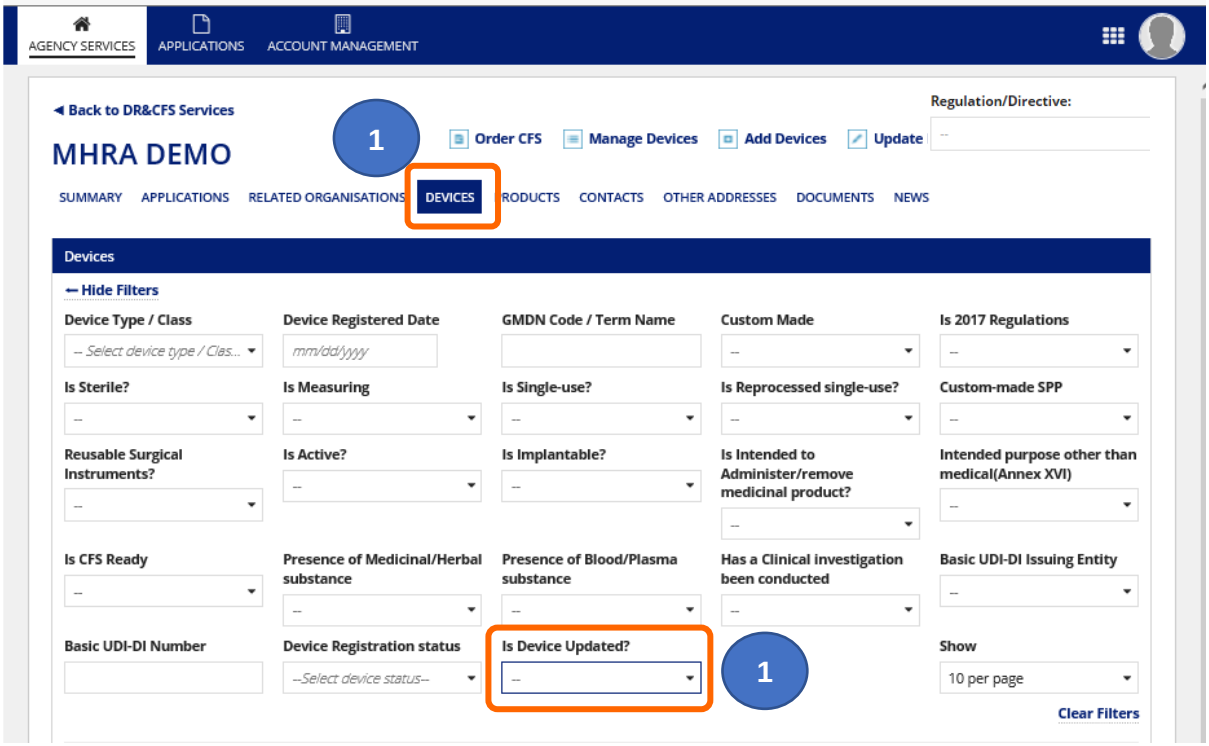
Email confirmation

1. 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.

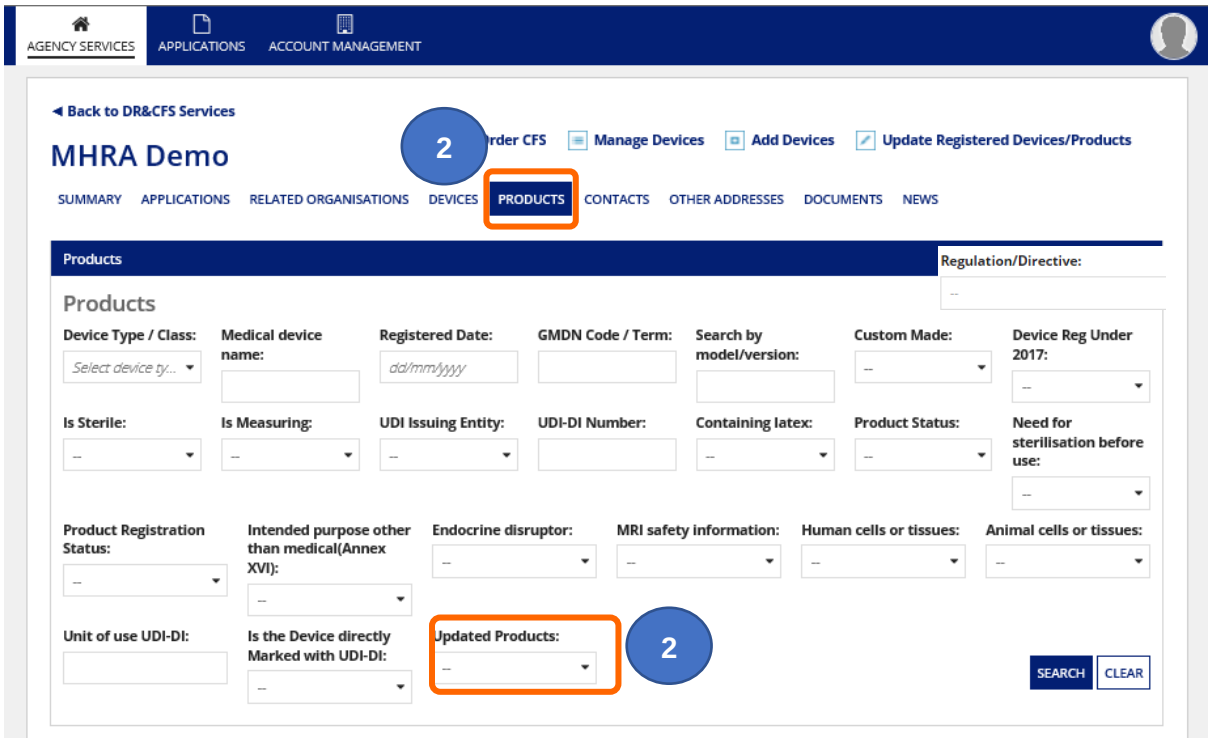
Version history

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

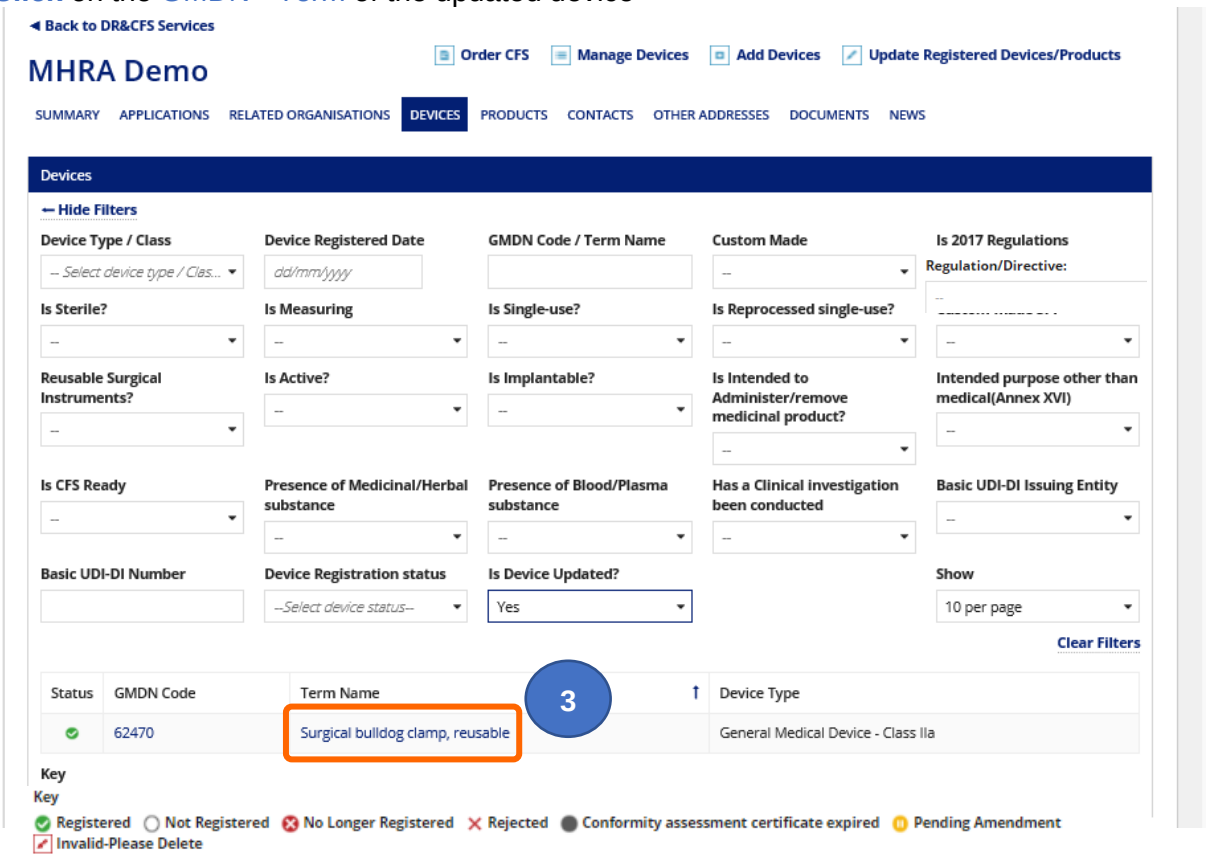
1. To view the version history for a device. Search for the device using the Is device updated filter? on the Device tab.



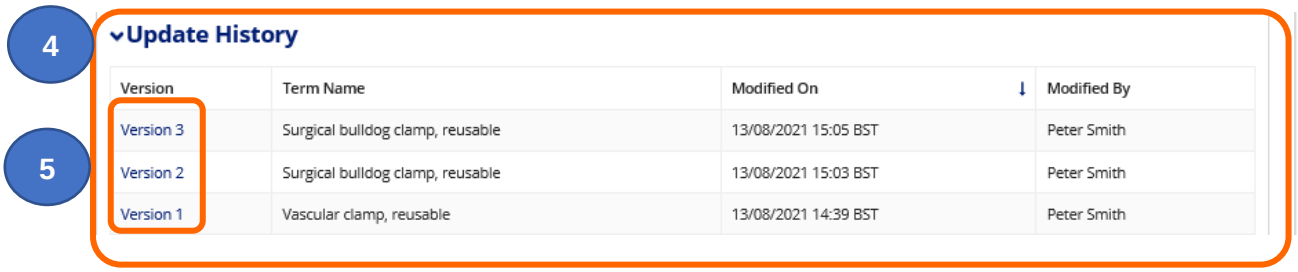
2. To view the version history for a product. Search for the product using the Updated Products filter on the Product tab.



3. **Click** on the GMDN® Term of the updated device

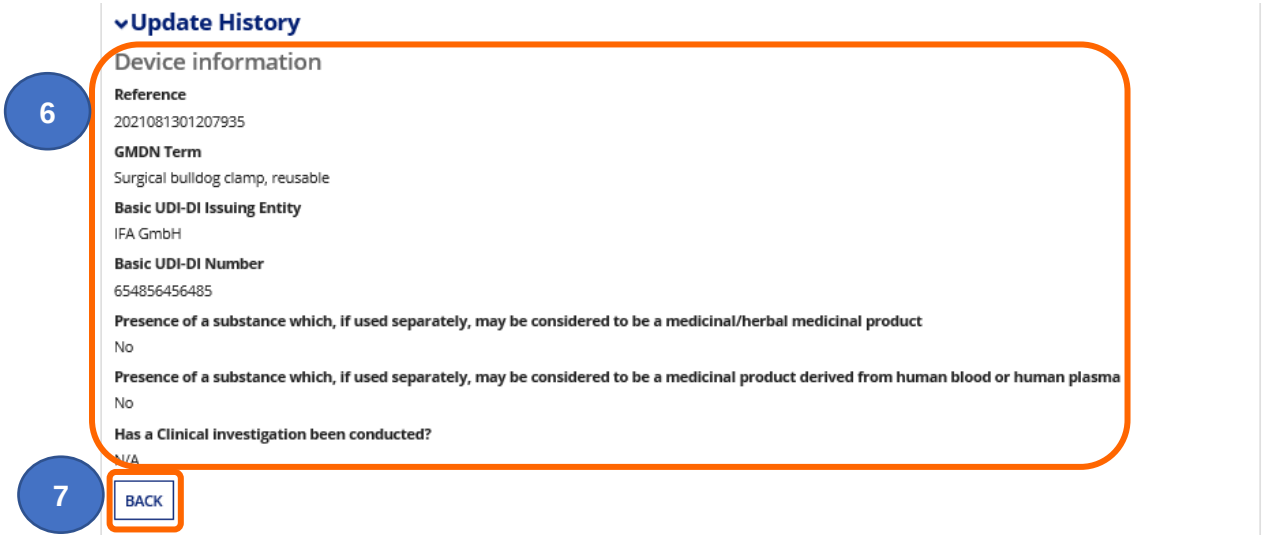


4. An Update History table will appear with a version entry for each update application submitted for the device, indicating when the device was modified and by whom.



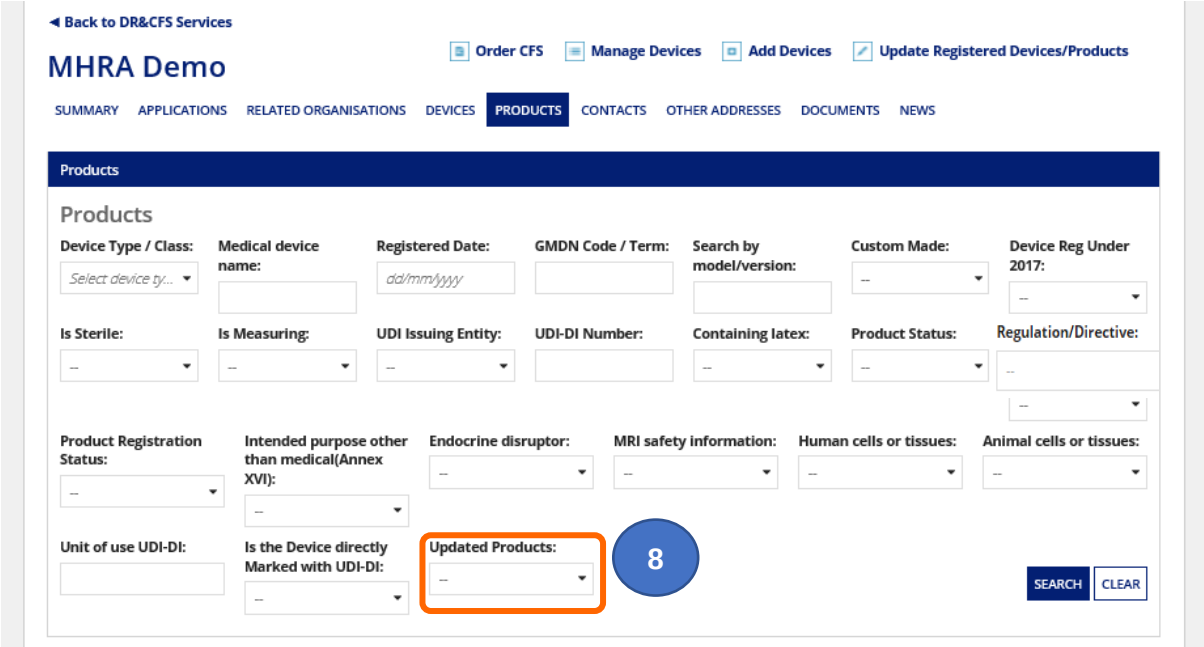
5. **Click** on each version to view updates made to the device.

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

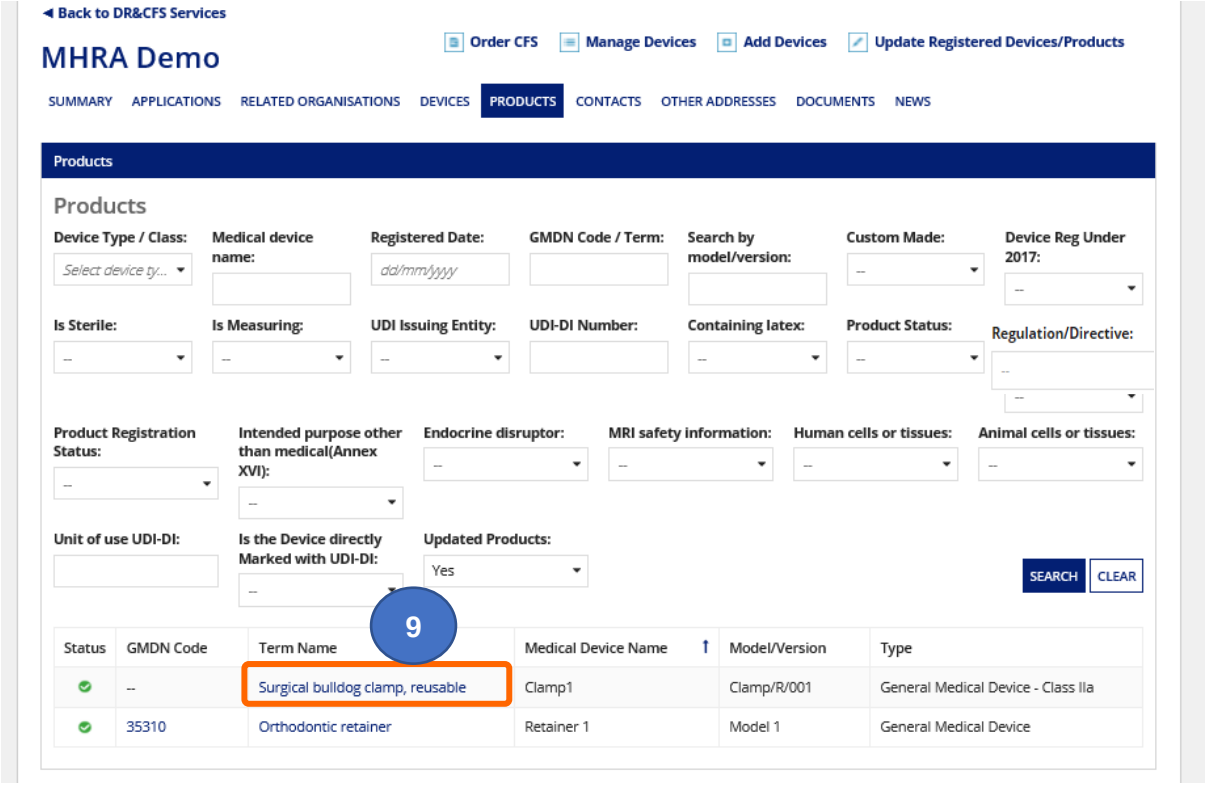


7. **Click** the Back button to go back to the Update History table and view other versions.

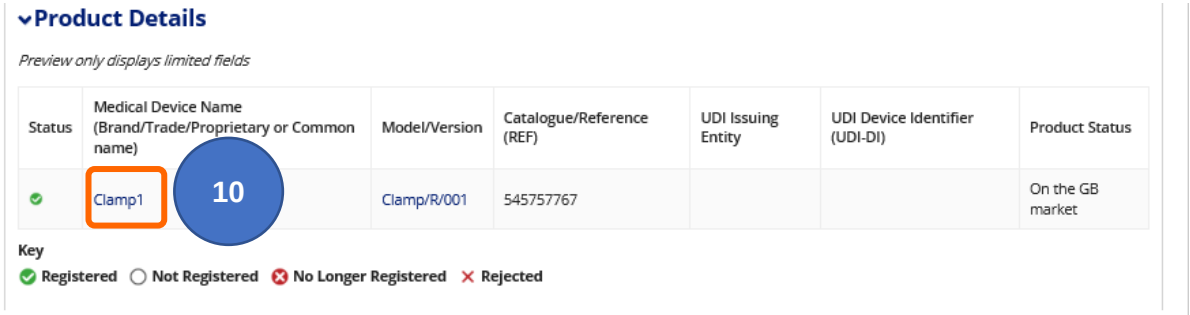
8. To view the version history for a product. Search for the product using the Updated Products filter on the Products tab.



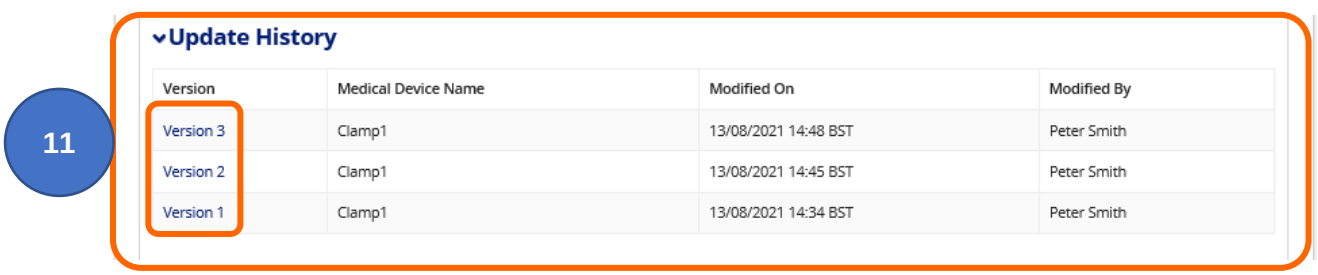
9. **Click** on the GMDN® Term of the updated product.



10. **Click** on the Medical Device Name of the product



11. 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. **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

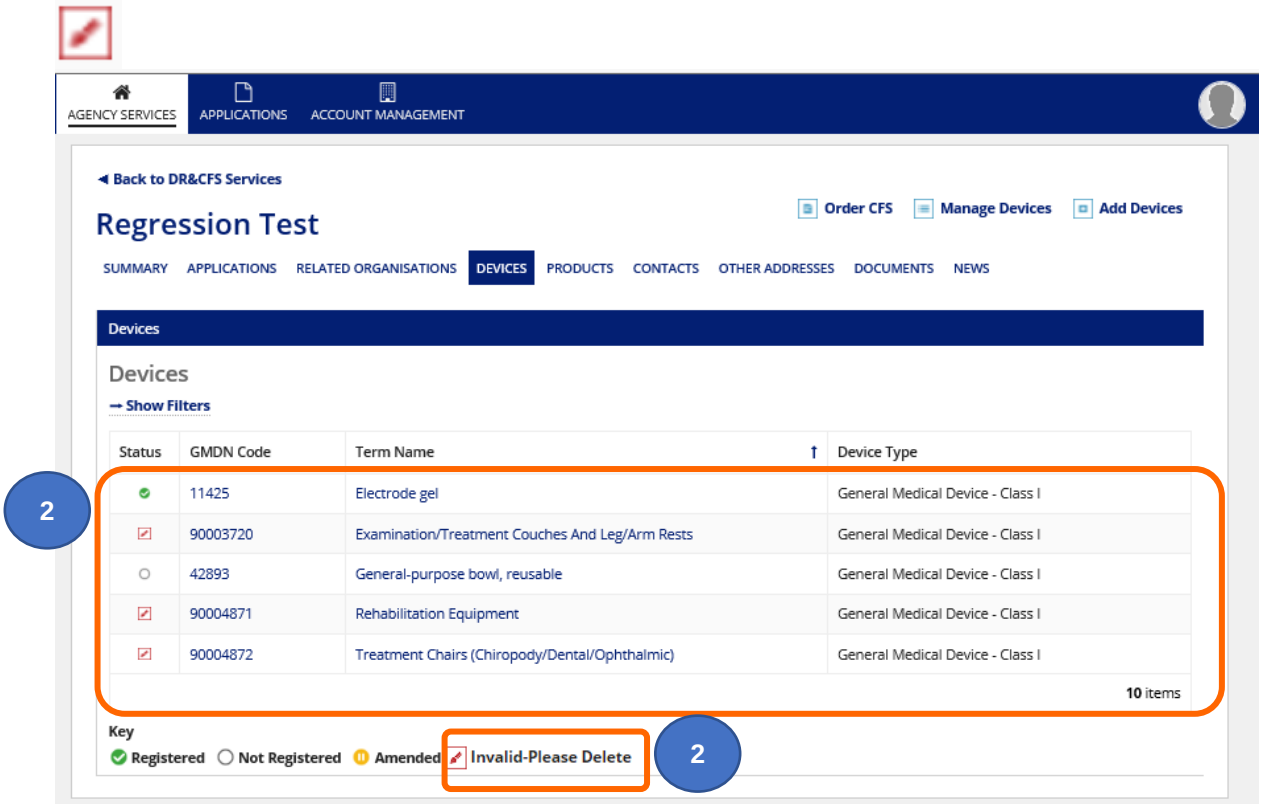
This section applies to Migrated customers **only**. Please see Determine if your account is migrated or re-registered. These are invalid terms and you cannot update these devices.

You will need to **add** all the devices you manufacture first and then **remove** the Pseudo GMDN® Terms.

Migrated Pseudo GMDN® Terms do not appear on the Public Access Registration Database (PARD). If you only have Migrated Pseudo GMDN® Terms on your account, PARD will display the following message in the device field: '**Devices pending update by manufacturer'**.

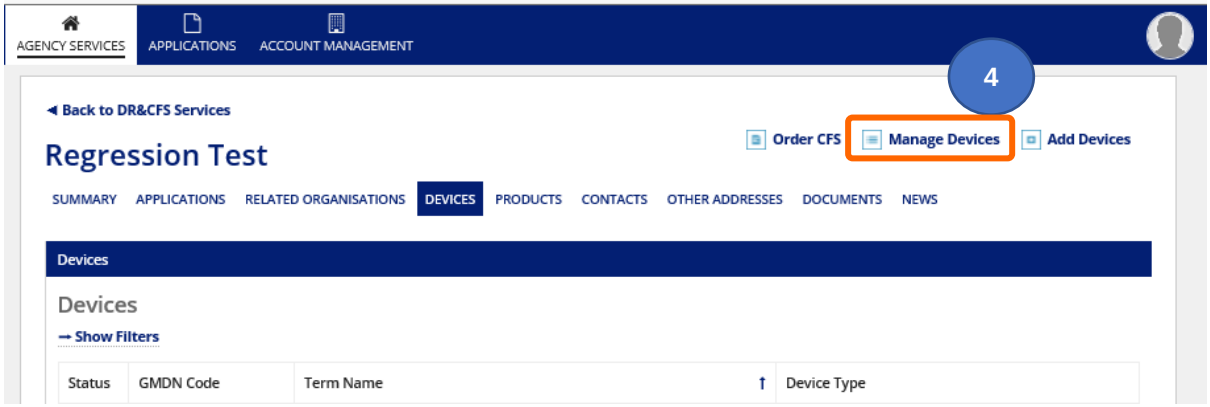
1. **Click** the Devices tab

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

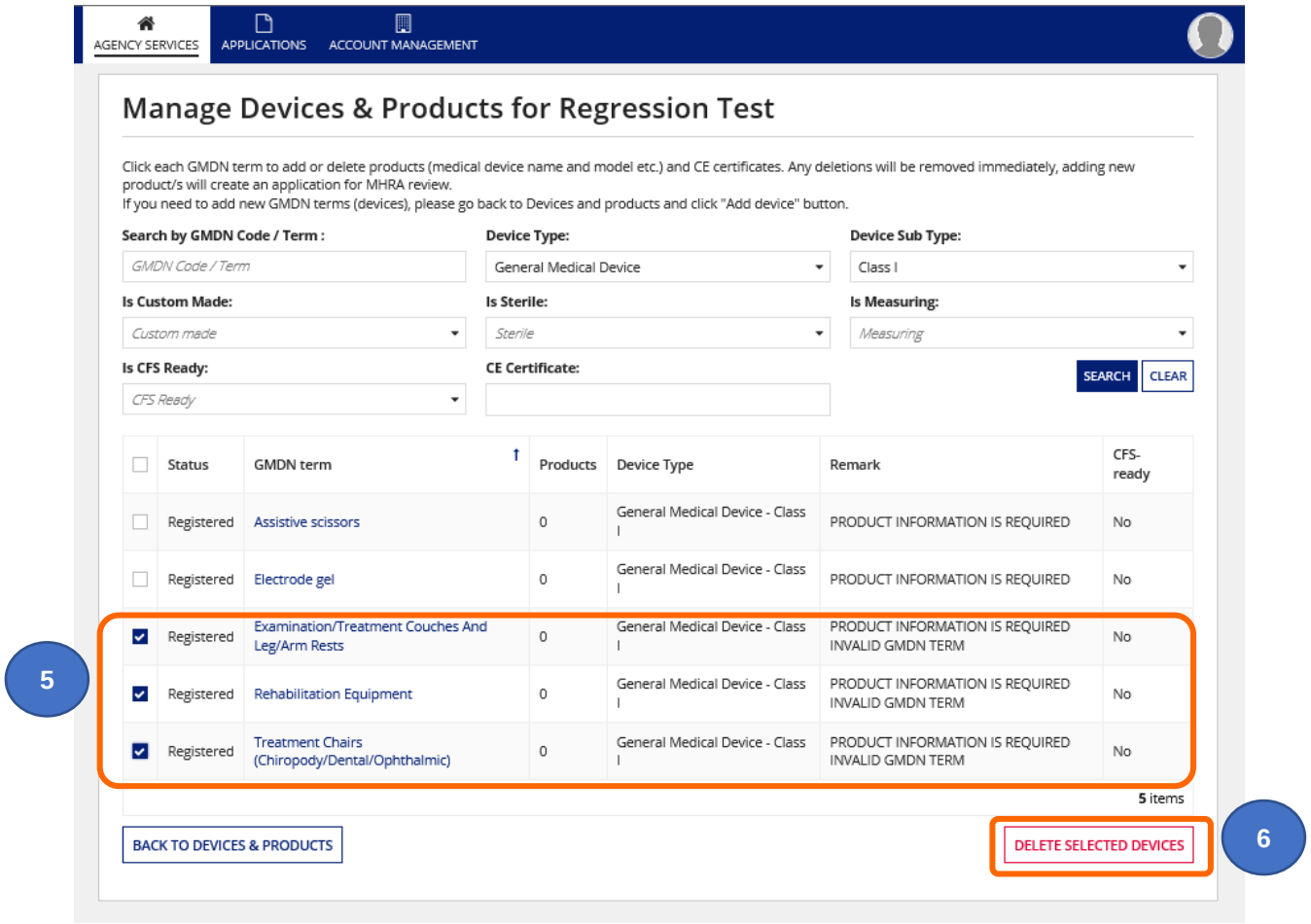


3. **After** following all the Add Devices using GMDN® instructions to add all the devices you manufactuer:

4. **Click** on the Manage Devices link.

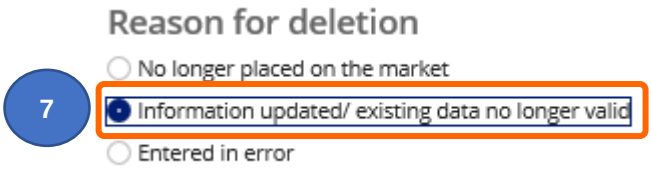


5. **Select** all the Pseudo GMDN® Terms migrated from our old system. You can identify these in your manage devices list by either searching for the device using filters or searching all devices that are **not** CFS ready by using the Is CFS ready? filter, the Remark column will indicate 'Invalid GMDN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



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

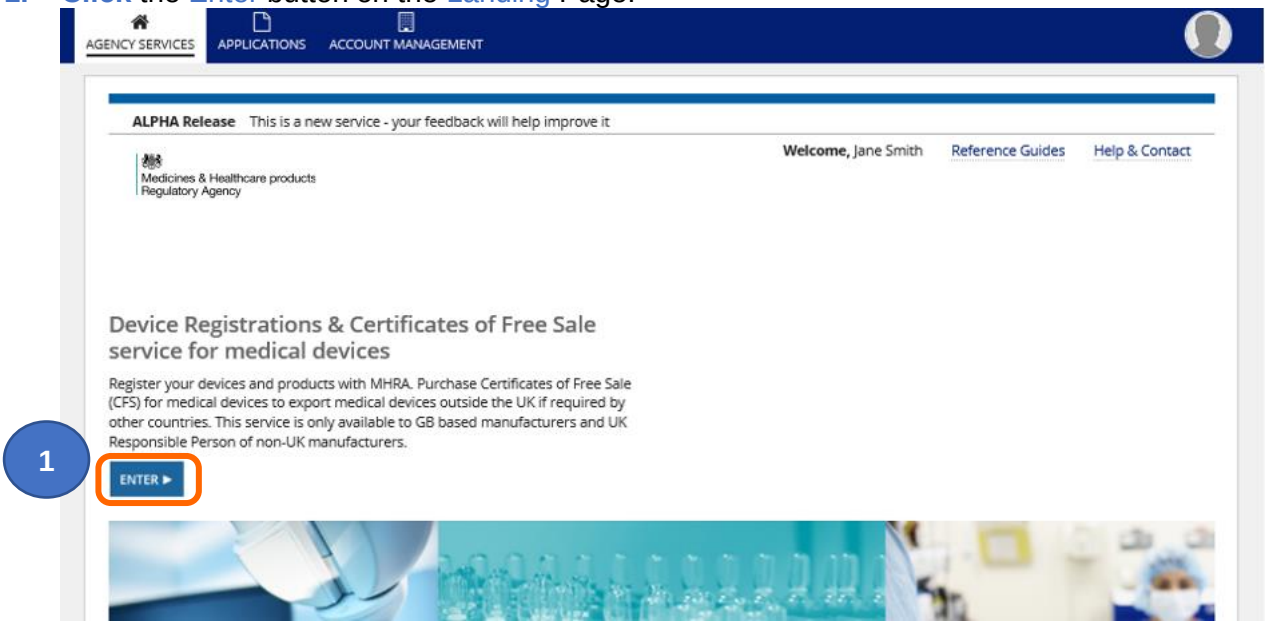
7. **Select** option Information updated/existing data no longer valid for Reason for deletion. The selecetd option will be applied to **all** the deleted devices. If the reasons for deletion are different, please create separate applications.



8. 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)

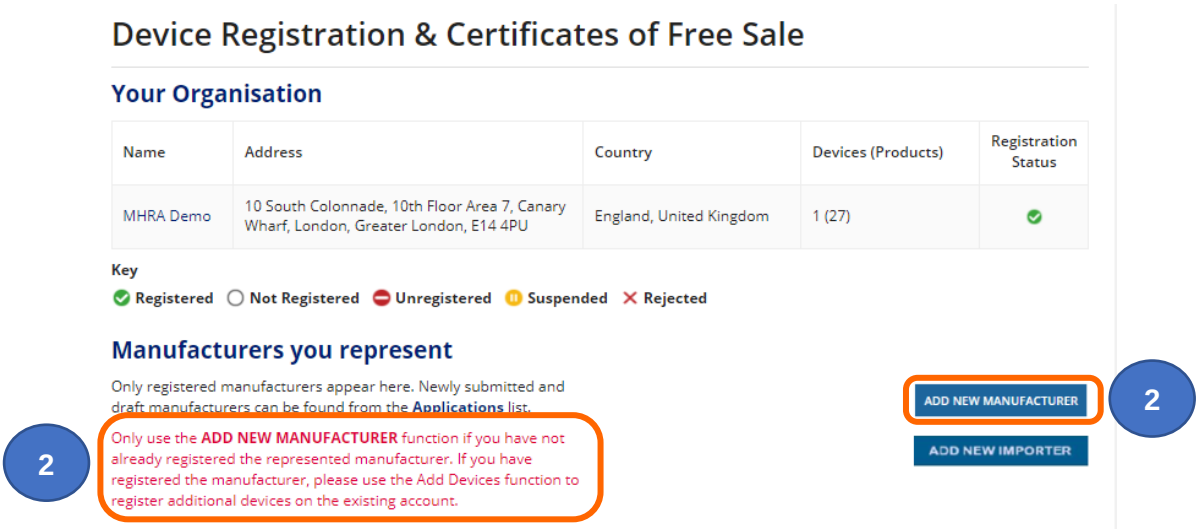
1. **Click** the Enter button on the Landing Page.



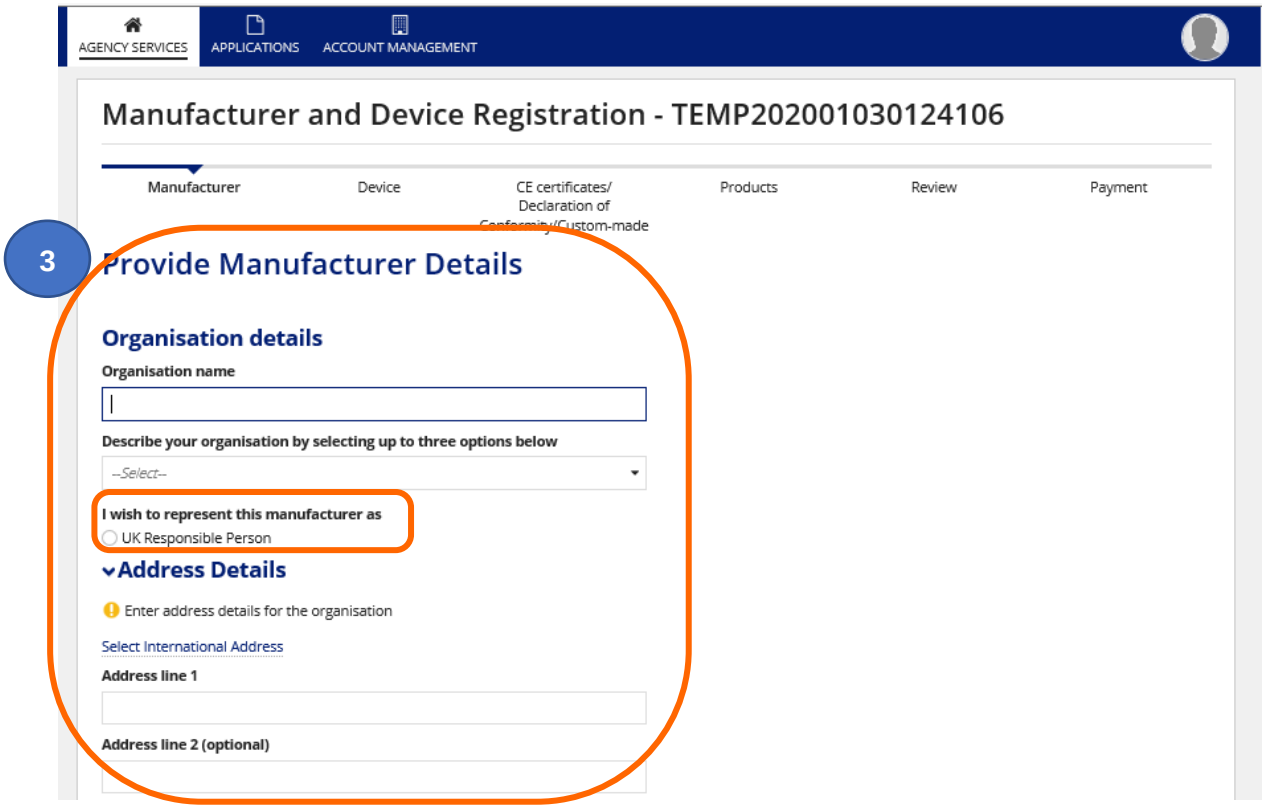
2. **Click** on the Add New Manufacturer button.

Please note. Only UK Responsible Persons (of manufacturers outside the UK) or NI-based Authorised Representatives (of manufacturers outside the 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.

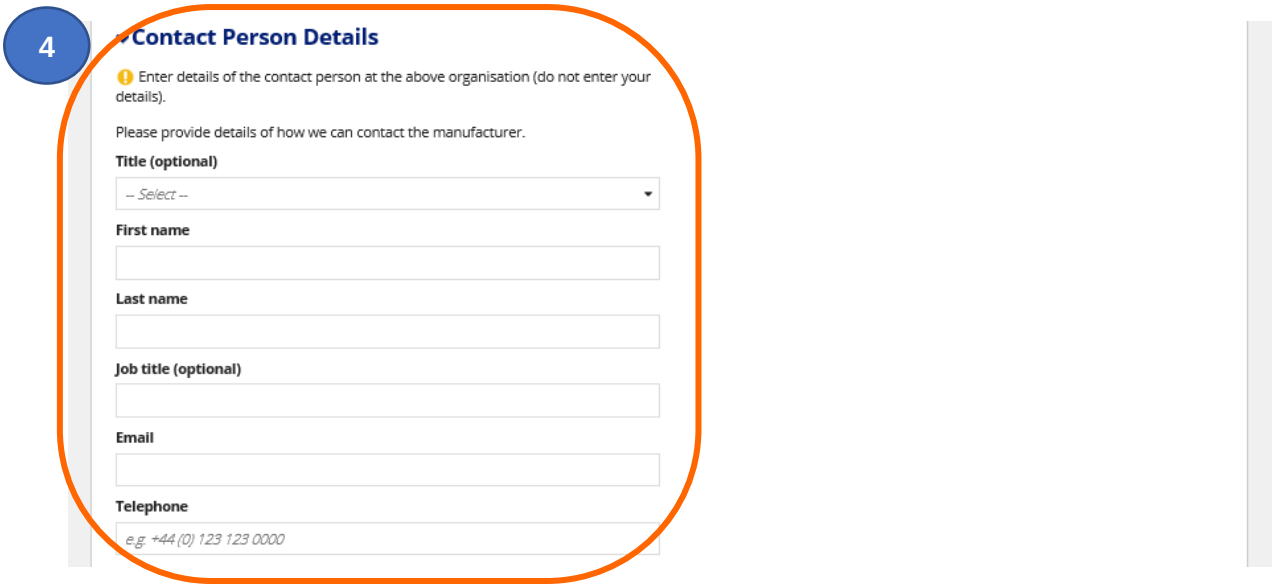
If you have already registered the represented manufacturer, please manage their existing account. Do not create multiple accounts for the same represented manufacturer, this results in additional unnecessary work and fees.



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.

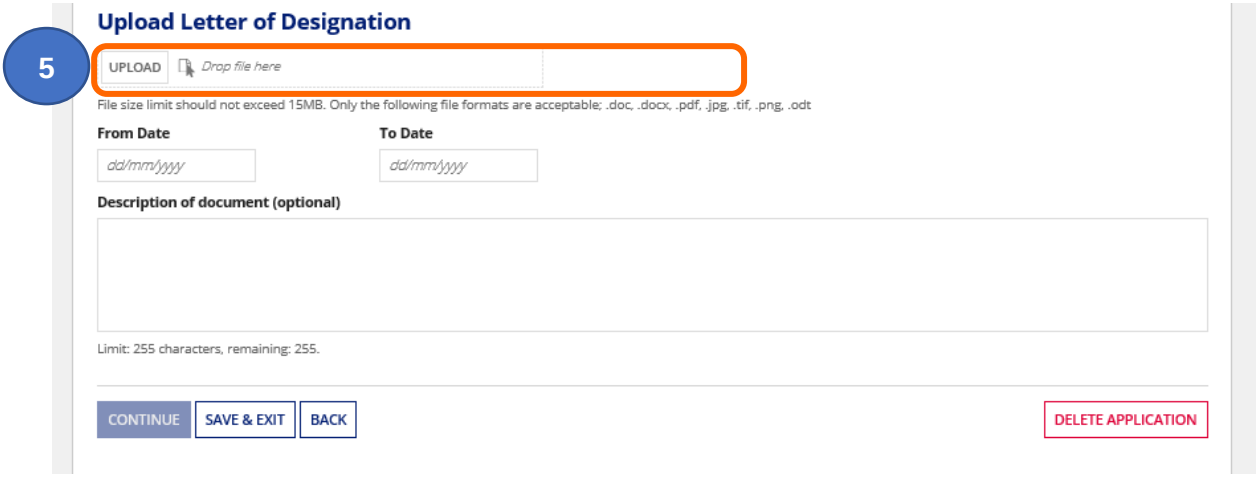


4. **Enter** details of the contact at the represented organisation – please do not enter your contact details here.



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 contract 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.



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

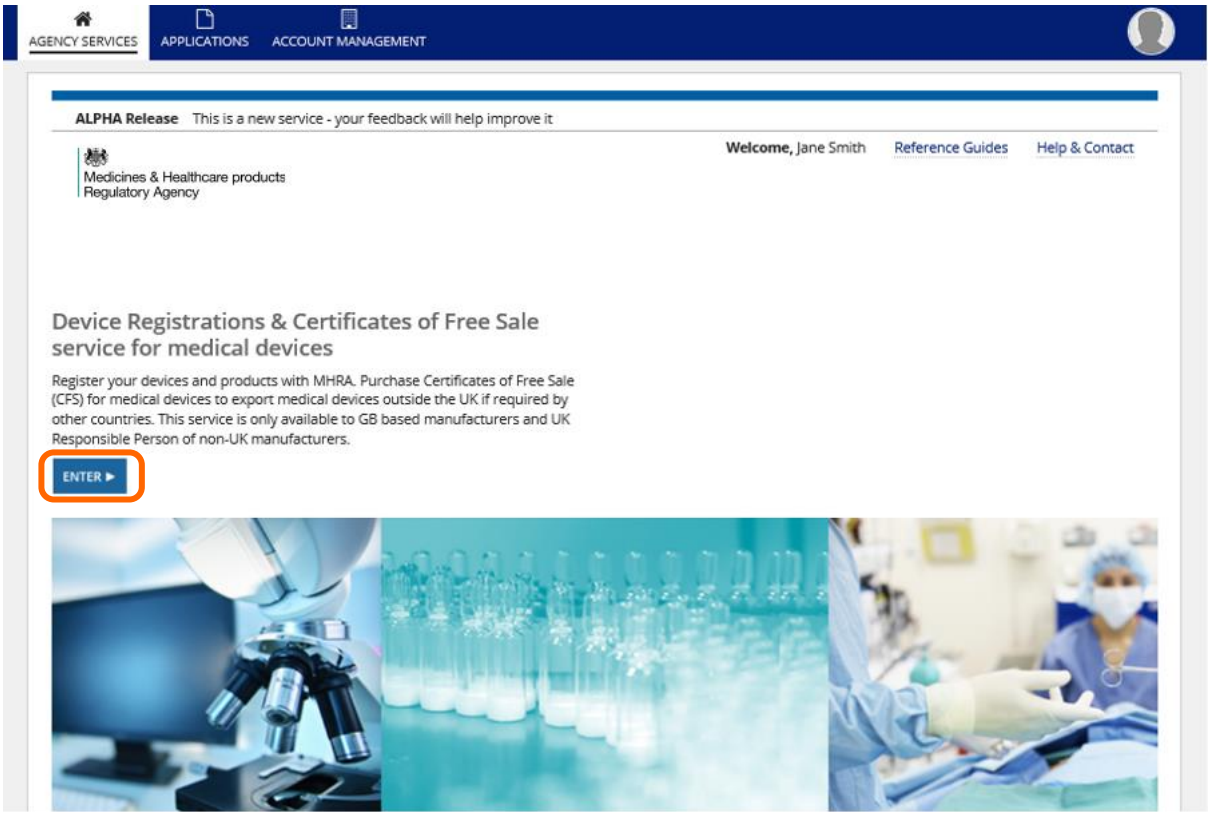
Please note you will receive email reminders 3, 2 and 1 month prior to expiry of your Letter of designation. If you do not upload a new Letter of Designation before the expiry of the existing one, your account will be **suspended** until you upload a valid letter. **A suspended account means you are 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 Registration Database (PARD). See Uploading New Letter of Designation in the **Account Management Reference Guide** to update Letter of Designation.

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.

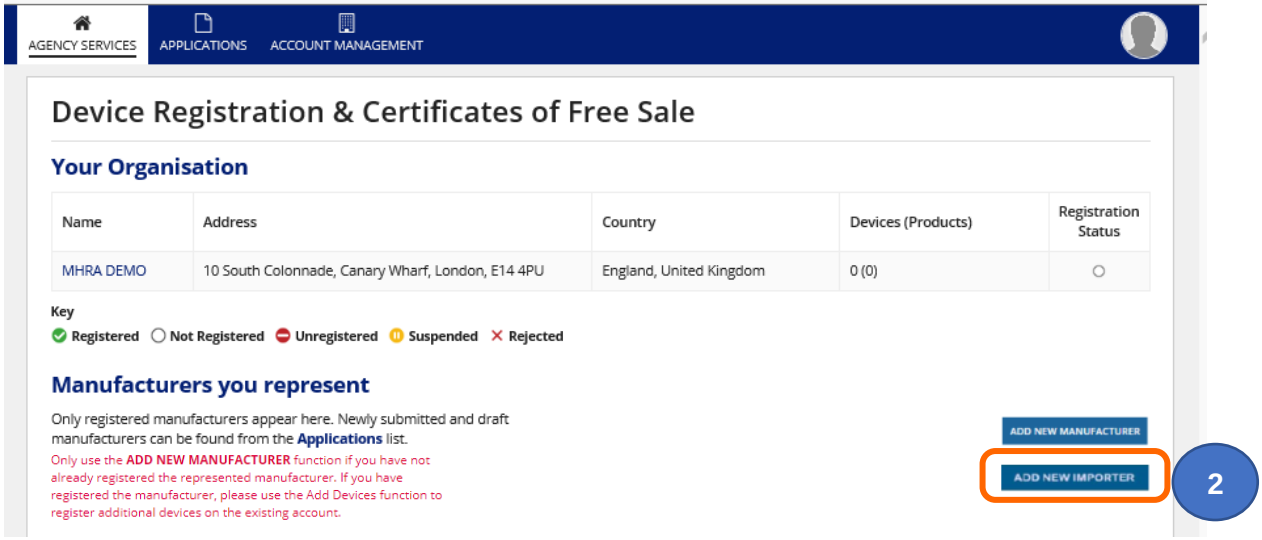
Adding Importers

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 EU).

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



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



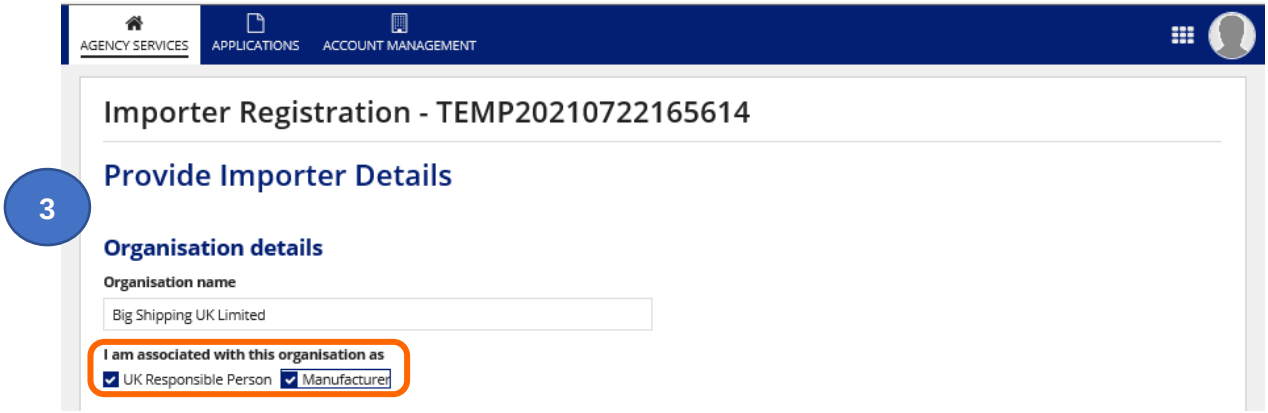
3. **Enter** the importer details:

- **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).

  Please note: If you have multiple roles, please select your associated role for **this** importer. If the importer imports for you as a manufacturer, select manufacturer. If they import for one or more manufacturers that you represent as a UKRP/NI Authorised Representative, select UKRP and/or NI Authorised Representative, as appropriate. If they import for you as a manufacturer and also for your represented manufacturer/s, please select Manufacturer and UKRP and/or NI Authorised Representative, as appropriate.

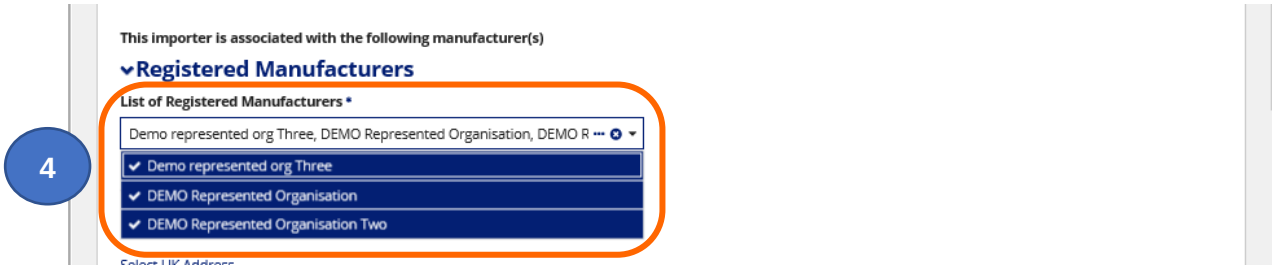
- Multiple associations can be ticked e.g. if you have a dual or triple role and also use the importer for your represented manufacturers in your capacity as UKRP or Northern Ireland Authorised Representative.

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

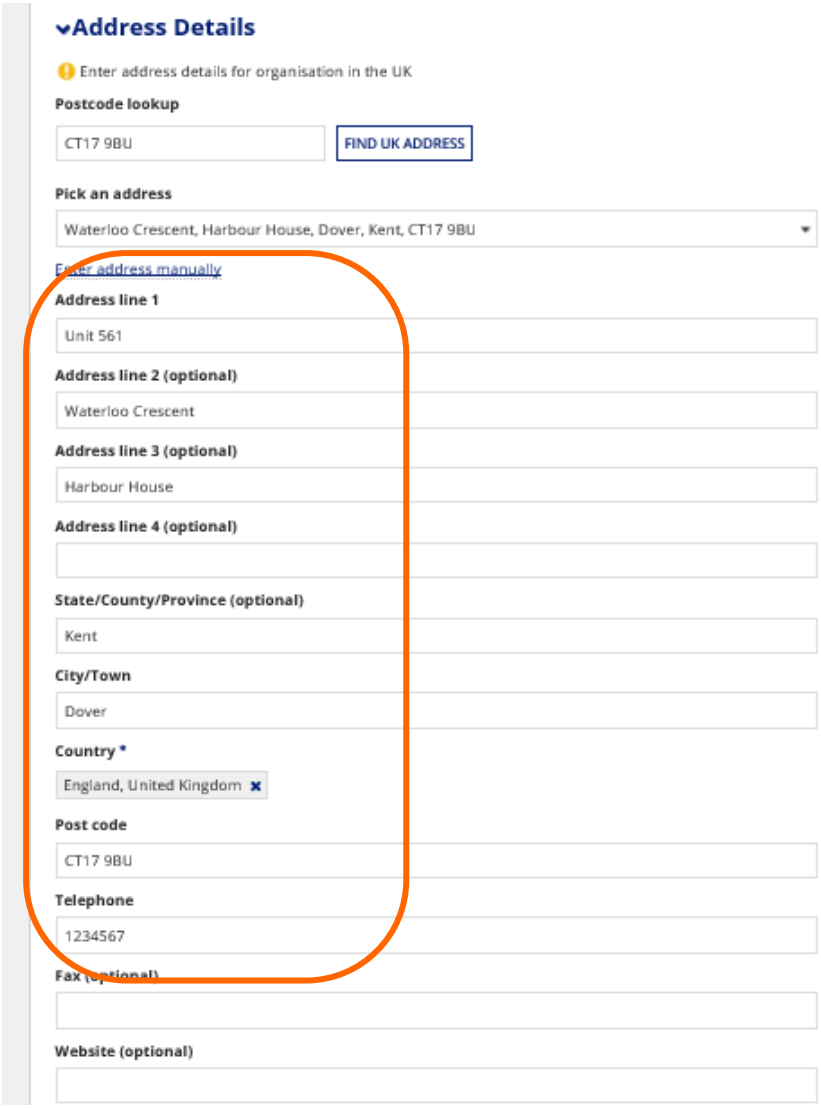


4. **Select** from the list of Registered Manufacturers you represent. Multiple manufacturers can be selected.

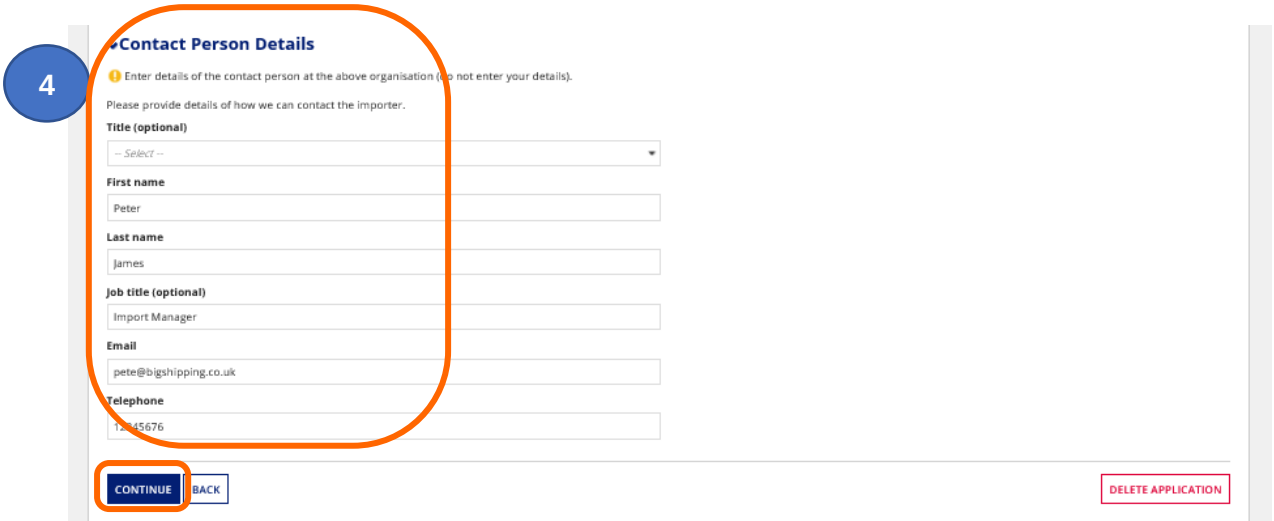
   Please note if you have selected that **you** are associated with this importer as a manufacturer, your organisation will automatically be included and will not appear in the List of Registered Manufactuers.



5. **Enter** all mandatory address fields for the importer

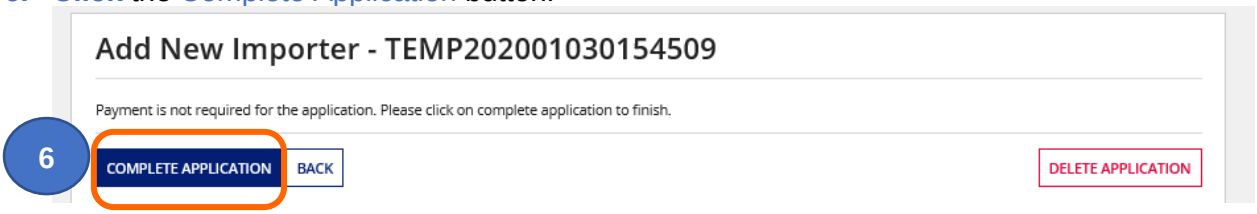


6. **Enter** the importer's contact details– please do not enter **your** contact details here.

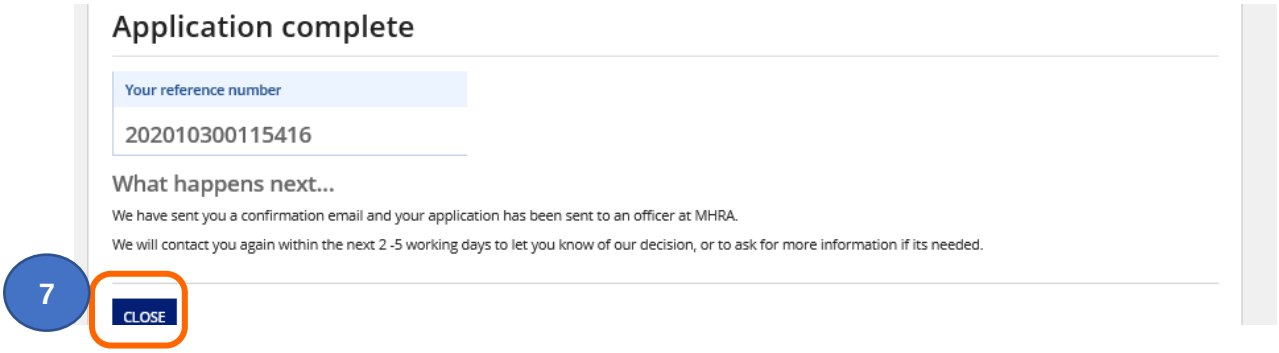


5. **Click** the Continue button.

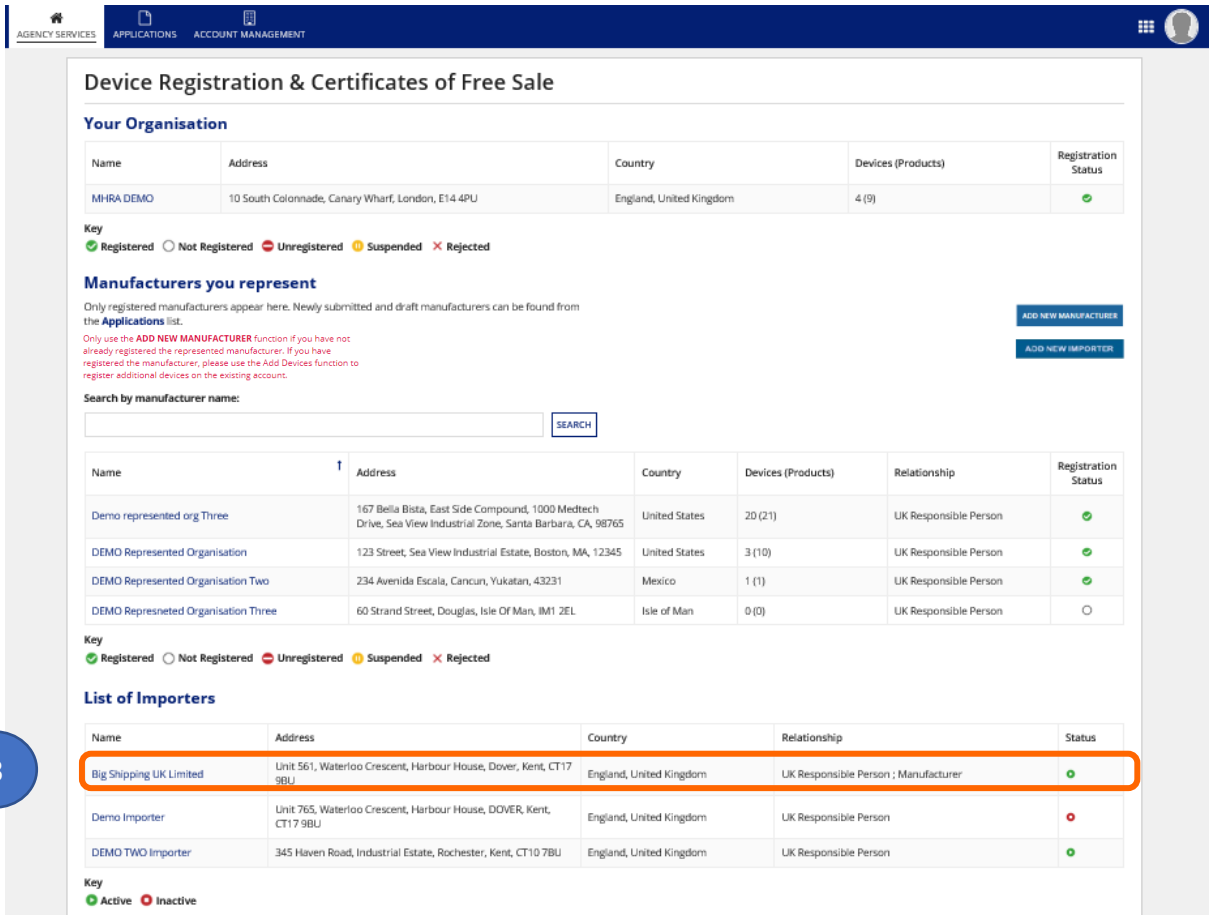
6. **Click** the Complete Application button.



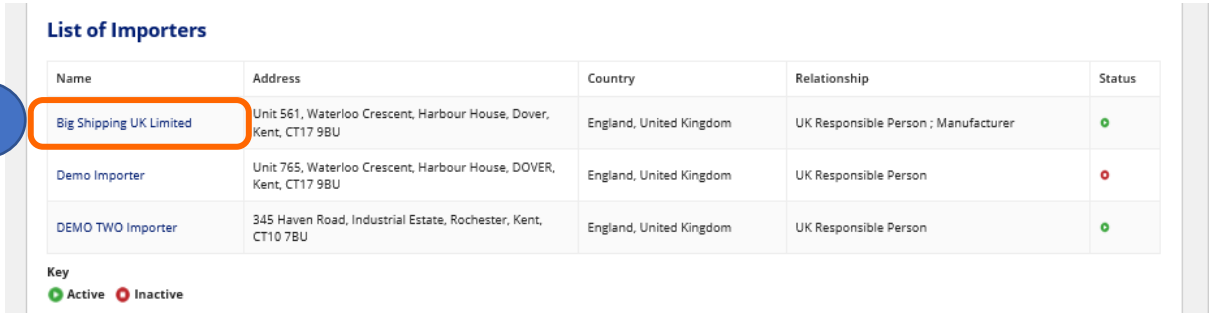
7. **Click** the Close button.



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.

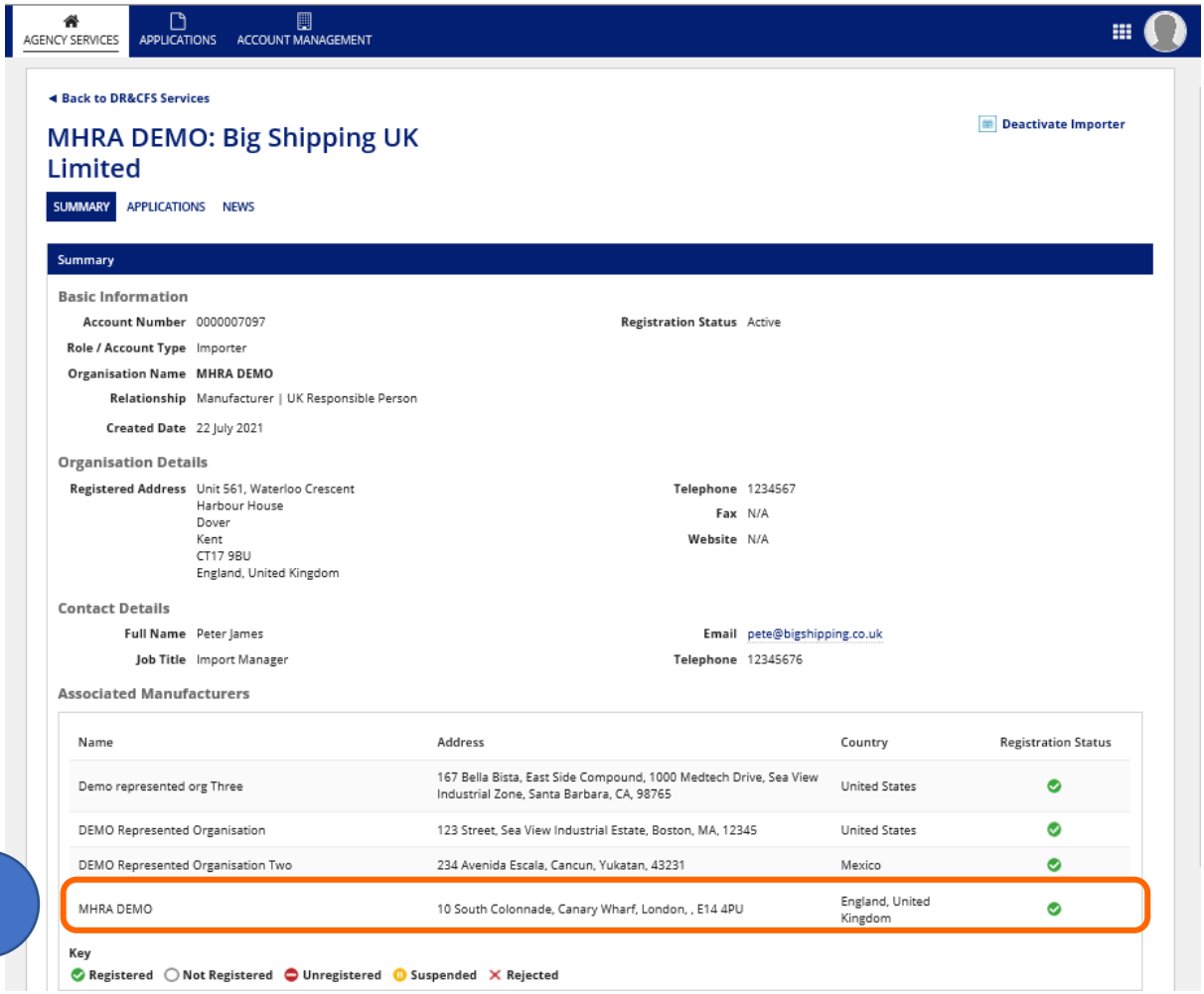


9. Click on the importer name in the List of Importers on the Organisation page.



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

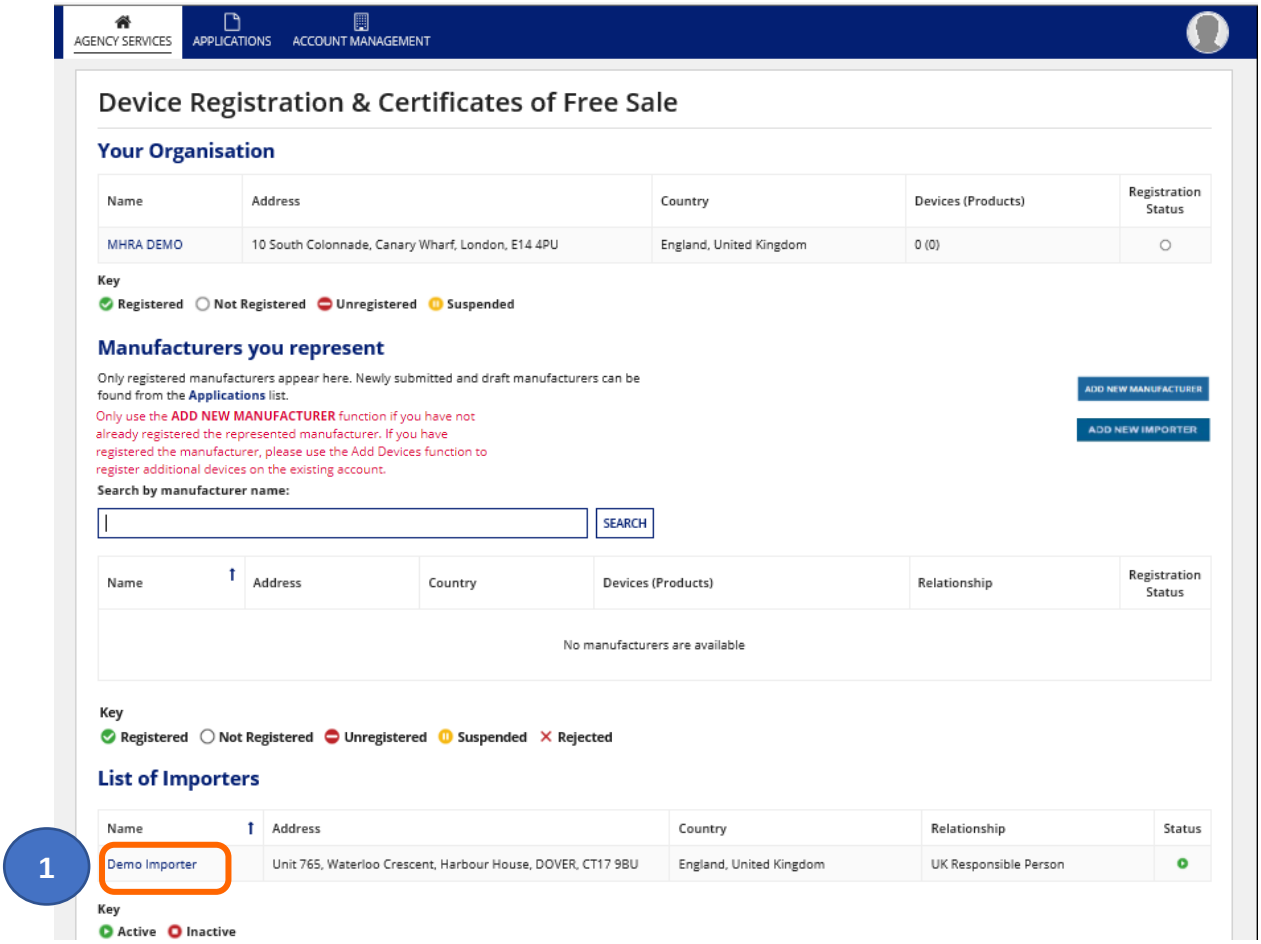
Please note if you or any of your represented manufacturers are no longer associated with an importer, you will need to deactivate the importer account. You can add the importer again with new associated manufacturers, if applicable. There is currently no fee to do this. Please see Deactivating Importers.



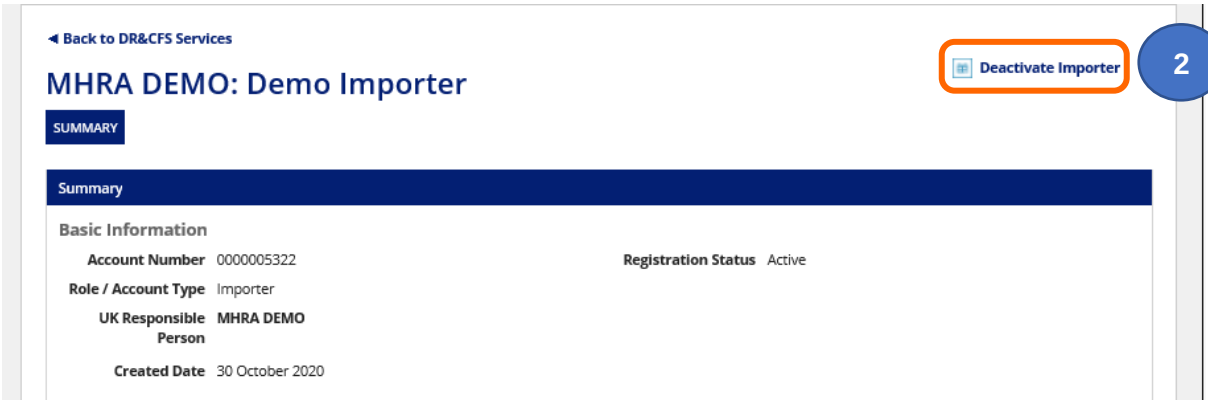
Deactivating Importers

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.



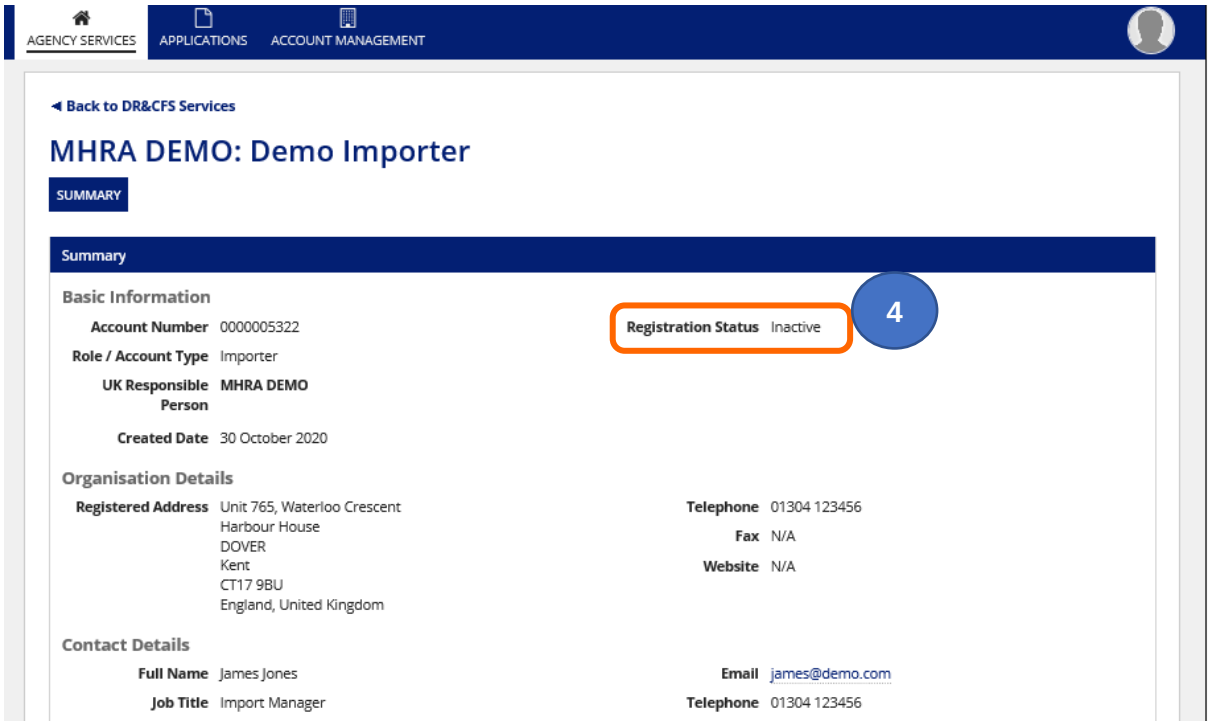
2. **Click** on the Deactivate Importer button.

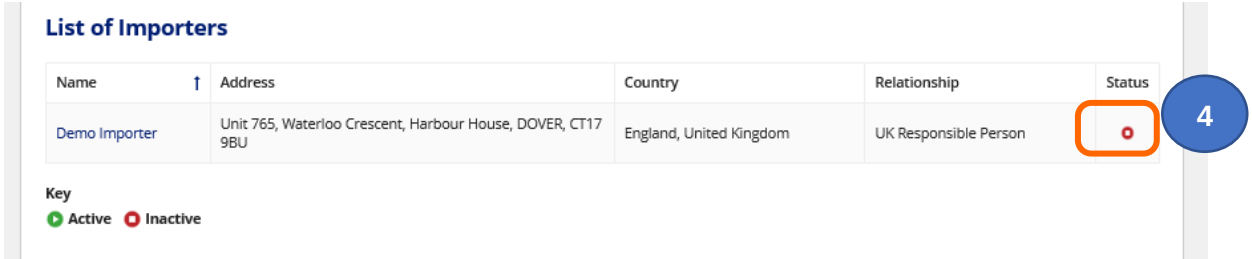


3. **Click** the Yes button to deactivate or the No button to cancel the action.

   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.



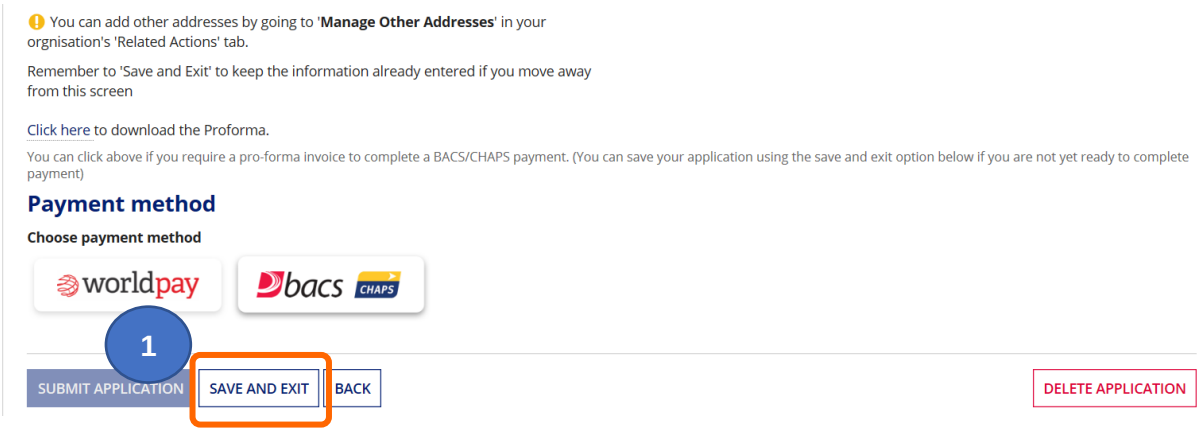


Save and exit: resume applications

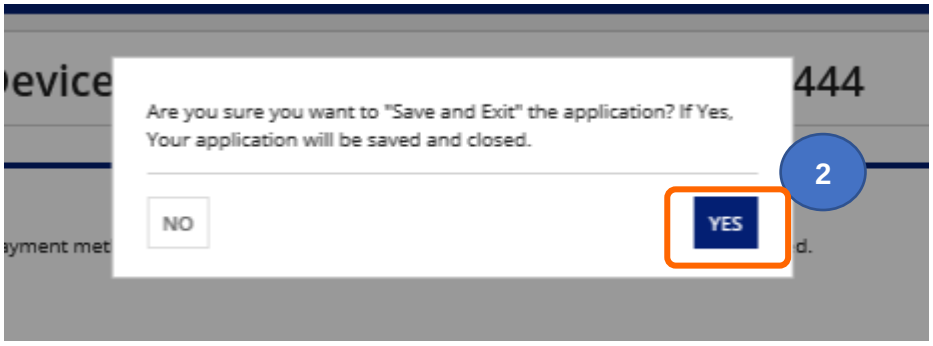
When completing an application, you may save, exit and return to completing the application from where you left off. This creates a TEMP (draft) application.

Please note TEMP applications will be automatically deleted 90 days from last saved on date. Please ensure that you regularly review your TEMP applications and submit to MHRA within 90 days of 'Last saved on' date indicated in the Applications table. Once deleted TEMP applications cannot be reinstated.

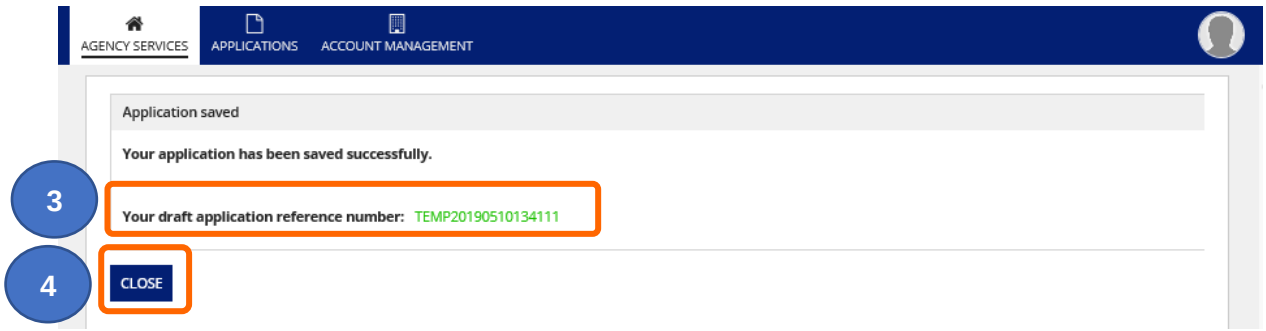
1. **Click** the Save and Exit button (if available on the page that you are on).



2. **Confirm** that you want to Save and Exit.

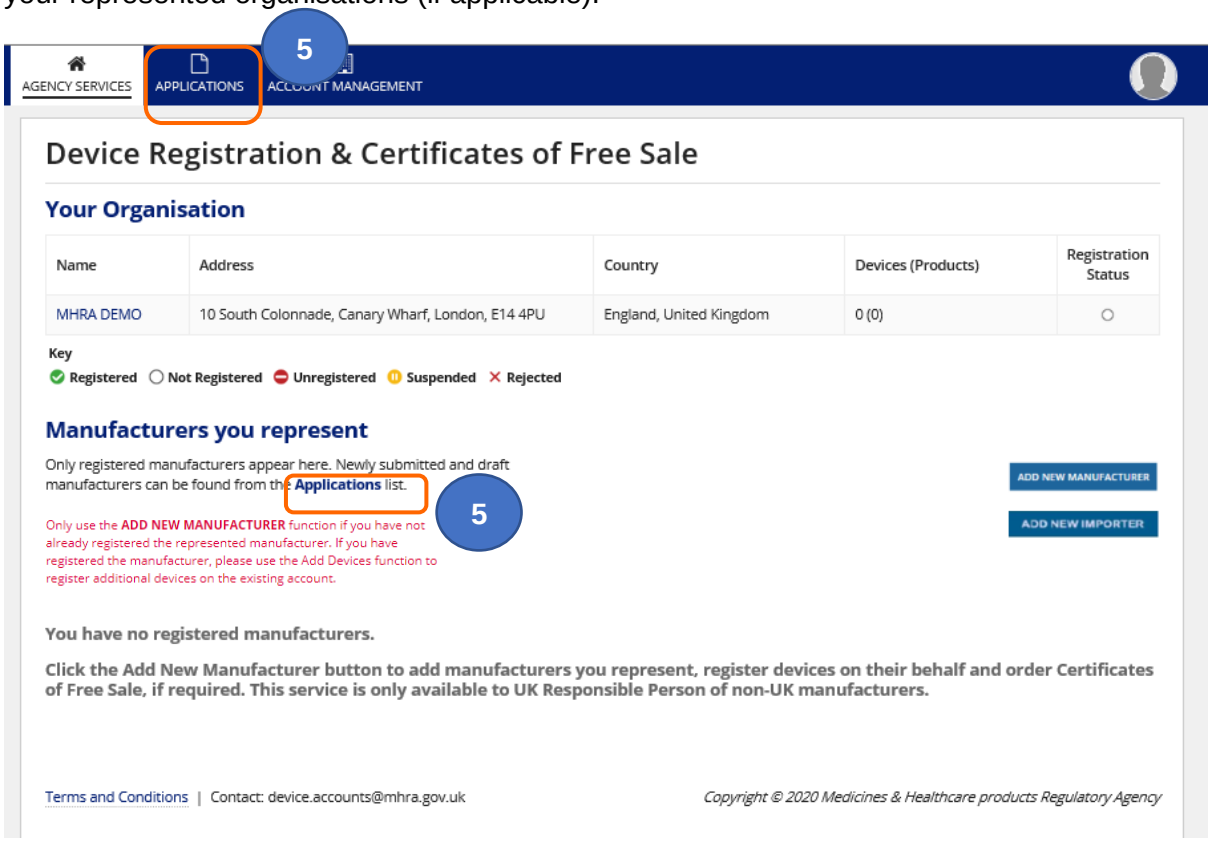


3. A TEMP (Draft) application will be created that you can access and resume work on

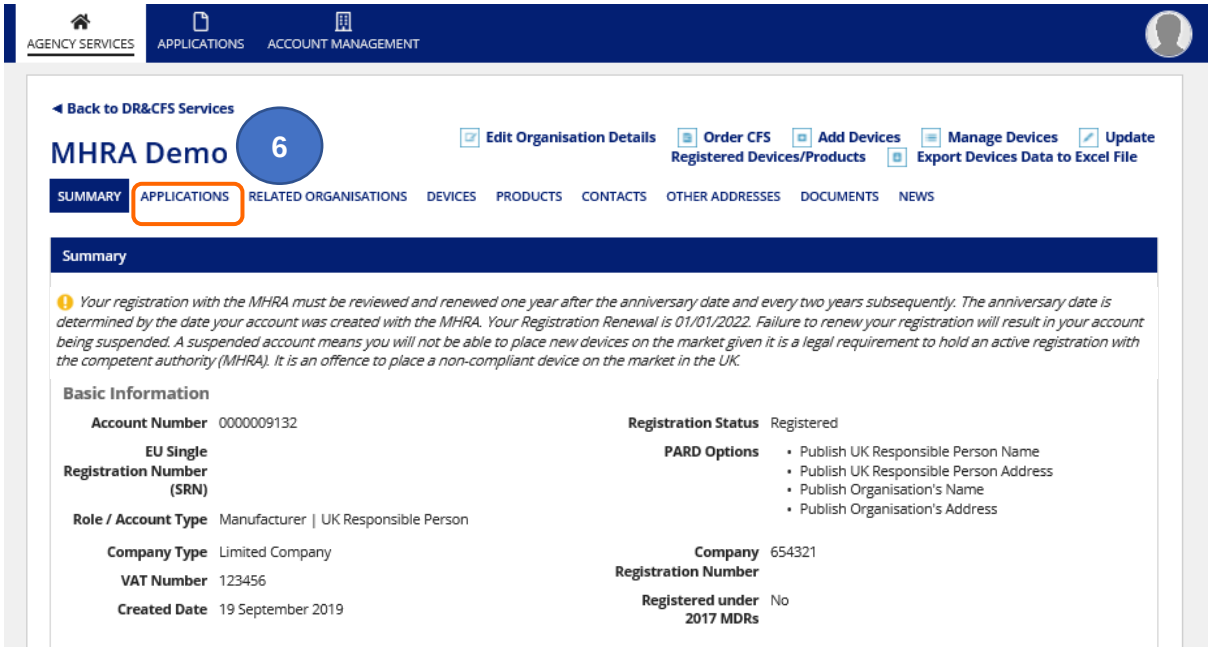


4. **Click** the Close button.

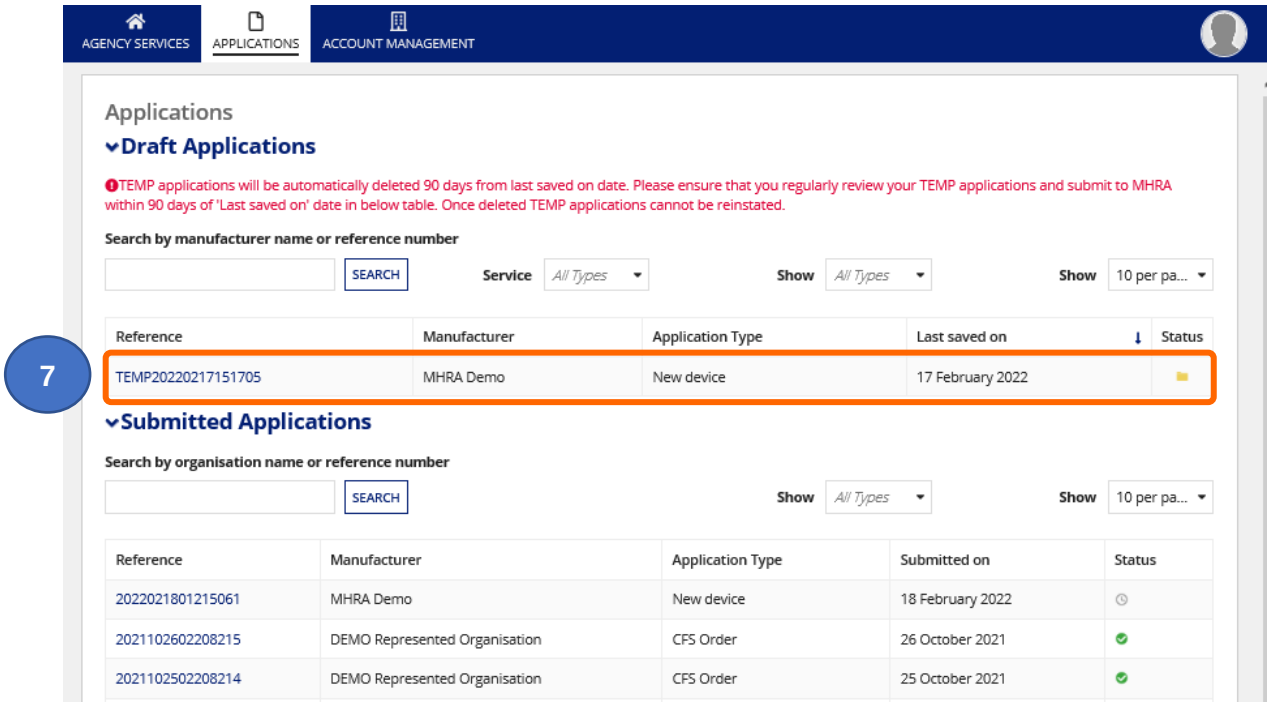
5. **Click** on the Applications tab on the home page or the Applications link on the Organisation page. This will display all the applications for your organisation and all of your represented organisations (if applicable).



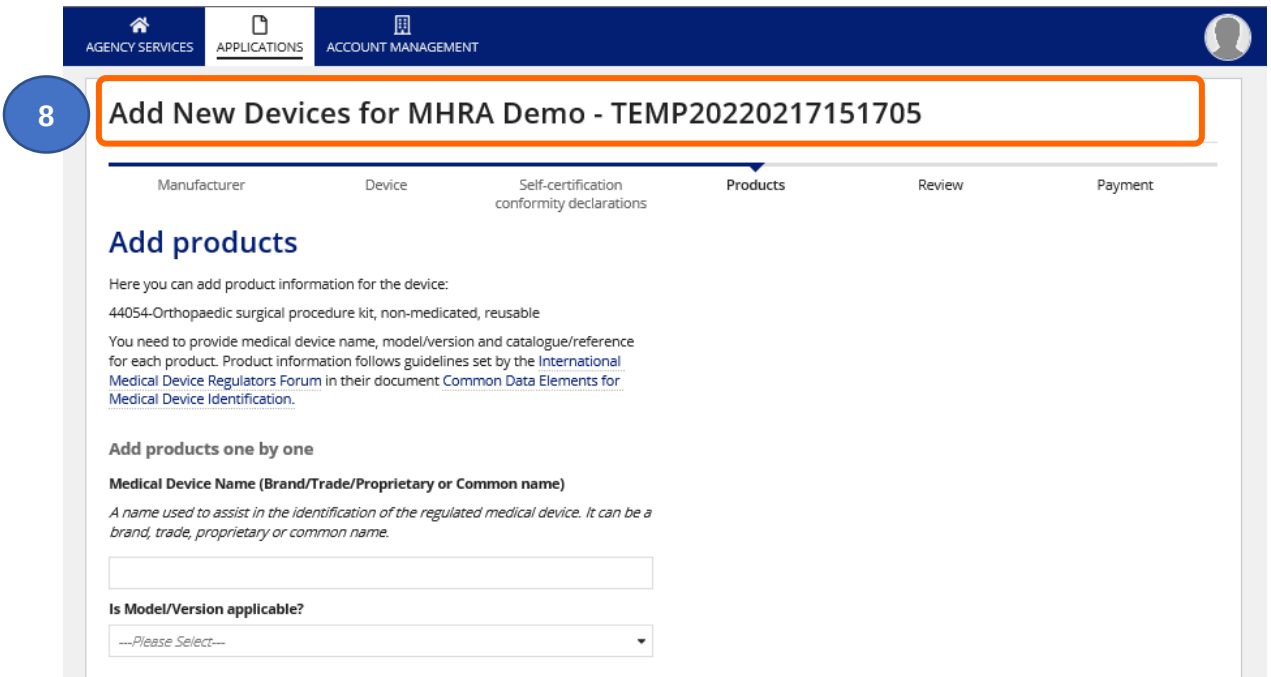
6. You can also **click** on the Applications tab within an organisation. This will only display the Applications for that organisation.



7. **Click** on the TEMP (draft) application's Reference to open it. TEMP applications will be automatically deleted 90 days from Last saved on date. Please ensure that you regularly review your TEMP applications and submit to MHRA within 90 days of 'Last saved on' date in below table. Once deleted TEMP applications cannot be reinstated.

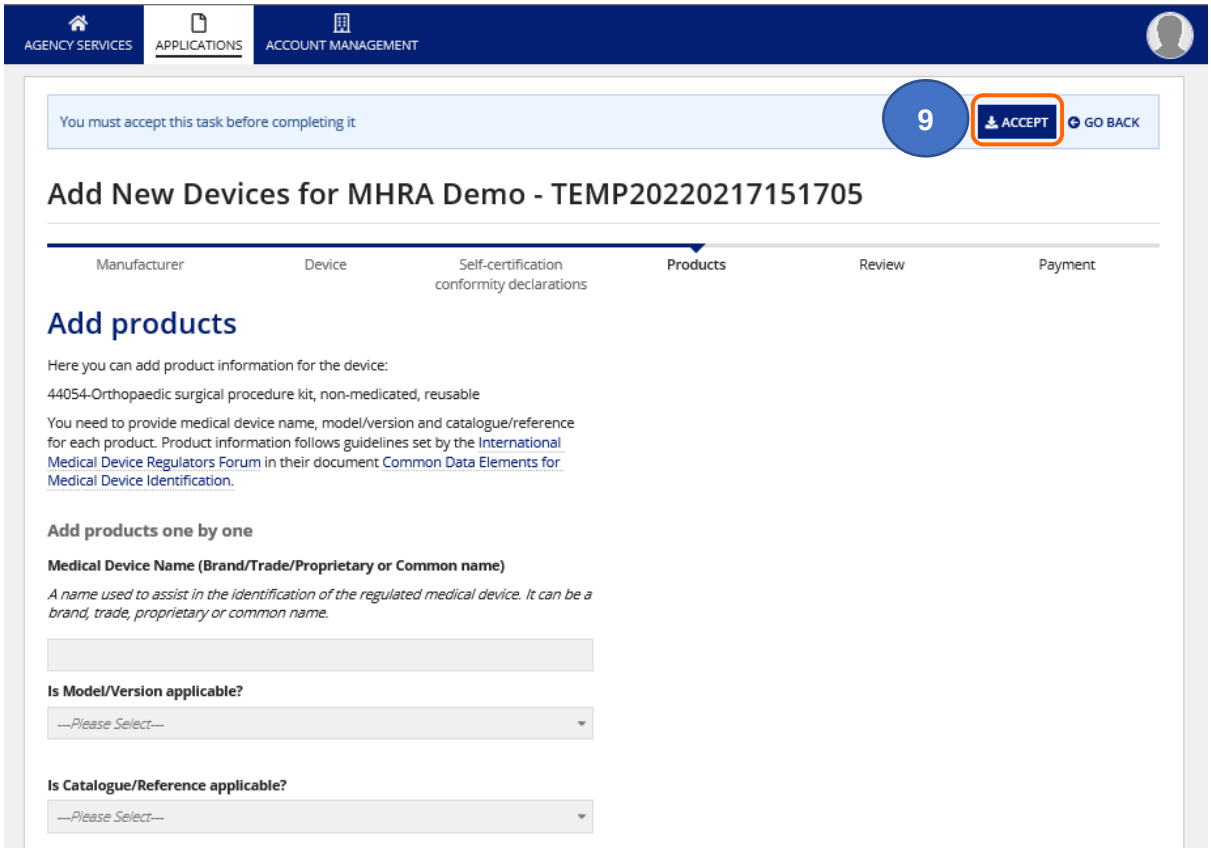


8. The application will open on the page where you clicked Save and Exit.



9. If you have multiple users on your account your 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 accesible to all users on the account with the exception of applications saved on the Payments page and applications created before a user was given access to the account.

   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