



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	2
Username and Password.....	3
New Users > Change temporary password.....	4
Forgot password > resets	4
MHRA Agency Services.....	6
Organisations	7
Determine if your account is migrated or re-registered.....	8
Registering new devices	9
Add devices using GMDN®	11
Upload Self-certification conformity declarations.....	13
Select from existing Self-certification conformity declarations.....	17
Upload Conformity Assessment Certificates (if applicable).....	18
Select from existing Conformity Assessment Certificates	20
Uploading expired CE certificates that are valid under EU MDR	21
Adding products individually.....	22
Add products in bulk – product template	25
Adding System or Procedure Packs (SPP)	33
Review information prior to making payment.....	38
Making Payments	40
Paying with worldpay	41
Pay by BACS/CHAPS.....	45
Complete Application.....	46
Public Access Registration Database (PARD)	48
Updating Registrations	49
Editing organisation details	49
Adding new devices	49
Export devices data to Excel file	49
Using filters to search for devices and products	51
Manage registered devices.....	53
Manage Conformity documents	56
Managing expired CE certificates that are valid under EU MDR.....	58
Add/remove products.....	59
Delete device/s	62
Update registered devices and products	66
Update Obsolete GMDN	68
Update Device Details	69
Update products individually	70
Update multiple products	73
Resolving data issues	74
Review updated devices and products.....	75
Version history.....	78
Removing migrated Pseudo GMDN® Terms.....	83
Adding a Manufacturer (only for UKRP in UK and EU AR in NI).....	86
Adding Importers	89
Deactivating Importers	94
Save and exit: resume applications	96
Annex I – Workflow	100

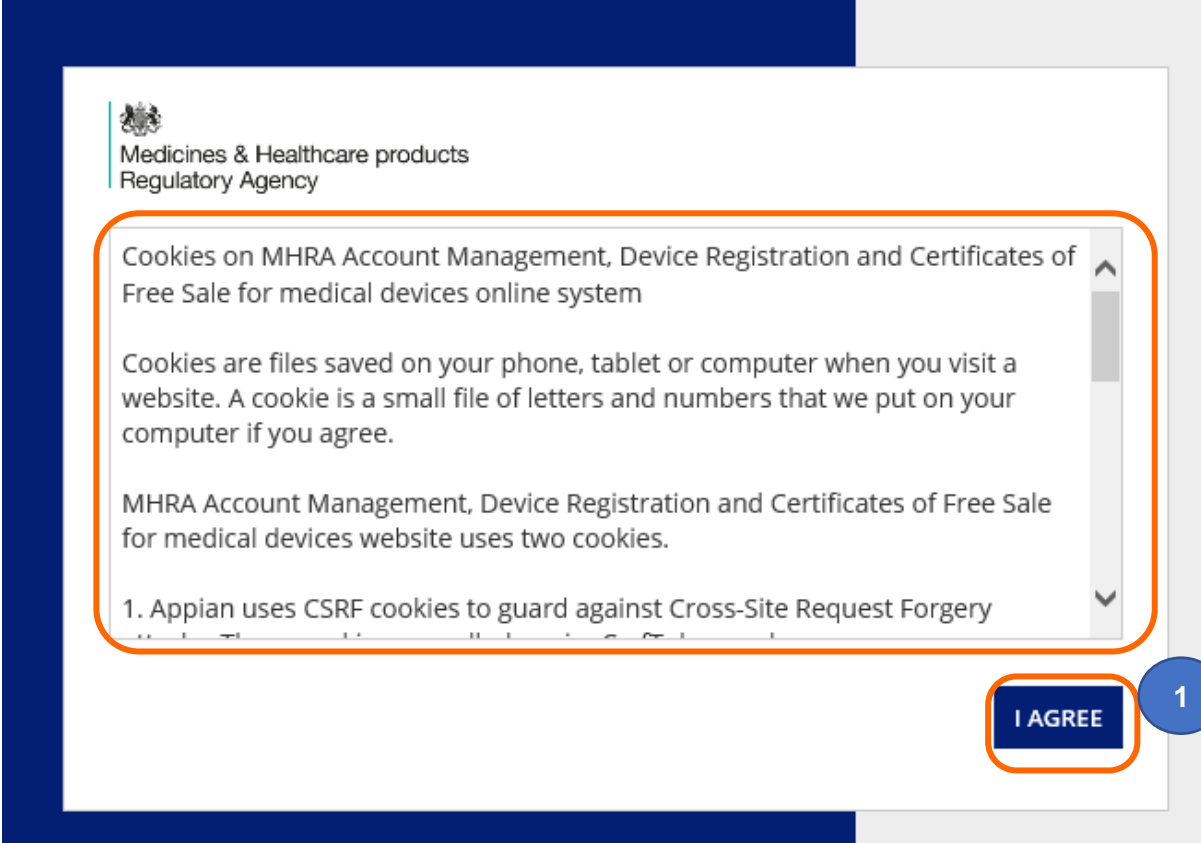
Logging in


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.



 Medicines & Healthcare products
Regulatory Agency

Cookies on MHRA Account Management, Device Registration and Certificates of Free Sale for medical devices online system

Cookies are files saved on your phone, tablet or computer when you visit a website. A cookie is a small file of letters and numbers that we put on your computer if you agree.

MHRA Account Management, Device Registration and Certificates of Free Sale for medical devices website uses two cookies.

1. Appian uses CSRF cookies to guard against Cross-Site Request Forgery

I AGREE 1

Username and Password

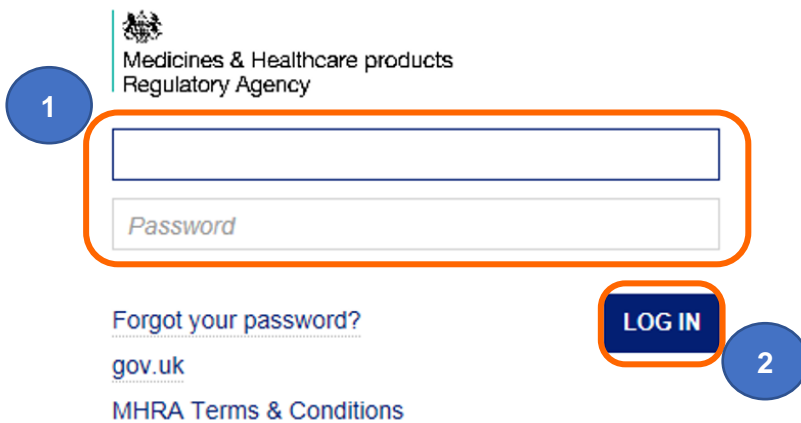
Once your Account request has been accepted by MHRA, two emails will be sent to the email address you entered in your account request application:


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.




Medicines & Healthcare products
Regulatory Agency

1

[Forgot your password?](#)

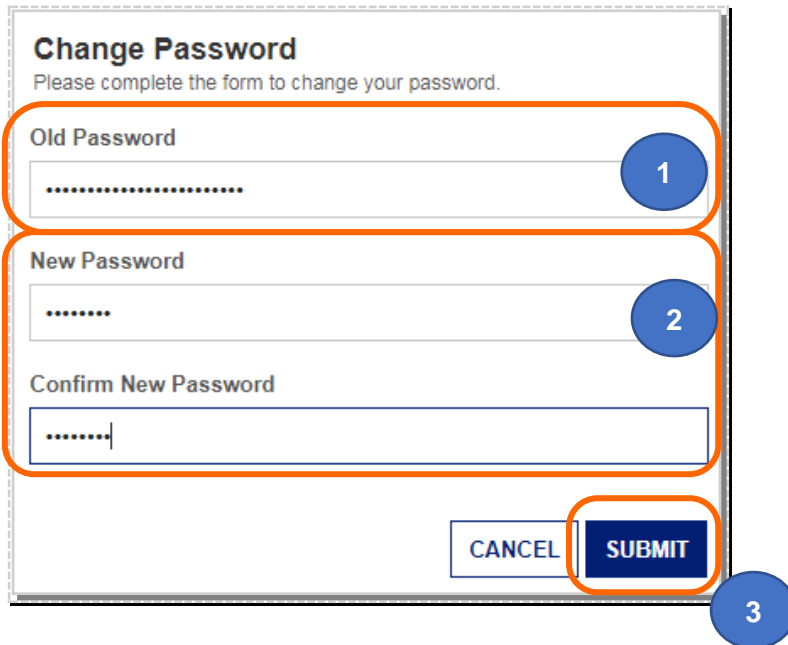
[gov.uk](#)

[MHRA Terms & Conditions](#)

[LOG IN](#)

2

New Users > Change temporary password



Change Password
Please complete the form to change your password.

Old Password 1

New Password 2

Confirm New Password

CANCEL SUBMIT 3

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

1

Forgot your password?

LOG IN

gov.uk

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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](#)

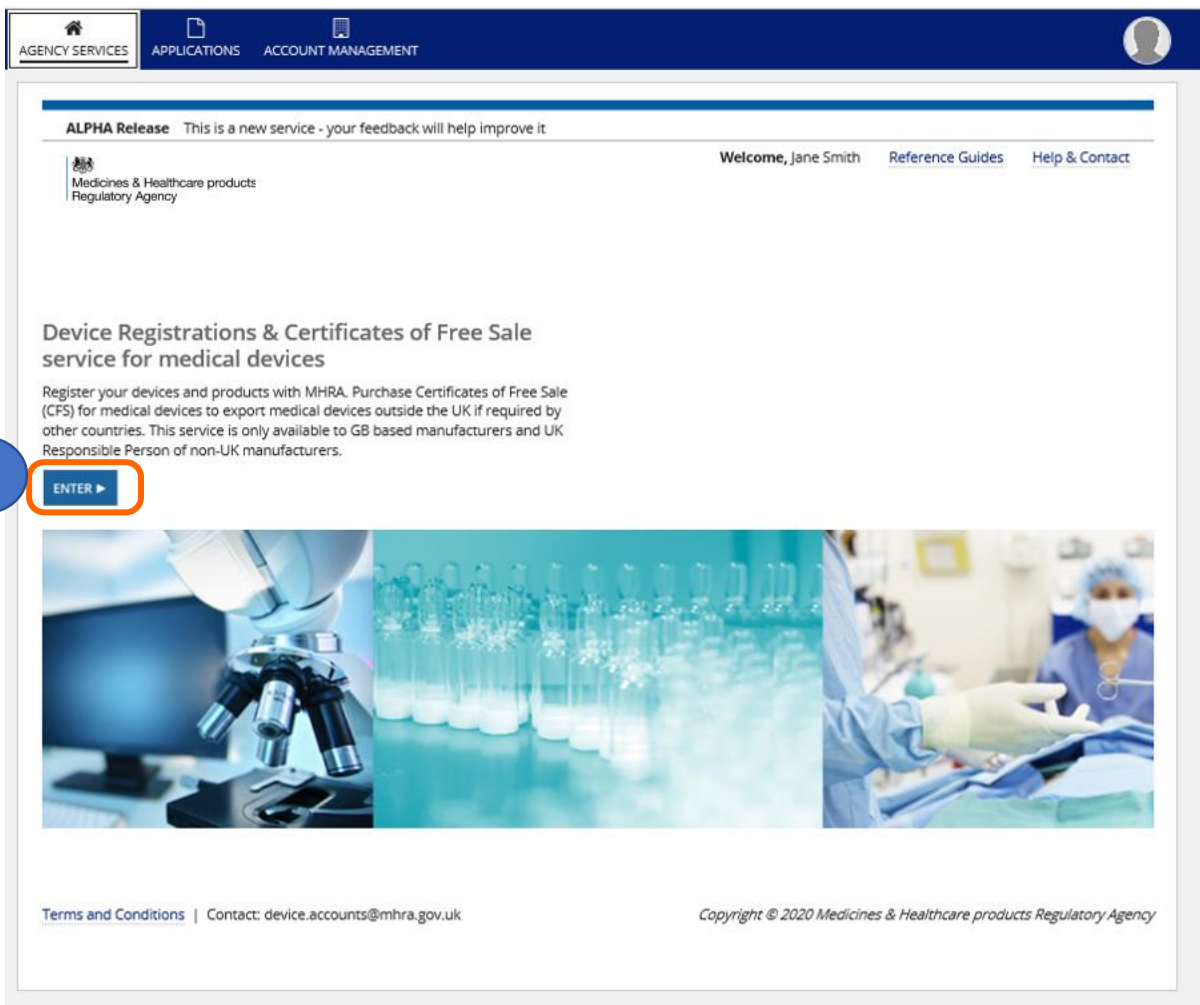
3

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.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

ALPHA Release This is a new service - your feedback will help improve it

Welcome, Jane Smith [Reference Guides](#) [Help & Contact](#)

Medicines & Healthcare products
Regulatory Agency

Device Registrations & Certificates of Free Sale service for medical devices

Register your devices and products with MHRA. Purchase Certificates of Free Sale (CFS) for medical devices to export medical devices outside the UK if required by other countries. This service is only available to GB based manufacturers and UK Responsible Person of non-UK manufacturers.

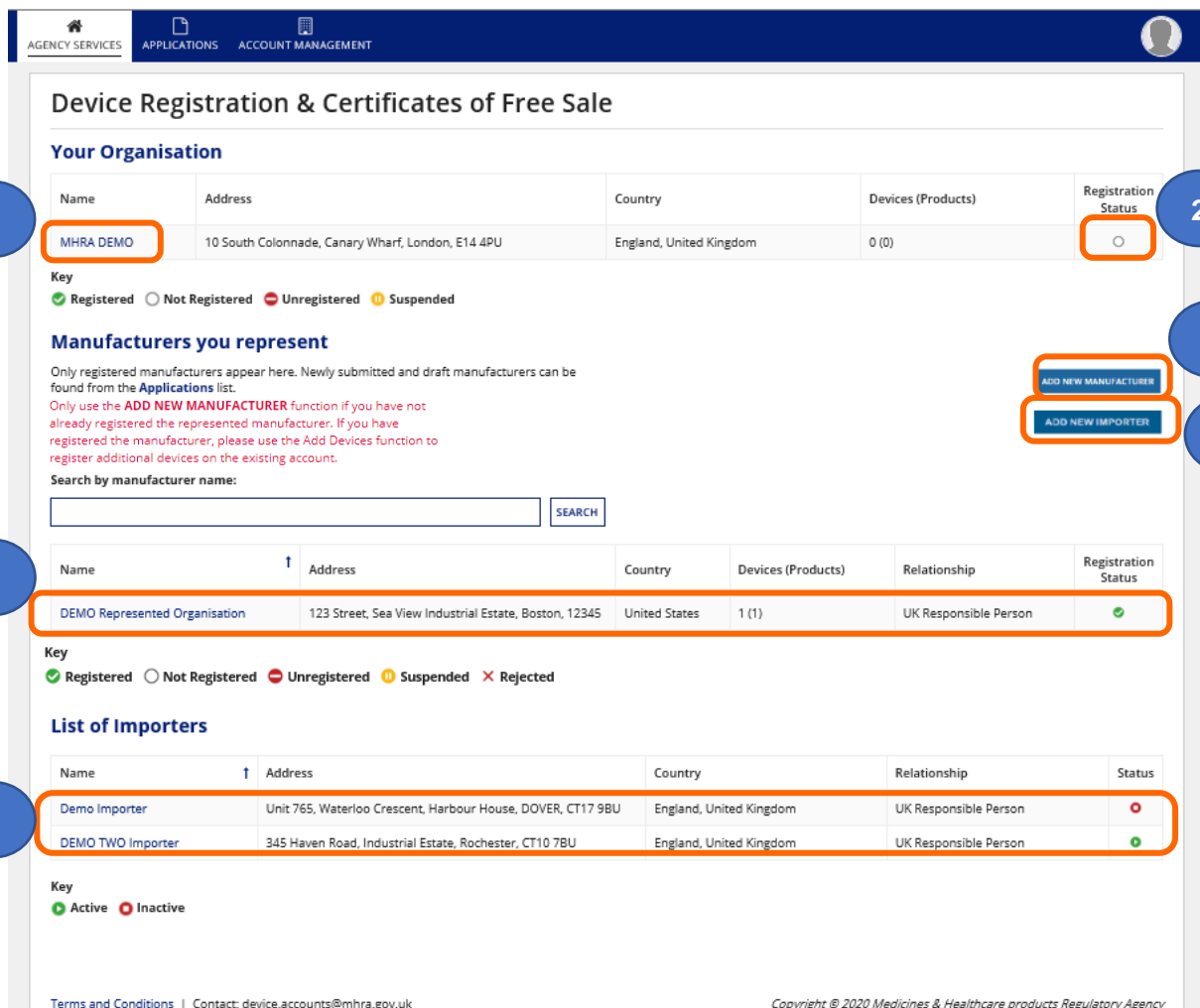
1 [ENTER ►](#)

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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.



The screenshot shows the 'Device Registration & Certificates of Free Sale' interface. It is divided into three main sections: 'Your Organisation', 'Manufacturers you represent', and 'List of Importers'. Each section contains a table of data and a key for the status indicators. Numbered callouts (1-6) highlight specific elements: 1 points to the 'Your Organisation' table row; 2 points to the 'Registration Status' column in the same table; 3 points to the 'ADD NEW MANUFACTURER' button; 4 points to the 'ADD NEW IMPORTER' button; 5 points to the 'Manufacturers you represent' table row; and 6 points to the 'List of Importers' table rows.

AGENCY SERVICES | **APPLICATIONS** | **ACCOUNT MANAGEMENT**

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	0 (0)	<input type="radio"/>

Key
 Registered Not Registered Unregistered Suspended

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the **Applications** list.
 Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

Search by manufacturer name:

Name	Address	Country	Devices (Products)	Relationship	Registration Status
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	1 (1)	UK Responsible Person	<input checked="" type="radio"/>

Key
 Registered Not Registered Unregistered Suspended Rejected

List of Importers

Name	Address	Country	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	UK Responsible Person	<input type="radio"/>
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	UK Responsible Person	<input checked="" type="radio"/>

Key
 Active Inactive

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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](#).

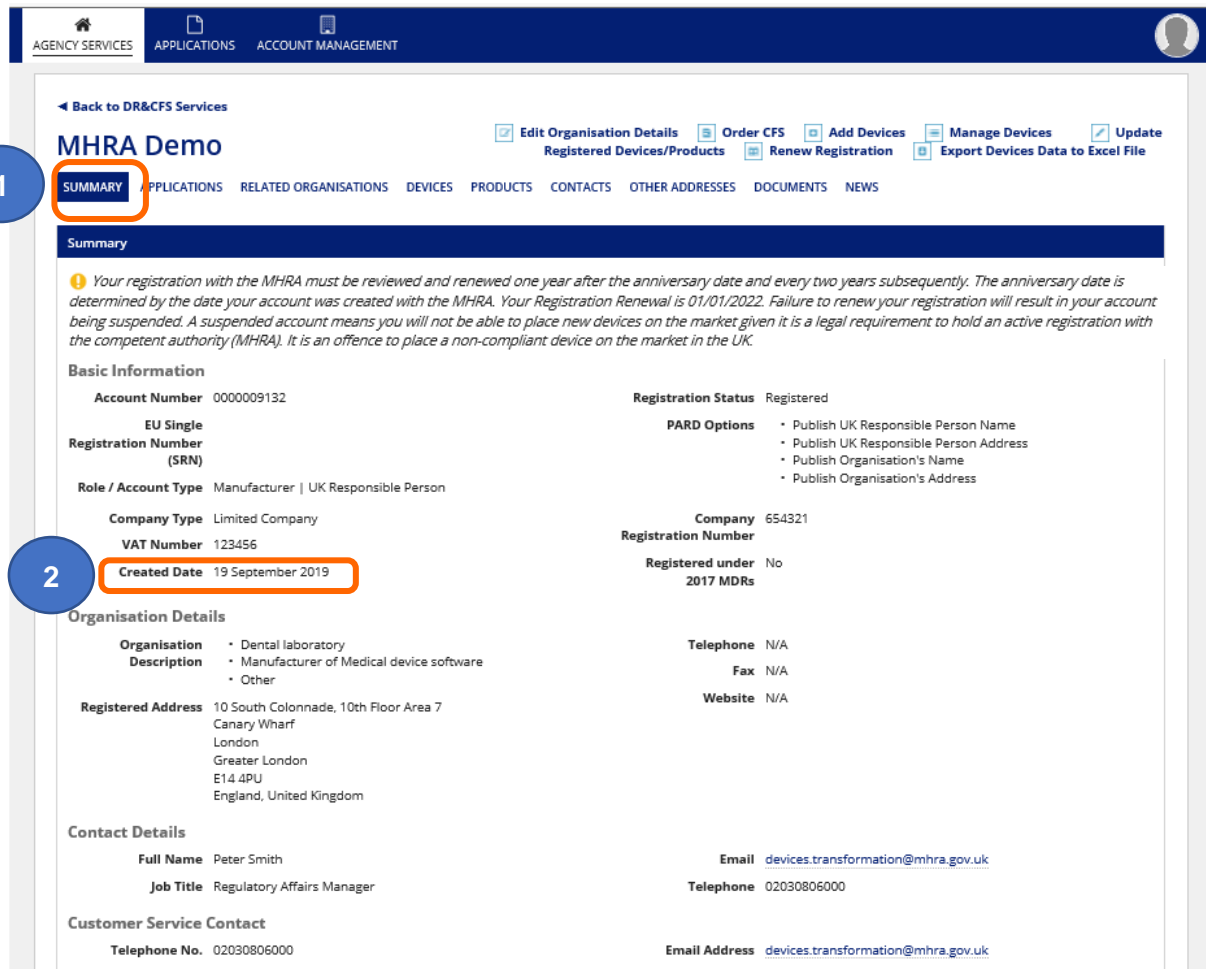
You need to determine if your account was [migrated](#) or [re-registered](#) as the information that you see in your account may differ.

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.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Back to DR&CFS Services

MHRA Demo

Edit Organisation Details
 Order CFS
 Add Devices
 Manage Devices
 Update Registered Devices/Products
 Renew Registration
 Export Devices Data to Excel File

1 **SUMMARY** APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Summary

⚠ Your registration with the MHRA must be reviewed and renewed one year after the anniversary date and every two years subsequently. The anniversary date is determined by the date your account was created with the MHRA. Your Registration Renewal is 01/01/2022. Failure to renew your registration will result in your account being suspended. A suspended account means you will not be able to place new devices on the market given it is a legal requirement to hold an active registration with the competent authority (MHRA). It is an offence to place a non-compliant device on the market in the UK.

Basic Information

Account Number 0000009132	Registration Status Registered
EU Single Registration Number (SRN)	PARD Options <ul style="list-style-type: none"> • Publish UK Responsible Person Name • Publish UK Responsible Person Address • Publish Organisation's Name • Publish Organisation's Address
Role / Account Type Manufacturer UK Responsible Person	Company 654321
Company Type Limited Company	Registration Number
VAT Number 123456	Registered under 2017 MDRs No
2 Created Date 19 September 2019	

Organisation Details

Organisation Description <ul style="list-style-type: none"> • Dental laboratory • Manufacturer of Medical device software • Other 	Telephone N/A
Registered Address 10 South Colonnade, 10th Floor Area 7 Canary Wharf London Greater London E14 4PU England, United Kingdom	Fax N/A
	Website N/A

Contact Details

Full Name Peter Smith	Email devices.transformation@mhra.gov.uk
Job Title Regulatory Affairs Manager	Telephone 02030806000

Customer Service Contact

Telephone No. 02030806000	Email Address devices.transformation@mhra.gov.uk
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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](#)).

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT
User Profile

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	0 (0)	○

Key
✔ Registered ○ Not Registered ✖ Unregistered ⏸ Suspended

Manufacturers you represent

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

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

Search by manufacturer name:

[ADD NEW MANUFACTURER](#)
[ADD NEW IMPORTER](#)

Name	Address	Country	Devices (Products)	Relationship	Registration Status
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	1 (1)	UK Responsible Person	✔

Key
✔ Registered ○ Not Registered ✖ Unregistered ⏸ Suspended ✘ Rejected

List of Importers

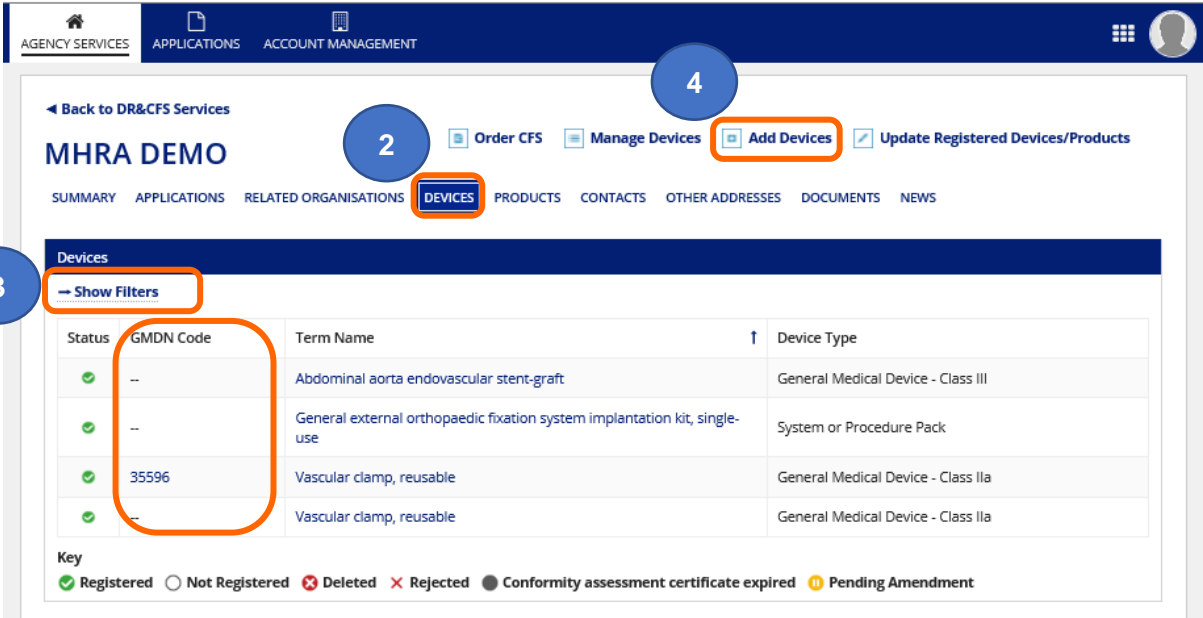
Name	Address	Country	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	UK Responsible Person	✖
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	UK Responsible Person	✔

Key
✔ Active ✖ Inactive

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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.

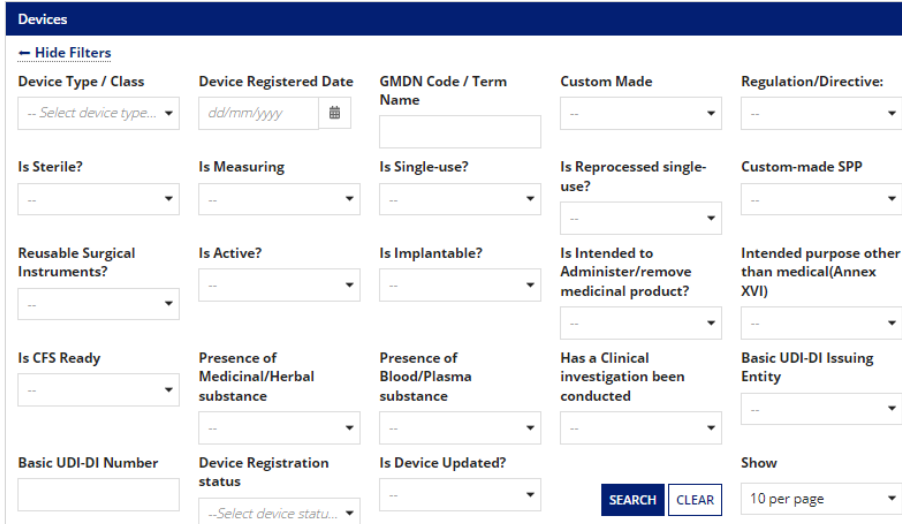


3. [Show Filters](#)

Status	GMDN Code	Term Name	Device Type
✓	--	Abdominal aorta endovascular stent-graft	General Medical Device - Class III
✓	--	General external orthopaedic fixation system implantation kit, single-use	System or Procedure Pack
✓	35596	Vascular clamp, reusable	General Medical Device - Class IIa
✓	--	Vascular clamp, reusable	General Medical Device - Class IIa

Key
 ✓ Registered ○ Not Registered ✗ Deleted ✗ Rejected ● Conformity assessment certificate expired ⚠ Pending Amendment

3. Click the [Show Filters](#) link to search for specific devices.



4. [Hide Filters](#)

Device Type / Class: -- Select device type...
 Device Registered Date: dd/mm/yyyy
 GMDN Code / Term Name:
 Custom Made: --
 Regulation/Directive: --

Is Sterile?: --
 Is Measuring: --
 Is Single-use?: --
 Is Reprocessed single-use?: --
 Custom-made SPP: --

Reusable Surgical Instruments?: --
 Is Active?: --
 Is Implantable?: --
 Is Intended to Administer/remove medicinal product?: --
 Intended purpose other than medical(Annex XVI): --

Is CFS Ready?: --
 Presence of Medicinal/Herbal substance: --
 Presence of Blood/Plasma substance: --
 Has a Clinical investigation been conducted: --
 Basic UDI-DI Issuing Entity: --

Basic UDI-DI Number:
 Device Registration status: --Select device statu...
 Is Device Updated?: --
 SEARCH CLEAR Show: 10 per page

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.

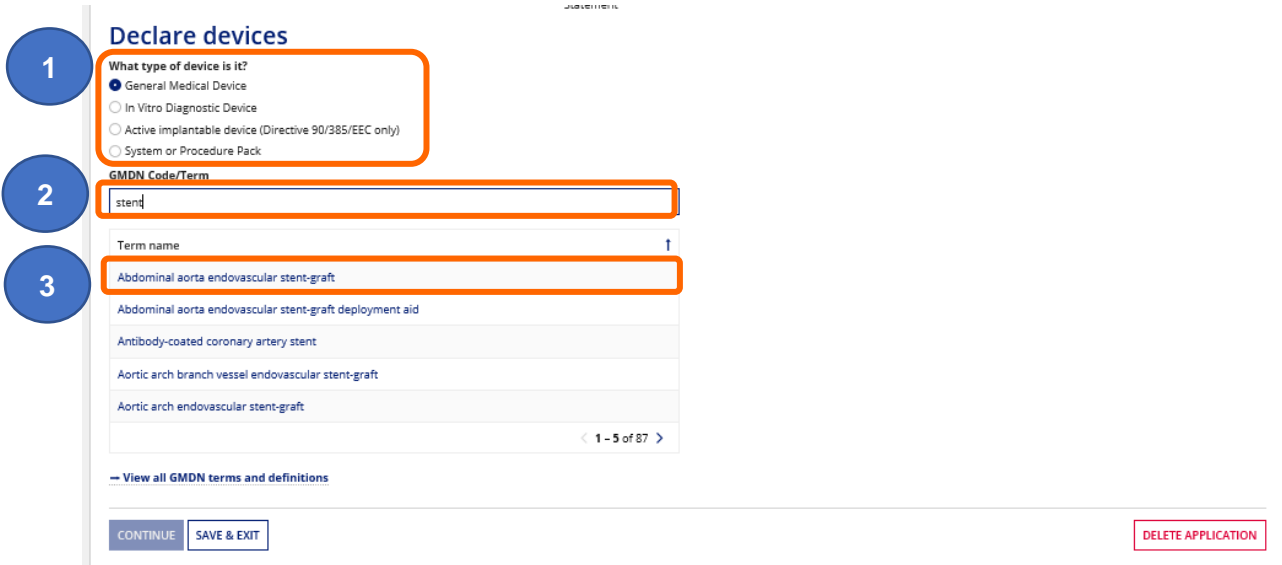
If you need to [update devices](#) or products for example add data to fields you did not complete at time of registration, or update obsolete GMDN® Code or Term, please refer to the [Update registered devices and products](#) section.

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.



1 What type of device is it?
 General Medical Device
 In Vitro Diagnostic Device
 Active implantable device (Directive 90/385/EEC only)
 System or Procedure Pack

2 GMDN Code/Term
 stent

3 Term name
 Abdominal aorta endovascular stent-graft
 Abdominal aorta endovascular stent-graft deployment aid
 Antibody-coated coronary artery stent
 Aortic arch branch vessel endovascular stent-graft
 Aortic arch endovascular stent-graft
 < 1 - 5 of 87 >

– View all GMDN terms and definitions

CONTINUE SAVE & EXIT DELETE APPLICATION

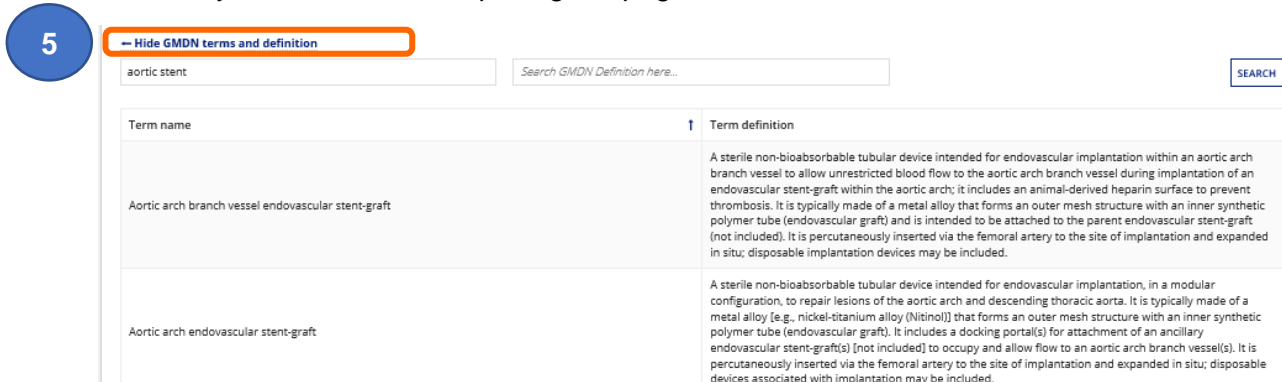
4. If you are unsure of a term’s definition you can select the **View all GMDN® Terms and definitions**. You will be presented with a list of terms which you are able to refine by typing keywords into the text box.



4 – View all GMDN terms and definitions

CONTINUE SAVE & EXIT DELETE APPLICATION

5. Once you have found the appropriate term, you can **Hide GMDN® Terms and definitions** to allow you to continue completing the page.



5 – Hide GMDN terms and definition

aortic stent Search GMDN Definition here... SEARCH

Term name	Term definition
Aortic arch branch vessel endovascular stent-graft	A sterile non-bioabsorbable tubular device intended for endovascular implantation within an aortic arch branch vessel to allow unrestricted blood flow to the aortic arch branch vessel during implantation of an endovascular stent-graft within the aortic arch; it includes an animal-derived heparin surface to prevent thrombosis. It is typically made of a metal alloy that forms an outer mesh structure with an inner synthetic polymer tube (endovascular graft) and is intended to be attached to the parent endovascular stent-graft (not included). It is percutaneously inserted via the femoral artery to the site of implantation and expanded in situ; disposable implantation devices may be included.
Aortic arch endovascular stent-graft	A sterile non-bioabsorbable tubular device intended for endovascular implantation, in a modular configuration, to repair lesions of the aortic arch and descending thoracic aorta. It is typically made of a metal alloy [e.g., nickel-titanium alloy (Nitinol)] that forms an outer mesh structure with an inner synthetic polymer tube (endovascular graft). It includes a docking portal(s) for attachment of an ancillary endovascular stent-graft(s) [not included] to occupy and allow flow to an aortic arch branch vessel(s). It is percutaneously inserted via the femoral artery to the site of implantation and expanded in situ; disposable devices associated with implantation may be included.

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.

Declare devices

What type of device is it?

- General Medical Device
 In Vitro Diagnostic Device
 Active Implantable Device
 System or Procedure Pack

GMDN Code/Term

37840 - Cartilage knife

[View all GMDN terms and definitions](#)

Is it custom made?

- Yes
 No

What risk classification applies to this device?

- Class I
 Class IIa
 Class IIb
 Class III

[Click here to know about risk classification.](#)

Which directive/regulation does this device comply with?

- UK MDR 2002 (SI 2002 No 618 as amended), Part II
 Directive 93/42/EEC
 EU medical devices regulations 2017/745

! MHRA will only accept registrations for sterile and/or measuring Class I and all Class IIa, IIb and III devices under (EU)2017/745 if the EU Notified Body is designated under the EU Medical Devices Regulation 2017/745.

Device labelled as sterile?

- Yes
 No

Single-use device?

- Yes
 No

Reprocessed single-use device?

- Yes
 No

Are any of the products related to this device active?

- Yes
 No

Device intended to administer and/or remove medicinal product?

- Yes
 No

Are any of the products related to this device measuring?

- Yes
 No

Basic UDI-DI Issuing Entity(optional)

--Please Select--

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product (optional) **!**

--Please Select--

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma (optional) **!**

--Please Select--

Has a Clinical investigation been conducted? (optional)

--Please Select--

6

7

CONTINUE SAVE & EXIT

DELETE APPLICATION

8

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>

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

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT

Add New Devices for MHRA Demo - TEMP20230418142616

Manufacturer
Device
Self-certification conformity declarations
Products
Review
Payment

Self-certification conformity declarations: 35310-Orthodontic retainer

- **Declaration of Conformity** – Class I medical devices that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed. General IVD medical devices that do not require certification by a UK Approved Body or EU Notified Body.
- **Custom-Made Statement** – All custom-made devices.
- **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.
- **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.

UK MDR 2002/ Medical Devices Directive 93/42 EEC & Medical Devices Regulation (EU) 2017/745

Select from existing Self-certification conformity declarations

<input type="checkbox"/> Filename	Document Reference	Conformity Assessment Type	
<input type="checkbox"/> Custom-made Statement 1	Custom1	CE - MDD/IVDD/AIMD	×

! At least 1 Declaration of Conformity/Custom-made Statement document must be selected

Upload a new Self-certification conformity declaration

3

Custom-made Statement - ...

DOCX – 11.73 KB

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

Filename must not contain any special characters other than hyphen (-) or underscore (_).

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to co-operate with our requests we will consider using our enforcement powers.

4

Conformity assessment

UKCA - UK MDR 2002 Part II/Part III/Part IV
▼

If you are providing Self-certification conformity declarations for CE marked devices, you must ensure that you have appointed an EU Authorised Representative (EC Rep) in one of the EU 27 countries or in Northern Ireland

Find out more about [Declaration of Conformity / Custom made statement / UK MDR 2002 Regulation 14 / Performance Evaluation / EU regulations](#)

5

Document Reference

UKCA_Retainer v01
▼

Reference must not contain any special characters other than hyphen (-) or underscore (_).

6

UPLOAD DOCUMENT
▼

7

CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION

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

Add New Devices for MHRA Demo - TEMP20230418142616

Manufacturer Device Self-certification conformity declarations Products Review Payment

Self-certification conformity declarations: 35310-Orthodontic retainer

- **Declaration of Conformity** – Class I medical devices that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed, General IVD medical devices that do not require certification by a UK Approved Body or EU Notified Body.
- **Custom-Made Statement** – All custom-made devices.
- **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.
- **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.

UK MDR 2002/ Medical Devices Directive 93/42 EEC & Medical Devices Regulation (EU) 2017/745

Conformity Assessment Type

ALL

2

Select from existing Self-certification conformity declarations

<input type="checkbox"/>	Filename	Document Reference	Conformity Assessment Type	
<input type="checkbox"/>	Custom-made Statement - Orthodontic Retainer	UKCA_Retainer v01	UKCA - UK MDR 2002 Part II/Part III/Part IV	×
<input checked="" type="checkbox"/>	Custom-made Statement 1	Custom1	CE - MDD/IVDD/AIMD	×

1

Upload a new Self-certification conformity declaration

UPLOAD Drop file here

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

Filename must not contain any special characters other than hyphen (-) or underscore (_).

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to cooperate with our requests we will consider using our enforcement powers.

Conformity assessment

Please select

If you are providing Self-certification conformity declarations for CE marked devices, you must ensure that you have appointed an EU Authorised Representative (EC Rep) in one of the EU 27 countries or in Northern Ireland

Find out more about [Declaration of Conformity / Custom made statement / UK MDR 2002 Regulation 14 / Performance Evaluation / EU regulations](#)

Document Reference

Reference must not contain any special characters other than hyphen (-) or underscore (_).

UPLOAD DOCUMENT

3

CONTINUE SAVE & EXIT BACK

DELETE APPLICATION

Upload Conformity Assessment Certificates (if applicable)

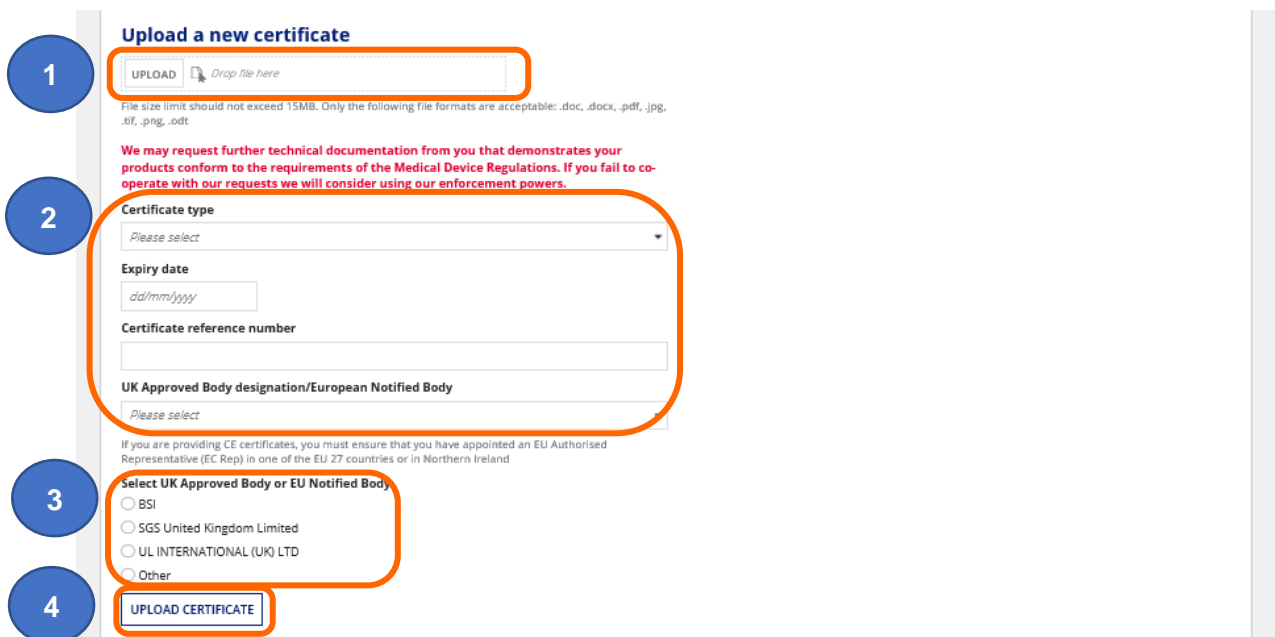
1. Click the **Upload** button and select the **Certificate** issued by a UK Approved Body or EU Notified Body, stored on your system.

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.



Upload a new certificate

1. **UPLOAD**

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to cooperate with our requests we will consider using our enforcement powers.

2. **Certificate type**
Please select

Expiry date
dd/mm/yyyy

Certificate reference number

UK Approved Body designation/European Notified Body
Please select

If you are providing CE certificates, you must ensure that you have appointed an EU Authorised Representative (EC Rep) in one of the EU 27 countries or in Northern Ireland

3. **Select UK Approved Body or EU Notified Body**

BSI

SGS United Kingdom Limited

UL INTERNATIONAL (UK) LTD

Other

4. **UPLOAD CERTIFICATE**

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.

- 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

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

6

Conformity Assessment Type
 ALL

Certificate Status
 ALL

7

Select from existing certificates

	Filename	Reference no	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
<input checked="" type="checkbox"/>	CE Certificate 3	CE4567	31/03/2022	Full Quality Assurance (Annex II excluding Section 4)	TÜV NORD CERT GmbH	CE - MDD/IVDD/AIMD
<input type="checkbox"/>	CE Certificate 3	AIMD1	31/07/2021	Full Quality Assurance (Annex II excluding Section 4)	BSI	CE - MDD/IVDD/AIMD
<input type="checkbox"/>	CE Certificate 1	CE123	31/05/2021	Full Quality Assurance (Annex II excluding Section 4)	BSI	CE - MDD/IVDD/AIMD

- 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.

8

CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION



Select from existing Conformity Assessment Certificates

- 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.
- 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

- 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'.

2

Conformity Assessment Type

Certificate Status

ALL

ALL

3

Select from existing certificates

	Filename	Reference no	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type		
<input type="checkbox"/>	UKCA Certificate 2	UKCA_BSI_54321	30/04/2028	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	✕	
<input type="checkbox"/>	UKCA Certificate 1	UKCA_BSI_12345	30/04/2028	Design Examination Certificate (Annex II with Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	✕	
<input type="checkbox"/>	MDR Assessment of Technical Documentation Annex IX Chapter II	EUMDR_321	30/04/2024	Technical Assessment (MDR Annex IX, Chapter II)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	✕	
<input type="checkbox"/>	MDR CE Certificate 1 Quality Management System Annex IX Chapters I and III	EUMDR_123	30/04/2024	Quality Management System (MDR Annex IX, Chapters I, III)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	✕	
<input type="checkbox"/>	CE Certificate 7	CE7	31/10/2022	✕	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	✕
<input checked="" type="checkbox"/>	CE Certificate 5	UKCA1	31/10/2021	✕	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	UKCA - MDD/IVDD/AIMD	✕
<input type="checkbox"/>	CE Certificate 4	CE123456	31/12/2019	✕	Type Examination (Annex V)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	✕
<input type="checkbox"/>	CE Certificate 1	CE123	31/12/2019	✕	Full Quality Assurance (Annex IV)	TÜV SÜD Product Service GmbH	CE - MDD/IVDD/AIMD	✕
<input type="checkbox"/>	CE Certificate 3	CE12345	31/12/2019	✕	Production Quality Assurance limited to sterile aspects (Annex V)	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	CE - MDD/IVDD/AIMD	✕
<input type="checkbox"/>	CE Certificate 2	CE1234	31/12/2019	✕	Design Examination (Annex IV with Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	✕

< 1 - 10 of 12 >

4

Select the certificates with the correct conformity assessment type

- 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.
- Click the '[Continue](#)' button or follow the [Upload Conformity Assessment Certificate](#) instructions to add another certificate.

5

CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION



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:

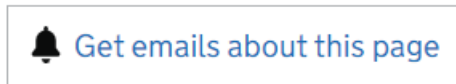
<https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-that-have-expiredexpiring-ce-certificates>

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:



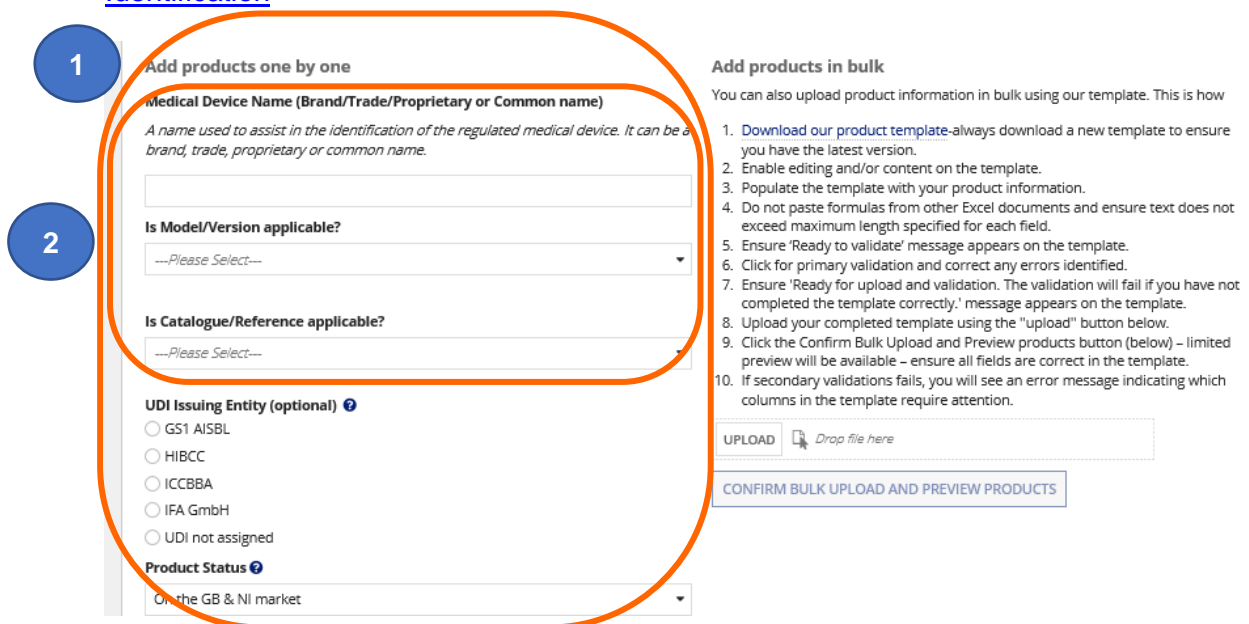
Adding products individually

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](#)



1 Add products one by one

2

Medical Device Name (Brand/Trade/Proprietary or Common name)
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Is Model/Version applicable?
--Please Select--

Is Catalogue/Reference applicable?
--Please Select--

UDI Issuing Entity (optional)

GS1 AISBL

HIBCC

ICCBBA

IFA GmbH

UDI not assigned


Product Status

On the GB & NI market

Add products in bulk

You can also upload product information in bulk using our template. This is how

1. Download our product template-always download a new template to ensure you have the latest version.
2. Enable editing and/or content on the template.
3. Populate the template with your product information.
4. Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
5. Ensure 'Ready to validate' message appears on the template.
6. Click for primary validation and correct any errors identified.
7. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctly.' message appears on the template.
8. Upload your completed template using the "upload" button below.
9. Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template.
10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.

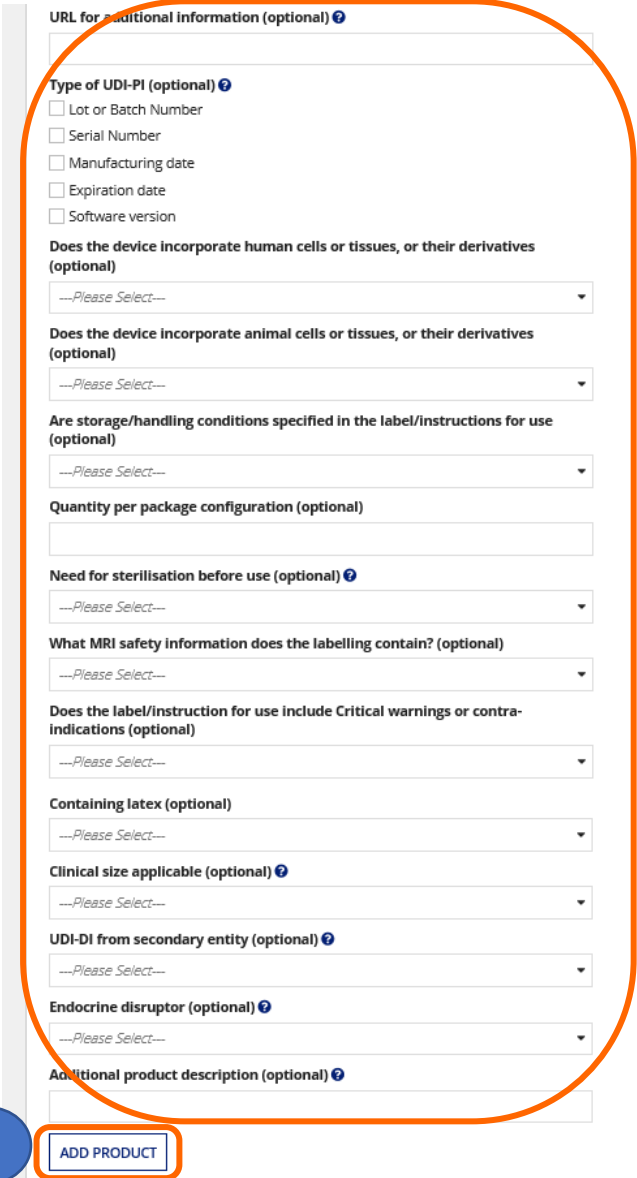
UPLOAD  Drop file here

CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

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.

- 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.



The screenshot shows a web form for device registration. A large orange circle highlights the main form area, which includes the following fields:

- 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---
- Clinical size applicable (optional) ⓘ
 - Please Select---
- UDI-DI from secondary entity (optional) ⓘ
 - Please Select---
- Endocrine disruptor (optional) ⓘ
 - Please Select---
- Additional product description (optional) ⓘ

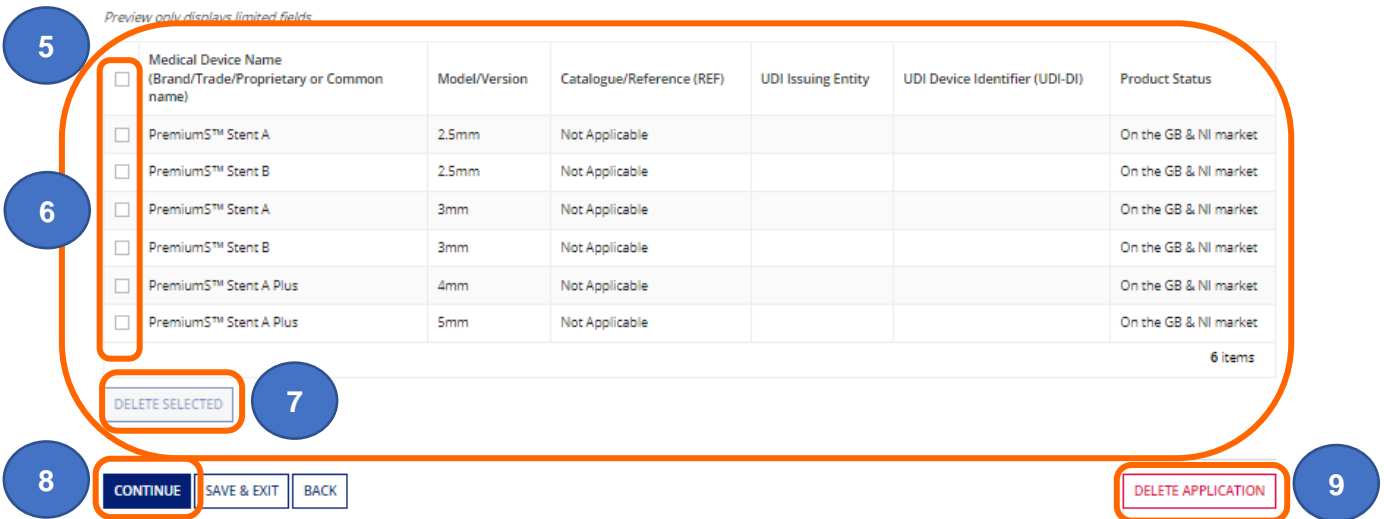
A blue circle with the number '3' is positioned to the left of the form. At the bottom of the form, a blue circle with the number '4' is positioned to the left of a button labeled 'ADD PRODUCT', which is also highlighted with an orange border.

- 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 preview](#) 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

Product preview (products: 6)

Preview only displays limited fields.



<input type="checkbox"/>	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
<input type="checkbox"/>	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market

6 items

DELETE SELECTED

CONTINUE SAVE & EXIT BACK

DELETE APPLICATION

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](#).

Add New Devices for MHRA Demo - TEMP20220217093240

Manufacturer Device Self-certification conformity declarations **Products** Review Payment

Add products

Here you can add product information for the device:
62573-Aortic arch endovascular stent-graft

You need to provide medical device name, model/version and catalogue/reference for each product. Product information follows guidelines set by the [International Medical Device Regulators Forum](#) in their document [Common Data Elements for Medical Device Identification](#).

Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Is Model/Version applicable?
---Please Select---

Is Catalogue/Reference applicable?
---Please Select---

UDI Issuing Entity (optional)

- GS1 AISBL
- HIBCC
- ICCBBA
- IFA GmbH
- UDI not assigned

Add products in bulk

You can also upload product information in bulk using our template. This is how

1. [Download our product template](#)—always download a new template to ensure you have the latest version.
2. Enable editing and/or content on the template.
3. Populate the template with your product information.
4. Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
5. Ensure 'Ready to validate' message appears on the template.
6. Click for primary validation and correct any errors identified.
7. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctly.' message appears on the template.
8. Upload your completed template using the "upload" button below.
9. Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template.
10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.

UPLOAD Drop file here

CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

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

AutoSave Product Bulk Upload Template - General Medical Device - Protected View - Excel Kerwick, Elke

File Home Insert Draw Page Layout Formulas Data Review View Help

PROTECTED VIEW Be careful—files from the Internet can contain viruses. Unless you need to edit, it's safer to stay in Protected View. **Enable Editing**

B26

General Medical Device Product Details

Click for primary validation

You need to provide Medical Device Name, Model/Version and Catalogue/Reference (REF) for each product. Please enter Unique Device Identifier (UDI) if available. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: [Common Data Elements for Medical Device Identification](#).

In the fields that require Yes/No response, entering anything other than Yes/No will be recorded as 'No'. In fields that have dropdown values, entering any value other than options in the dropdown will result in validation failure. Please ensure that you check all fields carefully before uploading particularly if you have copied and pasted into the template.

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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question.(Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its form, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI) (if device identifier (UDI-DI) and product you have assigned GS1 UDI-DI in 14-digit format. The GTIN should assigned HIBCC UDI-DI to your Check Character

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.

The screenshot shows an Excel spreadsheet titled "Product Bulk Upload Template - General Medical Device - Read-Only - Excel". A yellow security warning bar at the top states "SECURITY WARNING: Macros have been disabled." with an "Enable Content" button highlighted by a red circle and the number 3. Below this, a red error box with the text "There are errors within this file. Please check all columns" is also highlighted by a red circle and the number 4. The spreadsheet contains a table with columns for "Medical Device Name", "Model/Version", "Catalogue/Reference", "UDI Issuing Entity", and "Unique Device Identifier".

4. Key points to note when completing template:

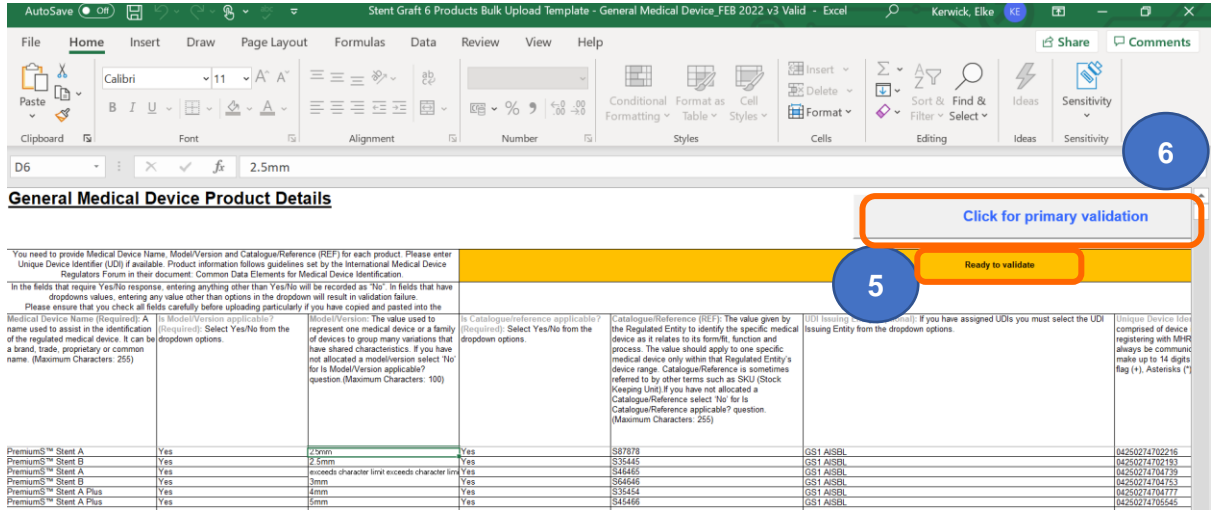
The red warning box will appear at the top of the template indicating that it is not ready for upload until you have populated, at minimum, all mandatory fields. Please read the important information in the headers of each column.

- 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 currently 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 Devices 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.

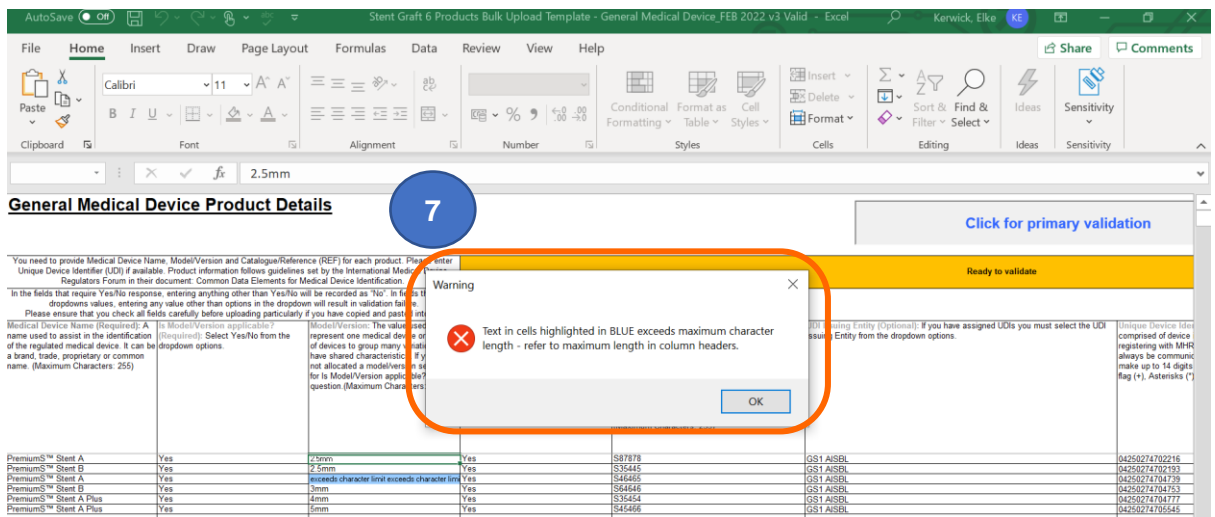
- Ensure that the red warning red box at the top of the template has turned amber and states 'Ready to Validate'.
- Click for primary validation



The screenshot shows the 'General Medical Device Product Details' section of an Excel spreadsheet. The status bar at the top right indicates 'Ready to validate' (highlighted with a blue circle '5'). A button labeled 'Click for primary validation' is visible in the top right corner (highlighted with a blue circle '6'). Below the status bar is a table with columns for 'Medical Device Name', 'Is Model/Version applicable?', 'Model/Version', 'Is Catalogue/Reference applicable?', 'Catalogue/Reference', 'UDI Issuing Entity', and 'Unique Device Identifier'. The table contains data for various 'Premiums™ Stent' products.

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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its formfit, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI): A unique identifier for a device comprised of device registration with MHRA always be communicated in the 14 digits flag (+), Asterisks (*)
Premiums™ Stent A	Yes	7.5mm	Yes	S87878	GS1 ANSEL	04250274702216
Premiums™ Stent B	Yes	2.5mm	Yes	S35445	GS1 ANSEL	04250274702193
Premiums™ Stent A	Yes	exceeds character limit exceeds character limit	Yes	S44665	GS1 ANSEL	04250274704739
Premiums™ Stent B	Yes	3mm	Yes	S64646	GS1 ANSEL	04250274704753
Premiums™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 ANSEL	04250274704777
Premiums™ Stent A Plus	Yes	5mm	Yes	S45456	GS1 ANSEL	04250274705545

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



The screenshot shows the same 'General Medical Device Product Details' section of the Excel spreadsheet. A 'Warning' dialog box is displayed in the center, stating: 'Text in cells highlighted in BLUE exceeds maximum character length - refer to maximum lengths in column headers.' The dialog box has an 'OK' button. The table below the dialog box shows the same data as in the previous screenshot, but with the 'Model/Version' cell for 'Premiums™ Stent A' highlighted in blue, indicating it exceeds the character limit.

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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its formfit, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI): A unique identifier for a device comprised of device registration with MHRA always be communicated in the 14 digits flag (+), Asterisks (*)
Premiums™ Stent A	Yes	7.5mm	Yes	S87878	GS1 ANSEL	04250274702216
Premiums™ Stent B	Yes	2.5mm	Yes	S35445	GS1 ANSEL	04250274702193
Premiums™ Stent A	Yes	exceeds character limit exceeds character limit	Yes	S44665	GS1 ANSEL	04250274704739
Premiums™ Stent B	Yes	3mm	Yes	S64646	GS1 ANSEL	04250274704753
Premiums™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 ANSEL	04250274704777
Premiums™ Stent A Plus	Yes	5mm	Yes	S45456	GS1 ANSEL	04250274705545

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

General Medical Device Product Details						
<p>You need to provide Medical Device Name, Model/Version and Catalogue/Reference (REF) for each product. Please enter Unique Device Identifier (UDI) if available. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: Common Data Elements for Medical Device Identification.</p> <p>In the fields that require Yes/No response, entering anything other than Yes/No will be recorded as 'No' in fields that have dropdown values, entering any value other than options in the dropdown will result in validation failure.</p> <p>Please ensure that you check all fields carefully before uploading particularly if you have copied and pasted into the template.</p>						
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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its form#, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI) (if assigned): The UDI is a unique code specific to each device. It is used for product identification and registration with MHRA. If you have assigned GS1 UDI-CI (GTIN) to your products, the GTIN should be entered in the 14-digit format. The GTIN should be preceded by a '0' to make up to 18 digits. If you have assigned HBCS UDI-DE to your products, do not include HBCS Prefix '1' or the Mod 43 Check Character
Premiums™ Stent A	Yes	2.5mm	Yes	S87878	GS1 AISBL	04250274702216
Premiums™ Stent B	Yes	2.5mm	Yes	S35445	GS1 AISBL	04250274702183
Premiums™ Stent A	Yes	3mm	Yes	S46465	GS1 AISBL	04250274704739
Premiums™ Stent B	Yes	3mm	Yes	S64646	GS1 AISBL	04250274704753
Premiums™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 AISBL	04250274704777
Premiums™ Stent A Plus	Yes	5mm	Yes	S45466	GS1 AISBL	04250274705545



9. Click for primary validation again.

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

General Medical Device Product Details						
<p>You need to provide Medical Device Name, Model/Version and Catalogue/Reference (REF) for each product. Please enter Unique Device Identifier (UDI) if available. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: Common Data Elements for Medical Device Identification.</p> <p>In the fields that require Yes/No response, entering anything other than Yes/No will be recorded as 'No' in fields that have dropdown values, entering any value other than options in the dropdown will result in validation failure.</p> <p>Please ensure that you check all fields carefully before uploading particularly if you have copied and pasted into the template.</p>						
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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its form#, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI) (if assigned): The UDI is a unique code specific to each device. It is used for product identification and registration with MHRA. If you have assigned GS1 UDI-CI (GTIN) to your products, the GTIN should be entered in the 14-digit format. The GTIN should be preceded by a '0' to make up to 18 digits. If you have assigned HBCS UDI-DE to your products, do not include HBCS Prefix '1' or the Mod 43 Check Character
Premiums™ Stent A	Yes	2.5mm	Yes	S87878	GS1 AISBL	04250274702216
Premiums™ Stent B	Yes	2.5mm	Yes	S35445	GS1 AISBL	04250274702183
Premiums™ Stent A	Yes	3mm	Yes	S46465	GS1 AISBL	04250274704739
Premiums™ Stent B	Yes	3mm	Yes	S64646	GS1 AISBL	04250274704753
Premiums™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 AISBL	04250274704777
Premiums™ Stent A Plus	Yes	5mm	Yes	S45466	GS1 AISBL	04250274705545



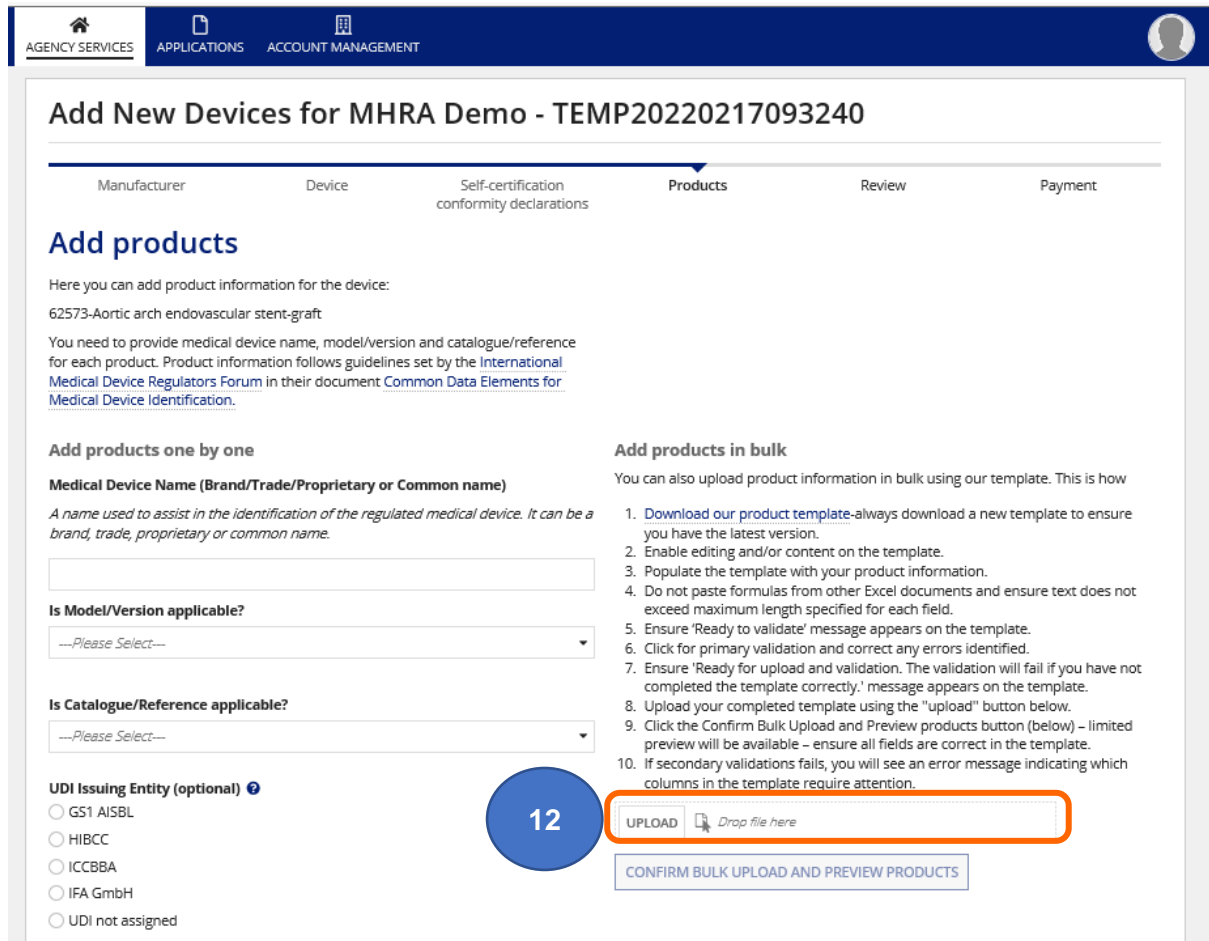
11. The 'Ready for upload and validation' message appears in the blue box. Save the document. If you don't save it before uploading secondary validation will fail.

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.

General Medical Device Product Details						
<p>You need to provide Medical Device Name, Model/Version and Catalogue/Reference (REF) for each product. Please enter Unique Device Identifier (UDI) if available. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: Common Data Elements for Medical Device Identification.</p> <p>In the fields that require Yes/No response, entering anything other than Yes/No will be recorded as 'No' in fields that have dropdown values, entering any value other than options in the dropdown will result in validation failure.</p>						
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. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for Is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/Reference applicable? (Required): Select Yes/No from the dropdown options.	Catalogue/Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its form#, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit) if you have not allocated a Catalogue/Reference select 'No' for Is Catalogue/Reference applicable? question. (Maximum Characters: 255)	UDI Issuing Entity (Optional): If you have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI) (if assigned): The UDI is a unique code specific to each device. It is used for product identification and registration with MHRA. If you have assigned GS1 UDI-CI (GTIN) to your products, the GTIN should be entered in the 14-digit format. The GTIN should be preceded by a '0' to make up to 18 digits. If you have assigned HBCS UDI-DE to your products, do not include HBCS Prefix '1' or the Mod 43 Check Character
Premiums™ Stent A	Yes	2.5mm	Yes	S87878	GS1 AISBL	04250274702216
Premiums™ Stent B	Yes	2.5mm	Yes	S35445	GS1 AISBL	04250274702183
Premiums™ Stent A	Yes	3mm	Yes	S46465	GS1 AISBL	04250274704739
Premiums™ Stent B	Yes	3mm	Yes	S64646	GS1 AISBL	04250274704753
Premiums™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 AISBL	04250274704777
Premiums™ Stent A Plus	Yes	5mm	Yes	S45466	GS1 AISBL	04250274705545



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



Add New Devices for MHRA Demo - TEMP20220217093240

Manufacturer Device Self-certification conformity declarations **Products** Review Payment

Add products

Here you can add product information for the device:
62573-Aortic arch endovascular stent-graft

You need to provide medical device name, model/version and catalogue/reference for each product. Product information follows guidelines set by the [International Medical Device Regulators Forum](#) in their document [Common Data Elements for Medical Device Identification](#).

Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Is Model/Version applicable?
---Please Select---

Is Catalogue/Reference applicable?
---Please Select---

UDI Issuing Entity (optional)

- GS1 AISBL
- HIBCC
- ICCBBA
- IFA GmbH
- UDI not assigned

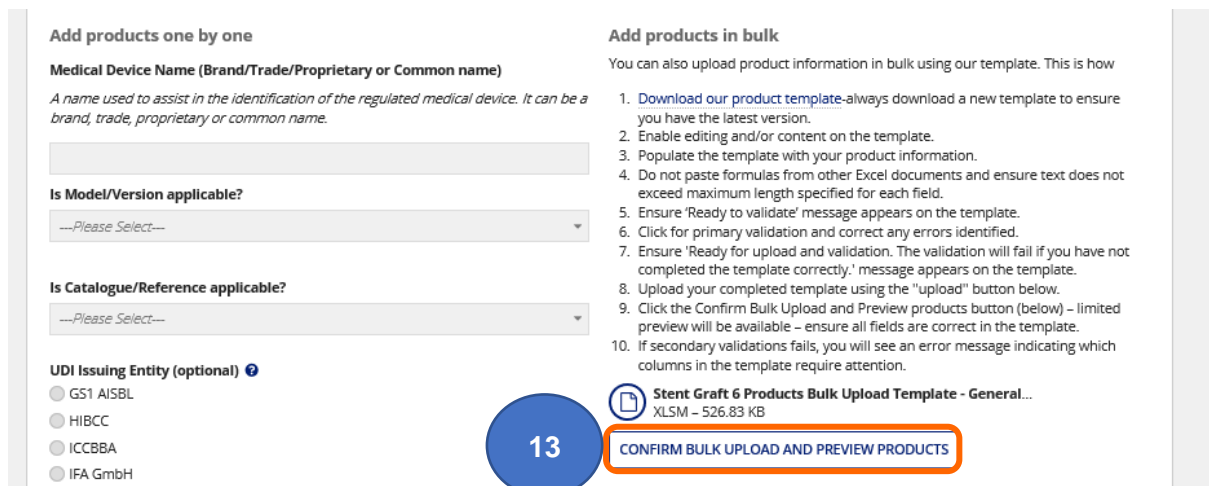
Add products in bulk

You can also upload product information in bulk using our template. This is how

1. Download our product template-always download a new template to ensure you have the latest version.
2. Enable editing and/or content on the template.
3. Populate the template with your product information.
4. Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
5. Ensure 'Ready to validate' message appears on the template.
6. Click for primary validation and correct any errors identified.
7. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctly.' message appears on the template.
8. Upload your completed template using the "upload" button below.
9. Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template.
10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.

12 Drop file here

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



Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Is Model/Version applicable?
---Please Select---

Is Catalogue/Reference applicable?
---Please Select---

UDI Issuing Entity (optional)

- GS1 AISBL
- HIBCC
- ICCBBA
- IFA GmbH

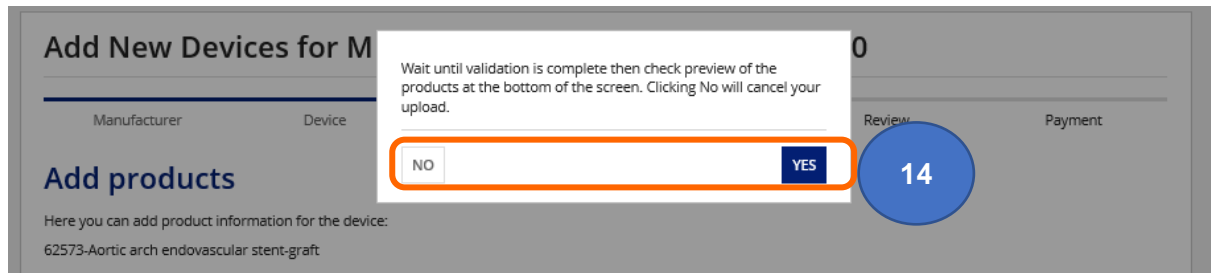
Add products in bulk

You can also upload product information in bulk using our template. This is how

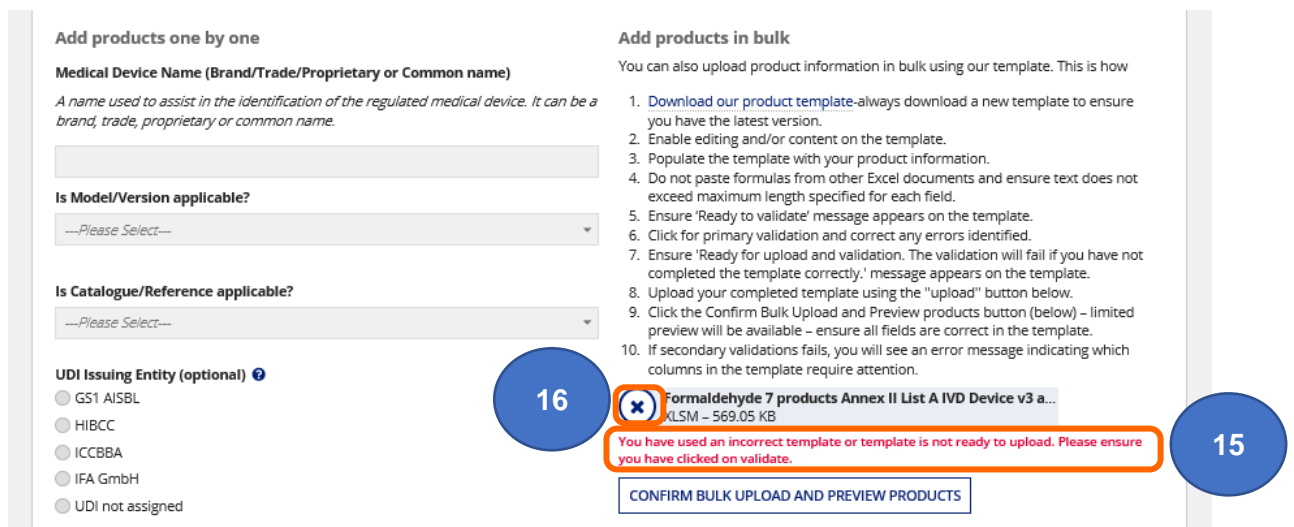
1. Download our product template-always download a new template to ensure you have the latest version.
2. Enable editing and/or content on the template.
3. Populate the template with your product information.
4. Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
5. Ensure 'Ready to validate' message appears on the template.
6. Click for primary validation and correct any errors identified.
7. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctly.' message appears on the template.
8. Upload your completed template using the "upload" button below.
9. Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template.
10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.

13

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

Product preview (products: 6)
Preview only displays limited fields

<input type="checkbox"/>	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
<input type="checkbox"/>	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market

6 items

Buttons: DELETE SELECTED, CONTINUE, SAVE & EXIT, BACK, DELETE APPLICATION

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:

- Hover** over the **document reference** until the **X** appears and **click** the **X** to remove all products you have just uploaded.
- Make any necessary amendments to the **bulk upload template**, **click for primary validation**, **save** it and **upload** again.

UDI Issuing Entity (optional) ⓘ

- GS1 AISBL
- HIBCC
- ICCBBA
- IFA GmbH
- UDI not assigned

23. If secondary validations fail, you will see an error message indicating which columns in the template require attention.

X Stent Graft 6 Products Bulk Upload Template - General...
XLSM - 526.83 KB

CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

Validation Complete

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.

Buttons: CONTINUE, SAVE & EXIT, BACK, DELETE APPLICATION

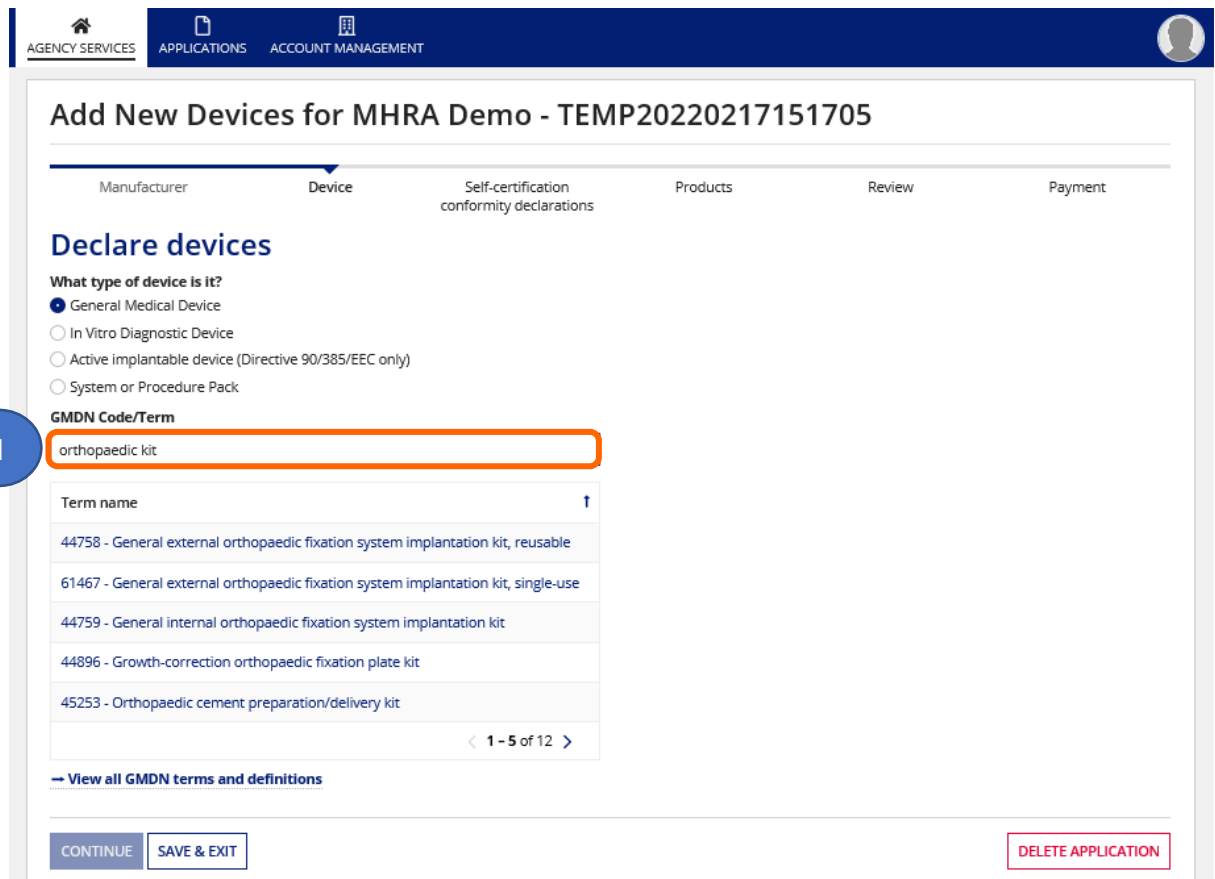
Adding System or Procedure Packs (SPP)

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.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Add New Devices for MHRA Demo - TEMP20220217151705

Manufacturer Device Self-certification conformity declarations Products Review Payment

Declare devices

What type of device is it?

- General Medical Device
- In Vitro Diagnostic Device
- Active implantable device (Directive 90/385/EEC only)
- System or Procedure Pack

GMDN Code/Term

1 orthopaedic kit

Term name ↑

- 44758 - General external orthopaedic fixation system implantation kit, reusable
- 61467 - General external orthopaedic fixation system implantation kit, single-use
- 44759 - General internal orthopaedic fixation system implantation kit
- 44896 - Growth-correction orthopaedic fixation plate kit
- 45253 - Orthopaedic cement preparation/delivery kit

< 1 - 5 of 12 >

[View all GMDN terms and definitions](#)

CONTINUE SAVE & EXIT DELETE APPLICATION

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

Declare devices

What type of device is it?

General Medical Device
 In Vitro Diagnostic Device
 Active Implantable Device
 System or Procedure Pack

GMDN Code/Term

4405B - General surgical procedure kit, non-medicated, reusable

[View all GMDN terms and definitions](#)

Which directive/regulation does this device comply with?

UK MDR 2002 (SI 2002 No 618 as amended), Part II
 Directive 93/42/EEC
 EU medical devices regulations 2017/745

! MHRA will only accept registrations for sterile System & Procedure Packs under (EU)2017/745 if the EU Notified Body is designated under the EU Medical Devices Regulation 2017/745.

Basic UDI-DI Issuing Entity(optional)

--Please Select--

Device labelled as sterile? **!**

Yes
 No

Single-use device?

Yes
 No

Reprocessed single-use device?

Yes
 No

Does the System or Procedure Pack incorporate a custom-made medical device that is not required to bear a UKCA/CE/CE (UK NI) marking?

Yes
 No

Are the chosen combination of medical devices compatible in view of their original intended use?

Yes
 No

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product (optional) **!**

--Please Select--

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma (optional) **!**

--Please Select--

Has a Clinical investigation been conducted? (optional)

--Please Select--

2

3

CONTINUE **SAVE & EXIT** **DELETE APPLICATION**

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.

Add New Devices for MHRA Demo - TEMP20220217151705

Manufacturer Device Self-certification conformity declarations **Products** Review Payment

Add products

Here you can add product information for the device:

44054-Orthopaedic surgical procedure kit, non-medicated, reusable

You need to provide medical device name, model/version and catalogue/reference for each product. Product information follows guidelines set by the [International Medical Device Regulators Forum](#) in their document [Common Data Elements for Medical Device Identification](#).

Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)

A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Orthokit1

Is Model/Version applicable?

---Please Select---

Is Catalogue/Reference applicable?

---Please Select---

UDI Issuing Entity (optional) ⓘ

- GS1 AISBL
 HIBCC
 ICCBBA
 IFA GmbH
 UDI not assigned

Product Status ⓘ

On the GB & NI market

4

5. Click the link to [Download our content list template](#), complete and save the template on your system.

5

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

- 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.


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

6

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)

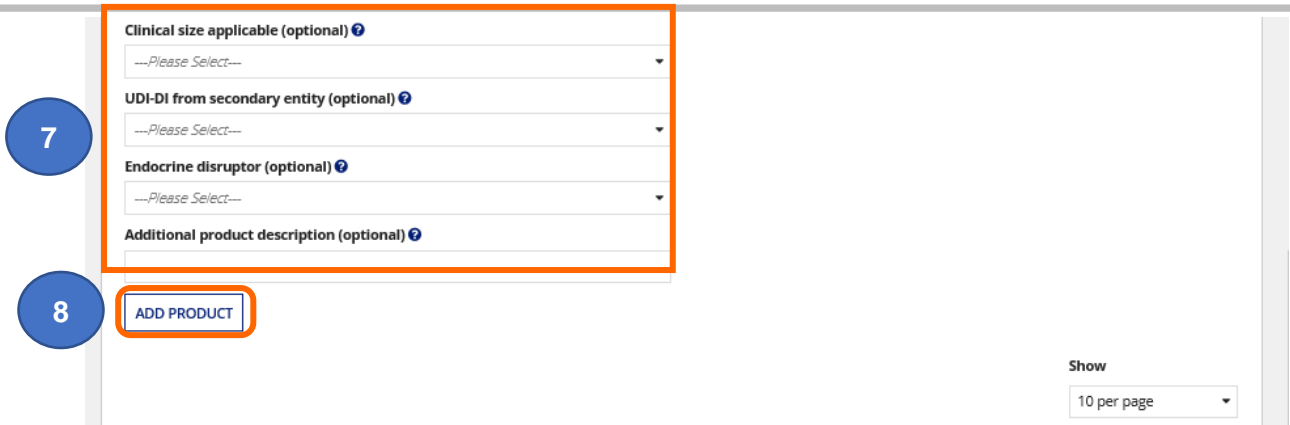
---Please Select---

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

---Please Select---

Containing latex (optional)

---Please Select---



7

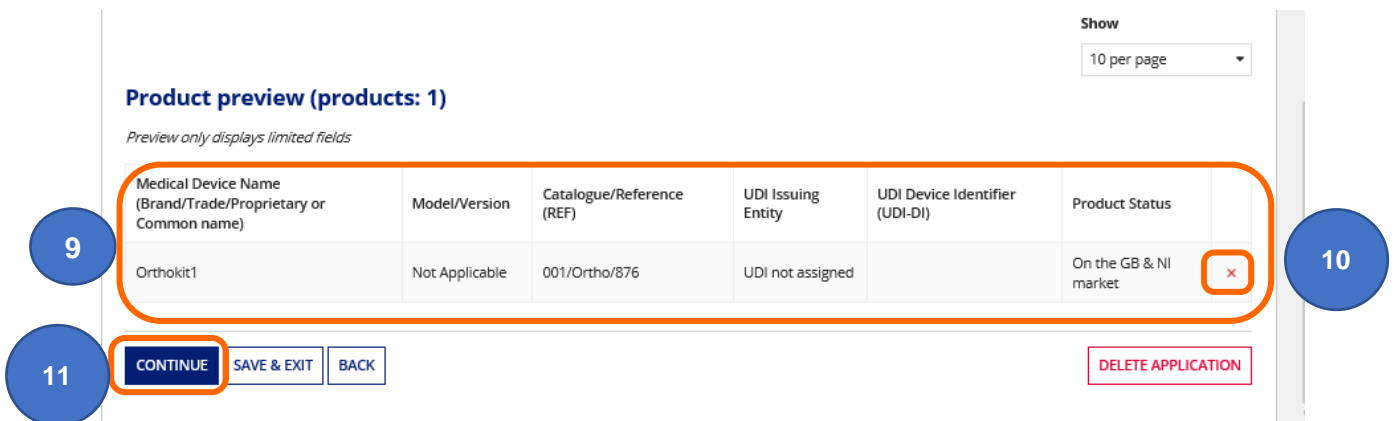
8

ADD PRODUCT

Show
10 per page

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.



9

10

11

Product preview (products: 1)
Preview only displays limited fields

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
Orthokit1	Not Applicable	001/Ortho/876	UDI not assigned		On the GB & NI market X

CONTINUE SAVE & EXIT BACK

DELETE APPLICATION

Show
10 per page

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. **Conformity 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.

Add New Devices - TEMP20210716103807

Manufacturer Device Self-certification conformity declarations Products **Review** Payment

Review Devices

1 **2** **3** **4**

Device Details **Conformity Assessment Certificates** **Products**

Device type
General Medical Device

Sterile?
Yes

Regulative/Directive?
European medical devices regulations EU 2017/745

Reprocessed single-use device?
No

Implantable Products?
No

Custom made?
No

Method of Sterilisation
Radiation, Gamma or Electron Beam

Annex XVI?
No

Active Products?
No

Risk classification
Class IIIa

Reusable surgical instruments?
Yes

Administer/Remove medicinal Product?
No

EDIT DEVICE **DELETE DEVICE**

Editing the device will remove or unlink all conformity assessment documents and products (model/version) for that device and you will need to re-enter them

ADD ANOTHER DEVICE

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

Further information on the legal requirements is available at the following links in relation to the [UK Medical Devices Regulations 2002](#) (in the form that they exist on 1 January 2021) and also regarding the [EU Medical devices and in-vitro diagnostic devices regulations](#).

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisations and or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £100 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our [terms and conditions](#).

I have read and agree to the terms and conditions

CONTINUE **SAVE & EXIT** **BACK** **DELETE APPLICATION**

- 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.

Add New Devices - TEMP20210716103807

Manufacturer Device Self-certification conformity declarations Products **Review** Payment

Review Devices

▼ **Lens nucleus manipulator**

Device Details		Conformity Assessment Certificates		Products
Device type General Medical Device	Custom made? No	Risk classification Class IIIa		
Sterile? Yes	Method of Sterilisation Radiation, Gamma or Electron Beam	Reusable surgical instruments? Yes		
Regulative/Directive? European medical devices regulations EU 2017/745				
Reprocessed single-use device? No	Annex XVII? No			
Implantable Products? No	Active Products? No	Administer/Remove medicinal Product? No		

[EDIT DEVICE](#) [DELETE DEVICE](#)

⚠ Editing the device will remove or unlink all conformity assessment documents and products (model/version) for that device and you will need to re-enter them

5 [ADD ANOTHER DEVICE](#)

6 [I have read and agree to the terms and conditions](#)

7 [CONTINUE](#) [SAVE & EXIT](#) [BACK](#) [DELETE APPLICATION](#)

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

Further information on the legal requirements is available at the following links in relation to the [UK Medical Devices Regulations 2002](#) (in the form that they exist on 1 January 2021) and also regarding the [EU Medical devices and in-vitro diagnostic devices regulations](#).

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

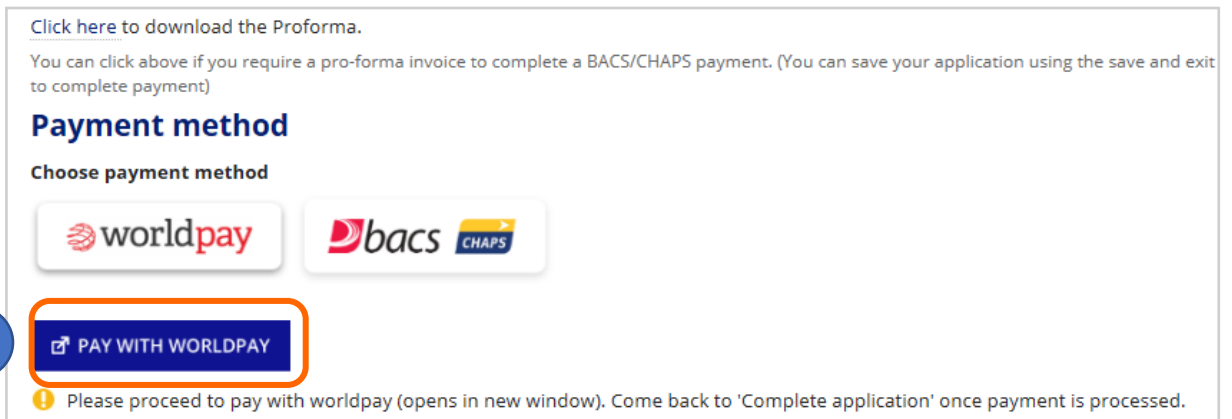
NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisations and or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £100 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our [terms and conditions](#).

- 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.
- Click the 'Continue' button to proceed to payment.

Paying with worldpay

1. Click on the [Pay with worldpay](#) button.





Click [here](#) to download the Proforma.


You can click above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit to complete payment)

Payment method

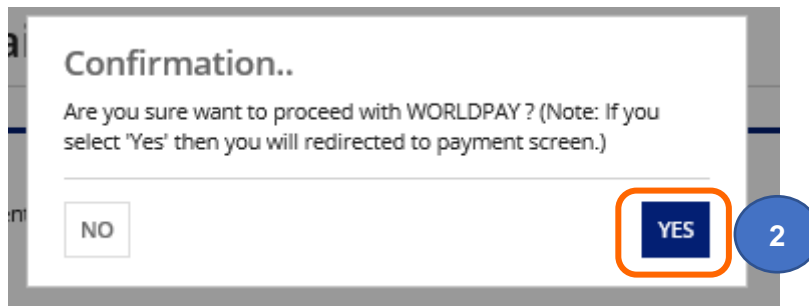
Choose payment method

1 [PAY WITH WORLDPAY](#)

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

2. A confirmation message will appear. Select the [Yes](#) button if you wish to proceed.

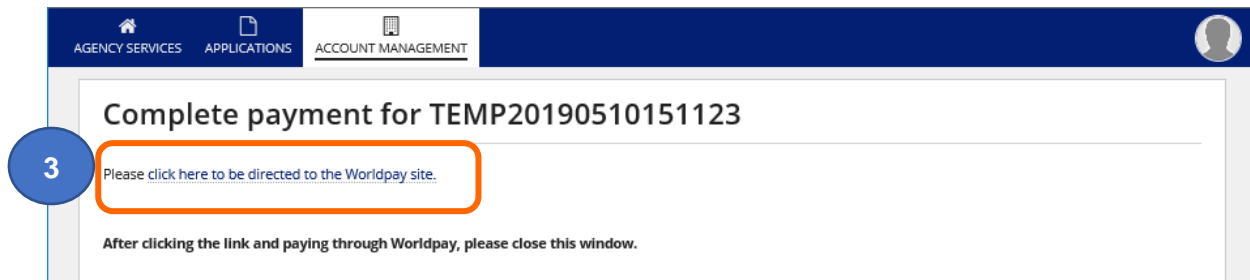


Confirmation..

Are you sure want to proceed with WORLDPAY ? (Note: If you select 'Yes' then you will redirected to payment screen.)

2

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



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Complete payment for TEMP20190510151123

3 [Please click here to be directed to the Worldpay site.](#)

After clicking the link and paying through Worldpay, please close this window.

4. Select the payment method.

Important note: Fee in screenshot is for illustrative purposes only. Check current [statutory fees](#) on our website.



Test Mode - This is not a live transaction.

Medicines & Healthcare products
Regulatory Agency

English

Order summary

Payment reference: DR28663190510142214

Description: Medical device registration/Update to an existing medical device registration

Amount (GBP): £100.00

Select payment method

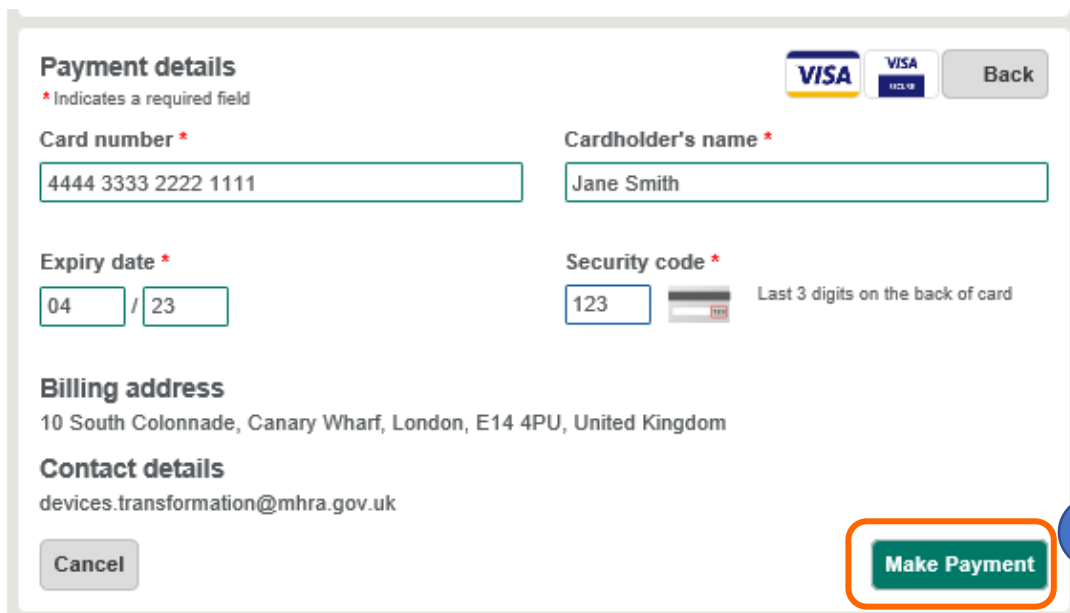
United Kingdom

VISA
Mastercard
maestro
AMERICAN EXPRESS
Diners Club INTERNATIONAL
Masterpass

Cancel payment

© Worldpay 2013-2019. All rights reserved.

5. Enter payment details and [click](#) the [Make payment](#) button.



Payment details

* Indicates a required field

VISA VISA Back

Card number * 4444 3333 2222 1111

Cardholder's name * Jane Smith

Expiry date * 04 / 23

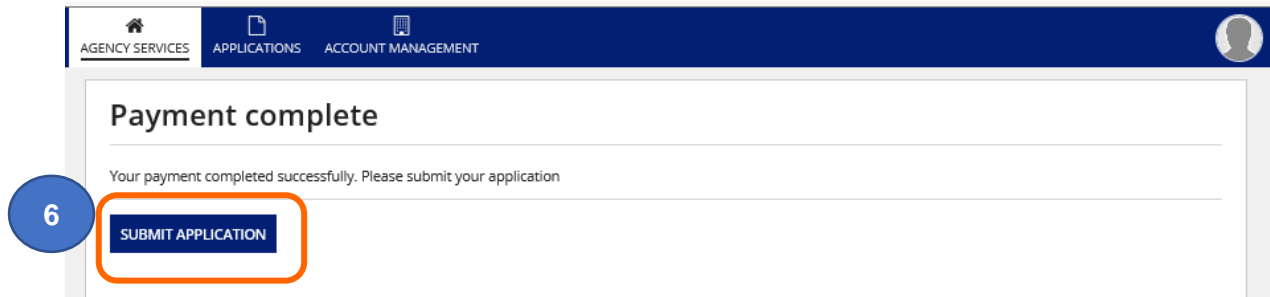
Security code * 123 Last 3 digits on the back of card

Billing address
10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom

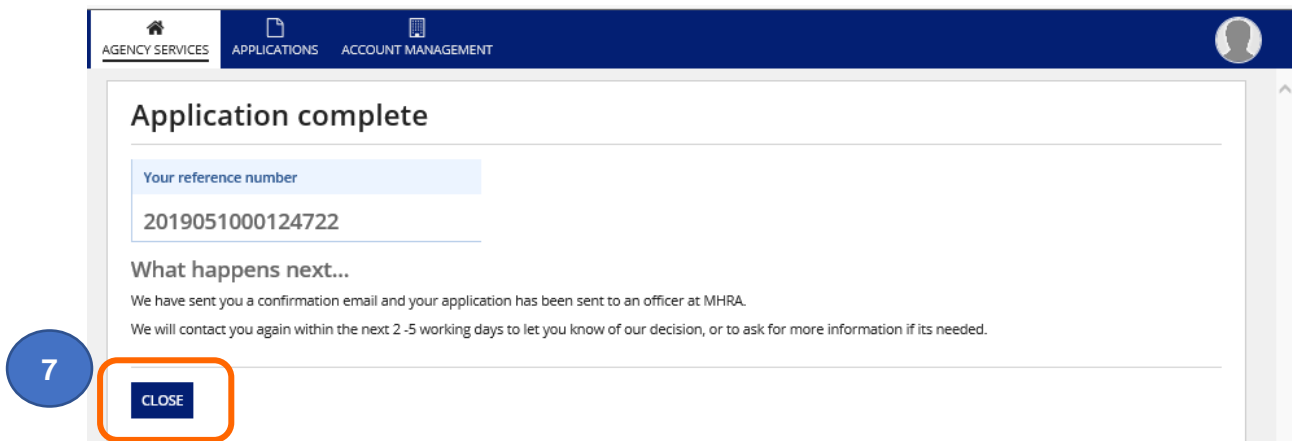
Contact details
devices.transformation@mhra.gov.uk

Cancel Make Payment

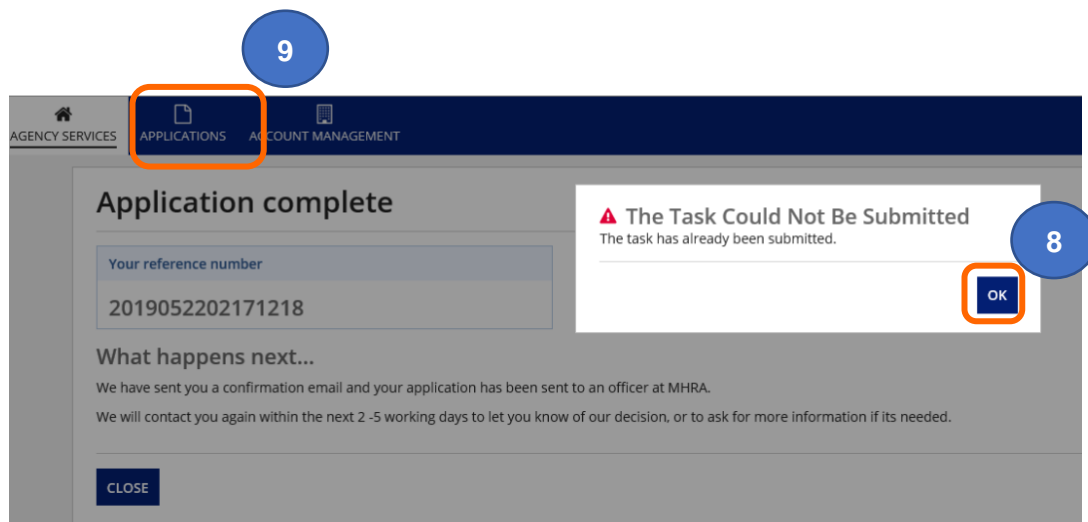
- Click** the [Submit Application](#) button. If you do not click this button (and your payment was successful) the TEMP application will remain in the [Applications Tab](#) and you will need to wait at least **24 hours** for the application to be auto-submitted to MHRA. Please ensure that you click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



- A [confirmation](#) screen will appear. **Click** the [Close](#) button.



- 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.

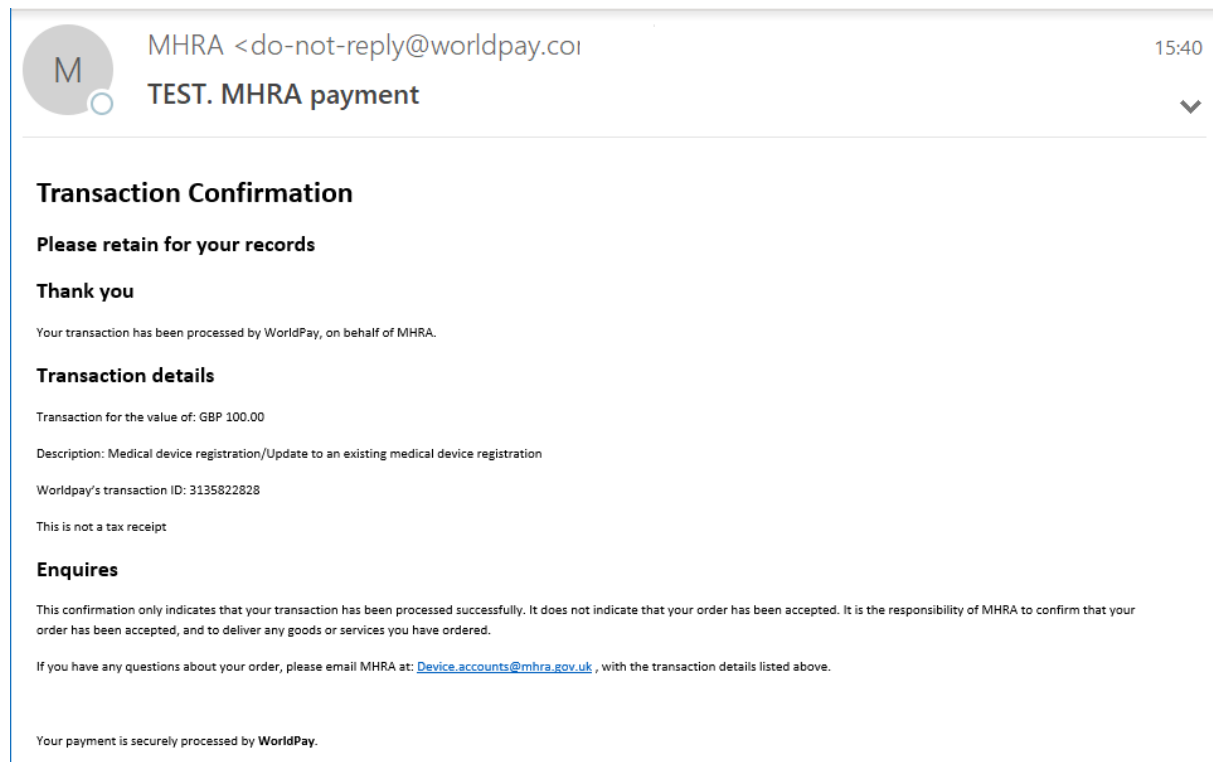


- Click** on the [Applications Tab](#) to see your submitted application.

10. You will receive a [confirmation](#) email from Woldpay.

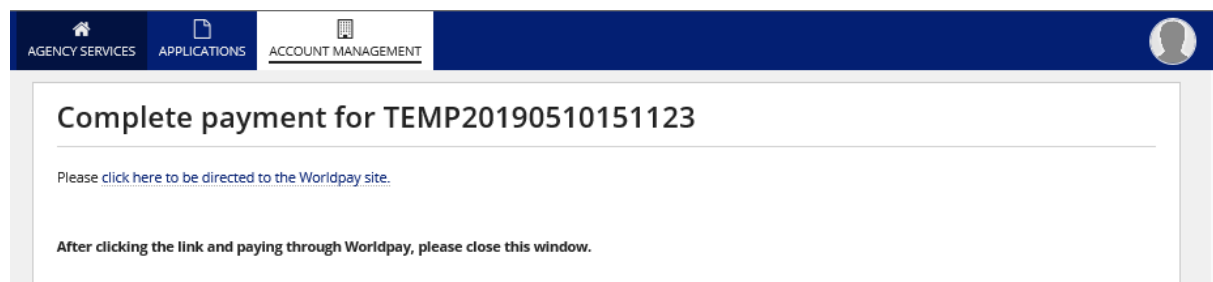
Please note MHRA does not issue tax receipts. The worldpay transaction email and the confirmation of registration email are the only documents you will receive in relation to payment for your registration.

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.


1


Click here to download the Proforma.

You can click above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit option to complete payment)

Payment method

Choose payment method





! The application will be completed only after the transfer is complete. This usually takes 5 days.

When making a payment via BACS or CHAPS you must quote the reference number below. Failure to do so will result in delay or rejection of the MHRA. The MHRA review of your application will only be completed once payment has been made and proof of payment has been received.

Reference number
 1710190820192042

For BACS/CHAPS payments please use the following details:

Account name: MHRA

Account number: 10004386

Sort code: 60-70-80

Swift code: NWBKGB2L

IBAN: GB68NWBK60708010004386

Bank: National Westminster Bank
 RBS, London Corporate Service Centre, 2nd Floor
 280 Bishopsgate
 London - EC2M 4RB

3

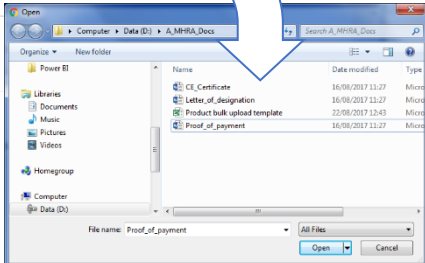
Please upload your proof of payment. This can be a copy of a bank statement indicating the payment date, amount and payee

4

SUBMIT APPLICATION

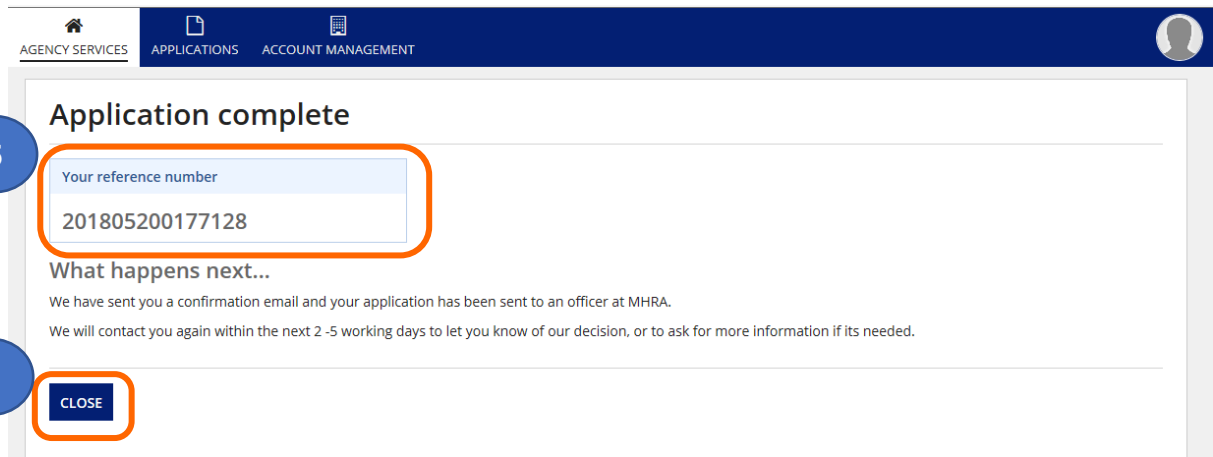
SAVE AND EXIT

BACK



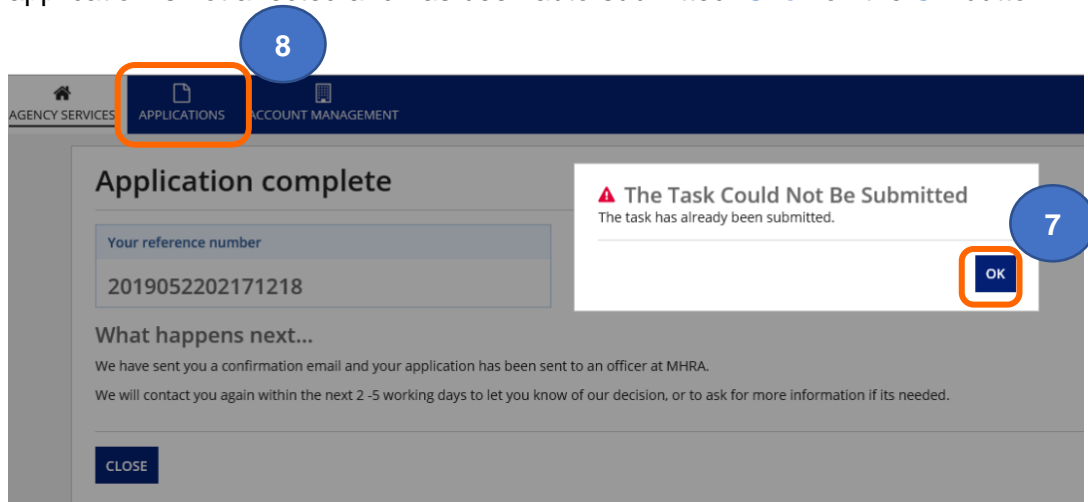
Complete Application

- Note the [Application reference number](#).



- Select the [Close](#) button.

- 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.




- [Click](#) on the [Applications](#) tab and [hover](#) over the [status icon](#) tab to see the progress of your submitted application.

Submitted Applications

Search by organisation name or reference number

Show *All Types* ▾
Show 10 per page ▾

Reference	Manufacturer	Application Type	Submitted on	Status
2022021801215061	MHRA Demo	New device	18 February 2022	
2021102602208215	DEMO Represented Organisation	CFS Order	26 October 2021	✓
2021102500208210	DEMO Represented Organisation	Registration Renewal	25 October 2021	✓



Application received email

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

We've received your New device application on 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](#).

Applications

▼ **Draft Applications**

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.

Search by manufacturer name or reference number

Service *All Types* Show *All Types* Show 10 per pa...

Reference	Manufacturer	Application Type	Last saved on	Status
TEMP20220217151705	MHRA Demo	New device	17 February 2022	

▼ **Submitted Applications**

Search by organisation name or reference number

Show *All Types* Show 10 per pa...

Reference	Manufacturer	Application Type	Submitted on	Status
2022021801215061	MHRA Demo	New device	18 February 2022	🕒
2021102602208215	DEMO Represented Organisation	CFS Order	26 October 2021	✅
2021102500208210	DEMO Represented Organisation	Registration Renewal	25 October 2021	✅

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/Update 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

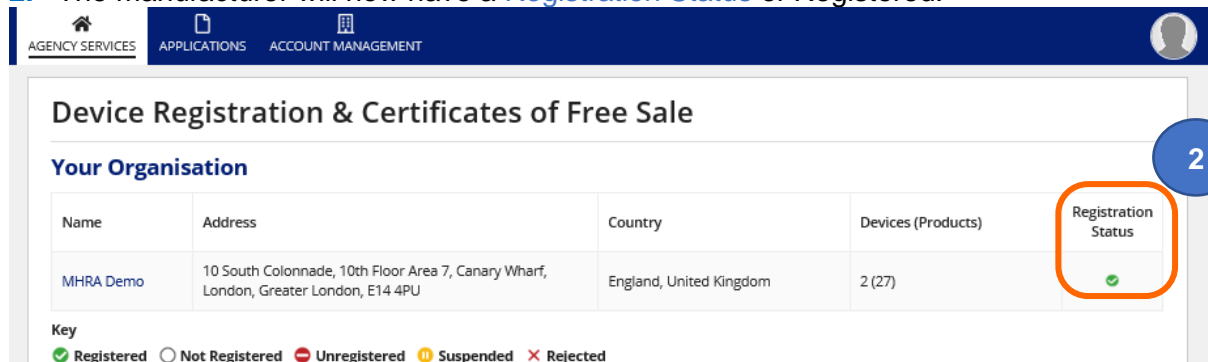
Manufacturer registration status: Registered

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.








AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United Kingdom	2 (27)	

Key
 Registered  Not Registered  Unregistered  Suspended  Rejected

Public Access Registration Database (PARDB)

Completed registrations will appear on the [Public Access Registration Database \(PARDB\)](#), 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 PARDB, please see **Renew Registration** and **Uploading new Letter of Designation** in the **Account Management Reference Guide**.

If your registration is not displaying on PARDB 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

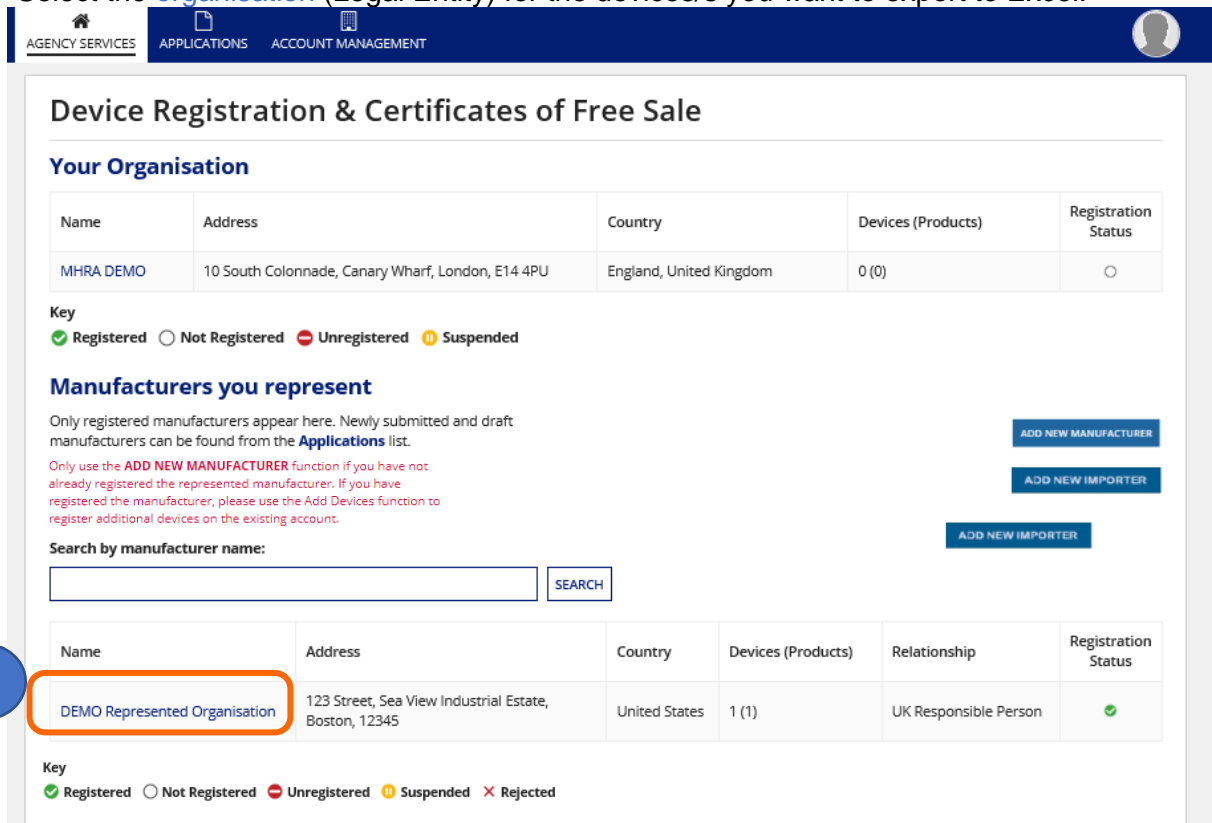
See the **Edit Organisation** section in the **Account Management Reference Guide** for instructions on how to update organisation name/s and/or address/s and upload new Letters of Designation – [statutory fees](#) will apply.

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.

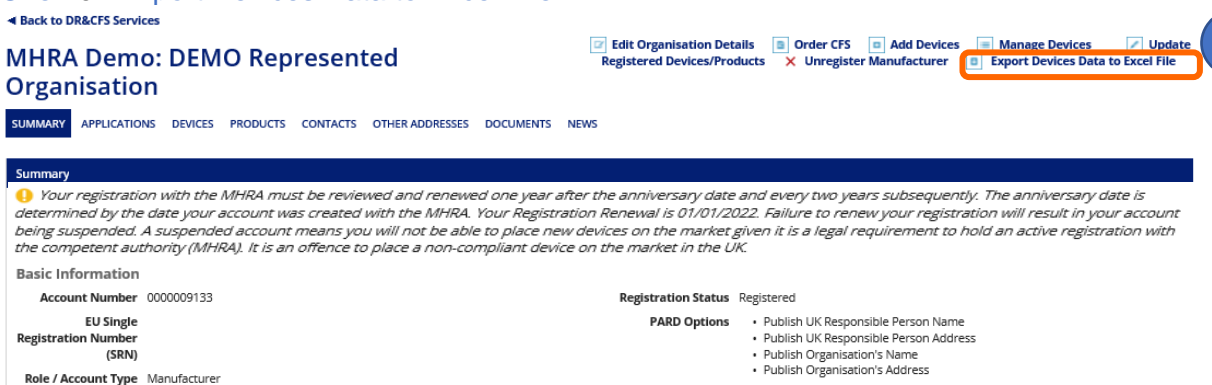


The screenshot shows the 'Device Registration & Certificates of Free Sale' page. Under the 'Manufacturers you represent' section, there is a table with the following data:

Name	Address	Country	Devices (Products)	Relationship	Registration Status
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	1 (1)	UK Responsible Person	Registered (Green checkmark)

A blue circle with the number '1' is positioned to the left of the 'DEMO Represented Organisation' row, which is also highlighted with an orange border.

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

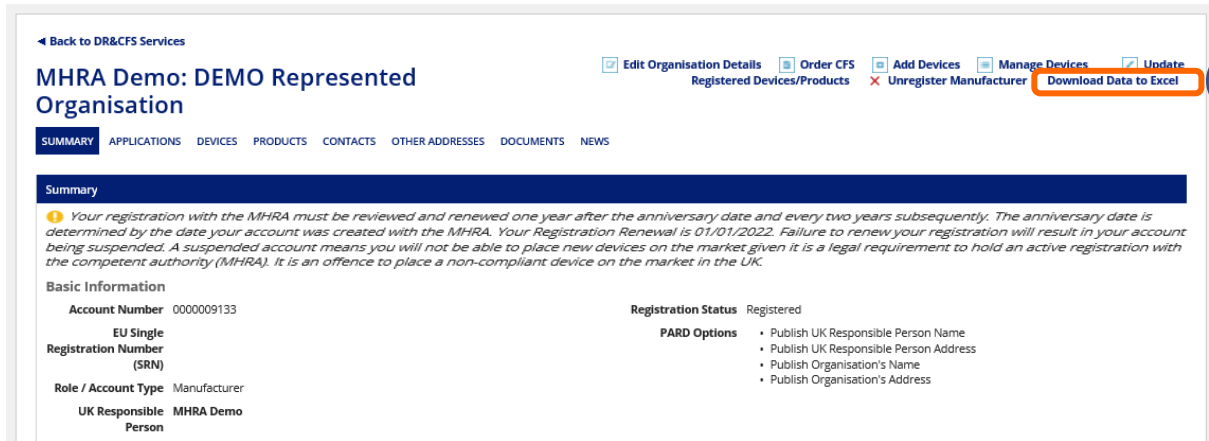


The screenshot shows the 'MHRA Demo: DEMO Represented Organisation' page. In the top right navigation bar, the link 'Export Devices Data to Excel File' is highlighted with an orange border. A blue circle with the number '2' is positioned to the right of this link.

Below the navigation bar, there is a 'Summary' section with the following information:

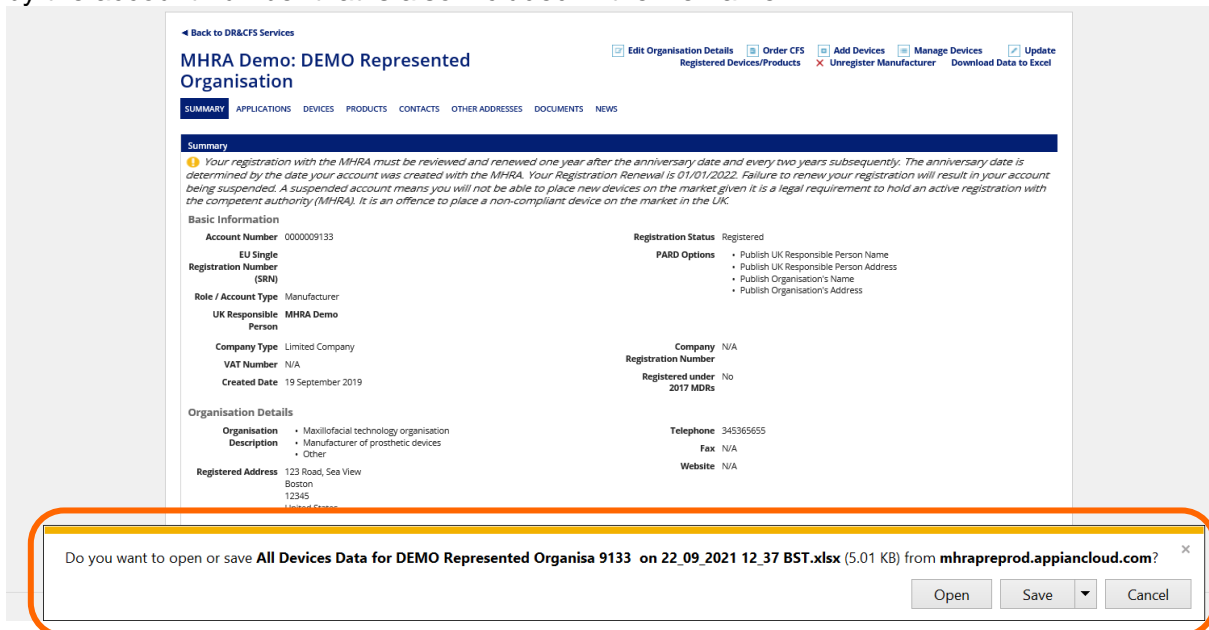
- Account Number:** 0000009133
- EU Single Registration Number (SRN):** (SRN)
- Role / Account Type:** Manufacturer
- Registration Status:** Registered
- PARD Options:**
 - Publish UK Responsible Person Name
 - Publish UK Responsible Person Address
 - Publish Organisation's Name
 - Publish Organisation's Address

3. Click on Download Data to Excel File link.

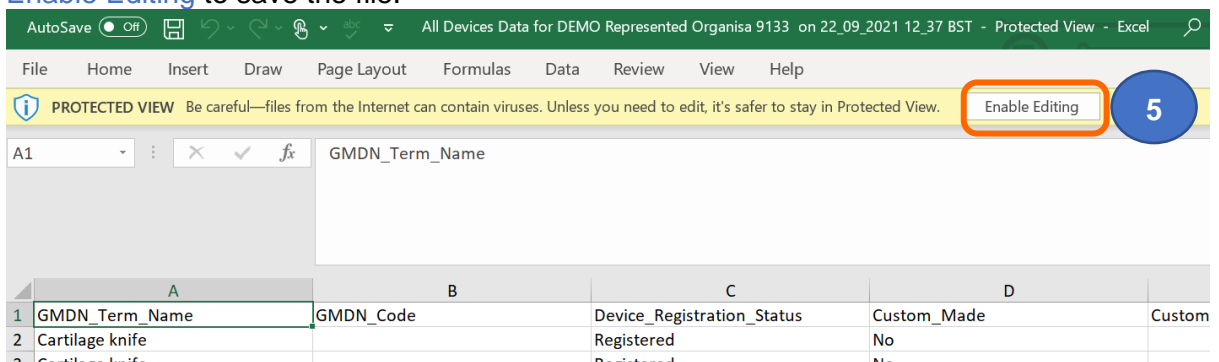


4. The Excel dialogue box will open. Open or save the file as required.

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.

SUMMARY APPLICATIONS RELATED ORGANISATIONS **DEVICES** PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Devices

[Hide Filters](#)

Device Type / Class <input type="text" value="-- Select device type / Clas..."/>	Device Registered Date <input type="text" value="dd/mm/yyyy"/>	GMDN Code / Term Name <input type="text"/>	Custom Made <input type="text" value="--"/>	Regulation/Directive: <input type="text" value="--"/>
Is Sterile? <input type="text" value="--"/>	Is Measuring <input type="text" value="--"/>	Is Single-use? <input type="text" value="--"/>	Is Reprocessed single-use? <input type="text" value="--"/>	Custom-made SPP <input type="text" value="--"/>
Reusable Surgical Instruments? <input type="text" value="--"/>	Is Active? <input type="text" value="--"/>	Is Implantable? <input type="text" value="--"/>	Is Intended to Administer/remove medicinal product? <input type="text" value="--"/>	Intended purpose other than medical(Annex XVI) <input type="text" value="--"/>
Is CFS Ready <input type="text" value="--"/>	Presence of Medicinal/Herbal substance <input type="text" value="--"/>	Presence of Blood/Plasma substance <input type="text" value="--"/>	Has a Clinical investigation been conducted <input type="text" value="--"/>	Basic UDI-DI Issuing Entity <input type="text" value="--"/>
Basic UDI-DI Number <input type="text"/>	Device Registration status <input type="text" value="No Longer Registered"/>	Is Device Updated? <input type="text" value="--"/>	Show <input type="text" value="10 per page"/>	

[Clear Filters](#)

Status	GMDN Code	Term Name	Device Type	Reason For Deletion
✘	41349	Allergen-specific immunoglobulin E (IgE) antibody IVD, control	In Vitro Diagnostic Device - IVD General	Entered in error
✘	--	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)	In Vitro Diagnostic Device - IVD General	
✔	90000186	Alphafetoprotein	In Vitro Diagnostic Device - IVD General	
✔	90000202	Anti-Streptolysin/Anti-Streptolysin O (qualitative)	In Vitro Diagnostic Device - IVD General	
✔	90000227	antinuclear antibody (enzyme-labeled), antigen, control	In Vitro Diagnostic Device - IVD General	
✘	--	Beta-haemolytic Streptococcus serological grouping IVD, kit, agglutination	In Vitro Diagnostic Device - IVD General	
✘	--	Boiling water sterilizer	General Medical Device - Class I	No longer placed on the market
✔	90000213	Brucella	In Vitro Diagnostic Device - IVD General	
✘	63236	Brucella abortus total antibody IVD, kit, agglutination	In Vitro Diagnostic Device - IVD General	No longer placed on the market
✘	63239	Brucella melitensis total antibody IVD, kit, agglutination	In Vitro Diagnostic Device - IVD General	Deleted By MHRA

<< < 1 - 10 of 101 > >>

Key
✔ Registered ○ Not Registered ✘ No Longer Registered ✘ Rejected ● Conformity assessment certificate expired ⚠ Pending Amendment ✔ Invalid-Please Delete

- To view when device was deleted and by whom, [click](#) on the **GMDN® Term** of the deleted device.

Status	GMDN Code	Term Name	Device Type	Reason For Deletion
✘	41349	Allergen-specific immunoglobulin E (IgE) antibody IVD, control	In Vitro Diagnostic Device - IVD General	Entered in error
✘	--	Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)	In Vitro Diagnostic Device - IVD General	
☑	90000186	Alphafetoprotein	In Vitro Diagnostic Device - IVD General	

- 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.

SUMMARY APPLICATIONS RELATED ORGANISATIONS **DEVICES** PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Devices

<< Back to all "Devices & Products"

41349 - Allergen-specific immunoglobulin E (IgE) antibody IVD, control

Device Type In Vitro Diagnostic Device

GMDN description A material which is used to verify the performance of an assay intended to be used for the qualitative and/or quantitative detection of an allergen specific immunoglobulin E (IgE) antibody in a clinical specimen.

Which directive/regulation does this device comply with? Directive 98/79/EC

Risk classification IVD General

Is this device subject to performance evaluation studies? Yes

Declaration of Conformity/Custom-made Statement

Filename	Document Reference	Conformity Assessment Type
Declaration of Conformity 1	DOC1	CE - MDD/IVDD/AIMD

Product Details

Preview only displays limited fields

Status	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
✘	Allergen 1	Allergen 1	AL/01/865473			On the GB & NI market

Key
 ✓ Registered ○ Not Registered ✘ No Longer Registered ✘ Rejected

Device History

Removed By jane.smith
 Removed on 05/08/2021 13:51



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.

1

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	4 (9)	✓

Key
 ✓ Registered ○ Not Registered ⚠ Unregistered ⏸ Suspended ✗ Rejected

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the [Applications](#) list.

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

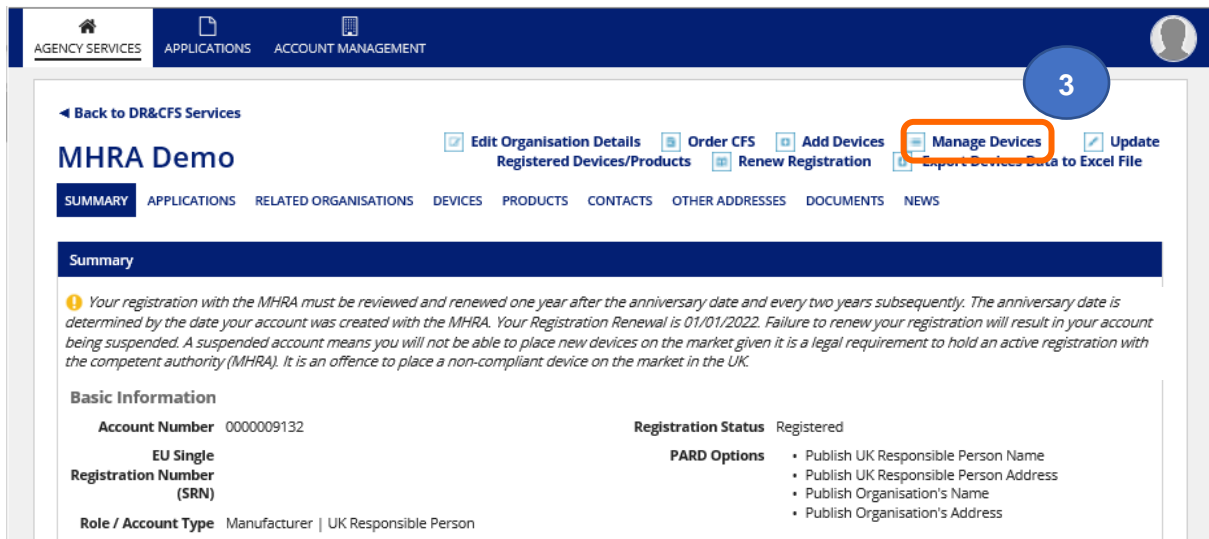
ADD NEW MANUFACTURER
ADD NEW IMPORTER
ADD NEW IMPORTER

Search by manufacturer name:

Name	Address	Country	Devices (Products)	Relationship	Registration Status
Demo represented org Three	167 Bella Bista, East Side Compound, 1000 Medtech Drive, Sea View Industrial Zone, Santa Barbara, CA, 98765	United States	20 (21)	UK Responsible Person	✓
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, MA, 12345	United States	3 (10)	UK Responsible Person	✓
DEMO Represented Organisation Two	234 Avenida Escala, Cancun, Yukatan, 43231	Mexico	1 (1)	UK Responsible Person	✓
DEMO Represented Organisation Three	60 Strand Street, Douglas, Isle Of Man, IM1 2EL	Isle of Man	0 (0)	UK Responsible Person	○

Key
 ✓ Registered ○ Not Registered ⚠ Unregistered ⏸ Suspended ✗ Rejected

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



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

◀ Back to DR&CFS Services

MHRA Demo

 Edit Organisation Details
 Order CFS
 Add Devices
 Manage Devices
 Update Registered Devices/Products
 Renew Registration
 Export Services Data to Excel File

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

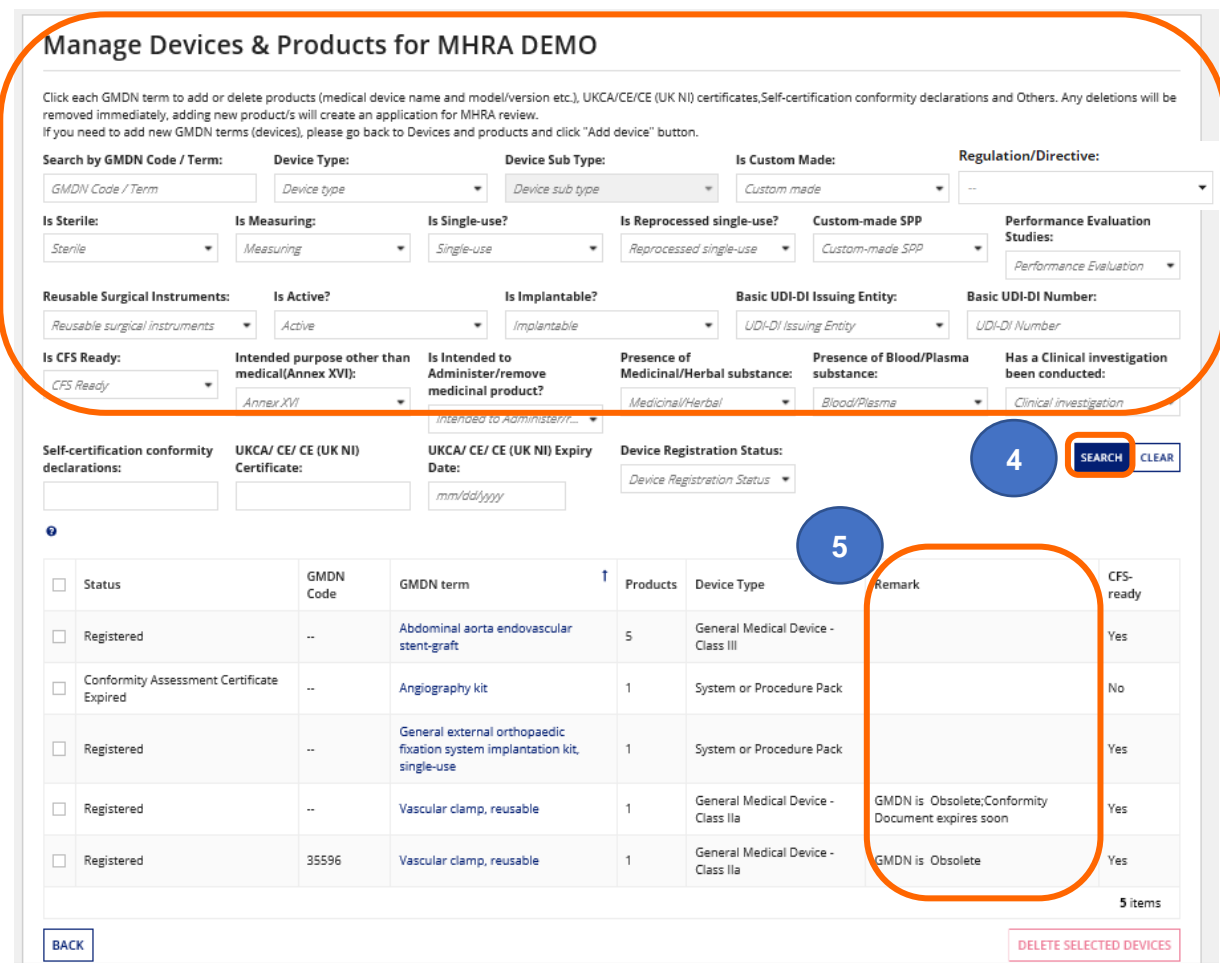
Summary

⚠ Your registration with the MHRA must be reviewed and renewed one year after the anniversary date and every two years subsequently. The anniversary date is determined by the date your account was created with the MHRA. Your Registration Renewal is 01/01/2022. Failure to renew your registration will result in your account being suspended. A suspended account means you will not be able to place new devices on the market given it is a legal requirement to hold an active registration with the competent authority (MHRA). It is an offence to place a non-compliant device on the market in the UK.

Basic Information

Account Number	0000009132	Registration Status	Registered
EU Single Registration Number (SRN)		PARD Options	<ul style="list-style-type: none"> • Publish UK Responsible Person Name • Publish UK Responsible Person Address • Publish Organisation's Name • Publish Organisation's Address
Role / Account Type	Manufacturer UK Responsible Person		

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](#).



Manage Devices & Products for MHRA DEMO

Click each GMDN term to add or delete products (medical device name and model/version etc.), UKCA/CE/CE (UK NI) certificates, Self-certification conformity declarations and Others. Any deletions will be removed immediately, adding new product/s will create an application for MHRA review. If you need to add new GMDN terms (devices), please go back to Devices and products and click "Add device" button.

Search by GMDN Code / Term: **Device Type:** **Device Sub Type:** **Is Custom Made:** **Regulation/Directive:**

Is Sterile: **Is Measuring:** **Is Single-use?** **Is Reprocessed single-use?** **Custom-made SPP** **Performance Evaluation Studies:**

Reusable Surgical Instruments: **Is Active?** **Is Implantable?** **Basic UDI-DI Issuing Entity:** **Basic UDI-DI Number:**

Is CFS Ready: **Intended purpose other than medical (Annex XVI):** **Is Intended to Administer/remove medicinal product?** **Presence of Medicinal/Herbal substance:** **Presence of Blood/Plasma substance:** **Has a Clinical investigation been conducted:**

Self-certification conformity declarations: **UKCA/ CE/ CE (UK NI) Certificate:** **UKCA/ CE/ CE (UK NI) Expiry Date:** **Device Registration Status:**

<input type="checkbox"/>	Status	GMDN Code	GMDN term	Products	Device Type	Remark	CFS-ready
<input type="checkbox"/>	Registered	--	Abdominal aorta endovascular stent-graft	5	General Medical Device - Class III		Yes
<input type="checkbox"/>	Conformity Assessment Certificate Expired	--	Angiography kit	1	System or Procedure Pack		No
<input type="checkbox"/>	Registered	--	General external orthopaedic fixation system implantation kit, single-use	1	System or Procedure Pack		Yes
<input type="checkbox"/>	Registered	--	Vascular clamp, reusable	1	General Medical Device - Class IIa	GMDN is Obsolete;Conformity Document expires soon	Yes
<input type="checkbox"/>	Registered	35596	Vascular clamp, reusable	1	General Medical Device - Class IIa	GMDN is Obsolete	Yes

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.

<input type="checkbox"/>	Status	GMDN Code	GMDN term	Products	Device Type	Remark	CFS-ready
<input type="checkbox"/>	Registered	--	Abdominal aorta endovascular stent-graft	5	General Medical Device - Class III		Yes
<input type="checkbox"/>	Conformity Assessment Certificate Expired	--	Angiography kit	1	System or Procedure Pack		No
<input type="checkbox"/>	Registered	--	General external orthopaedic fixation system implantation kit, single-use	1	System or Procedure Pack		Yes
<input type="checkbox"/>	Registered	35596	Vascular clamp, reusable	1	General Medical Device - Class IIa	GMDN is Obsolete	Yes
<input type="checkbox"/>	Registered		Vascular clamp, reusable	1	General Medical Device - Class IIa	GMDN is Obsolete;Conformity Document expires soon	Yes

5 items

BACK DELETE SELECTED DEVICES

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 Devices & Products for MHRA Demo

Manage device: "Abdominal aorta endovascular stent-graft"

Device type General Medical Device	Custom made? No	Risk classification Class III
Sterile? Yes	Method of Sterilisation Ethylene Oxide	
Regulative/Directive? Directive 93/42/EEC		
Single use device? Yes		
Reprocessed single-use device? No		
Implantable Products? Yes	Active Products? No	Administer/Remove medicinal Product? No

Conformity Assessment Certificates

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

Filename	Reference	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
CE Certificate 5	UKCA1	31/10/2021	Full Quality Assurance (Annex II excluding Section 4)	BSI	UKCA - MDD/IVDD/AIMD

EDIT CONFORMITY ASSESSMENT CERTIFICATES

Products (6)

Preview only displays limited fields

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
Premium Stent A	14F	S87878	GS1 AISBL	04250274702216	On the GB & NI market
Premium Stent B	14F	S35445	GS1 AISBL	04250274702193	On the GB & NI market
Premium Stent A	17F	S46465	GS1 AISBL	04250274704739	On the GB & NI market
Premium Stent B	17F	S46466	GS1 AISBL	04250274704753	On the GB & NI market
Premium Stent A	18F	S35454	GS1 AISBL	04250274704777	On the GB & NI market
Premium Stent A	20F	S45466	GS1 AISBL	04250274705545	On the GB & NI market

6 items

ADD/REMOVE PRODUCTS

BACK TO MANAGE DEVICES

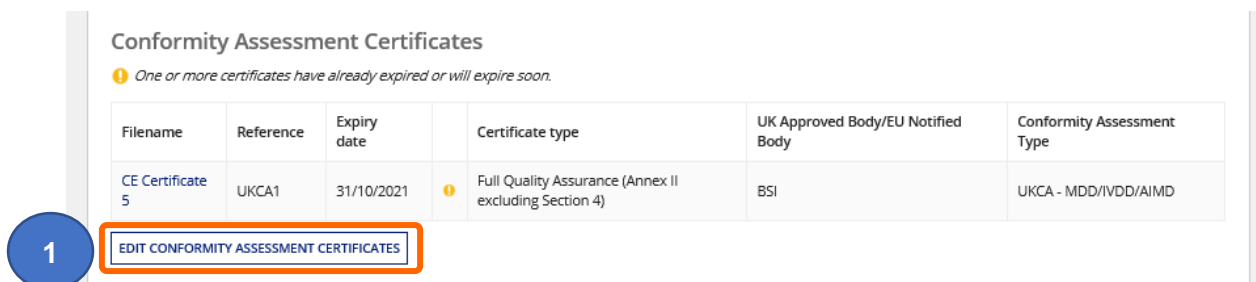
Manage Conformity documents

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.



Conformity Assessment Certificates

⚠ One or more certificates have already expired or will expire soon.

Filename	Reference	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
CE Certificate 5	UKCA1	31/10/2021	⚠ Full Quality Assurance (Annex II excluding Section 4)	BSI	UKCA - MDD/IVDD/AIMD

1 EDIT CONFORMITY ASSESSMENT CERTIFICATES

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.

2

Conformity Assessment Type

ALL

3

Certificate Status

ALL

Select from existing certificates

<input type="checkbox"/>	Filename	Reference no	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type	
<input type="checkbox"/>	UKCA Certificate 2	UKCA_BSI_54321	30/04/2028	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	×
<input type="checkbox"/>	UKCA Certificate 1	UKCA_BSI_12345	30/04/2028	Design Examination Certificate (Annex II with Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	×
<input type="checkbox"/>	MDR Assessment of Technical Documentation Annex IX Chapter II	EUMDR_321	30/04/2024	Technical Assessment (MDR Annex IX, Chapter II)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	×
<input type="checkbox"/>	MDR CE Certificate 1 Quality Management System Annex IX Chapters I and III	EUMDR_123	30/04/2024	Quality Management System (MDR Annex IX, Chapters I, III)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	×
<input type="checkbox"/>	CE Certificate 7	CE7	31/10/2022	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	×
<input checked="" type="checkbox"/>	CE Certificate 5	UKCA1	31/10/2021	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	UKCA - MDD/IVDD/AIMD	×
<input type="checkbox"/>	CE Certificate 4	CE123456	31/12/2019	Type Examination (Annex V)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	×
<input type="checkbox"/>	CE Certificate 1	CE123	31/12/2019	Full Quality Assurance (Annex IV)	TÜV SÜD Product Service GmbH	CE - MDD/IVDD/AIMD	×
<input type="checkbox"/>	CE Certificate 3	CE12345	31/12/2019	Production Quality Assurance limited to sterile aspects (Annex V)	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	CE - MDD/IVDD/AIMD	×
<input type="checkbox"/>	CE Certificate 2	CE1234	31/12/2019	Design Examination (Annex IV with Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	×

< 1 - 10 of 12 >

4

⚠ Select the certificates with the correct conformity assessment type

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.

5

APPLY CHANGES

BACK TO DEVICE SUMMARY



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:

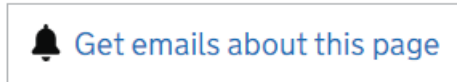
<https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registration-of-certain-medical-devices-that-have-expiredexpiring-ce-certificates>

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.

Products (6)

Preview only displays limited fields

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market

6 items

2

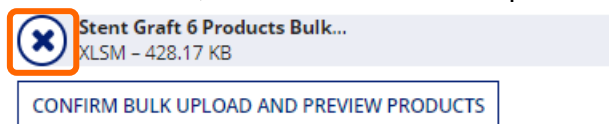
1

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.



Validation Complete

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.

- 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.

4

When deleting products, 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. You can delete up to 20 products in a single application.

Product preview (products: 6)

Preview only displays limited fields

<input type="checkbox"/>	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market

5

6

Selected Products: 2

DELETE SELECTED

APPLY CHANGES CANCEL

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

- Click the **Delete Selected** button

Additional product description (optional) ⓘ

ADD PRODUCT

Medical device name: Model/version: Catalogue/reference: UDI-DI: SEARCH CLEAR

When deleting products, 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. You can delete up to 20 products in a single application.

Show 10 per page

Product preview (products: 6)

Preview only displays limited fields

<input type="checkbox"/>	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market

Selected Products: 2

DELETE SELECTED

APPLY CHANGES CANCEL

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.

Product preview (products: 6)

Preview only displays limited fields

<input type="checkbox"/>	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
<input checked="" type="checkbox"/>	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
<input type="checkbox"/>	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market

6 items

DELETE SELECTED

9

Reason for deletion

- No longer placed on the market
- Information updated/ existing data no longer valid
- Entered in error

End of distribution date

dd/mm/yyyy

10

APPLY CHANGES CANCEL

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

- 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.



- 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](#).

- 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

1
Manage Devices & Products for MHRA DEMO

Click each GMDN term to add or delete products (medical device name and model/version etc.), UKCA/CE/CE (UK NI) certificates, Self-certification conformity declarations and Others. Any deletions will be removed immediately, adding new product/s will create an application for MHRA review. If you need to add new GMDN terms (devices), please go back to Devices and products and click "Add device" button.

Search by GMDN Code / Term:

Device Type:

Device Sub Type:

Is Custom Made:

Regulation/Directive:

Is Sterile:

Is Measuring:

Is Single-use?

Is Reprocessed single-use?

Custom-made SPP

Performance Evaluation Studies:

Reusable Surgical Instruments:

Is Active?

Is Implantable?

Basic UDI-DI Issuing Entity:

Basic UDI-DI Number:

Is CFS Ready:

Intended purpose other than medical(Annex XVI):

Is Intended to Administer/remove medicinal product?

Presence of Medicinal/Herbal substance:

Presence of Blood/Plasma substance:

Has a Clinical Investigation been conducted:

Self-certification conformity declarations:

UKCA/ CE/ CE (UK NI) Certificate:

UKCA/ CE/ CE (UK NI) Expiry Date:

Device Registration Status:

SEARCH **CLEAR**

<input type="checkbox"/>	Status	GMDN Code	GMDN term	Products	Device Type	Remark	CFS-ready
<input type="checkbox"/>	Registered	--	Abdominal aorta endovascular stent-graft	5	General Medical Device - Class III		Yes
<input type="checkbox"/>	Conformity Assessment Certificate Expired	--	Angiography kit	1	System or Procedure Pack		No
<input type="checkbox"/>	Registered	--	General external orthopaedic fixation system implantation kit, single-use	1	System or Procedure Pack		Yes
<input checked="" type="checkbox"/>	Registered	35596	Vascular clamp, reusable	1	General Medical Device - Class IIa	GMDN is Obsolete	Yes

BACK

DELETE SELECTED DEVICES

3

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.

Manage Devices & Products for MHRA DEMO

Click each GMDN term to add or delete products (medical device name and model/version etc.), UKCA/CE/CE (UK NI) certificates, Self-certification conformity declarations and Others. Any deletions will be removed immediately, adding new product/s will create an application for MHRA review. If you need to add new GMDN terms (devices), please go back to Devices and products and click "Add device" button.

You have made the following changes which need to be submitted to MHRA for approval.

GMDN term	Products modified	CE certificates/Documents modified	Device deleted	
Vascular clamp, reusable	No	No	Yes	✘

Reason for deletion

No longer placed on the market

Information updated/ existing data no longer valid

Entered in error

End of distribution date *

REMOVE DEVICE(S)

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](#).

Manage Devices & Products for M

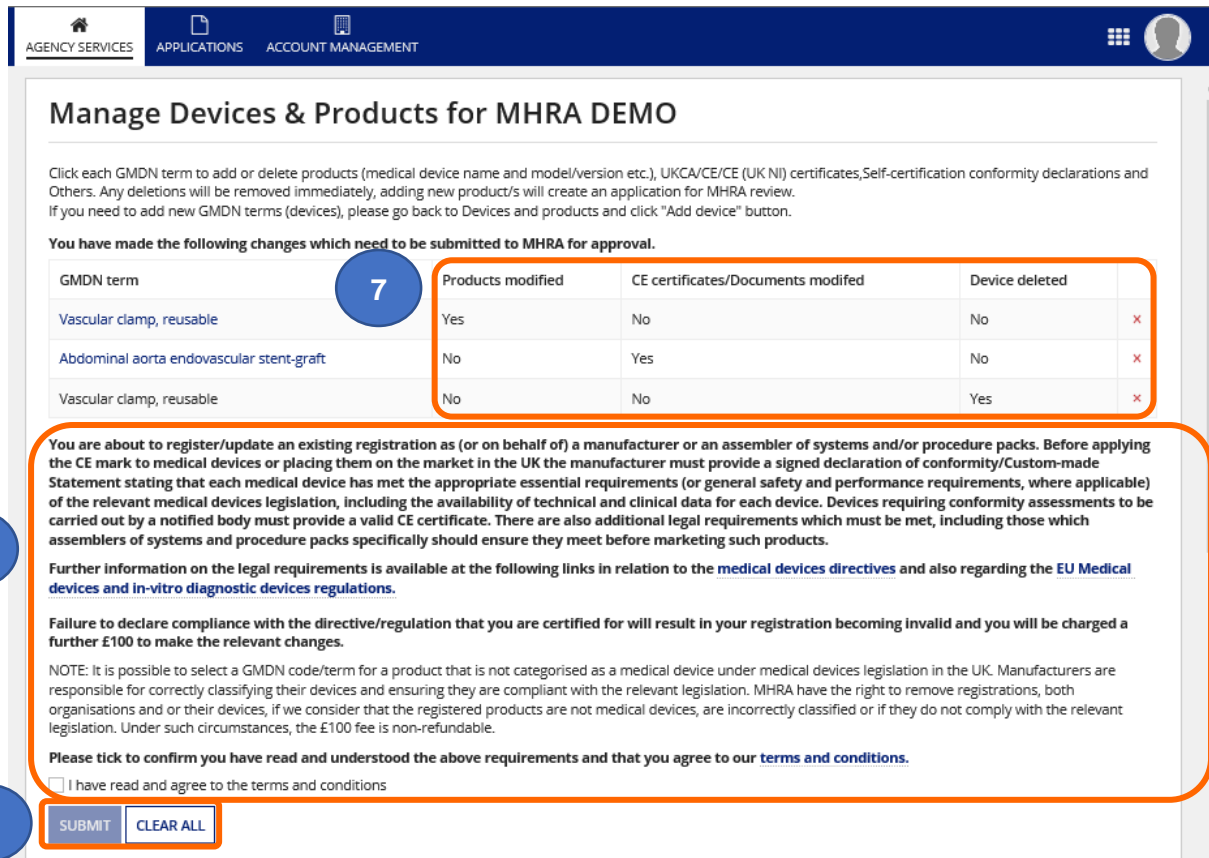
Click each GMDN term to add or delete products (medical device name and model/version etc.), UKCA/CE/CE (UK NI) certificates, Self-certification conformity declarations and Others. Any deletions will be removed immediately, adding new product/s will create an application for MHRA review. If you need to add new GMDN terms (devices), please go back to Devices and products and click "Add device" button.

Search by GMDN Code / Term: Device Type:

Is 2017 Regulations:

Are you sure want to remove selected device? This will remove the selected devices (and underlying products) from the manufacturer.

- You can **manage** multiple devices in a single application. Each time you click **Apply Changes** the device it will appear in a table at the top of the screen indicating what action has been taken. Click the red **X** in this table if you want to abandon all changes to the specific device.



Manage Devices & Products for MHRA DEMO

Click each GMDN term to add or delete products (medical device name and model/version etc.), UKCA/CE/CE (UK NI) certificates, Self-certification conformity declarations and Others. Any deletions will be removed immediately, adding new product/s will create an application for MHRA review. If you need to add new GMDN terms (devices), please go back to Devices and products and click "Add device" button.

You have made the following changes which need to be submitted to MHRA for approval.

GMDN term	Products modified	CE certificates/Documents modified	Device deleted
Vascular clamp, reusable	Yes	No	No X
Abdominal aorta endovascular stent-graft	No	Yes	No X
Vascular clamp, reusable	No	No	Yes X

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

Further information on the legal requirements is available at the following links in relation to the [medical devices directives](#) and also regarding the [EU Medical devices and in-vitro diagnostic devices regulations](#).

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisations and or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £100 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our [terms and conditions](#).

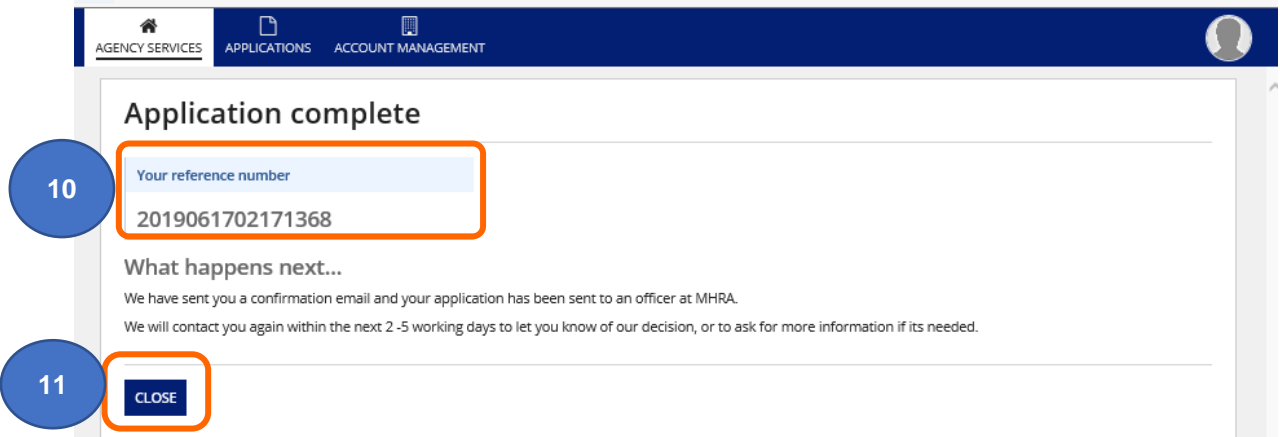
I have read and agree to the terms and conditions

SUBMIT **CLEAR ALL**

- 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'
- 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.

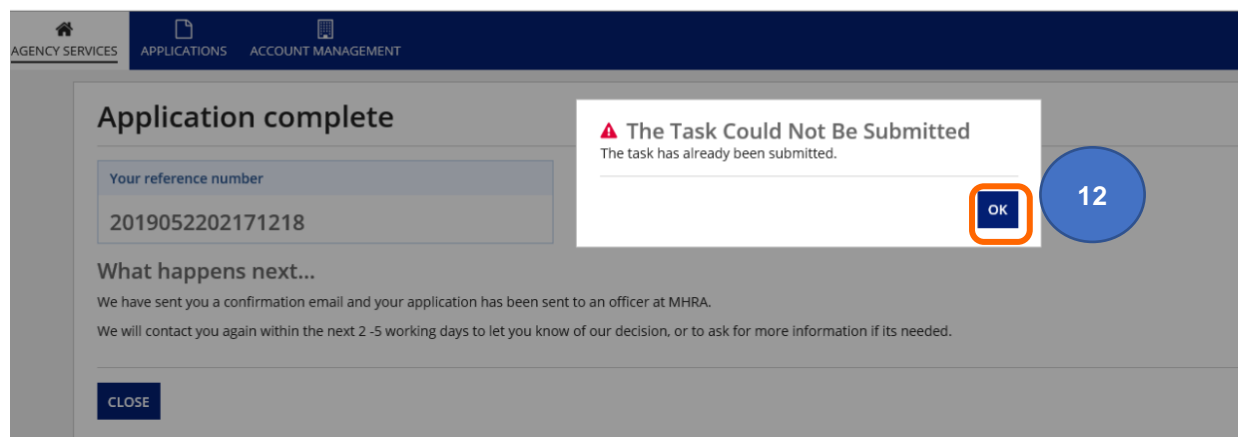
10. After submitting, note the **application number**, the application will now show as **in progress** within the list of applications. While the application is in progress you will not be able to order a CFS for the device(s) or make further updates to device/s in the application, until the application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

1

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT

☰

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	4 (9)	✔

Key
✔ Registered ○ Not Registered ✘ Unregistered ⏸ Suspended ✘ Rejected

Manufacturers you represent

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

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

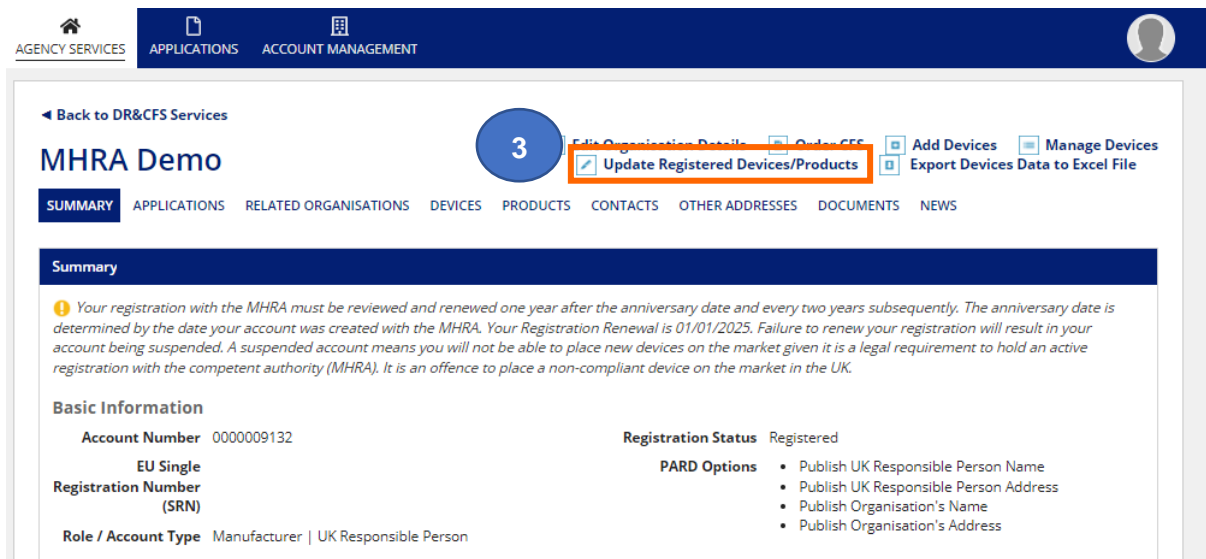
Search by manufacturer name:

SEARCH

ADD NEW MANUFACTURER
ADD NEW IMPORTER
ADD NEW IMPORTER

Name	Address	Country	Devices (Products)	Relationship	Registration Status
Demo represented org Three	167 Bella Bista, East Side Compound, 1000 Medtech Drive, Sea View Industrial Zone, Santa Barbara, CA, 98765	United States	20 (21)	UK Responsible Person	✔
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, MA, 12345	United States	3 (10)	UK Responsible Person	✔
DEMO Represented Organisation Two	234 Avenida Escala, Cancun, Yukatan, 43231	Mexico	1 (1)	UK Responsible Person	✔

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



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Back to DR&CFS Services

MHRA Demo

3 Update Registered Devices/Products

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Summary

Your registration with the MHRA must be reviewed and renewed one year after the anniversary date and every two years subsequently. The anniversary date is determined by the date your account was created with the MHRA. Your Registration Renewal is 01/01/2025. Failure to renew your registration will result in your account being suspended. A suspended account means you will not be able to place new devices on the market given it is a legal requirement to hold an active registration with the competent authority (MHRA). It is an offence to place a non-compliant device on the market in the UK.

Basic Information

Account Number 0000009132 Registration Status Registered

EU Single Registration Number (SRN) PARD Options

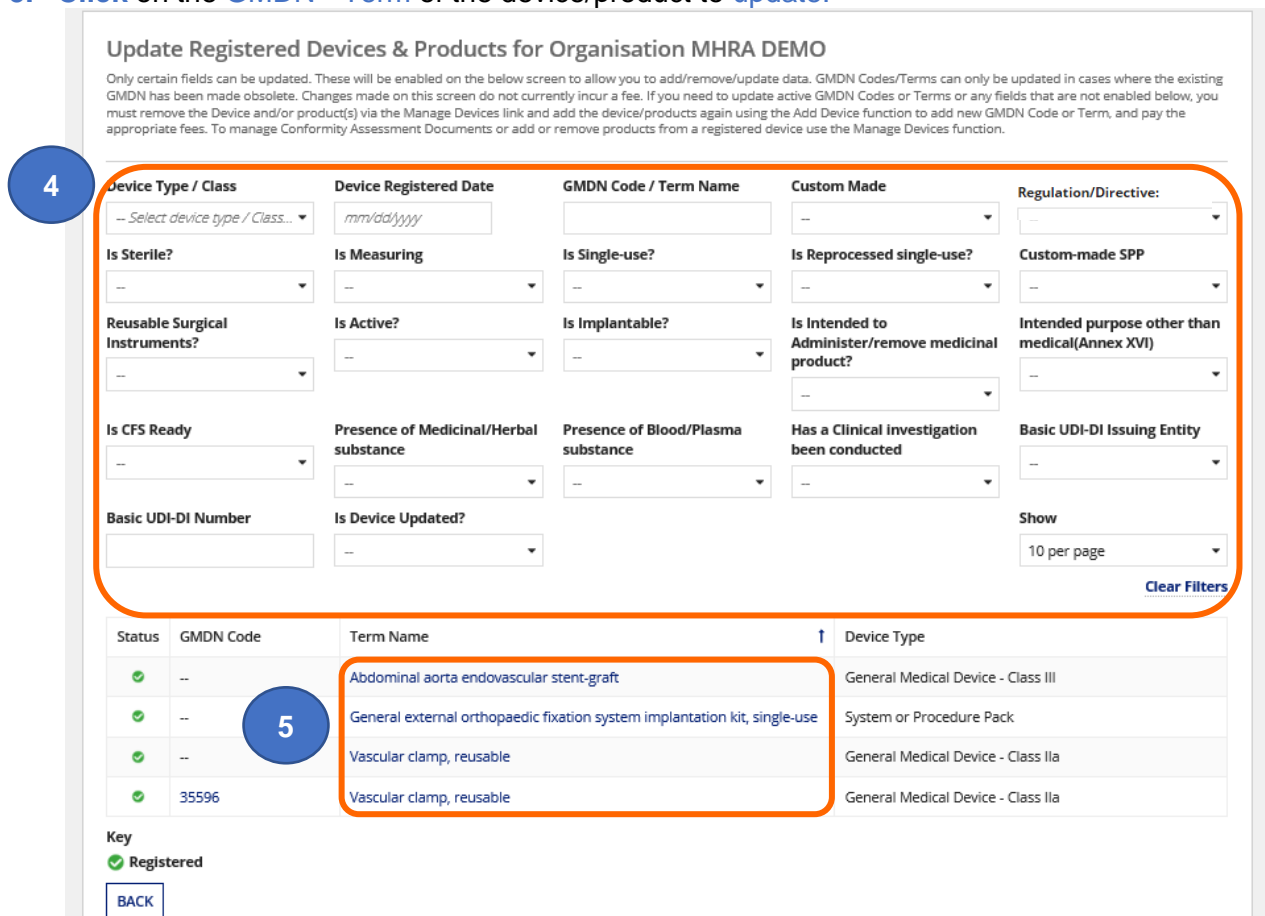
- Publish UK Responsible Person Name
- Publish UK Responsible Person Address
- Publish Organisation's Name
- Publish Organisation's Address

Role / Account Type Manufacturer | UK Responsible Person

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.



Update Registered Devices & Products for Organisation MHRA DEMO

Only certain fields can be updated. These will be enabled on the below screen to allow you to add/remove/update data. GMDN 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 below, you must remove the Device and/or product(s) via the Manage Devices link and add the device/products again using the Add Device function to add new GMDN Code or Term, and pay the appropriate fees. To manage Conformity Assessment Documents or add or remove products from a registered device use the Manage Devices function.

4

Device Type / Class: -- Select device type / Class...
 Device Registered Date: mm/dd/yyyy
 GMDN Code / Term Name:
 Custom Made: --
 Regulation/Directive: --

Is Sterile?: --
 Is Measuring: --
 Is Single-use?: --
 Is Reprocessed single-use?: --
 Custom-made SPP: --

Reusable Surgical Instruments?: --
 Is Active?: --
 Is Implantable?: --
 Is Intended to Administer/remove medicinal product?: --
 Intended purpose other than medical(Annex XVI): --

Is CFS Ready: --
 Presence of Medicinal/Herbal substance: --
 Presence of Blood/Plasma substance: --
 Has a Clinical investigation been conducted: --
 Basic UDI-DI Issuing Entity: --

Basic UDI-DI Number:
 Is Device Updated?: --
 Show: 10 per page

Clear Filters

Status	GMDN Code	Term Name	Device Type
✓	--	Abdominal aorta endovascular stent-graft	General Medical Device - Class III
✓	--	General external orthopaedic fixation system implantation kit, single-use	System or Procedure Pack
✓	--	Vascular clamp, reusable	General Medical Device - Class IIa
✓	35596	Vascular clamp, reusable	General Medical Device - Class IIa

5

Key
 ✓ Registered

BACK

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 Registered Devices & Products for Organisation MHRA Demo

Only certain fields can be updated. These will be enabled on the below screen to allow you to add/remove/update data. GMDN 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 below, you must remove the Device and/or product(s) via the Manage Devices link and add the device/products again using the Add Device function to add new GMDN Code or Term, and pay the appropriate fees. To manage Conformity Assessment Documents or add or remove products from a registered device use the Manage Devices function.

[Back to all "Devices & Products"](#)

6 **35596 - Vascular clamp, reusable**

Device Type General Medical Device

GMDN description A hand-held manual surgical instrument designed to directly compress a blood vessel (vein or artery) to create a temporary haemostasis (arrest or prevention of bleeding). It typically has a self-retaining, scissors-like design with ring handles; the working end has blades of various designs (e.g., curved, angled, semicircular) specific for different applications. It is available in various sizes, is typically made of high-grade stainless steel, and may utilize inserts made of various materials (e.g., carbide, silicone). This is a reusable device.

GMDN Code/Term

1 Select new GMDN to replace the existing obsolete GMDN. If you are updating the GMDN in this application, you cannot update products until the update GMDN application has been completed

Which directive/regulation does this device comply with? Directive 93/42/EEC

Is custom made No

Risk classification Class IIa

Is sterile Yes

Method of sterilisation Ethylene Oxide

Single use device? No

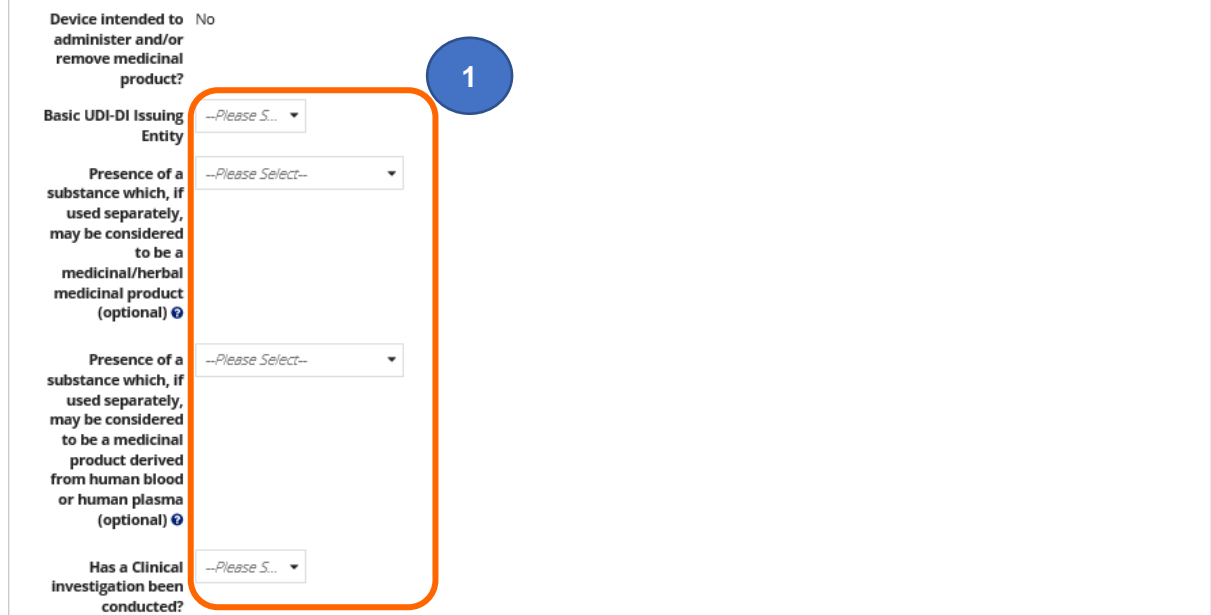
Reprocessed single-use Device? No

Are any of the products related to this device implantable? No

Are any of the products related to this device active? No

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.



Device intended to administer and/or remove medicinal product? No

Basic UDI-DI Issuing Entity

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product (optional)

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma (optional)

Has a Clinical investigation been conducted?

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.

▼ Conformity Assessment Certificates

If you wish to manage Conformity Assessment document(s) use the Manage Devices function

Filename	Reference	Expiry date	Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
CE Certificate 3	AIMD1	31/07/2021	Full Quality Assurance (Annex II excluding Section 4)	BSI	CE - MDD/IVDD/AIMD

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.

1 [Product Details](#)

Medical device name: Model/version: Catalogue/reference:

Show

2 ! You must not update products both individually and in multiples in the same application. Please create separate applications.

Total updated products : 0


<input type="checkbox"/>	Medical Device Name	Status	Is Model/Version applicable?	Model/Version	Is Catalogue/Reference applicable?	Catalogue/Reference (REF) ⓘ	UDI Issuing Entity (optional) ⓘ	UDI Device Identifier (UDI-DI) (if assigned) ⓘ	Unit of use UDI-DI (optional) ⓘ	Is the Device directly Marked with UDI-DI (optional) ⓘ	Direct Marking DI different from UDI-DI	Direct Marking DI number
<input type="checkbox"/>	Safehandle		Yes	Safe/01	Yes	SH-001/123						
<input type="checkbox"/>	Safehandle-B version		Yes	B Version	Yes	SH02/B/001						

3

ⓘ Please use the scrollbar to view all product data fields.

- 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.

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT



Product Information

Medical Device Name

Is Model/Version applicable?

Model/Version

Is Catalogue/Reference applicable?

Catalogue/Reference (REF)


UDI Issuing Entity (optional) GS1 AISBL
 HIBCC
 ICCBBA
 IFA GmbH
 UDI not assigned

Product Status
Please update the product status

URL for additional information (optional)

4

4


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)

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

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


Quantity per package configuration (optional)


Need for sterilisation before use (optional) 


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


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

Containing latex (optional)

Clinical size applicable (optional) 

UDI-DI from secondary entity (optional) 

Endocrine disruptor (optional) 

Additional product description (optional) 

5

APPLY CHANGES

CANCEL

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.

1 **Product Details**

Medical device name: Model/version: Catalogue/reference: SEARCH CLEAR

Show

2 **!** You must not update products both individually and in multiples in the same application. Please create separate applications.

Total updated products : 0

<input checked="" type="checkbox"/>	Medical Device Name	Status	Is Model/Version applicable?	Model/Version	Is Catalogue/Reference applicable?	Catalogue/Reference (REF) ⓘ	UDI Issuing Entity (optional) ⓘ	UDI Device Identifier (UDI-DI) (if assigned) ⓘ	Unit of use UDI-DI (optional) ⓘ	Is the Device directly Marked with UDI-DI (optional) ⓘ	Direct Marking different from UDI-DI
3 <input checked="" type="checkbox"/>	Safehandle		Yes	Safe/01	Yes	SH-001/123	Select UDI Entity	4		Please Select	Please Select
<input checked="" type="checkbox"/>	Safehandle-B version		Yes	B Version	Yes	SH02/B/001	Select UDI Entity			Please Select	Please Select

4 **!** Please use the scrollbar to view all product data fields.

APPLY CHANGES SAVE AND EXIT CANCEL DELETE APPLICATION

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.

Total updated products : 1

<input checked="" type="checkbox"/>	Medical Device Name	Status	Is Model/Version applicable?	Model/Version	Is Catalogue/Reference applicable?	Catalogue/Reference (REF) ⓘ	UDI Issuing Entity (optional) ⓘ	UDI Device Identifier (UDI-DI) (if assigned) ⓘ	Unit of use UDI-DI (optional) ⓘ	Is the Device directly Marked with UDI-DI (optional) ⓘ	Direct Marking DI different from UDI-DI	Direct Marking DI number	Package Number (optical)
<input checked="" type="checkbox"/>	Safehandle		Yes	Safe/01	Yes	safe/01	ICCBBBA			Yes	Yes		Yes
<input checked="" type="checkbox"/>	Safehandle-B version		Yes	B Version	Yes	SH02/B/001	Select UDI Entity			Please Select	Please Select		Please

1 - 2 of 2

ⓘ Please use the scrollbar to view all product data fields.

7

APPLY CHANGES SAVE AND EXIT

CANCEL

DELETE APPLICATION

6

Please check the following columns for data errors:

- Safehandle : Model/Version; Catalogue/Reference
- Safehandle : Unique Device Identifier (UDI)
- Safehandle : Direct Marking DI number
- Safehandle : Package DI Number level1, Package Type level1
- Safehandle : Commercial distribution end date
- Safehandle : Storage Handling Description
- Safehandle : Method of Sterilisation
- Safehandle : Critical Warning Description
- Safehandle : Clinical Size Description
- Safehandle : Secondary UDI Issuing Entity

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.

- Once you have completed updating products, and resolved any data issues, the [Apply Changes](#) and [Save and Exit](#) buttons will be enabled.

Total updated products : 1

<input checked="" type="checkbox"/>	Medical Device Name	Status	Is Model/Version applicable?	Model/Version	Is Catalogue/Reference applicable?	Catalogue/Reference (REF)	UDI Issuing Entity (optional)	UDI Device Identifier (UDI-DI) (if assigned)	Unit of use UDI-DI (optional)	Is the Device directly Marked with UDI-DI (optional)	Direct Marking DI different from UDI-DI	Direct Marking DI number	Package Number (option)
<input checked="" type="checkbox"/>	Safehandle		Yes	Safe/01	Yes	SH-001/123	IFA GmbH	4466676E		No	Please Select		Please
<input checked="" type="checkbox"/>	Safehandle-B version		Yes	B Version	Yes	SH02/B/001	Select UDI Entity			Please Select	Please Select		Please

Please use the scrollbar to view all product data fields.

8
APPLY CHANGES
SAVE AND EXIT

CANCEL
DELETE APPLICATION

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

- On the [Review](#) page, click the > icon to display the [Updated device details](#). Only fields that you have updated will display here.

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Review

GMDN Term	Device modified	Products modified
Vascular clamp, reusable	YES	YES

1
Updated device details

Basic UDI-DI Issuing Entity
ICCBBA

Basic UDI-DI Number
75768787698698

Contains Medicinal/Herbal substance?
No

Contains Blood/Plasma substance?
No

Clinical investigation been conducted?
Yes

Clinical Investigation Details

Country	MHRA Reference Number	IRAS Number	Short Title and Version Number of the Study	Clinical Investigation Plan Code Number
United States			VasClamp	US/FDA/465475

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

Review

GMDN Code	GMDN Term	Device modified	Products modified
12235	Scalpel handle, reusable	NO	YES

- > Updated device details
 - Updated Product details

Click on Medical Device Name to view full details

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference
Safehandle		

- Click on the **Medical Device Name** to view the updates.
- Only fields that you have updated will display here.

Review

GMDN Code	GMDN Term	Device modified	Products modified
12235	Scalpel handle, reusable	NO	YES

- > Updated device details
- Updated Product details

— Show All Products

UDI Issuing Entity IFA GmbH	UDI Device Identifier 4466676878889		
Directly Marked with UDI No			
UDI-PI Type Lot or Batch Number; Manufacturing date			
Incorporates Human Cells No	Incorporates Animal Cells No	Storage/Handling Yes	
Storage/Handling Description See IFU	Sterilisation Before Use Yes		
Sterilisation method Steam	MRI Safety MR Unsafe	Critical Warnings No	
Containing Latex No			
UDI-DI From Secondary Entity No			
Endocrine Disruptor No			

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

Further information on the legal requirements is available at the following links in relation to the [medical devices directives](#) and also regarding the [EU Medical devices and in-vitro diagnostic devices regulations](#).

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisations and or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £100 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our [terms and conditions](#).

I have read and agree to the terms and conditions

- SUBMIT
 - SAVE AND EXIT

- BACK
- CANCEL

- Read the important information and **agree** to our terms and conditions.
- Click the **Submit** button to apply the changes, or **click** the **Save and Exit** button to save a TEMP (draft) application.
- Click the **Back button** to go back and continue updating, or **click** the **Cancel** button to cancel **all** updates in the application.

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

Application complete

8
2023051101217988

What happens next...

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

9 **10**

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

- 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.

10

<input type="checkbox"/>	Medical Device Name	Status	Is Model/Version applicable?	Model/Version	Is Catalogue/Reference applicable?	Catalogue/Reference (REF) ⓘ	UDI Issuing Entity (optional) ⓘ	UDI Device Identifier (UDI-DI)(if assigned) ⓘ	Unit of use UDI-DI (optional) ⓘ	Is the Device directly Marked with UDI-DI (optional) ⓘ	Direct Marking DI different from UDI-DI	Direct Marking DI number	Package DI Number (optional) ⓘ	Part DI Nur level
<input type="checkbox"/>	Safehandle	Updated	Yes	Safe/01	Yes	SH-001/123	IFA GmbH	4466676878889		No				
<input type="checkbox"/>	Safehandle-B version		Yes	B Version	Yes	SH02/B/001								

ⓘ Please use the scrollbar to view all product data fields.

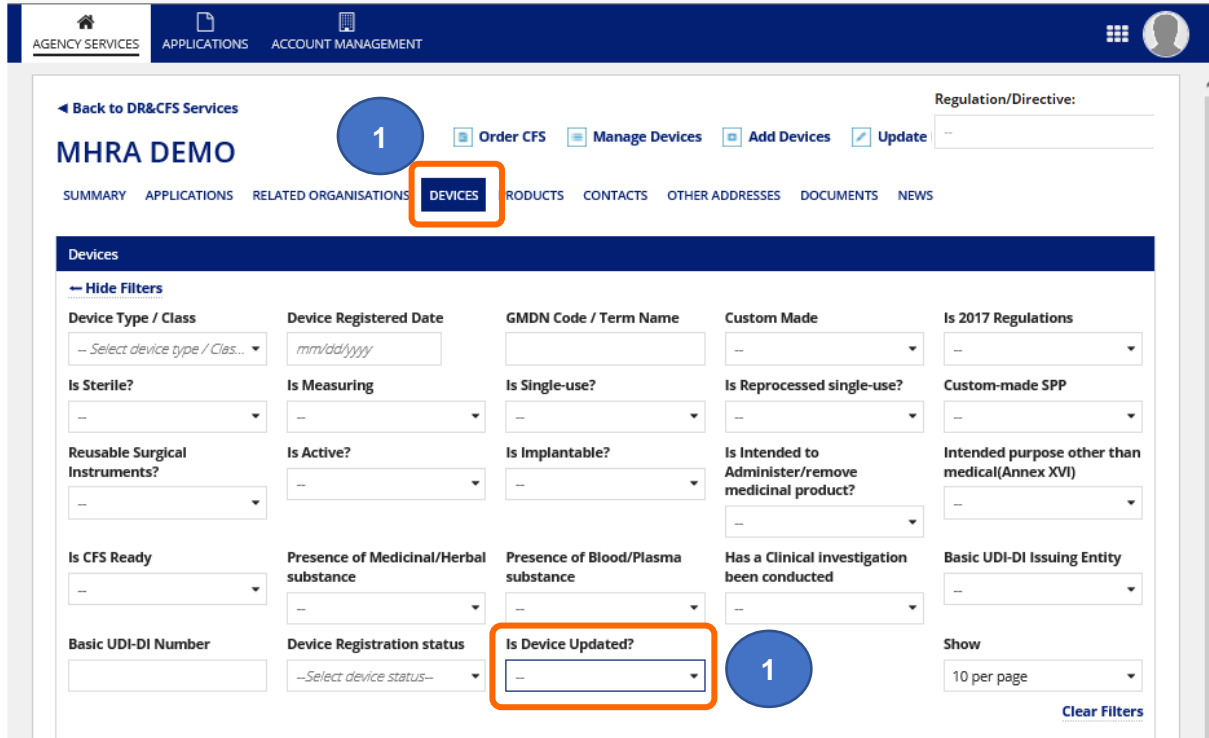
Email confirmation

- 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.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Back to DR&CFS Services

MHRA DEMO

SUMMARY APPLICATIONS RELATED ORGANISATIONS **DEVICES** PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Order CFS Manage Devices Add Devices Update

Regulation/Directive:

Devices

Hide Filters

Device Type / Class: -- Select device type / Clas...
 Device Registered Date: mm/dd/yyyy
 GMDN Code / Term Name:
 Custom Made: --
 Is 2017 Regulations: --

Is Sterile?: --
 Is Measuring: --
 Is Single-use?: --
 Is Reprocessed single-use?: --
 Custom-made SPP: --

Reusable Surgical Instruments?: --
 Is Active?: --
 Is Implantable?: --
 Is Intended to Administer/remove medicinal product?: --
 Intended purpose other than medical(Annex XVI): --

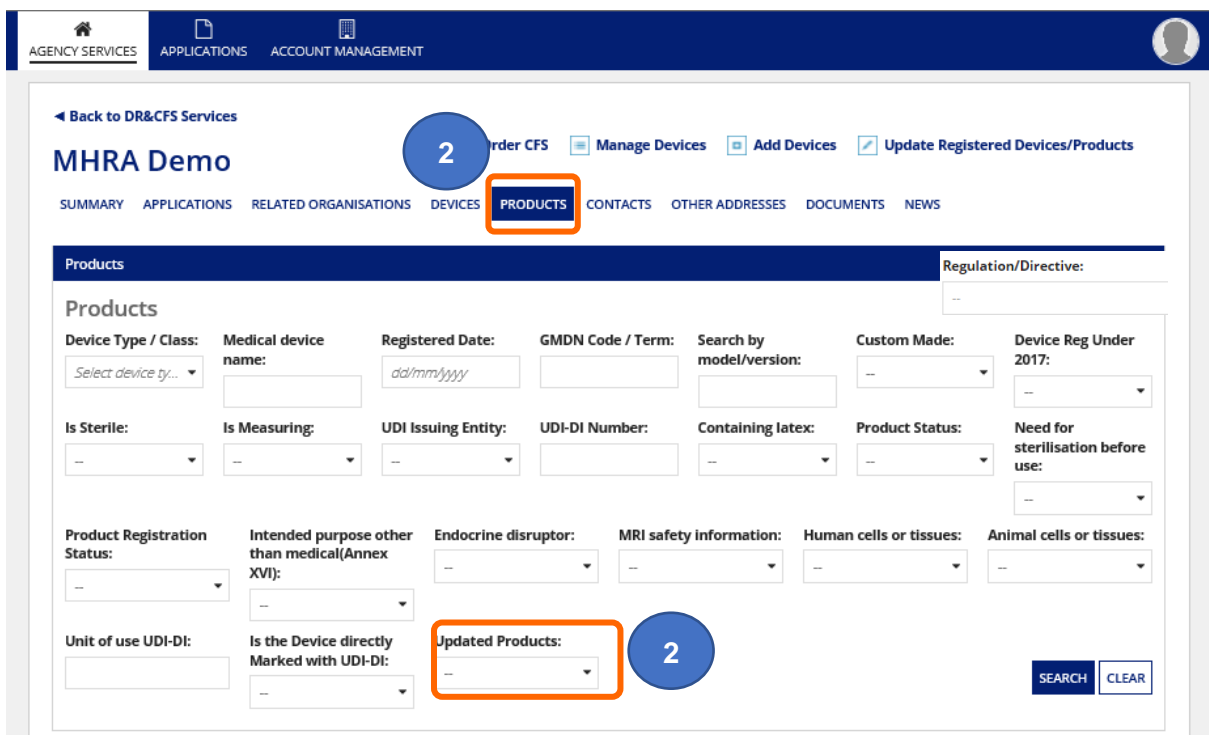
Is CFS Ready: --
 Presence of Medicinal/Herbal substance: --
 Presence of Blood/Plasma substance: --
 Has a Clinical investigation been conducted: --
 Basic UDI-DI Issuing Entity: --

Basic UDI-DI Number:
 Device Registration status: --Select device status--
Is Device Updated?: -- 1

Show: 10 per page

Clear Filters

2. To view the [version history](#) for a product. Search for the product using the [Updated Products](#) filter on the Product tab.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Back to DR&CFS Services

MHRA Demo

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES **PRODUCTS** CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Order CFS Manage Devices Add Devices Update Registered Devices/Products

Regulation/Directive:

Products

Device Type / Class: Select device ty...
 Medical device name:
 Registered Date: dd/mm/yyyy
 GMDN Code / Term:
 Search by model/version:
 Custom Made: --
 Device Reg Under 2017: --

Is Sterile: --
 Is Measuring: --
 UDI Issuing Entity: --
 UDI-DI Number:
 Containing latex: --
 Product Status: --
 Need for sterilisation before use: --

Product Registration Status: --
 Intended purpose other than medical(Annex XVI): --
 Endocrine disruptor: --
 MRI safety information: --
 Human cells or tissues: --
 Animal cells or tissues: --

Unit of use UDI-DI:
 Is the Device directly Marked with UDI-DI: --
Updated Products: -- 2

SEARCH CLEAR

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

[← Back to DR&CFS Services](#)

[Order CFS](#)
[Manage Devices](#)
[Add Devices](#)
[Update Registered Devices/Products](#)

MHRA Demo

[SUMMARY](#)
[APPLICATIONS](#)
[RELATED ORGANISATIONS](#)
[DEVICES](#)
[PRODUCTS](#)
[CONTACTS](#)
[OTHER ADDRESSES](#)
[DOCUMENTS](#)
[NEWS](#)

Devices

← Hide Filters

Device Type / Class <input type="text" value="-- Select device type / Clas..."/>	Device Registered Date <input type="text" value="dd/mm/yyyy"/>	GMDN Code / Term Name <input type="text"/>	Custom Made <input type="text" value="--"/>	Is 2017 Regulations Regulation/Directive: <input type="text" value="--"/>
Is Sterile? <input type="text" value="--"/>	Is Measuring <input type="text" value="--"/>	Is Single-use? <input type="text" value="--"/>	Is Reprocessed single-use? <input type="text" value="--"/>	
Reusable Surgical Instruments? <input type="text" value="--"/>	Is Active? <input type="text" value="--"/>	Is Implantable? <input type="text" value="--"/>	Is Intended to Administer/remove medicinal product? <input type="text" value="--"/>	Intended purpose other than medical(Annex XVI) <input type="text" value="--"/>
Is CFS Ready <input type="text" value="--"/>	Presence of Medicinal/Herbal substance <input type="text" value="--"/>	Presence of Blood/Plasma substance <input type="text" value="--"/>	Has a Clinical Investigation been conducted <input type="text" value="--"/>	Basic UDI-DI Issuing Entity <input type="text" value="--"/>
Basic UDI-DI Number <input type="text"/>	Device Registration status <input type="text" value="--Select device status--"/>	Is Device Updated? <input type="text" value="Yes"/>		Show <input type="text" value="10 per page"/>

[Clear Filters](#)

Status	GMDN Code	Term Name	Device Type
✔	62470	Surgical bulldog clamp, reusable	General Medical Device - Class Ila

Key
 ✔ Registered ○ Not Registered ✖ No Longer Registered ✖ Rejected ● Conformity assessment certificate expired ⚠ Pending Amendment
 ❌ Invalid-Please Delete

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.

4 ▼ Update History

Version	Term Name	Modified On	Modified By
5 Version 3	Surgical bulldog clamp, reusable	13/08/2021 15:05 BST	Peter Smith
Version 2	Surgical bulldog clamp, reusable	13/08/2021 15:03 BST	Peter Smith
Version 1	Vascular clamp, reusable	13/08/2021 14:39 BST	Peter Smith

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.

Update History

Device information

Reference
2021081301207935

GMDN Term
Surgical bulldog clamp, reusable

Basic UDI-DI Issuing Entity
IFA GmbH

Basic UDI-DI Number
654856456485

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product
No

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma
No

Has a Clinical investigation been conducted?
N/A

7 BACK

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.

◀ Back to DR&CFS Services

Order CFS Manage Devices Add Devices Update Registered Devices/Products

MHRA Demo

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Products

Products

Device Type / Class:	Medical device name:	Registered Date:	GMDN Code / Term:	Search by model/version:	Custom Made:	Device Reg Under 2017:
<input type="text" value="Select device ty..."/>	<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="--"/>	<input type="text" value="--"/>
Is Sterile:	Is Measuring:	UDI Issuing Entity:	UDI-DI Number:	Containing latex:	Product Status:	Regulation/Directive:
<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>
Product Registration Status:	Intended purpose other than medical(Annex XVI):	Endocrine disruptor:	MRI safety information:	Human cells or tissues:	Animal cells or tissues:	
<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	<input type="text" value="--"/>	
Unit of use UDI-DI:	Is the Device directly Marked with UDI-DI:	Updated Products:				
<input type="text"/>	<input type="text" value="--"/>	<input type="text" value="--"/>				

SEARCH
CLEAR

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

← Back to DR&CFS Services

Order CFS Manage Devices Add Devices Update Registered Devices/Products

MHRA Demo

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Products

Products

Device Type / Class: Medical device name: Registered Date: GMDN Code / Term: Search by model/version: Custom Made: Device Reg Under 2017:

Is Sterile: Is Measuring: UDI Issuing Entity: UDI-DI Number: Containing latex: Product Status: Regulation/Directive:

Product Registration Status: Intended purpose other than medical(Annex XVI): Endocrine disruptor: MRI safety information: Human cells or tissues: Animal cells or tissues:

Unit of use UDI-DI: Is the Device directly Marked with UDI-DI: Updated Products:

SEARCH CLEAR

Status	GMDN Code	Term Name	Medical Device Name	Model/Version	Type
✓	--	Surgical bulldog clamp, reusable	Clamp1	Clamp/R/001	General Medical Device - Class IIa
✓	35310	Orthodontic retainer	Retainer 1	Model 1	General Medical Device

10. Click on the Medical Device Name of the product

Product Details

Preview only displays limited fields

Status	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
✓	Clamp1	Clamp/R/001	545757767			On the GB market

Key
 ✓ Registered ○ Not Registered ✗ No Longer Registered ✗ Rejected

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.

Update History

Version	Medical Device Name	Modified On	Modified By
Version 3	Clamp1	13/08/2021 14:48 BST	Peter Smith
Version 2	Clamp1	13/08/2021 14:45 BST	Peter Smith
Version 1	Clamp1	13/08/2021 14:34 BST	Peter Smith

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



The screenshot shows a table titled "Update History" with the following data:

Update History	
Reference	2021081301207933
Medical Device Name	Clamp1
Model/Version	Clamp/R/001
Catalogue/Reference (REF)	545757767
UDI Issuing Entity	N/A
UDI Device Identifier	N/A
Unit of use UDI-DI	N/A

Callout 12 points to the table content. Callout 13 points to a "BACK" button located below the table.

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:



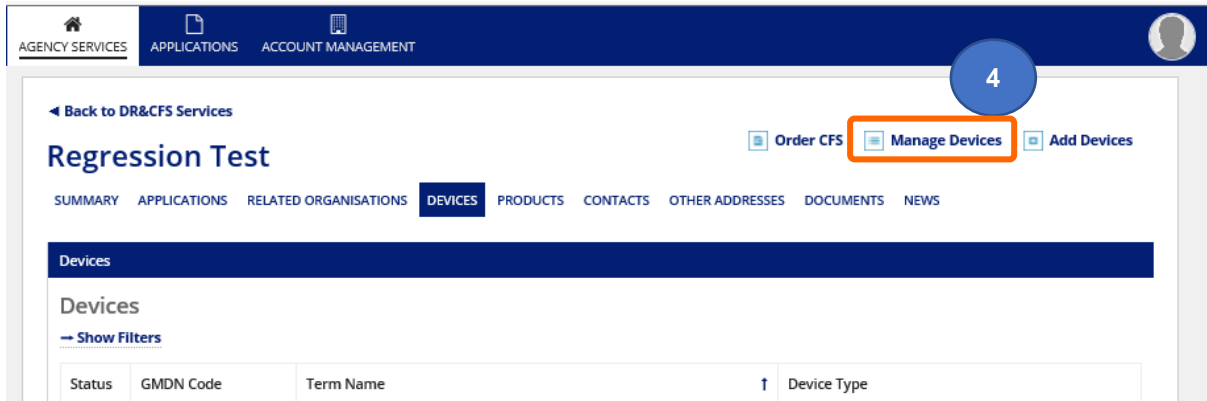
The screenshot shows the 'Regression Test' page in the MHRA system. The 'DEVICES' tab is selected, and a table of devices is displayed. A blue circle with the number '2' highlights the table. A red circle with the number '2' highlights the 'Invalid-Please Delete' status in the key below the table.

Status	GMDN Code	Term Name	Device Type
<input checked="" type="checkbox"/>	11425	Electrode gel	General Medical Device - Class I
<input checked="" type="checkbox"/>	90003720	Examination/Treatment Couches And Leg/Arm Rests	General Medical Device - Class I
<input type="checkbox"/>	42893	General-purpose bowl, reusable	General Medical Device - Class I
<input checked="" type="checkbox"/>	90004871	Rehabilitation Equipment	General Medical Device - Class I
<input checked="" type="checkbox"/>	90004872	Treatment Chairs (Chiropody/Dental/Ophthalmic)	General Medical Device - Class I

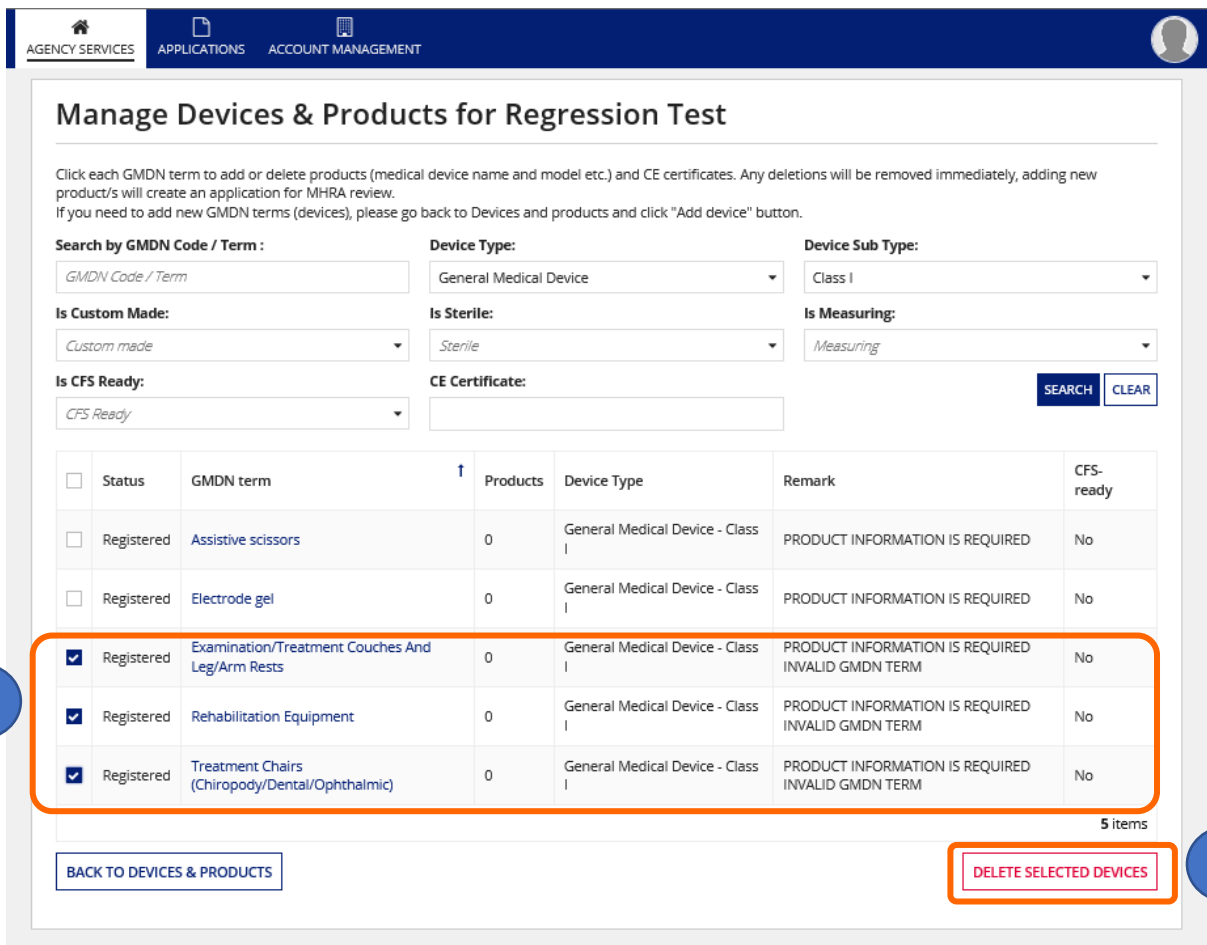
10 items

Key
 Registered
 Not Registered
 Amended
 Invalid-Please Delete

3. **After** following all the [Add Devices using GMDN®](#) instructions to add all the devices you manufacturer:
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 selected option will be applied to **all** the deleted devices. If the reasons for deletion are different, please create separate applications.

Reason for deletion

7 No longer placed on the market

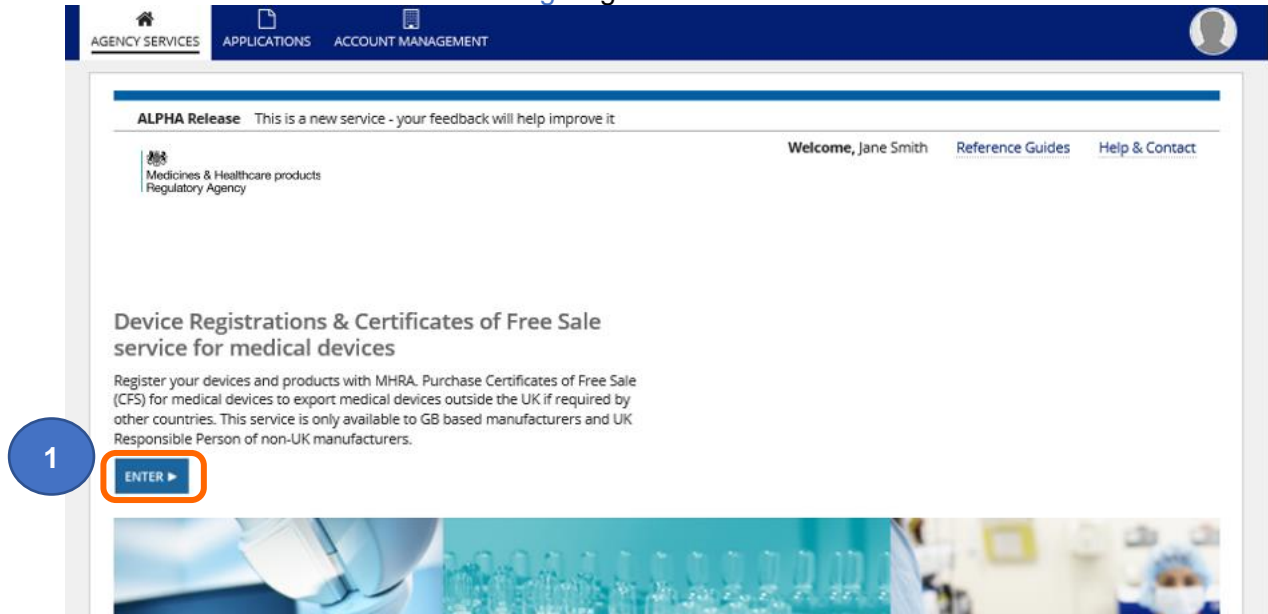
Information updated/ existing data no longer valid

Entered in error

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.

Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United Kingdom	1 (27)	

Key

Registered Not Registered Unregistered Suspended Rejected

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the [Applications](#) list.

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

[ADD NEW MANUFACTURER](#)

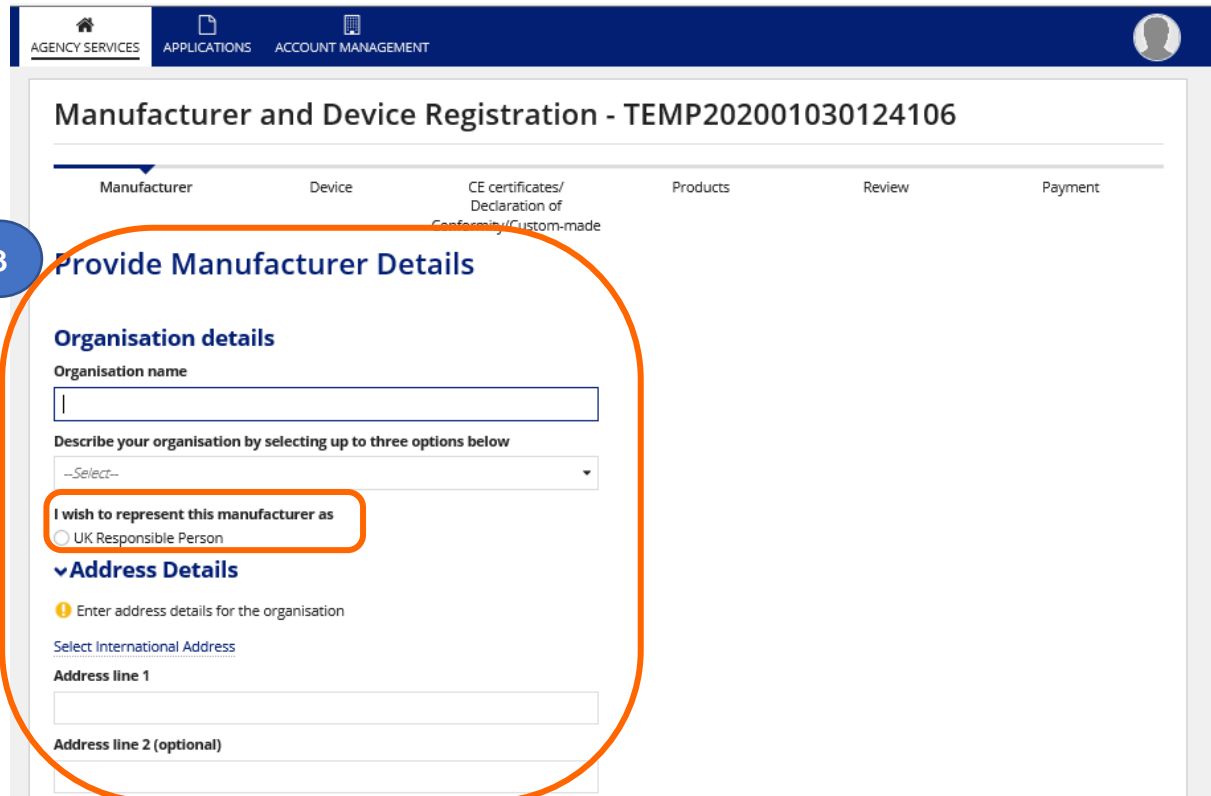
[ADD NEW IMPORTER](#)

2

2

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.



3 Provide Manufacturer Details

Organisation details

Organisation name

Describe your organisation by selecting up to three options below

--Select--

I wish to represent this manufacturer as

UK Responsible Person

Address Details

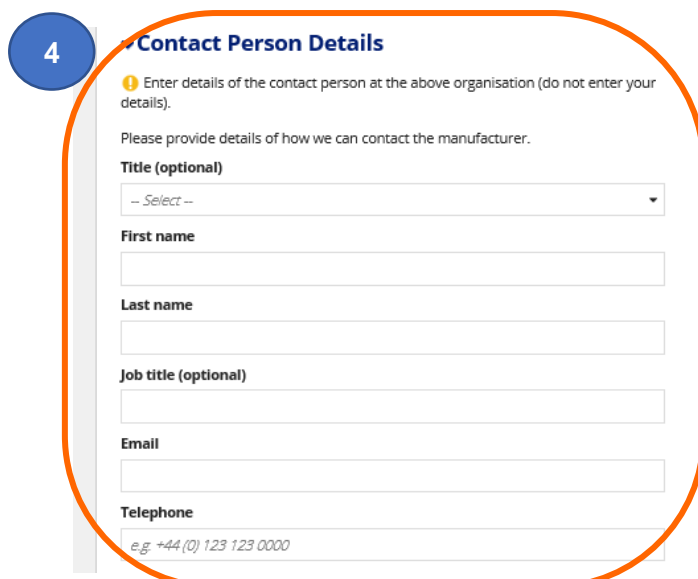
Enter address details for the organisation

Select International Address

Address line 1

Address line 2 (optional)

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



4 Contact Person Details

Enter details of the contact person at the above organisation (do not enter your details).

Please provide details of how we can contact the manufacturer.

Title (optional)

-- Select --

First name

Last name

Job title (optional)

Email

Telephone

e.g. +44 (0) 123 123 0000

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](#).

5

Upload Letter of Designation

UPLOAD
Drop file here

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

From Date

To Date

Description of document (optional)

Limit: 255 characters, remaining: 255.

CONTINUE
SAVE & EXIT
BACK


DELETE APPLICATION

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 \(PAR\)](#). See [Uploading New Letter of Designation](#) in the [Account Management Reference Guide](#) to update Letter of Designation.

6

Upload Letter of Designation



Designation Letter

PDF - 6.89 KB

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

From Date *

To Date *

Description of document (optional)

Limit: 255 characters, remaining: 255.

CONTINUE
SAVE & EXIT
BACK

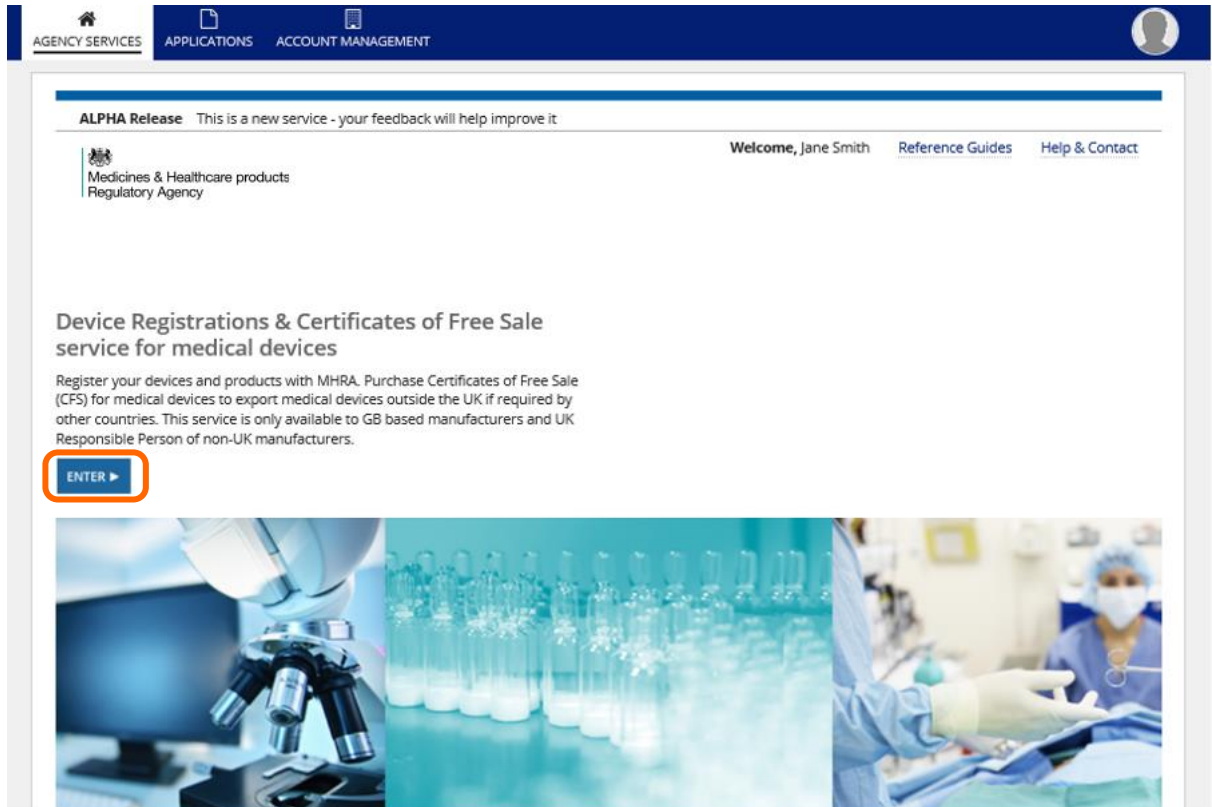
DELETE APPLICATION

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.

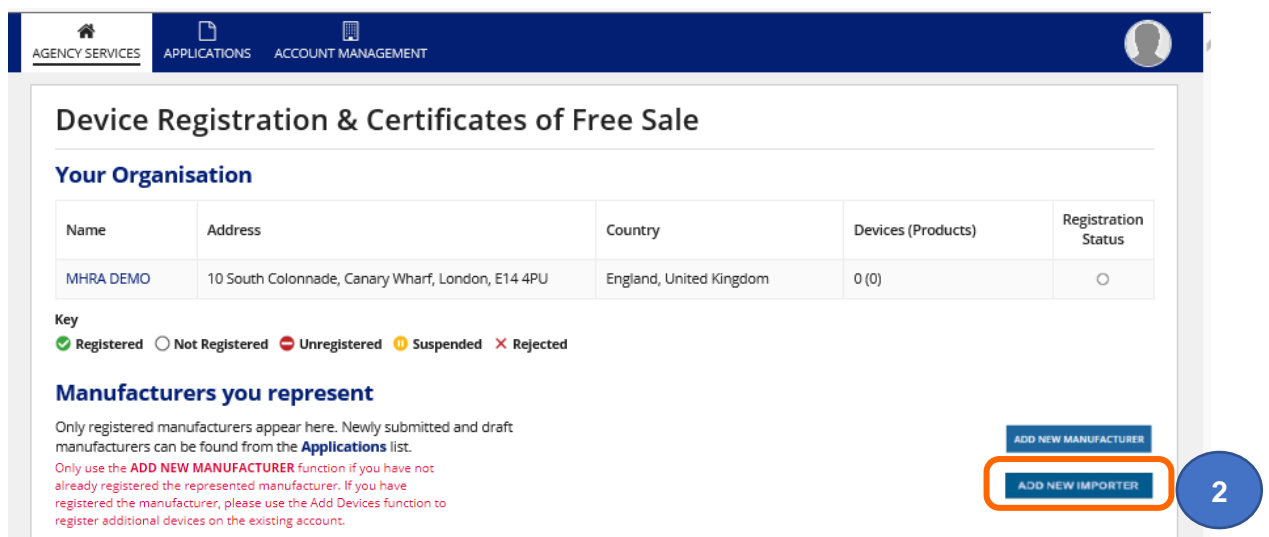
Adding Importers

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.

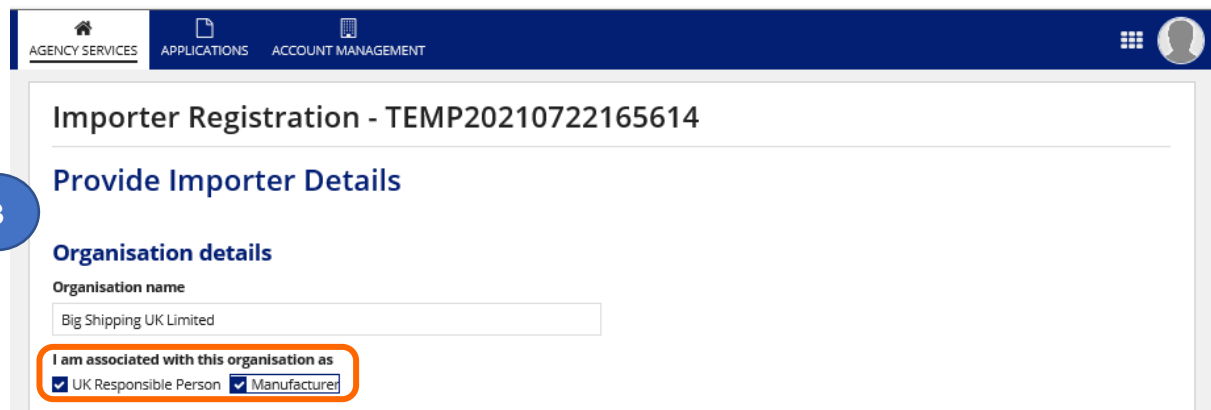


3. Enter the importer details:

- **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).

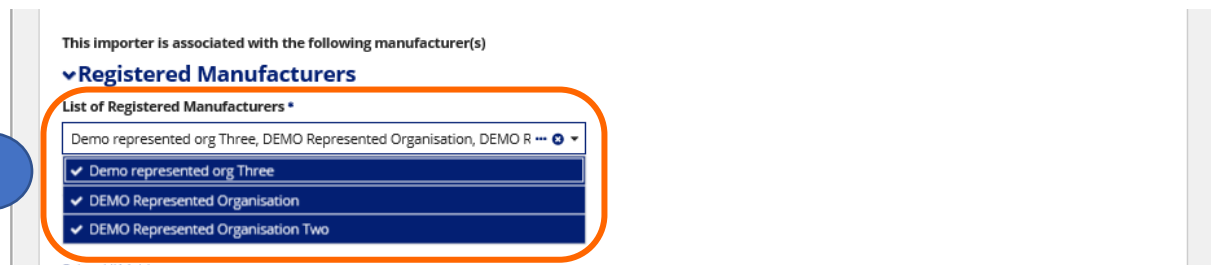
Please note: If you have multiple roles, please select your associated role for **this** importer. If the importer imports for you as a manufacturer, select manufacturer. If they import for one or more manufacturers that you represent as a UKRP/NI Authorised Representative, select UKRP and/or NI Authorised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



5. Enter all mandatory address fields for the importer

▼Address Details

 Enter address details for organisation in the UK

Postcode lookup

CT17 9BU

Pick an address

Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU

[Enter address manually](#)

Address line 1

Unit 561

Address line 2 (optional)

Waterloo Crescent

Address line 3 (optional)

Harbour House

Address line 4 (optional)

State/County/Province (optional)

Kent

City/Town

Dover

Country *

England, United Kingdom

Post code

CT17 9BU

Telephone


1234567

Fax (optional)

Website (optional)

6. Enter the importer's [contact details](#)– please do not enter **your** contact details here.

4 **▼Contact Person Details**

 Enter details of the contact person at the above organisation (do not enter your details).
Please provide details of how we can contact the importer.

Title (optional)

— Select —

First name

Peter

Last name

James

Job title (optional)

Import Manager

Email

pete@bigshipping.co.uk

Telephone

12345676

5. Click the [Continue](#) button.

6. Click the [Complete Application](#) button.

Add New Importer - TEMP202001030154509

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

6
COMPLETE APPLICATION
BACK

DELETE APPLICATION

7. Click the [Close](#) button.

Application complete

Your reference number

202010300115416

What happens next...


We have sent you a confirmation email and your application has been sent to an officer at MHRA.

We will contact you again within the next 2 -5 working days to let you know of our decision, or to ask for more information if its needed.

7

CLOSE

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](#).

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT


Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	4 (9)	✔

Key
✔ Registered ○ Not Registered ✘ Unregistered ● Suspended ✘ Rejected

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the [Applications](#) list.

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the **Add Devices** function to register additional devices on the existing account.

ADD NEW MANUFACTURER
ADD NEW IMPORTER

Search by manufacturer name:

SEARCH

Name	Address	Country	Devices (Products)	Relationship	Registration Status
Demo represented org Three	167 Bella Bista, East Side Compound, 1000 Medtech Drive, Sea View Industrial Zone, Santa Barbara, CA, 98765	United States	20 (21)	UK Responsible Person	✔
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, MA, 12345	United States	3 (10)	UK Responsible Person	✔
DEMO Represented Organisation Two	234 Avenida Escala, Cancun, Yukatan, 43231	Mexico	1 (1)	UK Responsible Person	✔
DEMO Represented Organisation Three	60 Strand Street, Douglas, Isle Of Man, IM1 2EL	Isle of Man	0 (0)	UK Responsible Person	○

Key
✔ Registered ○ Not Registered ✘ Unregistered ● Suspended ✘ Rejected

List of Importers

Name	Address	Country	Relationship	Status
Big Shipping UK Limited	Unit 561, Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU	England, United Kingdom	UK Responsible Person : Manufacturer	✔
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, Kent, CT17 9BU	England, United Kingdom	UK Responsible Person	✘
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, Kent, CT10 7BU	England, United Kingdom	UK Responsible Person	✔

Key
✔ Active ✘ Inactive

9. Click on the importer name in the [List of Importers](#) on the [Organisation](#) page.

9

Name	Address	Country	Relationship	Status
Big Shipping UK Limited	Unit 561, Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU	England, United Kingdom	UK Responsible Person ; Manufacturer	Active
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, Kent, CT17 9BU	England, United Kingdom	UK Responsible Person	Inactive
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, Kent, CT10 7BU	England, United Kingdom	UK Responsible Person	Active

Key
● Active ● Inactive

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

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

10

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

[Back to DR&CFS Services](#)
[Deactivate Importer](#)

MHRA DEMO: Big Shipping UK Limited

SUMMARY APPLICATIONS NEWS

Summary

Basic Information

Account Number: 0000007097 Registration Status: Active

Role / Account Type: Importer

Organisation Name: MHRA DEMO

Relationship: Manufacturer | UK Responsible Person

Created Date: 22 July 2021

Organisation Details

Registered Address: Unit 561, Waterloo Crescent, Harbour House, Dover, Kent, CT17 9BU, England, United Kingdom

Telephone: 1234567
 Fax: N/A
 Website: N/A

Contact Details

Full Name: Peter James Email: pete@bigshipping.co.uk

Job Title: Import Manager Telephone: 12345676

Associated Manufacturers

Name	Address	Country	Registration Status
Demo represented org Three	167 Bella Bista, East Side Compound, 1000 Medtech Drive, Sea View Industrial Zone, Santa Barbara, CA, 98765	United States	Registered
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, MA, 12345	United States	Registered
DEMO Represented Organisation Two	234 Avenida Escala, Cancun, Yukatan, 43231	Mexico	Registered
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	Registered

Key
● Registered ○ Not Registered ● Unregistered ● Suspended ✗ Rejected



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.

The screenshot shows the 'Device Registration & Certificates of Free Sale' interface. It includes a navigation bar with 'AGENCY SERVICES', 'APPLICATIONS', and 'ACCOUNT MANAGEMENT'. The main content area is divided into sections: 'Your Organisation', 'Manufacturers you represent', and 'List of Importers'. The 'List of Importers' table has the following data:

Name	Address	Country	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	UK Responsible Person	Active

The 'Demo Importer' row is highlighted with a red circle, and a blue circle with the number '1' is positioned to its left. The 'Status' column shows a green dot indicating the importer is active.

2. **Click** on the [Deactivate Importer](#) button.

The screenshot shows the 'MHRA DEMO: Demo Importer' summary page. It includes a navigation bar with 'Back to DR&CFS Services'. The main content area is divided into sections: 'SUMMARY' and 'Summary'. The 'Summary' section has the following data:

Basic Information	
Account Number	0000005322
Registration Status	Active
Role / Account Type	Importer
UK Responsible Person	MHRA DEMO
Created Date	30 October 2020

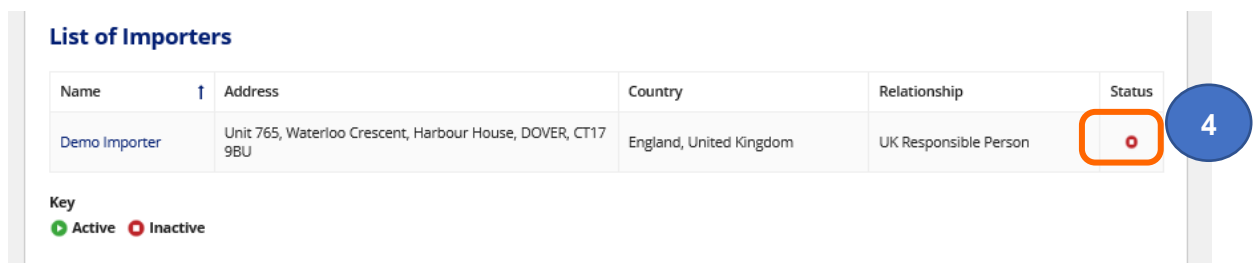
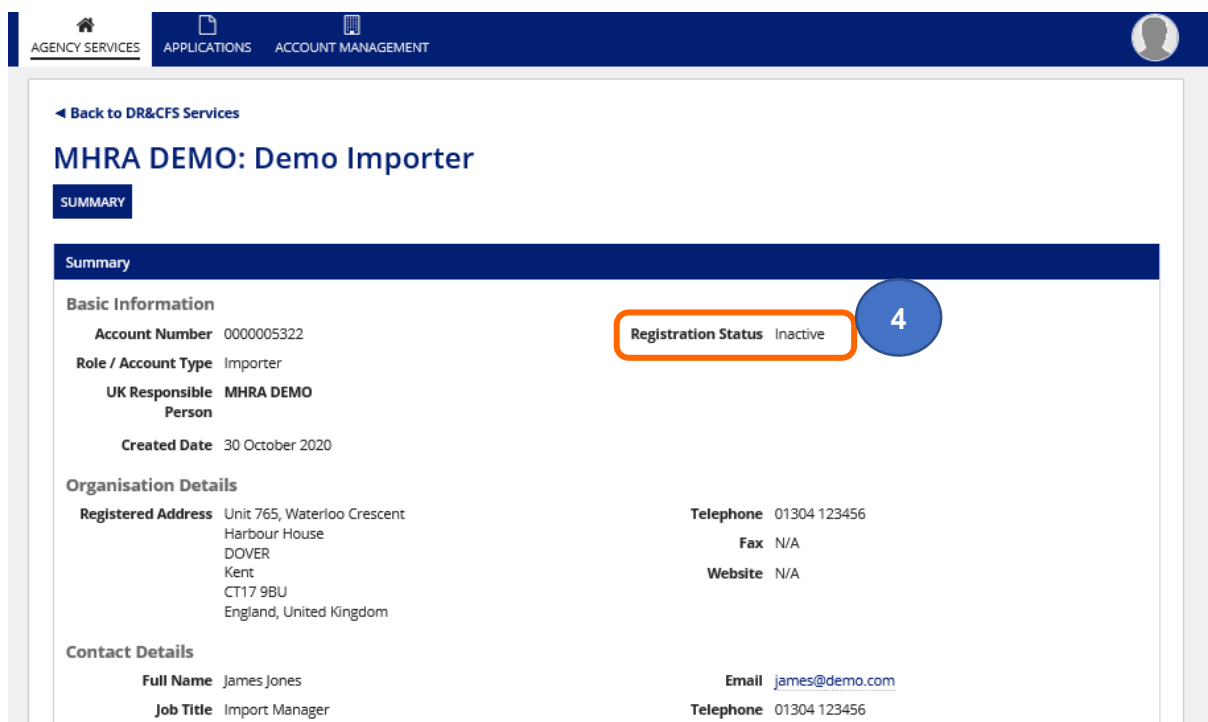
The 'Deactivate Importer' button is highlighted with a red circle, and a blue circle with the number '2' is positioned to its right.

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).

 You can add other addresses by going to 'Manage Other Addresses' in your organisation's 'Related Actions' tab.



Remember to 'Save and Exit' to keep the information already entered if you move away from this screen

[Click here](#) to download the Proforma.

You can click above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit option below if you are not yet ready to complete payment)

Payment method

Choose payment method

1

SUBMIT APPLICATION **SAVE AND EXIT** BACK

DELETE APPLICATION

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

device 444

Are you sure you want to "Save and Exit" the application? If Yes, Your application will be saved and closed.

NO **YES** 2

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

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Application saved

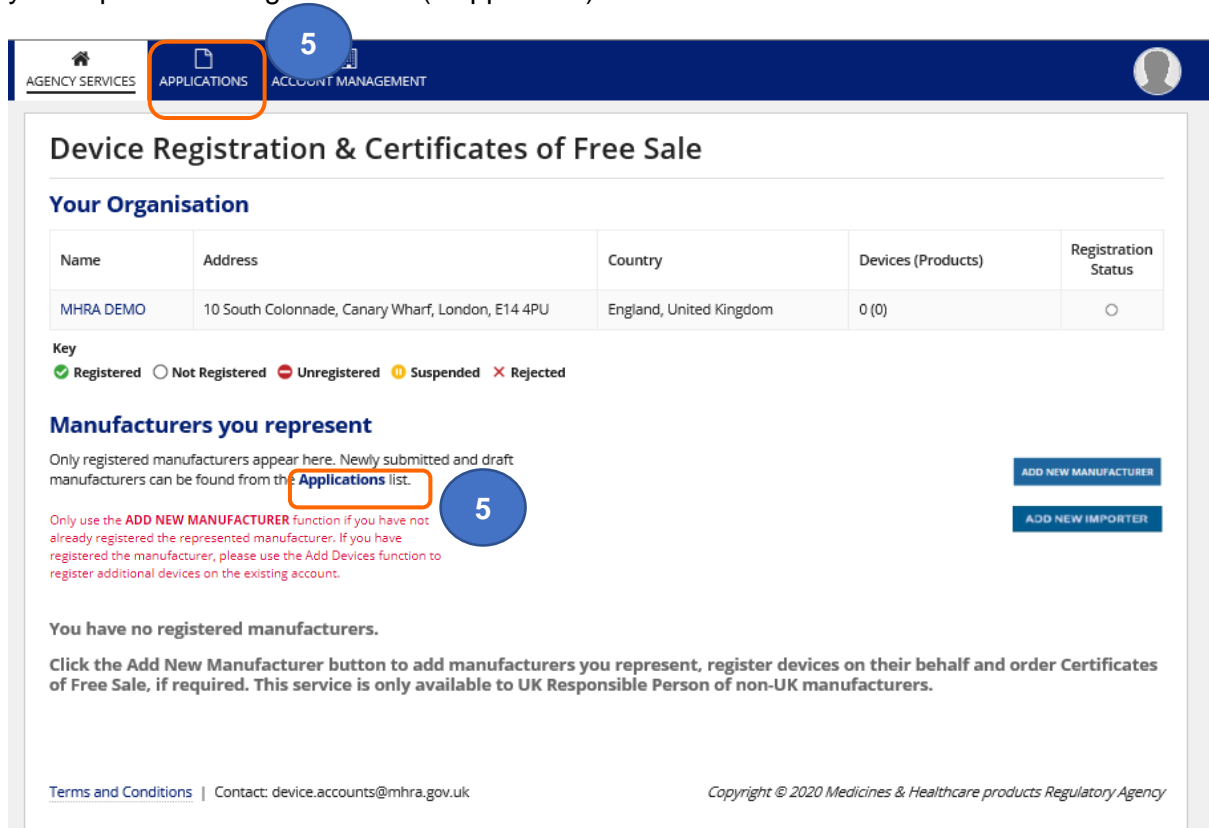
Your application has been saved successfully.

3 Your draft application reference number: TEMP20190510134111

4 CLOSE

4. Click the **Close** button.

- 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).



Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	0 (0)	<input type="radio"/>

Key
 Registered Not Registered Unregistered Suspended Rejected

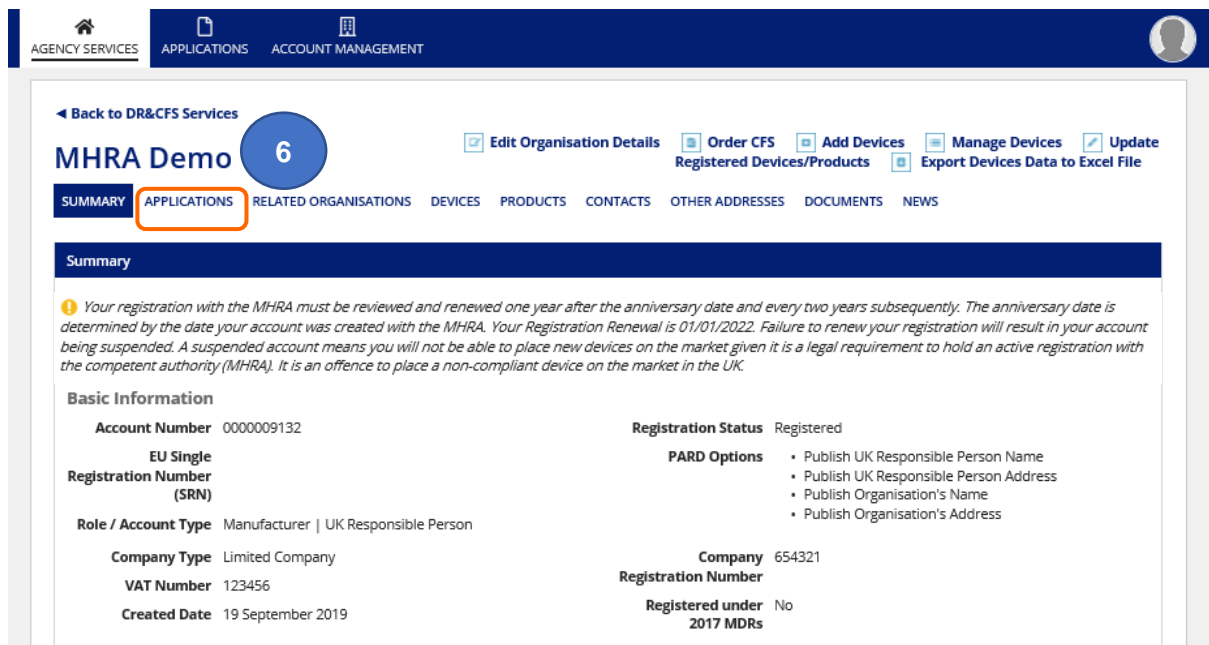
Manufacturers you represent
 Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the **Applications list**.

Only use the **ADD NEW MANUFACTURER** function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

You have no registered manufacturers.
 Click the Add New Manufacturer button to add manufacturers you represent, register devices on their behalf and order Certificates of Free Sale, if required. This service is only available to UK Responsible Person of non-UK manufacturers.

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



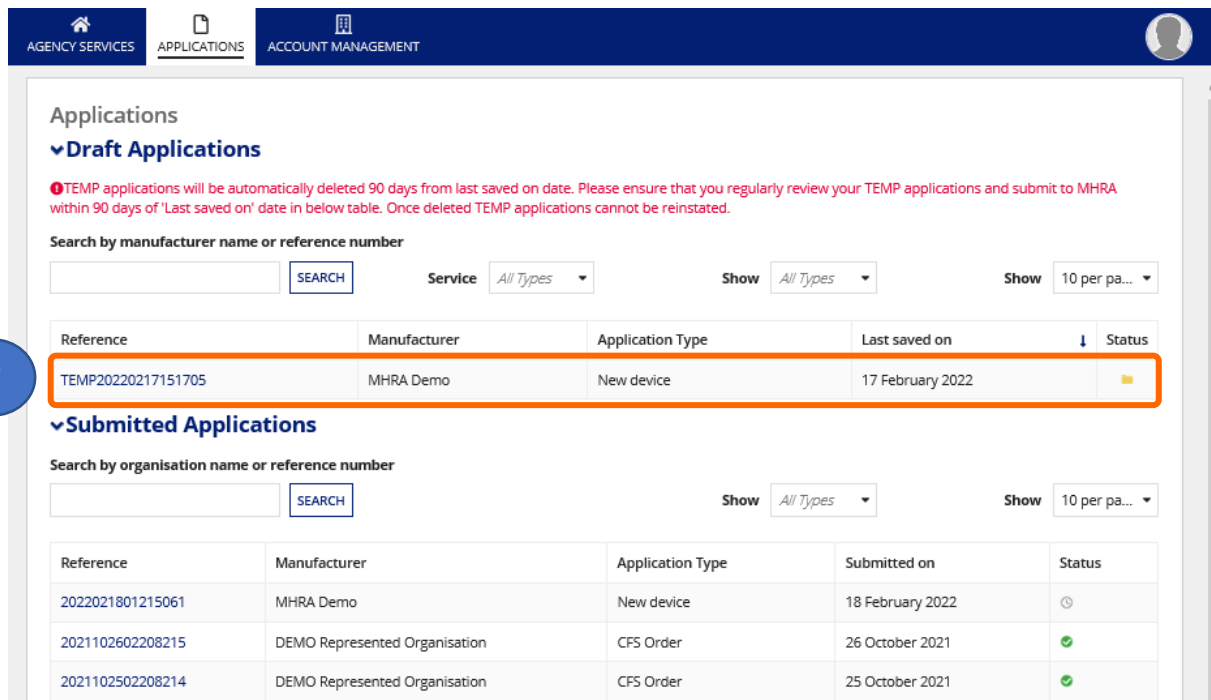
MHRA Demo

Summary

Basic Information

Account Number	000009132	Registration Status	Registered
EU Single Registration Number (SRN)		PARD Options	<ul style="list-style-type: none"> Publish UK Responsible Person Name Publish UK Responsible Person Address Publish Organisation's Name Publish Organisation's Address
Role / Account Type	Manufacturer UK Responsible Person	Company Registration Number	654321
Company Type	Limited Company	Registered under 2017 MDRs	No
VAT Number	123456		
Created Date	19 September 2019		

- 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.



Applications

▼ Draft Applications

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.

Search by manufacturer name or reference number

Service *All Types* Show *All Types* Show 10 per pa...

Reference	Manufacturer	Application Type	Last saved on	Status
TEMP20220217151705	MHRA Demo	New device	17 February 2022	

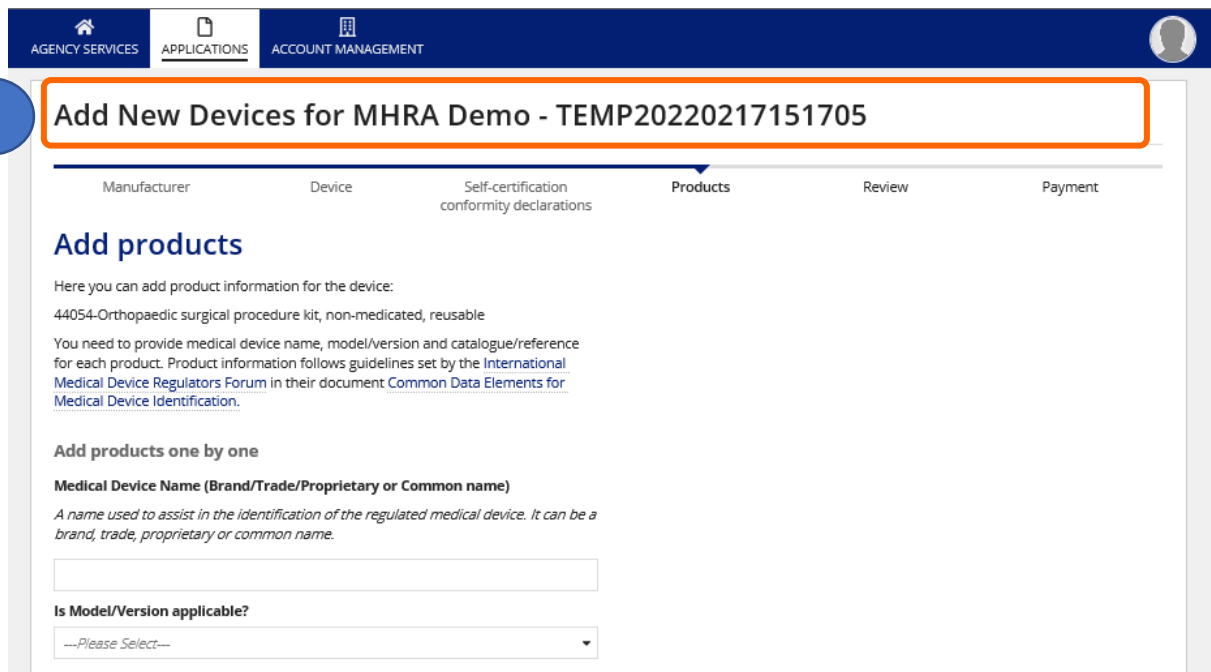
▼ Submitted Applications

Search by organisation name or reference number

Show *All Types* Show 10 per pa...

Reference	Manufacturer	Application Type	Submitted on	Status
2022021801215061	MHRA Demo	New device	18 February 2022	
2021102602208215	DEMO Represented Organisation	CFS Order	26 October 2021	✓
2021102502208214	DEMO Represented Organisation	CFS Order	25 October 2021	✓

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



8 Add New Devices for MHRA Demo - TEMP20220217151705

Manufacturer Device Self-certification conformity declarations **Products** Review Payment

Add products

Here you can add product information for the device:

44054-Orthopaedic surgical procedure kit, non-medicated, reusable

You need to provide medical device name, model/version and catalogue/reference for each product. Product information follows guidelines set by the [International Medical Device Regulators Forum](#) in their document [Common Data Elements for Medical Device Identification](#).

Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)

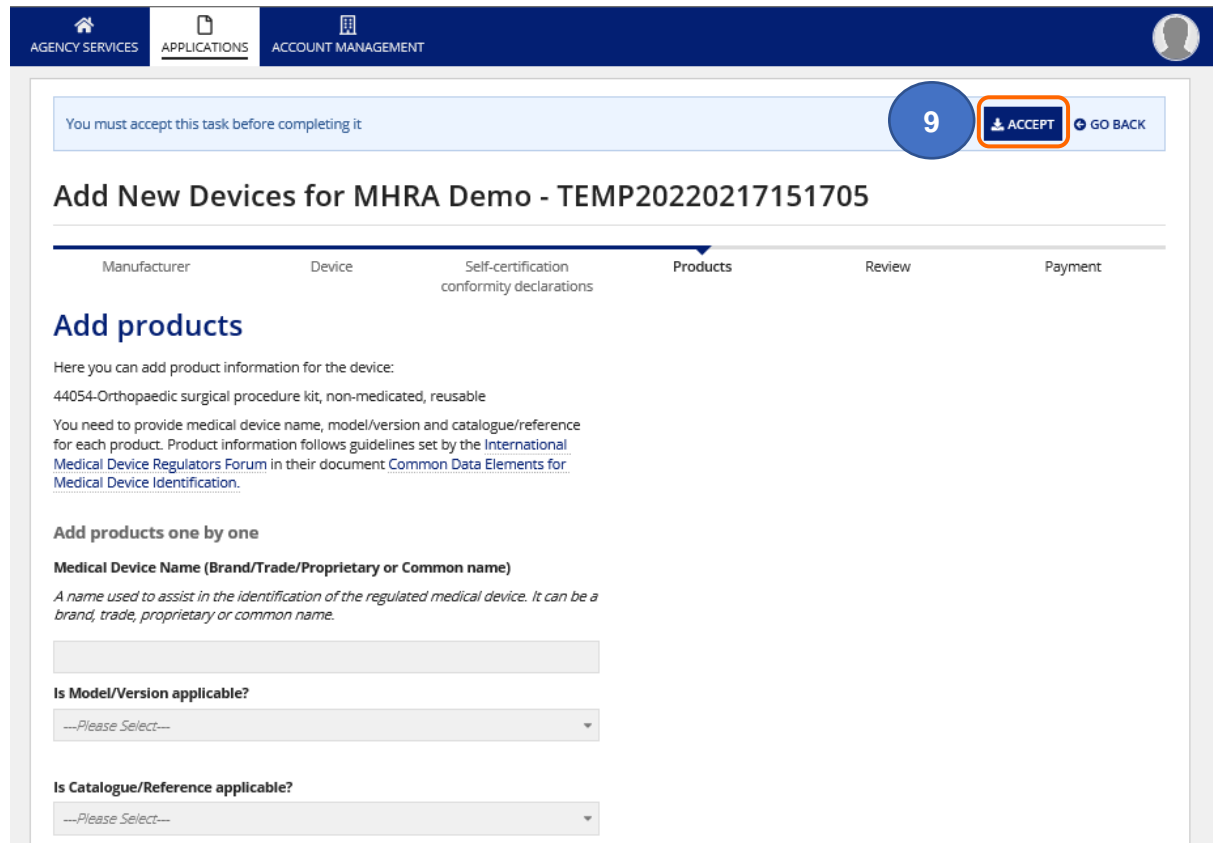
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Is Model/Version applicable?

---Please Select---

- If you have multiple users on your account you will need to **Click** on the **Accept** task button in order to continue with the application or **Click** on the **Go Back** button to go back to the Applications list. All **TEMP** applications will be visible and 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.



The screenshot displays the 'Add New Devices for MHRA Demo - TEMP20220217151705' page. At the top, there is a navigation bar with 'AGENCY SERVICES', 'APPLICATIONS', and 'ACCOUNT MANAGEMENT'. A notification bubble with the number '9' is present. Below the notification, there are 'ACCEPT' and 'GO BACK' buttons. The main content area shows a progress bar with steps: Manufacturer, Device, Self-certification conformity declarations, Products (current step), Review, and Payment. The 'Add products' section includes instructions and a form with a text input field and two dropdown menus for 'Is Model/Version applicable?' and 'Is Catalogue/Reference applicable?'.

Annex I – Workflow

