



Medicines & Healthcare products
Regulatory Agency

Account Management

Reference Guide

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

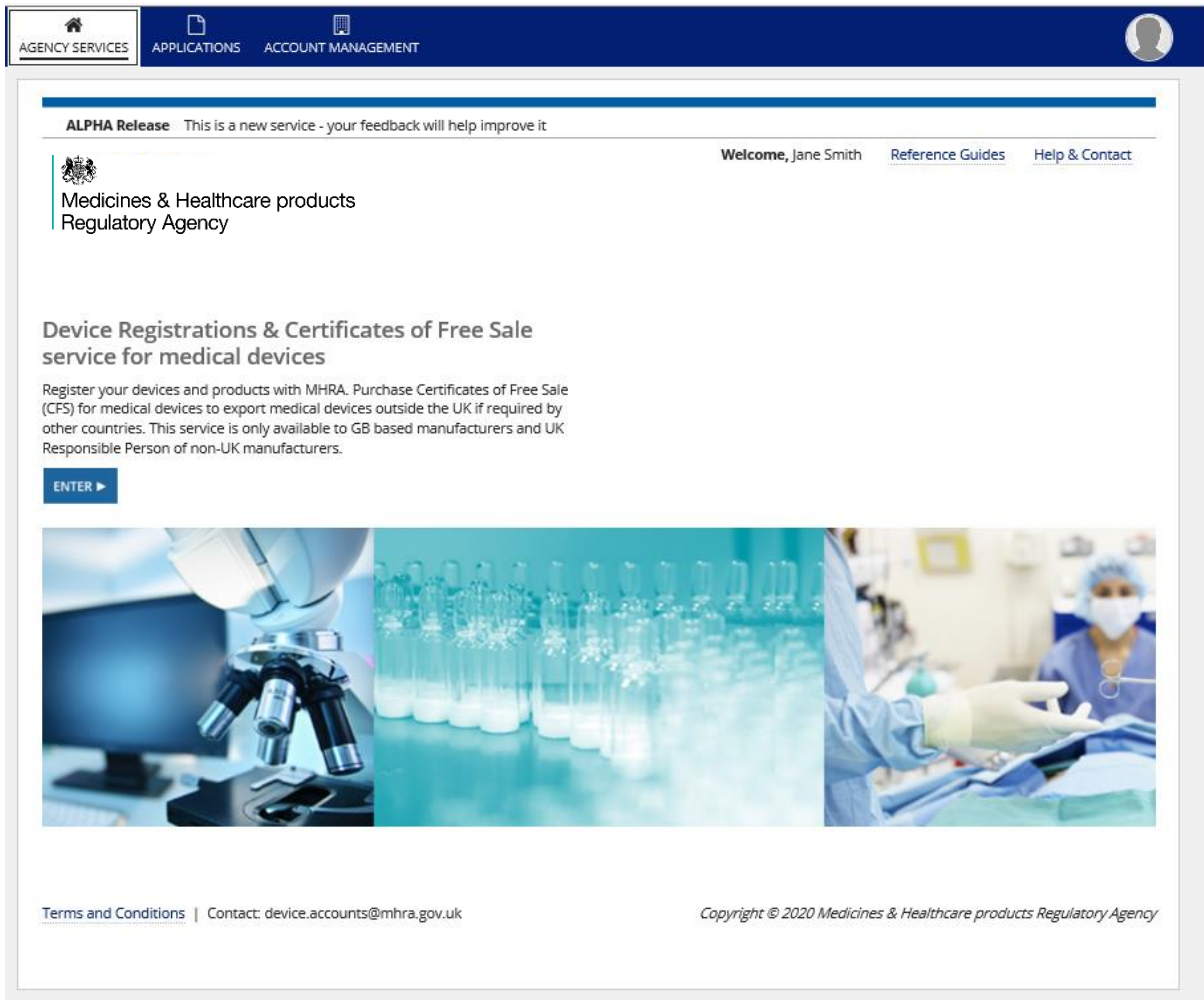
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MHRA – Agency Services

We aim to enhance the experience of customers using services offered by the MHRA Devices division, and to improve the quality of data collected across our services. Having an MHRA Devices account will allow customers to manage their own data more efficiently, through a range of self-service functions.

This Reference Guide aims to help users understand the features of the MHRA Devices account and how it relates to the services offered for Device Registrations and Certificates of Free Sale for medical devices.



The screenshot displays the MHRA Agency Services web application interface. At the top, a dark blue navigation bar contains three menu items: 'AGENCY SERVICES' (with a home icon), 'APPLICATIONS' (with a document icon), and 'ACCOUNT MANAGEMENT' (with a mobile phone icon). A user profile icon is visible on the right side of the navigation bar. Below the navigation bar, a white content area features a blue header with the text 'ALPHA Release This is a new service - your feedback will help improve it'. The main content area includes the MHRA logo and the text 'Medicines & Healthcare products Regulatory Agency'. A welcome message 'Welcome, Jane Smith' is displayed, along with links for 'Reference Guides' and 'Help & Contact'. The primary heading is 'Device Registrations & Certificates of Free Sale service for medical devices', followed by a descriptive paragraph: '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.' Below this text is a blue button labeled 'ENTER ►'. A large image banner at the bottom shows a microscope, laboratory glassware, and a medical professional in a clinical setting. At the very bottom, there are links for 'Terms and Conditions' and 'Contact: device.accounts@mhra.gov.uk', and a copyright notice: 'Copyright © 2020 Medicines & Healthcare products Regulatory Agency'.

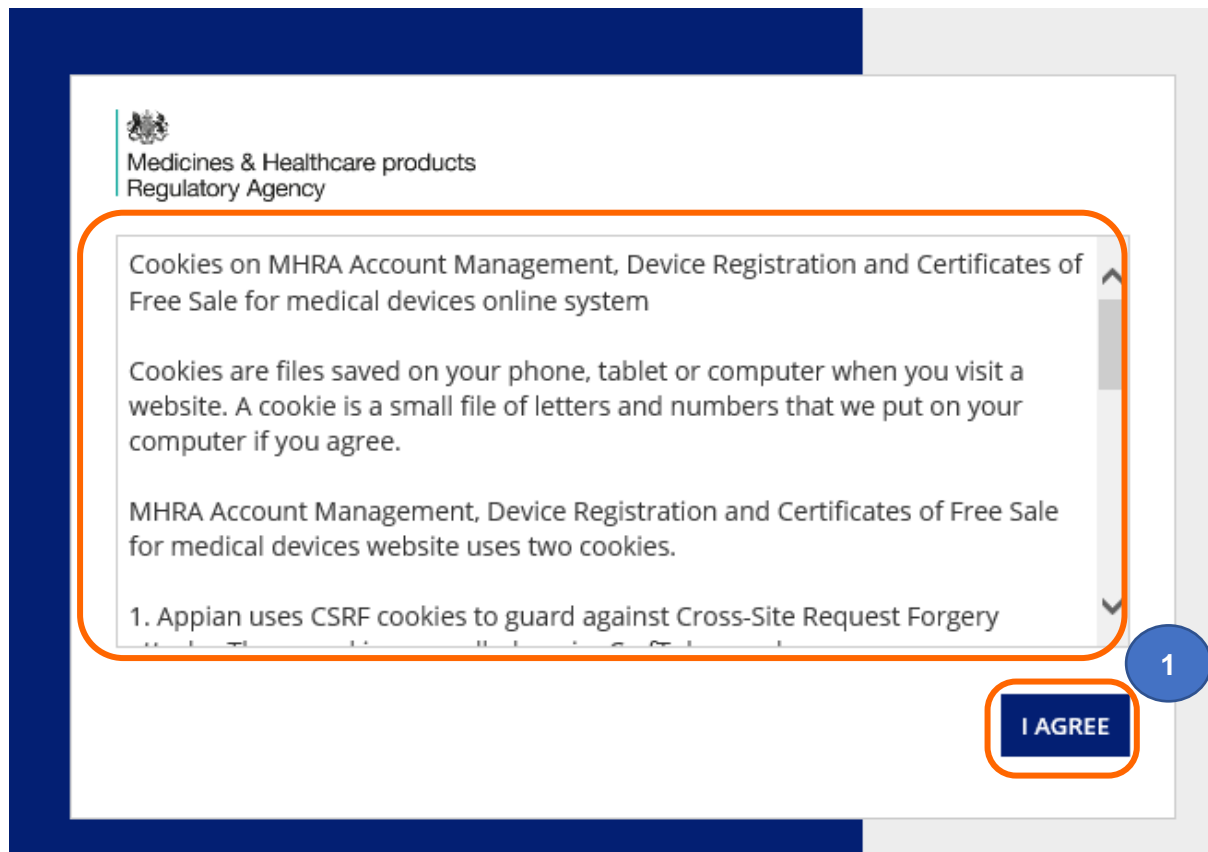
Logging in

Access MHRA Agency Services website

Read and agree to Cookie Policy

Before accessing MHRA Agency Services, you will need to read and 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.



The screenshot shows the MHRA Agency Services website with a cookie policy notification. The notification is titled "Cookies on MHRA Account Management, Device Registration and Certificates of Free Sale for medical devices online system". It explains that cookies are files saved on your phone, tablet or computer when you visit a website. It also states that the website uses two cookies: 1. Appian uses CSRF cookies to guard against Cross-Site Request Forgery. A blue circle with the number "1" is placed over the "I AGREE" button, which is highlighted with an orange border.

Username and Password

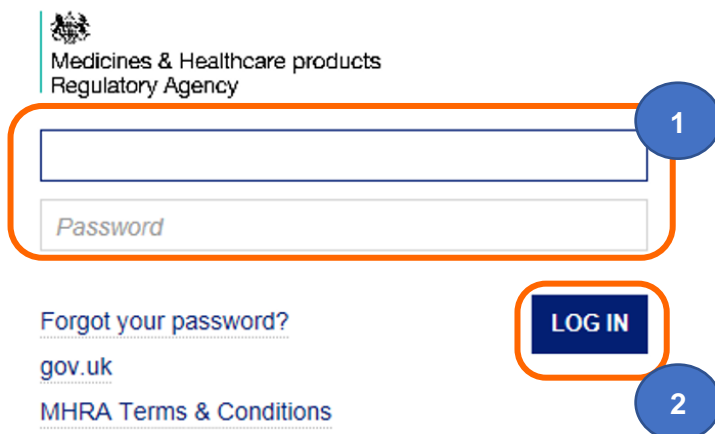
Once your Account request has been accepted by MHRA, two emails will be sent to the email address you entered in your account request application:

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.



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[Forgot your password?](#)

[gov.uk](#)

[MHRA Terms & Conditions](#)

LOG IN

New Users > Change temporary password

Change Password

Please complete the form to change your password.

Old Password 1

New Password 2

Confirm New Password


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

3

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](#).

You will be sent an email containing a password reset 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.

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Password

[Forgot your password?](#)

1

LOG IN

[gov.uk](#)

[MHRA Terms & Conditions](#)





Medicines & Healthcare products
Regulatory Agency

Forgot Password

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](#)

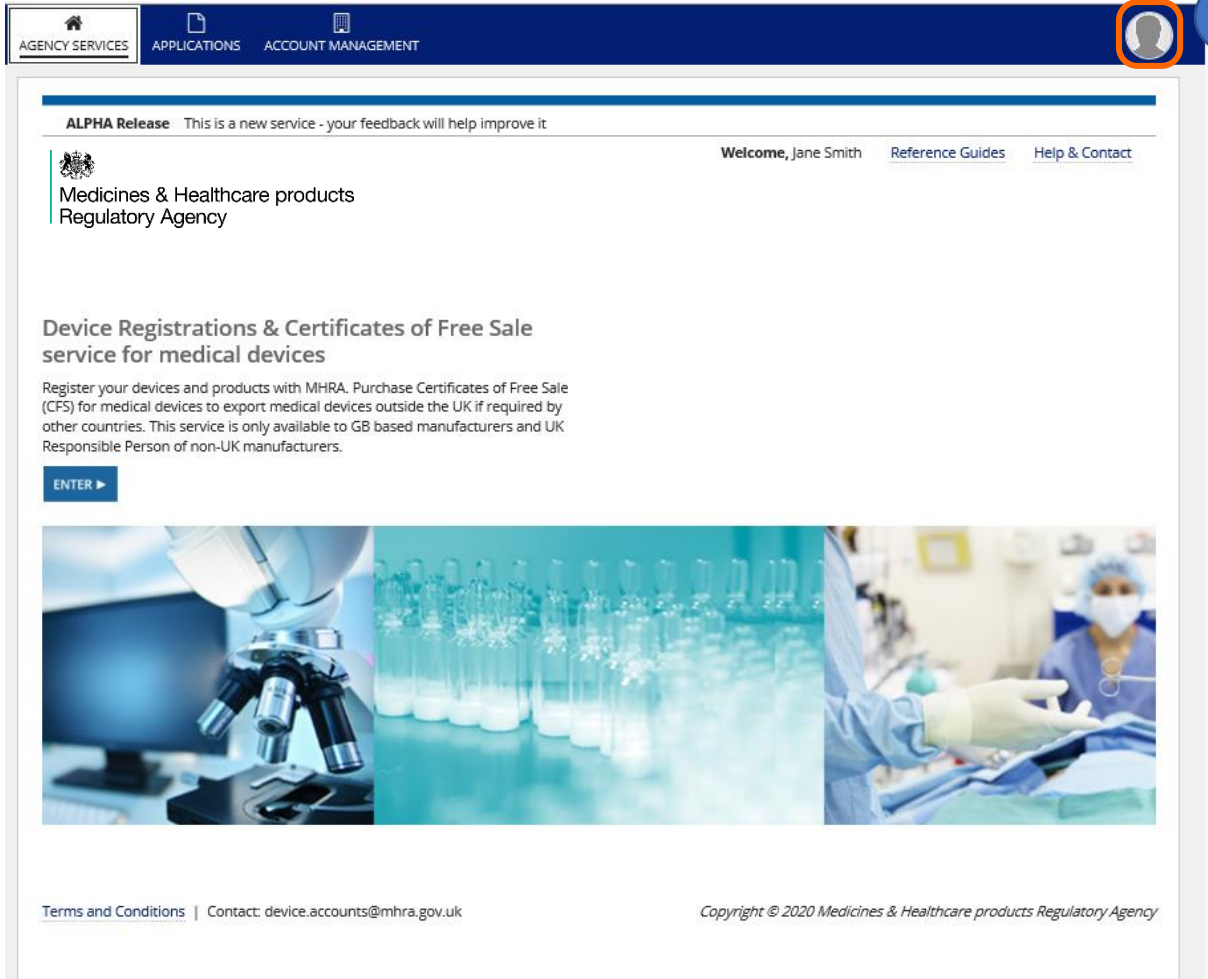
SEND EMAIL

My profile

Each user has a profile area where they can edit their user information (limited to user photo, and user blurb).

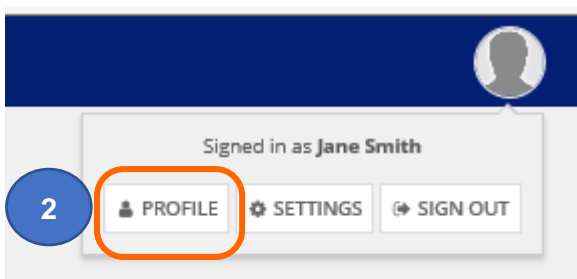
When you sign into your organisations account you will be taken to the service landing page. At the top right of the screen is an icon with a [silhouetted figure](#).

1. Click on the [silhouette](#) to access your profile



The screenshot shows the top navigation bar with three tabs: 'AGENCY SERVICES', 'APPLICATIONS', and 'ACCOUNT MANAGEMENT'. On the right side of the bar, there is a silhouette icon of a person, which is circled in red and labeled with a blue circle containing the number '1'. Below the navigation bar, the main content area displays a welcome message for 'Jane Smith' and a section for 'Device Registrations & Certificates of Free Sale service for medical devices'. The page footer includes 'Terms and Conditions', 'Contact: device.accounts@mhra.gov.uk', and 'Copyright © 2020 Medicines & Healthcare products Regulatory Agency'.

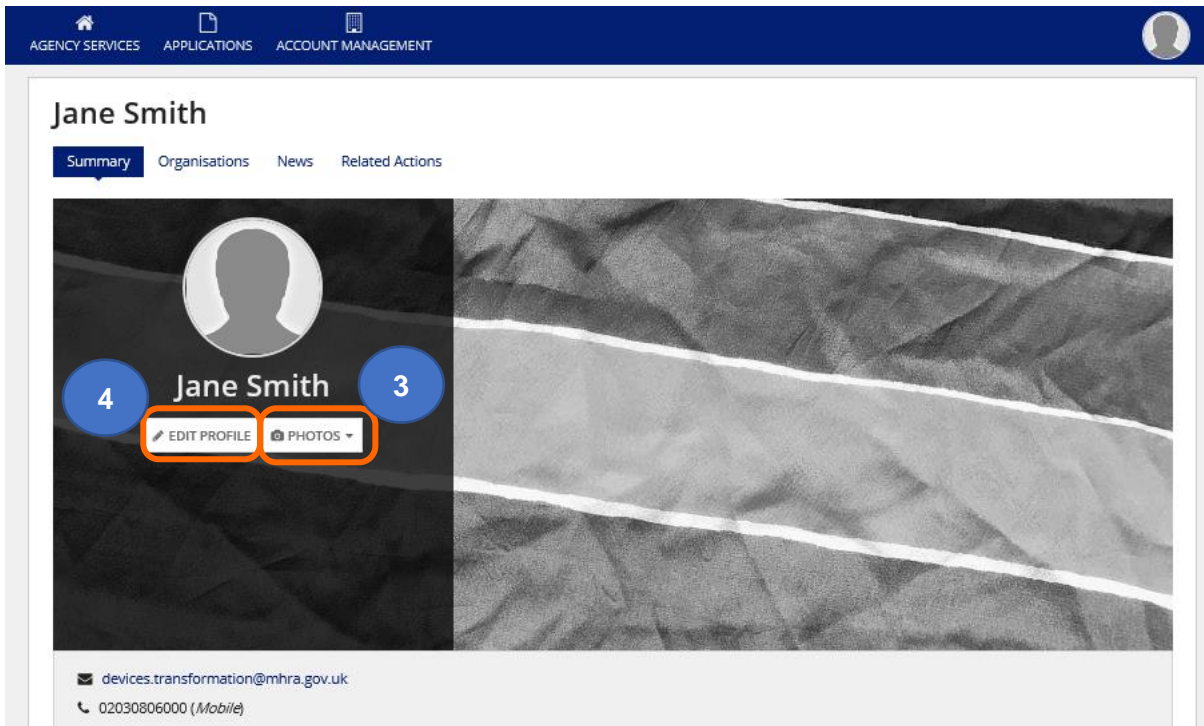
2. Click on the [Profile](#) button.



The screenshot shows a user profile dropdown menu. At the top, it says 'Signed in as Jane Smith'. Below this, there are three buttons: 'PROFILE', 'SETTINGS', and 'SIGN OUT'. The 'PROFILE' button is circled in red and labeled with a blue circle containing the number '2'.

Updating profile information

3. On the [Summary](#) tab, [click](#) on [Photos](#) to upload your photo (not mandatory).
4. On the [Summary](#) tab, [click](#) on [Edit Profile](#).



5. Please note that only the “Blurb” can be edited (this is not a mandatory field), all other changes need to be made via [Edit Organisation Details function](#).
6. Make any required changes, [click](#) the [Save Changes](#) button.

Edit Profile

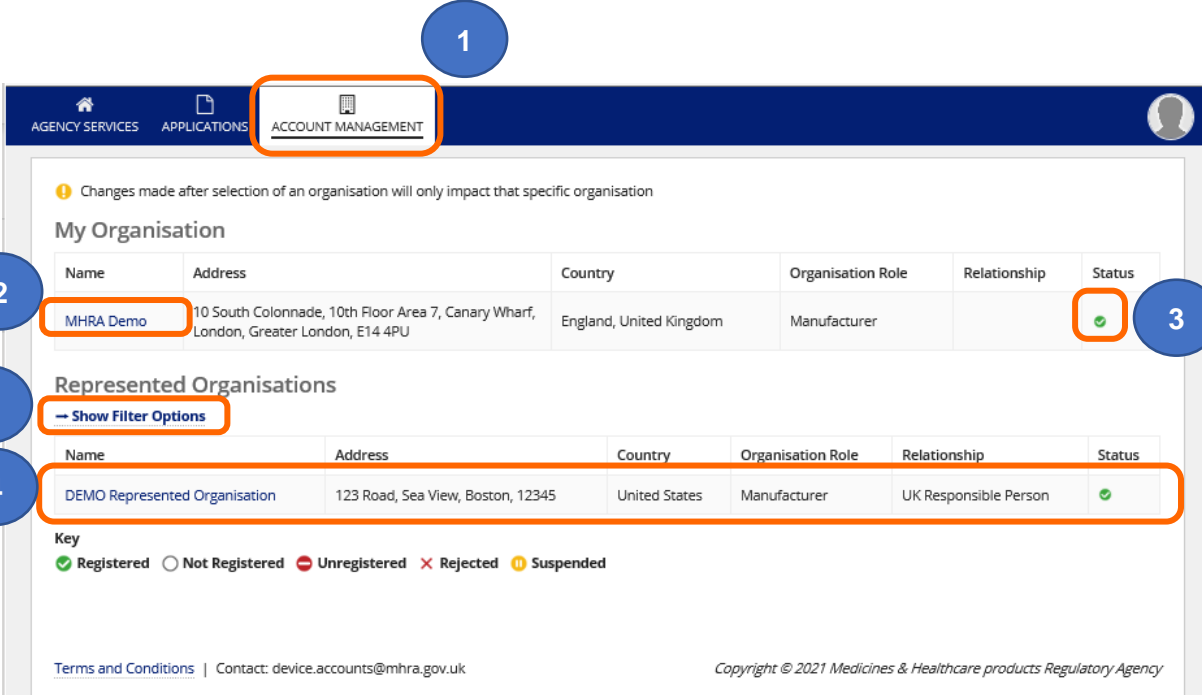
* First Name	<input type="text" value="Jane"/>	Mobile Phone	<input type="text" value="02030806000"/>
* Last Name	<input type="text" value="Smith"/>	Office Phone	<input type="text"/>
Nickname	<input type="text"/>	Address 1	<input type="text"/>
* Email	<input type="text" value="devices.transformation@mhra.gov.uk"/>	Address 2	<input type="text"/>
Supervisor	<input type="text"/>	Address 3	<input type="text"/>
Title	<input type="text"/>	Town	<input type="text"/>
Blurb	<input type="text"/>	City	<input type="text"/>
	<small>0/140</small>	Post Code	<input type="text"/>
		Country	<input type="text"/>

Enter Account Management

Organisation page

1. Click on the [Account Management](#) tab
2. [My organisation](#) is the one that the account was setup for.
3. Note that the organisation in this example is 'Registered'. If the status is 'Not registered' this may 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.
4. A UK Responsible Person or Authorised Representative (in NI) who has added [represented manufacturers](#) will see them in the [Represented organisations](#) table.

Please note Importers are not displayed here, please add/deactivate and review these via the [Agency Services](#) tab. See the [Device Registration Reference Guide](#) for full step by step instructions.



1

AGENCY SERVICES APPLICATIONS **ACCOUNT MANAGEMENT**

Changes made after selection of an organisation will only impact that specific organisation

My Organisation

Name	Address	Country	Organisation Role	Relationship	Status
MHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United Kingdom	Manufacturer		Registered

Represented Organisations

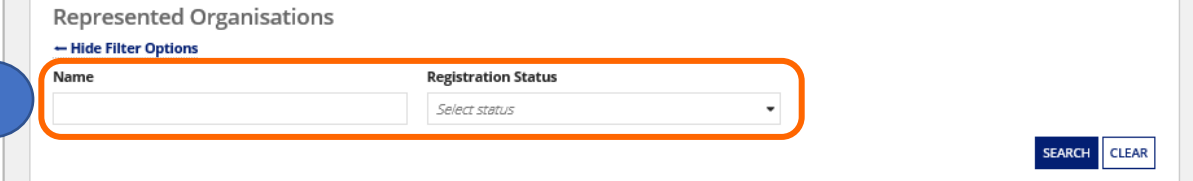
[Show Filter Options](#)

Name	Address	Country	Organisation Role	Relationship	Status
DEMO Represented Organisation	123 Road, Sea View, Boston, 12345	United States	Manufacturer	UK Responsible Person	Registered

Key
 Registered Not Registered Unregistered Rejected Suspended

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5. Click the [Show filter options](#) link to search by represented organisation name or registration status



Represented Organisations

[Hide Filter Options](#)

Name

Registration Status

SEARCH CLEAR

News Feed

The [News](#) tab gives you a view of actions taken on each account. This includes actions that do not generate an application.

1. Click on the [organisation](#) that you want to review. Click on the [News](#) tab.

◀ Back to DR&CFS Services

MHRA DEMO

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

News

Application	Activity	Action taken by	Action taken on
202011090015768	Registration renewal completed	MHRA	09 November 2020, 3:17 pm
202011090015768	Registration renewal submitted	Jane Smith	09 November 2020, 3:17 pm
202011060115725	Register manufacturer completed	MHRA	06 November 2020, 12:03 pm
202011060115725	Add new manufacturer application submitted	Jane Smith	06 November 2020, 12:01 pm
No application	Contact added for MHRA DEMO	Jane Smith	05 November 2020, 2:10 pm
No application	Contact added for MHRA DEMO	Jane Smith	05 November 2020, 2:09 pm
202011040115639	Add new importer application completed	Jane Smith	04 November 2020, 4:04 pm
202010300115416	Add new importer application completed	Jane Smith	30 October 2020, 3:06 pm
No application	Contact user updated for MHRA DEMO	Jane Smith	13 October 2020, 12:25 pm

9 items

2. Click on the [Application number](#) or [No application](#) link.

MHRA DEMO: DEMO Represented Organisation

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

News

Application	Activity	Action taken by	Action taken on
202011090215772	Devices or products are deleted	Jane Smith	09 November 2020, 4:34 pm
No application	Devices or products are deleted	Jane Smith	09 November 2020, 4:34 pm
202011090115770	Add device application submitted	Jane Smith	09 November 2020, 4:32 pm

3. Click on [Amended Devices](#) to view details of the action taken.

DR&CFS Services / MHRA DEMO / ▶ Back to DEMO Represented Organisation

Device Amendment - Reference: 202011090215772

AMENDED SUMMARY **AMENDED DEVICES** AMENDED NEWS

Devices

Number of devices: 1

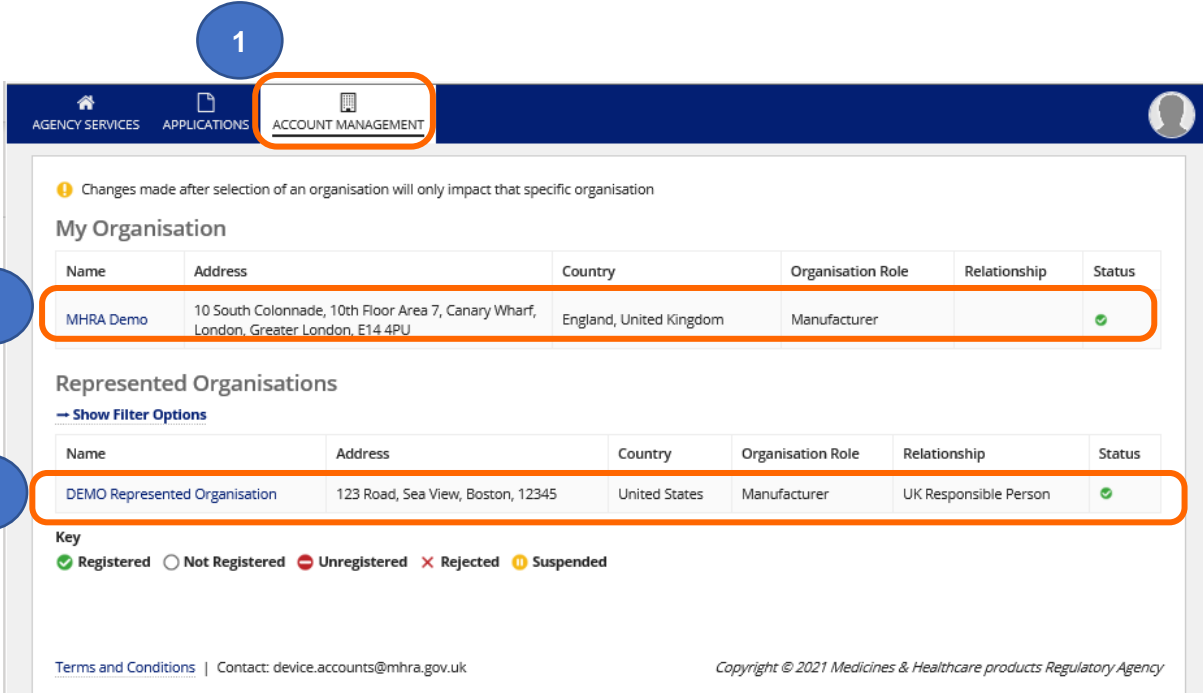
GMDN code - term	Status
Dura mater knife	Deleted

Managing organisations

1. The [Account Management](#) tab allows you to view your organisation and represented manufacturers.
2. **Your** organisation will be displayed in the [My Organisation](#) table. 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. Any [manufacturers](#) that you represent will be displayed within the [Represented Organisations](#) table. Selecting an organisation from either table (by **clicking** on the [organisation name](#)) will allow you to see further information about each represented manufacturer, and update data for your organisation or the manufacturer you represent.

Please note that you cannot Add Devices, Manage Devices, Update registered devices and products or Order Certificates of Free Sale if you have accessed the organisation from the [Account Management Tab](#) – you must go to the [Agency Services tab](#) and **Select** the manufacturer to take these actions.

The only actions that can be taken from the [Account Management Tab](#) are Edit Organisation and Unregister Manufacturer. If the account is suspended due to expired Letter of Designation or Renew Registration these options will not appear and action must be taken from the [Agency Services tab](#).



1

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Changes made after selection of an organisation will only impact that specific organisation

My Organisation

Name	Address	Country	Organisation Role	Relationship	Status
MHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United Kingdom	Manufacturer		Registered

Represented Organisations

→ Show Filter Options

Name	Address	Country	Organisation Role	Relationship	Status
DEMO Represented Organisation	123 Road, Sea View, Boston, 12345	United States	Manufacturer	UK Responsible Person	Registered

Key
 Registered (green checkmark) Not Registered (grey circle) Unregistered (red circle with slash) Rejected (red X) Suspended (yellow warning icon)

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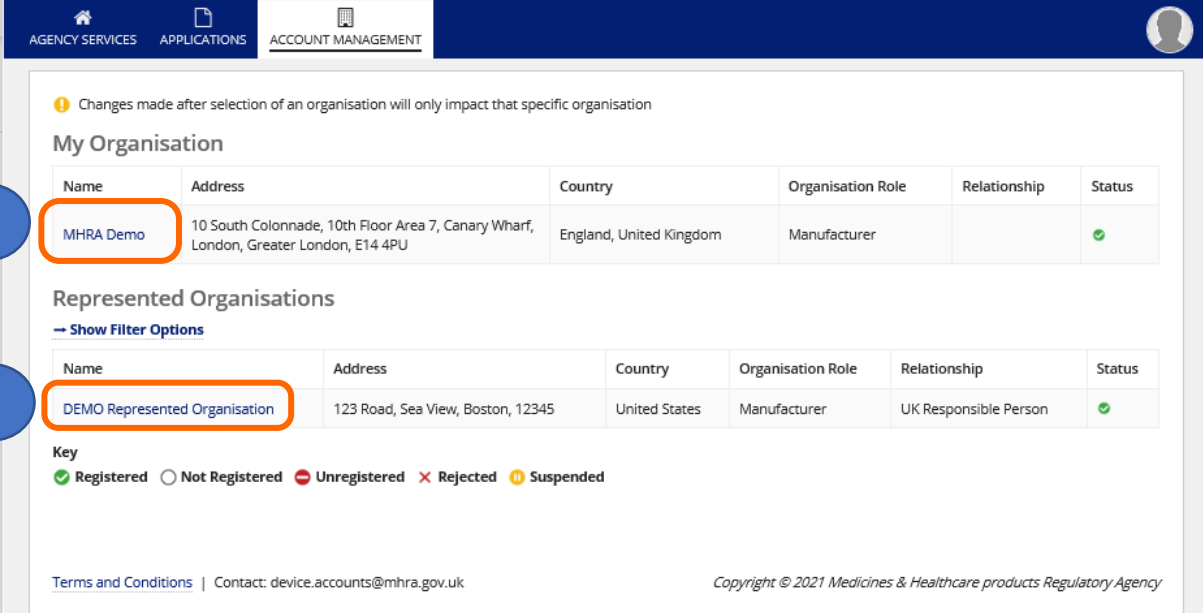
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Editing organisation details

1. Users can **edit** their organisation details or details of **manufacturers** they represent. Organisation name, address, telephone, website, fax and Customer Service Contact can all be edited. However, **there is a charge** associated with any changes to address or organisation name where the proposed changes would result in an update needing to be made to a **registered manufacturer**.
2. Examples:
 - If a UK Responsible Person or Authorised Representative in Northern Ireland, who represents 5 registered manufacturers wishes to change **their** name, they would be required to pay a **statutory fee** for their own organisation plus a **statutory fee** for each of the 5 registrations that would need to be updated because of the name change. You will be taken to a screen to upload new Letters of Designation. You must ensure that you review your represented manufacturers **before** making any changes to your organisation name. If any represented manufacturers are suspended due to **Renew Registration** or **Expired Letter of Designation** you will also be charged. If you no longer represent a manufacturer, please follow the **Unregister manufacturer** instructions.
 - If a sole manufacturer (who has a registered status) wishes to change their name or address, then one **statutory fee** would be payable due to changes to the one registration.
3. Name and address changes are only permitted where there is no change in the legal entity of the organisation to which the change relates.
4. If a UK Responsible Person or Authorised Representative in Northern Ireland updates the organisation details of a represented organisation, they must **upload a new letter of designation** for the represented organisation. The changes will not be applied until MHRA has reviewed and accepted the change.
5. If a UK Responsible Person or Authorised Representative in Northern Ireland no longer represents a manufacturer, they must **Unregister** the represented organisation. Please follow the **Unregister Manufacturer** instructions. The registration status of the represented organisation will change to 'Unregistered', and they will no longer be able to legally place medical devices on the UK market.
6. Please note that when an **Edit Organisation** application is submitted and whilst it is under review by MHRA you will not be able to make certain changes to your account until the application has been completed by MHRA. You will see warning messages in the system depending on the type of action you attempt to take.
7. **Importer** accounts can only be deactivated, no changes can be made. If you need to make changes to Importer details, you need to **deactivate** the Importer and add them again with the new details. There is currently no charge to do this. Importers can be added and deactivated from the organisation page via the **Agency Services tab**. See Adding Importers and Deactivating Importers in the **Device Registration Reference Guide**.

1. Click on the name of the organisation that you want to edit.

If you are a UK Responsible Person or Authorised Representative in Northern Ireland and wish to change your organisation name/address, you must ensure that you review your represented manufacturers before making any changes to your organisation. If you no longer represent a manufacturer, please follow the [Unregister manufacturer](#) instructions. If any represented manufacturers are suspended due to [Renew Registration](#), submit the Renew registration application for the suspended manufacturers before you change your organisation name/address.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Changes made after selection of an organisation will only impact that specific organisation

My Organisation

Name	Address	Country	Organisation Role	Relationship	Status
MHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United Kingdom	Manufacturer		✓

Represented Organisations

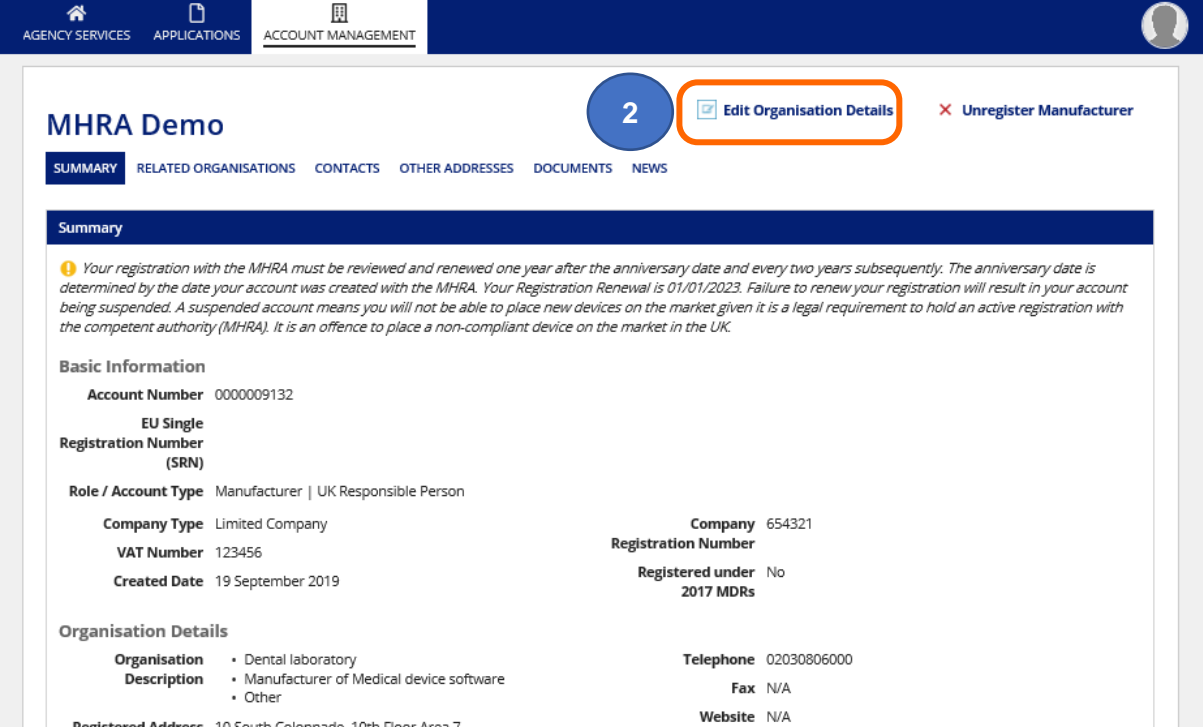
→ Show Filter Options

Name	Address	Country	Organisation Role	Relationship	Status
DEMO Represented Organisation	123 Road, Sea View, Boston, 12345	United States	Manufacturer	UK Responsible Person	✓

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

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2. Click on the Edit Organisation Details link.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

MHRA Demo

[Edit Organisation Details](#) ✗ Unregister Manufacturer

SUMMARY RELATED ORGANISATIONS 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 01/01/2023. 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	000009132	Company	654321
EU Single Registration Number (SRN)		Registration Number	
Role / Account Type	Manufacturer UK Responsible Person	Registered under 2017 MDRs	No
Company Type	Limited Company	Telephone	02030806000
VAT Number	123456	Fax	N/A
Created Date	19 September 2019	Website	N/A

Organisation Details

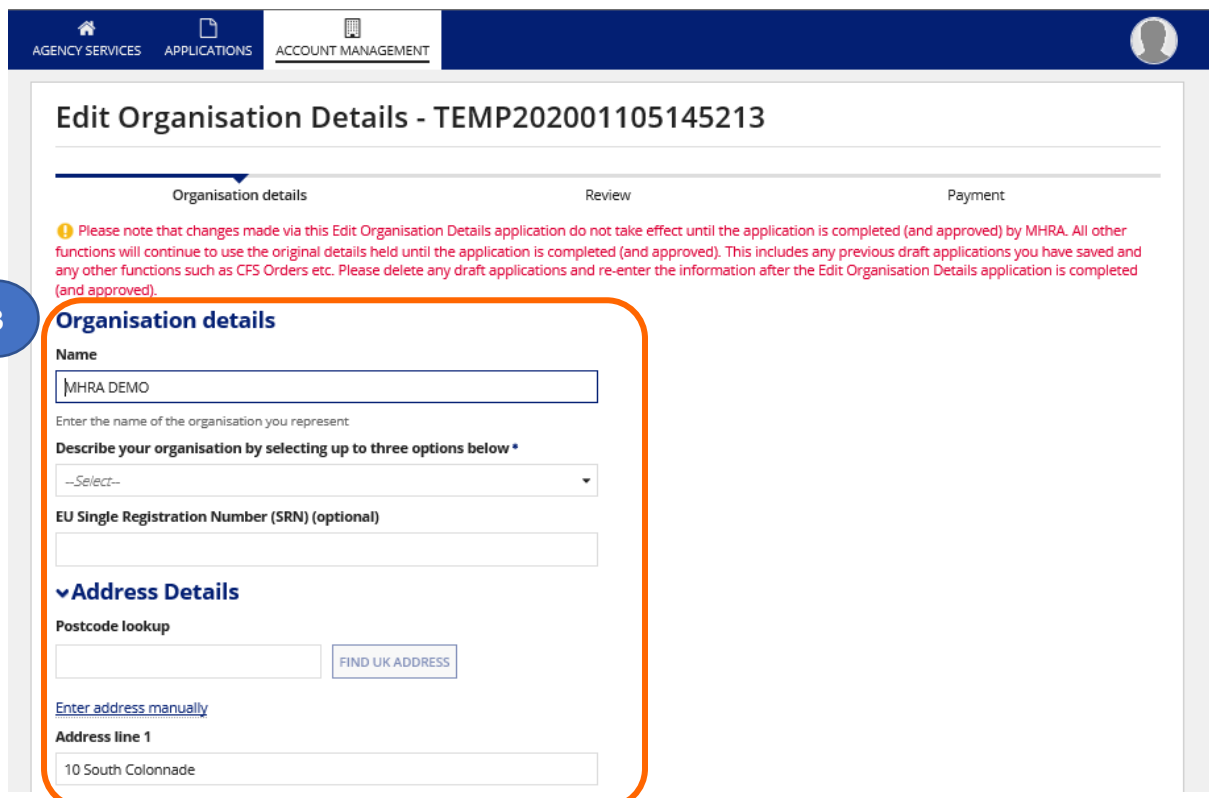
Organisation Description	<ul style="list-style-type: none"> Dental laboratory Manufacturer of Medical device software Other
Registered Address	10 South Colonnade 10th Floor Area 7

3. Make any required changes to the organisation and/or address details.

Please note that making **any** changes to organisation name and/or address will incur a [statutory fee](#). This applies even if you change one character or add or remove a space.

If you are a UK Responsible Person or Authorised Representative in Northern Ireland and change your organisation name or address, the [statutory fee](#) will be payable for your organisation and for each organisation that you represent.

Changes to organisation description, adding the EU SRN (if known), updating telephone, fax and website details and adding or updating Customer Service Contact details do not currently incur a fee.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Edit Organisation Details - TEMP202001105145213

Organisation details Review Payment

! Please note that changes made via this Edit Organisation Details application do not take effect until the application is completed (and approved) by MHRA. All other functions will continue to use the original details held until the application is completed (and approved). This includes any previous draft applications you have saved and any other functions such as CFS Orders etc. Please delete any draft applications and re-enter the information after the Edit Organisation Details application is completed (and approved).

3 Organisation details

Name

Enter the name of the organisation you represent

Describe your organisation by selecting up to three options below *

EU Single Registration Number (SRN) (optional)

▼ Address Details

Postcode lookup

[Enter address manually](#)

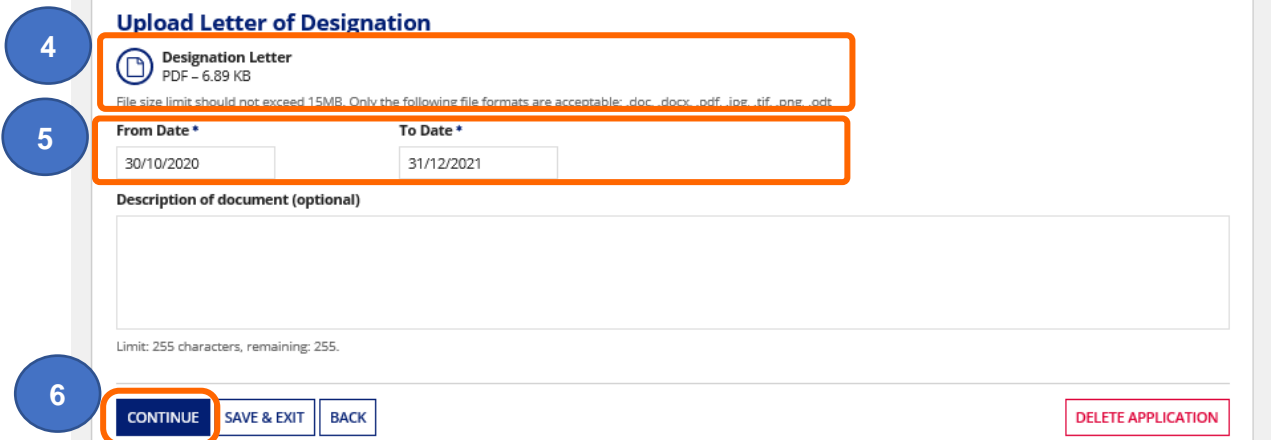
Address line 1

4. **Upload** a new [letter of designation](#) reflecting the changes (if you are a UK responsible Person or Authorised Representative in Northern Ireland and have added represented organisations).

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. **Enter** new [letter of designation](#) validity dates.

Please note that the **Upload** option for the letter of designation will only appear once you make a change to the organisation details.



The screenshot shows a web form titled "Upload Letter of Designation". It includes a file upload section, date selection fields, a description text area, and a navigation bar with buttons for "CONTINUE", "SAVE & EXIT", "BACK", and "DELETE APPLICATION".

4 **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

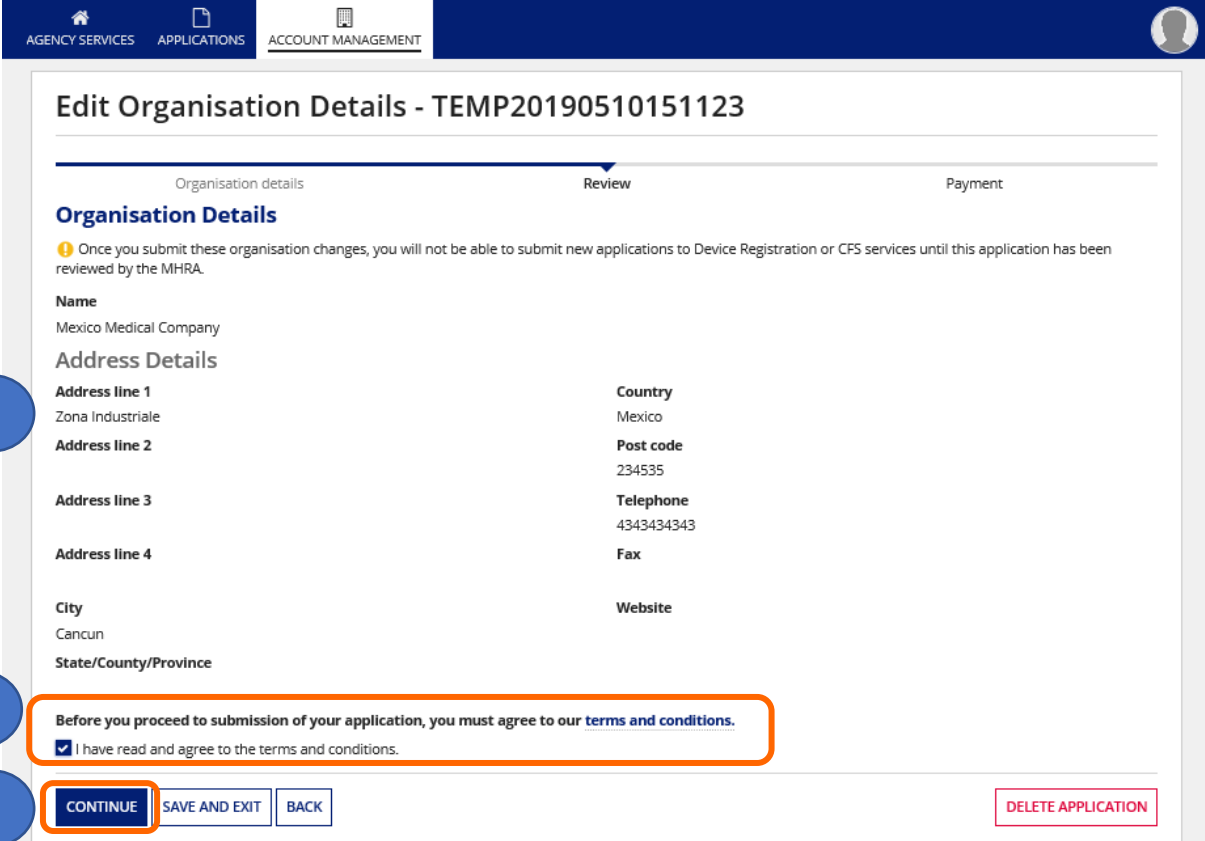
5 **From Date *** **To Date ***
30/10/2020 31/12/2021

Description of document (optional)
Limit: 255 characters, remaining: 255.

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

6. **Click** the [Continue](#) button to proceed to Review and Payment.

7. **Review** changes. Once payment has been made the application is non-refundable.
8. **Read** and **accept** the terms and conditions.
9. **Click** the **Continue** button to progress to Payment (if the change is chargeable) and complete the application. See the **Making Payments** section in the **Device Registration Reference Guide**.



Edit Organisation Details - TEMP20190510151123

Organisation details Review Payment

Organisation Details

⚠ Once you submit these organisation changes, you will not be able to submit new applications to Device Registration or CFS services until this application has been reviewed by the MHRA.

Name
Mexico Medical Company

Address Details

Address line 1 Zona Industriale	Country Mexico
Address line 2	Post code 234535
Address line 3	Telephone 4343434343
Address line 4	Fax
City Cancun	Website
State/County/Province	

8 Before you proceed to submission of your application, you must agree to our [terms and conditions](#).
 I have read and agree to the terms and conditions.

9 **CONTINUE** SAVE AND EXIT BACK **DELETE APPLICATION**

Updating Role from Authorised Representative to UKRP

The role of GB-based Authorised Representative ceased to exist on 01 January 2021.

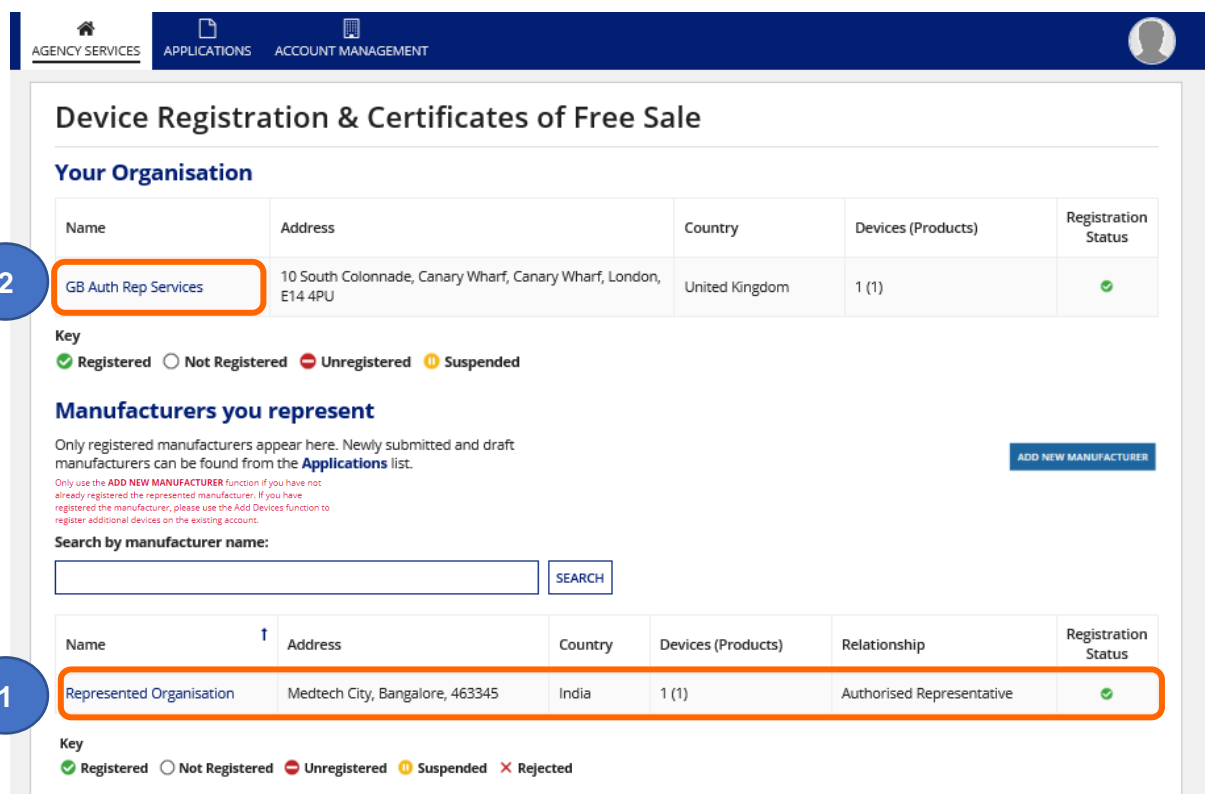
If you previously registered represented manufacturers with MHRA as an Authorised Representative in Great Britain (England, Scotland, Wales) you can update your role to UK Responsible Person and continue to represent all, or some, of the organisations you currently represent. Please take the following action to update your role from Authorised Representative to UK Responsible Person.

Please Note if you are an Authorised Representative in Northern Ireland you can remain as an Authorised Representative.

1. **Check** your list of existing Represented Organisations.

Please note if you will **not** be representing any of these as a UKRP please follow the instructions to [Unregister Manufacturer](#) **before** you update your role from Authorised Representative to UKRP otherwise you will be required to upload a Letter of Designation for the manufacturer and pay the associated [statutory fee](#).

2. Select **Your Organisation** to update your role from Authorised Representative to UK Responsible Person.



Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
GB Auth Rep Services	10 South Colonnade, Canary Wharf, Canary Wharf, London, E14 4PU	United Kingdom	1 (1)	Registered

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. [ADD NEW MANUFACTURER](#)

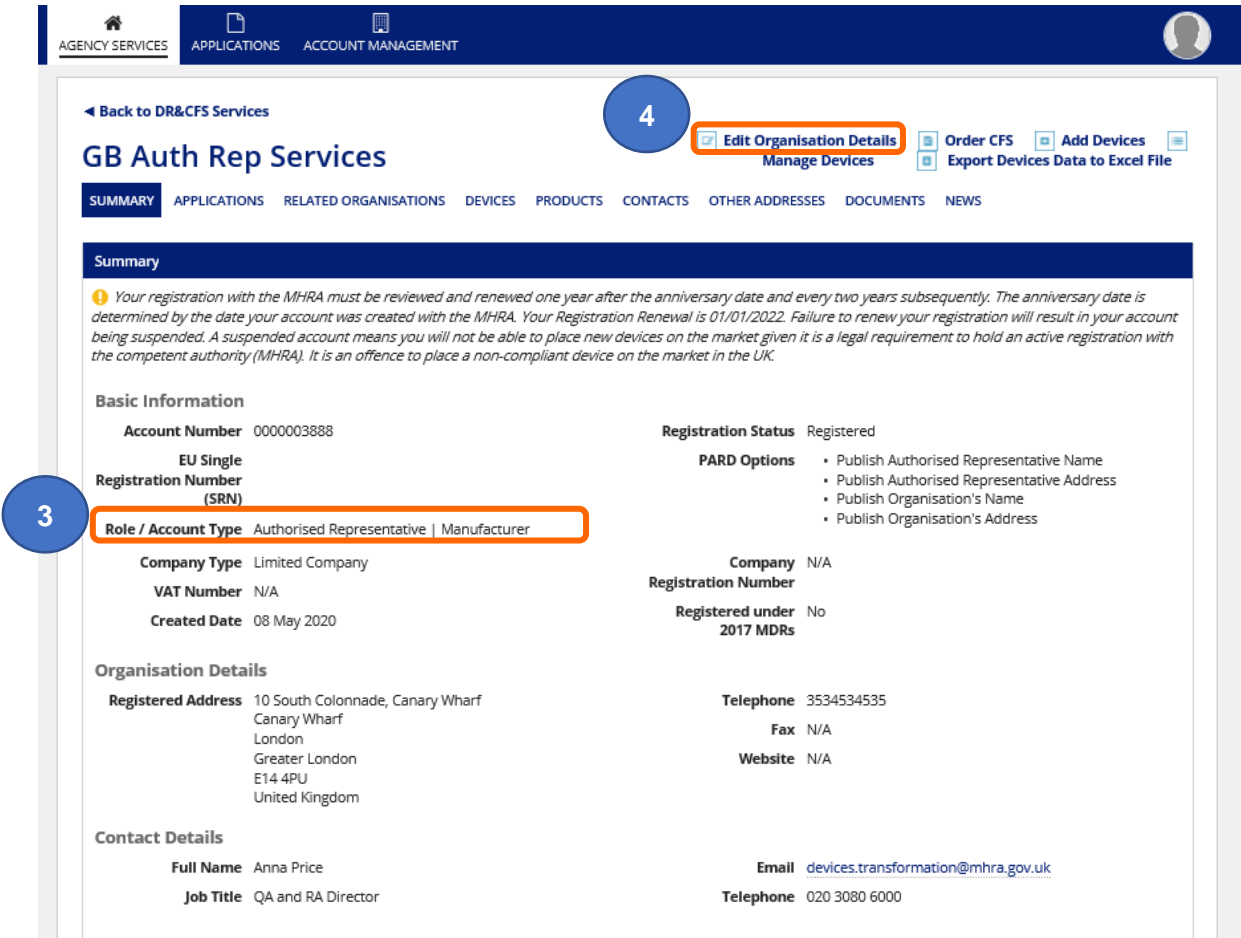
Only use the ADD NEW MANUFACTURER function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to register additional devices on the existing account.

Search by manufacturer name:

Name	Address	Country	Devices (Products)	Relationship	Registration Status
Represented Organisation	Medtech City, Bangalore, 463345	India	1 (1)	Authorised Representative	Registered

Key
 Registered Not Registered Unregistered Suspended Rejected

3. Your organisation currently has dual a role of **Authorised Representative** and **Manufacturer**.
4. Click on the **Edit Organisation Details** link.



[← Back to DR&CFS Services](#)
4

 Edit Organisation Details Manage Devices
 Order CFS
 Add Devices
 Export Devices Data to Excel File

GB Auth Rep Services

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

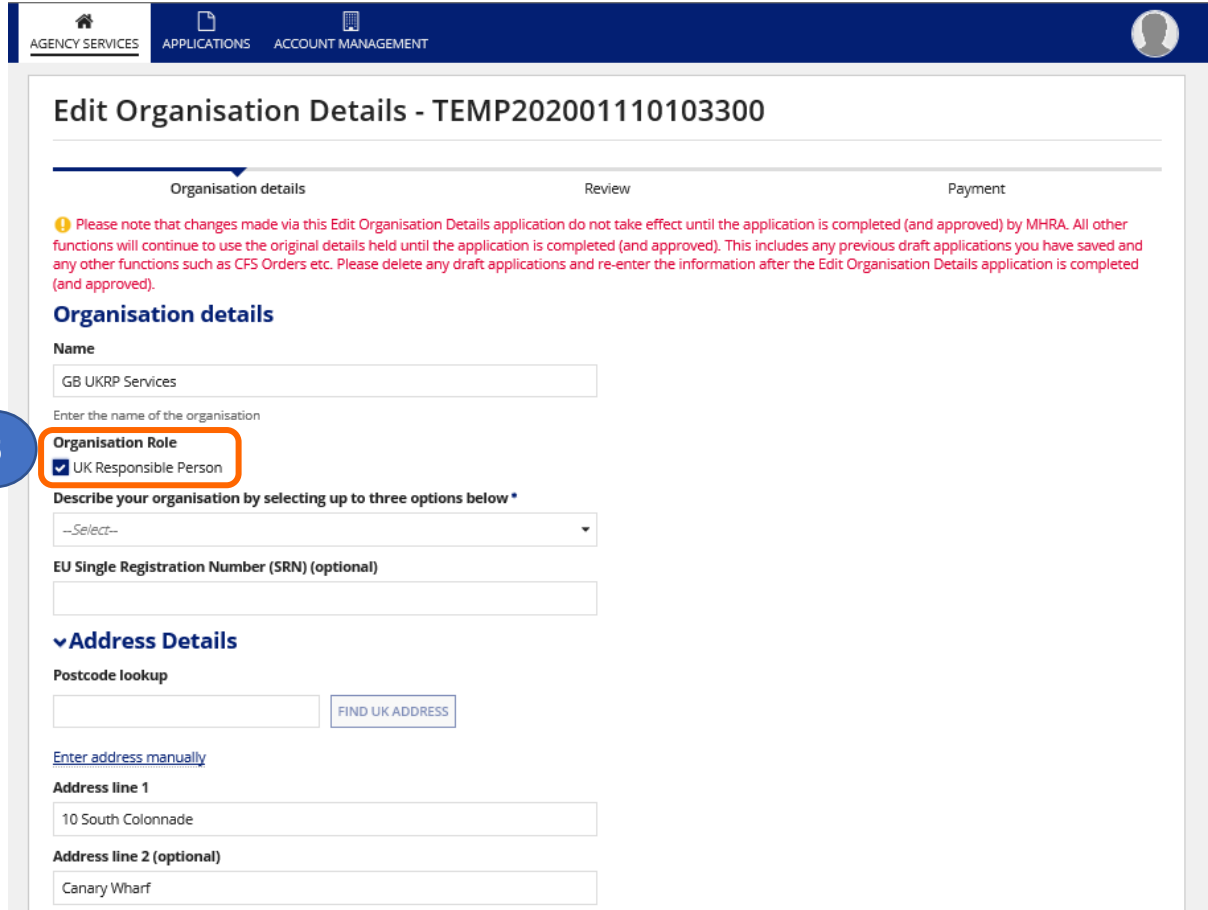
Summary

! 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		Registration Status Registered
Account Number 0000003888		PARD Options
EU Single Registration Number (SRN)		<ul style="list-style-type: none"> • Publish Authorised Representative Name • Publish Authorised Representative Address • Publish Organisation's Name • Publish Organisation's Address
Role / Account Type Authorised Representative Manufacturer		
Company Type Limited Company		Company Registration Number N/A
VAT Number N/A		Registered under 2017 MDRs No
Created Date 08 May 2020		
Organisation Details		Telephone 3534534535
Registered Address 10 South Colonnade, Canary Wharf Canary Wharf London Greater London E14 4PU United Kingdom		Fax N/A
		Website N/A
Contact Details		Email devices.transformation@mhra.gov.uk
Full Name Anna Price		Telephone 020 3080 6000
Job Title QA and RA Director		

5. **Select** Organisation Role **UK Responsible Person**.

Please note if any changes need to be made to organisation details, do them now otherwise you will have to create another application to change the details and pay another [statutory fee](#).



Edit Organisation Details - TEMP202001110103300

Organisation details Review Payment

! Please note that changes made via this Edit Organisation Details application do not take effect until the application is completed (and approved) by MHRA. All other functions will continue to use the original details held until the application is completed (and approved). This includes any previous draft applications you have saved and any other functions such as CFS Orders etc. Please delete any draft applications and re-enter the information after the Edit Organisation Details application is completed (and approved).

Organisation details

Name

Enter the name of the organisation

Organisation Role
 UK Responsible Person

Describe your organisation by selecting up to three options below *

EU Single Registration Number (SRN) (optional)

Address Details

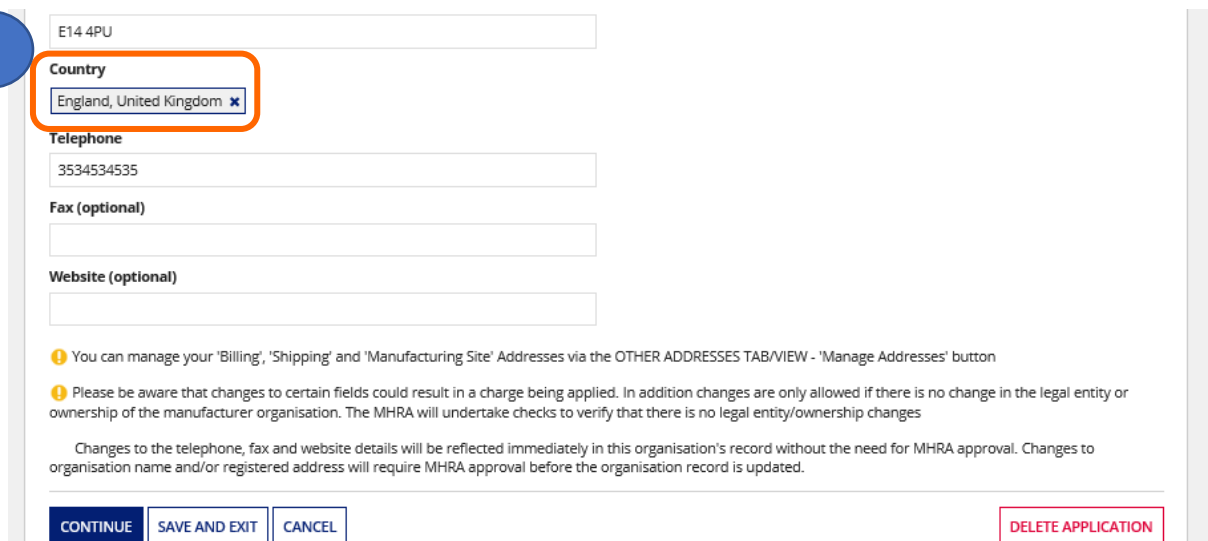
Postcode lookup

[Enter address manually](#)

Address line 1

Address line 2 (optional)

6. You must **select** your Country (England, Scotland, Wales, Northern Ireland).



Country

Telephone

Fax (optional)

Website (optional)

! You can manage your 'Billing', 'Shipping' and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button

! Please be aware that changes to certain fields could result in a charge being applied. In addition changes are only allowed if there is no change in the legal entity or ownership of the manufacturer organisation. The MHRA will undertake checks to verify that there is no legal entity/ownership changes

Changes to the telephone, fax and website details will be reflected immediately in this organisation's record without the need for MHRA approval. Changes to organisation name and/or registered address will require MHRA approval before the organisation record is updated.

7. Click the **Continue** button to go to the Upload Letter of Designation page.

E14 4PU

Country
England, United Kingdom ✕

Telephone
3534534535

Fax (optional)

Website (optional)

ⓘ You can manage your 'Billing', 'Shipping' and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button

ⓘ Please be aware that changes to certain fields could result in a charge being applied. In addition changes are only allowed if there is no change in the legal entity or ownership of the manufacturer organisation. The MHRA will undertake checks to verify that there is no legal entity/ownership changes

Changes to the telephone, fax and website details will be reflected immediately in this organisation's record without the need for MHRA approval. Changes to organisation name and/or registered address will require MHRA approval before the organisation record is updated.

7

CONTINUE

SAVE AND EXIT

CANCEL

DELETE APPLICATION

8. Upload a new letter of Designation for each manufacturer that you represent as a UKRP.

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](#).

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT

Edit Organisation Details - TEMP202001110103300

Organisation details
Review
Payment

ⓘ Please note that changes made via this Edit Organisation Details application do not take effect until the application is completed (and approved) by MHRA. All other functions will continue to use the original details held until the application is completed (and approved). This includes any previous draft applications you have saved and any other functions such as CFS Orders etc. Please delete any draft applications and re-enter the information after the Edit Organisation Details application is completed (and approved).

Upload Letter of designation

ⓘ This change will require you to update the documentation for the Manufacturers you represent

Manufacturer Name	Document Type	Upload Document	From Date	To Date
Represented Organisation	Letter Of Designation	<div style="border: 1px dashed #ccc; padding: 5px; display: inline-block;"> UPLOAD Drop file here </div>	dd/mm/yyyy	dd/mm/yyyy

8

CONTINUE

SAVE AND EXIT

BACK

DELETE APPLICATION

9. Click the **Continue** button to be taken to the **review** page.

10. Review the details, read our Terms and Conditions and tick the I have read and agree to the terms and conditions box.

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT
[User Profile Icon]

Organisation Details

! Once you submit these organisation changes, you will not be able to submit new applications to Device Registration or CFS services until this application has been reviewed by the MHRA.

Name
GB UKRP Services

EU Single Registration Number (SRN)

Address Details

Address line 1 10 South Colonnade	Country England, United Kingdom
Address line 2 Canary Wharf	Post code E14 4PU
Address line 3	Telephone 3534534535
Address line 4 Canary Wharf	Fax
City London	Website
State/County/Province Greater London	

Represented Organisation Documents

The below are the documents uploaded for all represented organisations

Manufacturer Name	Document	Document Type	From Date	To Date
Represented Organisation	Designation Letter	Letter Of Designation	10/11/2020	31/01/2022

Before you proceed to submission of your application, you must agree to our [terms and conditions](#).

I have read and agree to the terms and conditions.

CONTINUE
SAVE AND EXIT
BACK
DELETE APPLICATION

11. Click the Continue button to be taken to the payment page. The statutory fee will be payable for Your Organisation and each represented manufacturer. See the Making Payments section in the Device Registration Reference Guide.

12. Your role will be updated to UKRP and your association with your represented organisations will be UK Responsible Person.

Manufacturers you represent

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

ADD NEW MANUFACTURER
ADD NEW IMPORTER

Search by manufacturer name:

 SEARCH

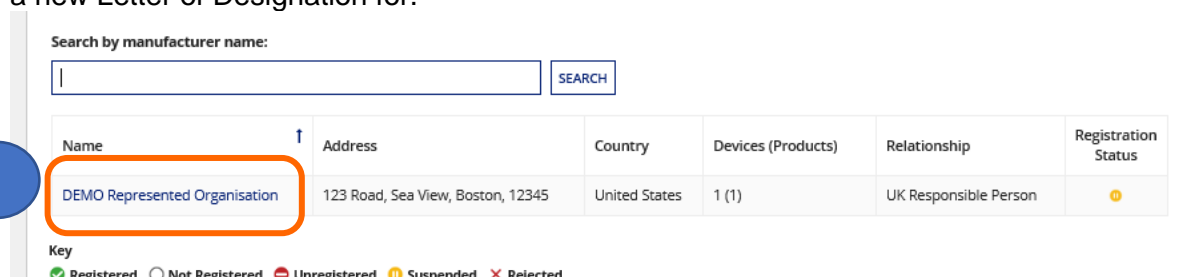
Name	Address	Country	Devices (Products)	Relationship	Registration Status
DEMO Represented Organisation	123 Road, Sea View, Boston, 12345	United States	1 (1)	UK Responsible Person	✔
Represented Organisation	Medtech City, Bangalore, 463354	India	1 (1)	UK Responsible Person	✔

Key
✔ Registered
 ○ Not Registered
 ⊖ Unregistered
 ⏸ Suspended

Uploading new Letter of Designation

You must always have a valid [Letter of Designation](#) uploaded for each [manufacturer](#) that you represent as a UK Responsible Person or Authorised Representative (in Northern Ireland). 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 new 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 market in the UK.** Your details will also be removed from the [Public Access Registration Database \(PARC\)](#).

1. From the [Agency Services](#) tab [click](#) on the name of the organisation you want to upload a new Letter of Designation for.



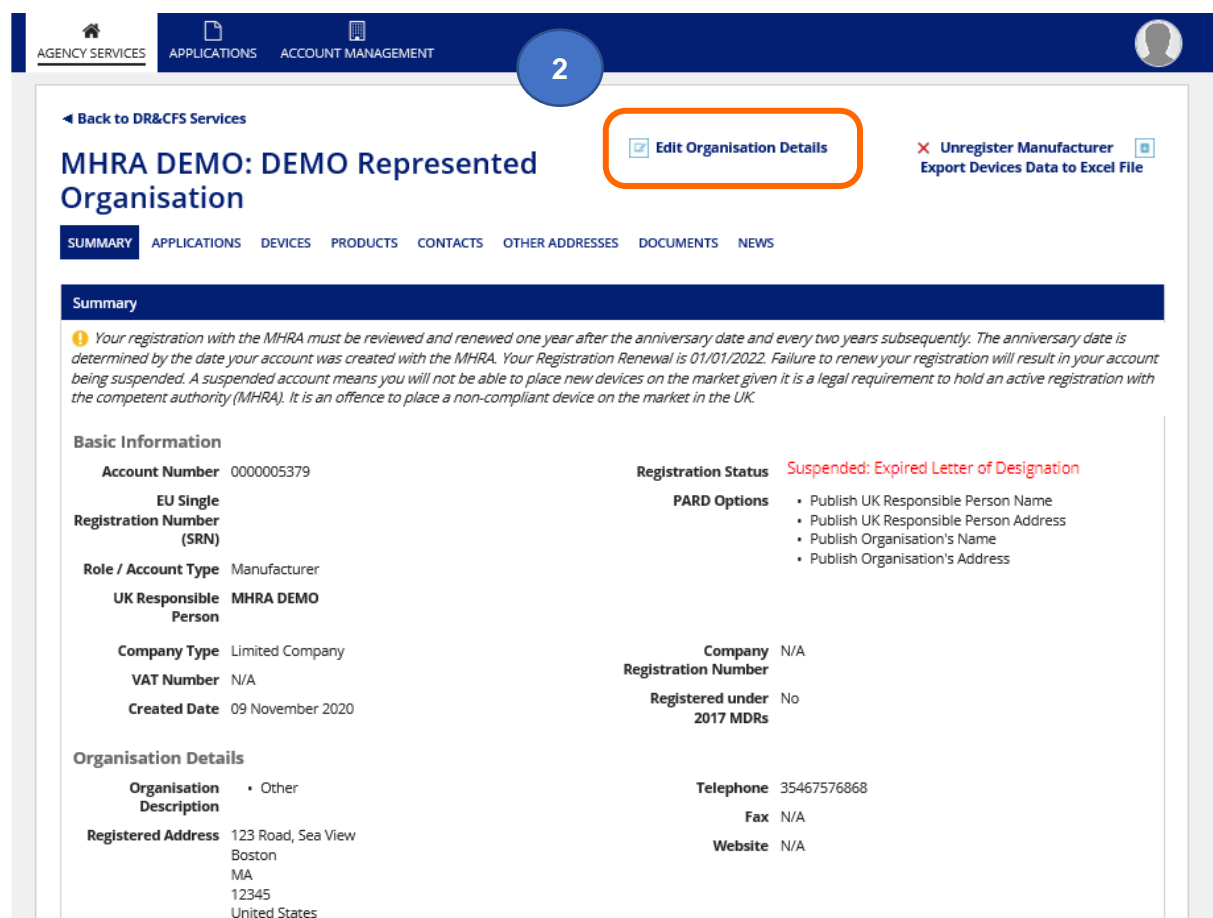
Search by manufacturer name:

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

Key

Registered
 Not Registered
 Unregistered
 Suspended
 Rejected

2. [Review](#) the organisation details and [click](#) on the [Edit Organisation](#) Details link.



[Back to DR&CFS Services](#)

 [Edit Organisation Details](#)

 [Unregister Manufacturer](#)

MHRA DEMO: DEMO Represented Organisation

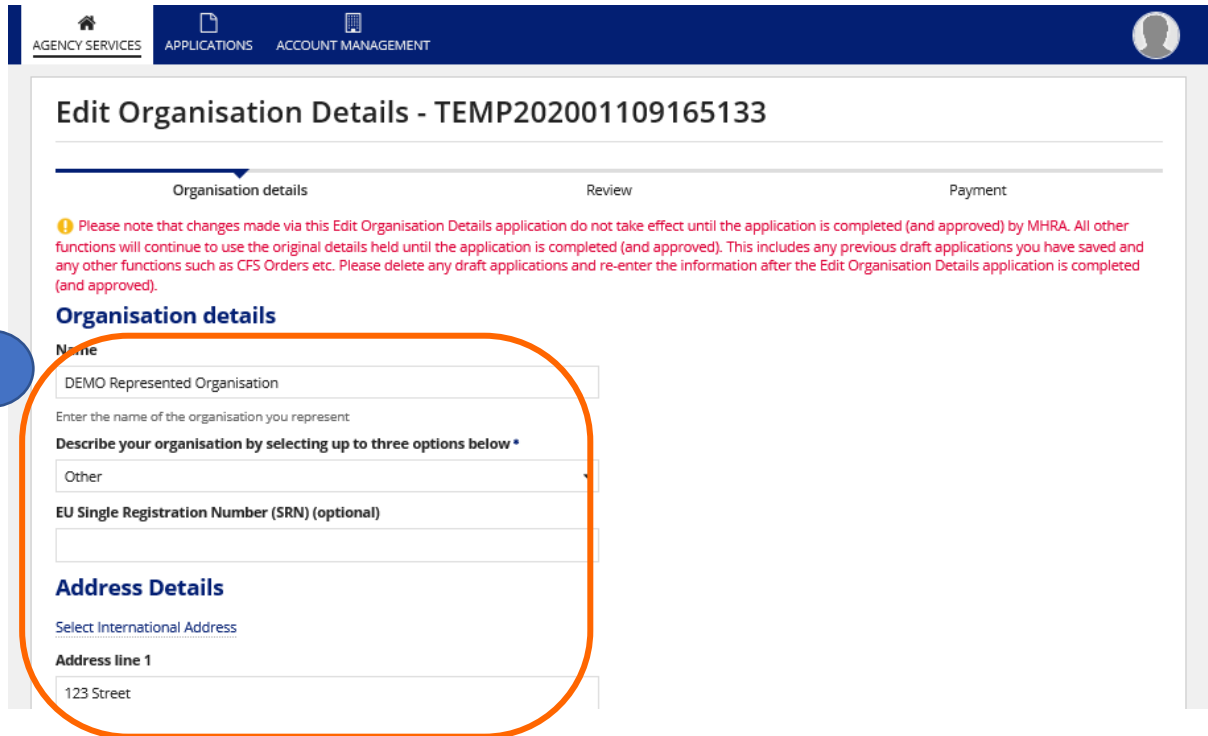
[SUMMARY](#)
[APPLICATIONS](#)
[DEVICES](#)
[PRODUCTS](#)
[CONTACTS](#)
[OTHER ADDRESSES](#)
[DOCUMENTS](#)
[NEWS](#)

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 0000005379 EU Single Registration Number (SRN) Role / Account Type Manufacturer UK Responsible Person MHRA DEMO Company Type Limited Company VAT Number N/A Created Date 09 November 2020	Registration Status Suspended: Expired Letter of Designation 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
Organisation Details Organisation Description Other Registered Address 123 Road, Sea View Boston MA 12345 United States	Company N/A Registration Number Registered under 2017 MDRs No Telephone 35467576868 Fax N/A Website N/A

3. If any changes need to be made to organisation details, do them now otherwise you will have to create another application to change the details and pay another [statutory fee](#).



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

Edit Organisation Details - TEMP202001109165133

Organisation details Review Payment

⚠ Please note that changes made via this Edit Organisation Details application do not take effect until the application is completed (and approved) by MHRA. All other functions will continue to use the original details held until the application is completed (and approved). This includes any previous draft applications you have saved and any other functions such as CFS Orders etc. Please delete any draft applications and re-enter the information after the Edit Organisation Details application is completed (and approved).

Organisation details

Name

DEMO Represented Organisation

Enter the name of the organisation you represent

Describe your organisation by selecting up to three options below *

Other

EU Single Registration Number (SRN) (optional)

Address Details

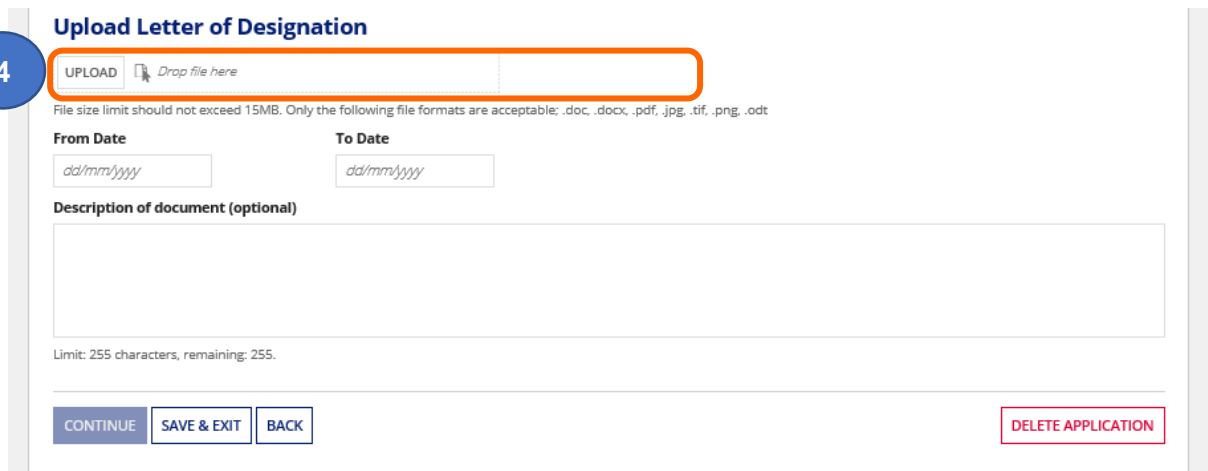
Select International Address

Address line 1

123 Street

4. Upload the new [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](#).



Upload Letter of Designation

4

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

dd/mm/yyyy dd/mm/yyyy


Description of document (optional)

Limit: 255 characters, remaining: 255.

CONTINUE SAVE & EXIT BACK DELETE APPLICATION

5. Enter the new Letter of Designation validity dates. The maximum validity is 5 years.

Upload Letter of Designation
This is an official letter on headed paper, from the manufacturer stating your company's name and address, and that you as an UK responsible person of a non-EU manufacturer are acting with the consent of the manufacturer.


 **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

5 **From Date *** **To Date ***

Description of document (optional)

Limit: 255 characters, remaining: 255.

 You can manage your 'Billing', 'Shipping' and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button


 Please be aware that changes to certain fields could result in a charge being applied. In addition changes are only allowed if there is no change in the legal entity or ownership of the manufacturer organisation. The MHRA will undertake checks to verify that there is no legal entity/ownership changes

Changes to the telephone, fax and website details will be reflected immediately in this organisation's record without the need for MHRA approval. Changes to organisation name and/or registered address will require MHRA approval before the organisation record is updated.

6 **CONTINUE** **SAVE AND EXIT** **CANCEL** **DELETE APPLICATION**

6. Click the Continue button to go to the Review page. Check the details and either click Back or Delete Application if something is not correct.

Organisation Details

 Once you submit these organisation changes, you will not be able to submit new applications to Device Registration or CFS services until this application has been reviewed by the MHRA.

Name
DEMO Represented Organisation

EU Single Registration Number (SRN)

Address Details

Address line 1 123 Road	Country United States
Address line 2 Sea View	Post code 12345
Address line 3	Telephone 35467576868
Address line 4	Fax
City Boston	Website
State/County/Province MA	

Represented Organisation Documents

The below document is uploaded for represented organisation

Document	Document Type	From Date	To Date
Designation Letter	Letter Of Designation	09/11/2020	31/12/2021

Before you proceed to submission of your application, you must agree to our [terms and conditions](#).

I have read and agree to the terms and conditions.

7 **CONTINUE** **SAVE AND EXIT** **BACK** **DELETE APPLICATION**

7. Read our terms and conditions and click the Continue button to go to the payment page. The [statutory fee](#) is payable per new letter. See the [Making Payments](#) section in the [Device Registration Reference Guide](#).

Renew Registration

You should review your registration and the registrations of any represented manufactures frequently to make sure they up to date. It is a legal requirement to inform MHRA of any changes to your registrations per section 7A (general medical devices), section 33A (in vitro diagnostic medical devices) and section 21A (active implantable medical devices) of the Medical Devices Regulations (2002) SI 618 (as amended) concerning registration of persons placing medical devices on the market, as and when they occur. Please do not wait for reminder emails. **It is an offence to place a non-compliant device on the market in the UK.**

We have implemented the [Renew registration](#) process as a reminder to review your registrations and confirm they are up to date. The first reminder date is 1 year after the account request was completed by MHRA, and then at least every 2 years. For accounts that were created before 01 January 2021 the first review and renew reminder dates were set to between 01 January 2022 and 30 June 2022. You will receive automated email reminders 3, 2 and 1 month before your renewal date – you can review and submit the [Renew registration](#) application from 3 months before the renewal date. Your anniversary date will remain the same. There is currently no fee for this application.

Please review organisation details and all registered devices and products to ensure the data is correct and up to date. Follow the **Manage Registered Devices** instructions in the [Device Registration Reference Guide](#) and watch the [video tutorial](#) for steps on how to review your devices and take any necessary action. This includes uploading new Conformity documents, adding or removing products, adding devices, or removing devices (that you no longer manufacture, or migrated devices with Pseudo Global Medical Device Nomenclature (GMDN®), where applicable).

If new devices need to be added to your registration/s this is a separate transaction that incurs the current [statutory fee](#) per application. Please see the **Device Registration Reference Guide**.

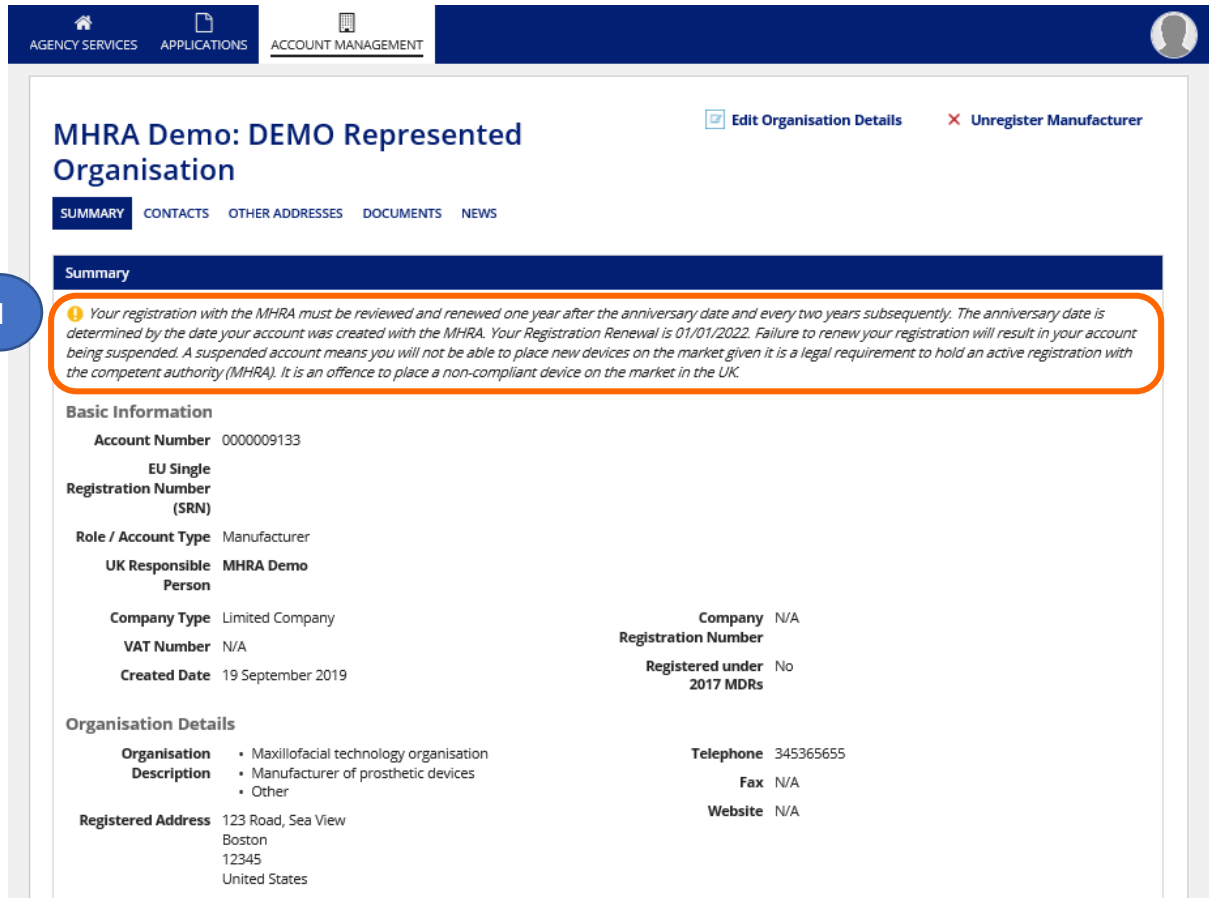
Please note if organisation name and/or address has changed you must update these before renewing your registration, you cannot do this within the Renew registration application. Follow the instructions for [Editing Organisation details](#), the [statutory fee](#) is payable.

Please update any data fields that were not previously populated using the **Update registered devices and products** functionality. In particular we urge you to provide the UDI-DIs for your devices (where applicable) as these will be crucial for monitoring and ensuring patient safety. Please see the **Device Registration Reference Guide**.

If you are a UK Responsible Person (UKRP) or an Authorised Representative (in Northern Ireland) it is your responsibility to review and renew registration for each organisation that you represent. Your represented organisation's renewal dates may be different to your own.

If you do not review your registrations and submit the Renew registration application your account will be [suspended](#) and the accounts of any organisations that you represent will be [suspended](#), even if their renewal dates are different. Suspended accounts are removed from the [Public Access Registration Database \(PARD\)](#) and you will not be able to add new devices or order Certificates of Free Sale until you have reviewed your registrations and completed the [Renew registration](#) process for your account and your represented manufacturers. Please also watch the Renew Registration [video tutorial](#).

1. Check the [renewal date](#) on the [Summary](#) page. This may be different for your organisation and any manufacturers that you represent.



MHRA Demo: DEMO Represented Organisation

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

[Edit Organisation Details](#) [Unregister Manufacturer](#)

SUMMARY CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Summary

1 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.

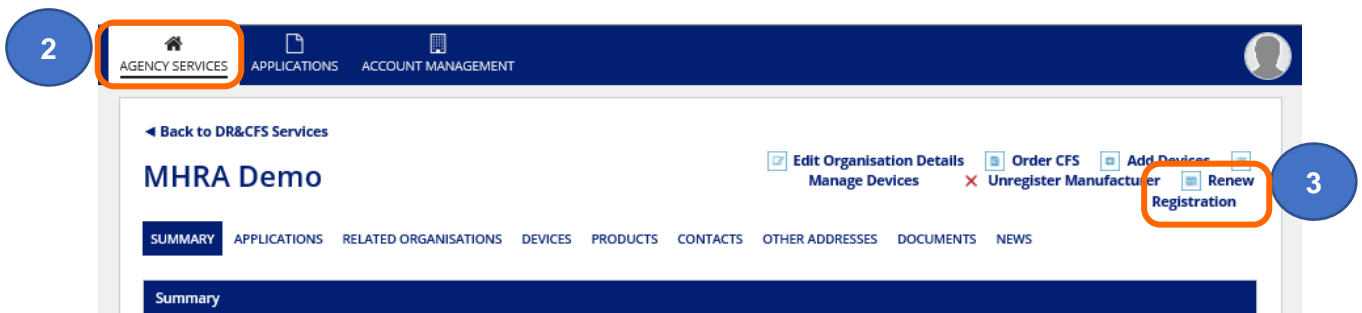
Basic Information

Account Number	0000009133	Company	N/A
EU Single Registration Number (SRN)		Registration Number	
Role / Account Type	Manufacturer	Registered under 2017 MDRs	No
UK Responsible Person	MHRA Demo Person		
Company Type	Limited Company		
VAT Number	N/A		
Created Date	19 September 2019		

Organisation Details

Organisation Description	<ul style="list-style-type: none"> • Maxillofacial technology organisation • Manufacturer of prosthetic devices • Other 	Telephone	345365655
Registered Address	123 Road, Sea View Boston 12345 United States	Fax	N/A
		Website	N/A

2. To Renew Registration you must access the [Summary](#) page of the organisation via the [Agency Services](#) tab – **not** the Account Management tab.
3. Three months before renewal date the [Renew Registration](#) option will appear on the [Summary](#) page. You must renew your registration **before** the Registration renewal date otherwise your account will be [suspended](#). [Click](#) on the [Renew Registration](#) link.



MHRA Demo

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

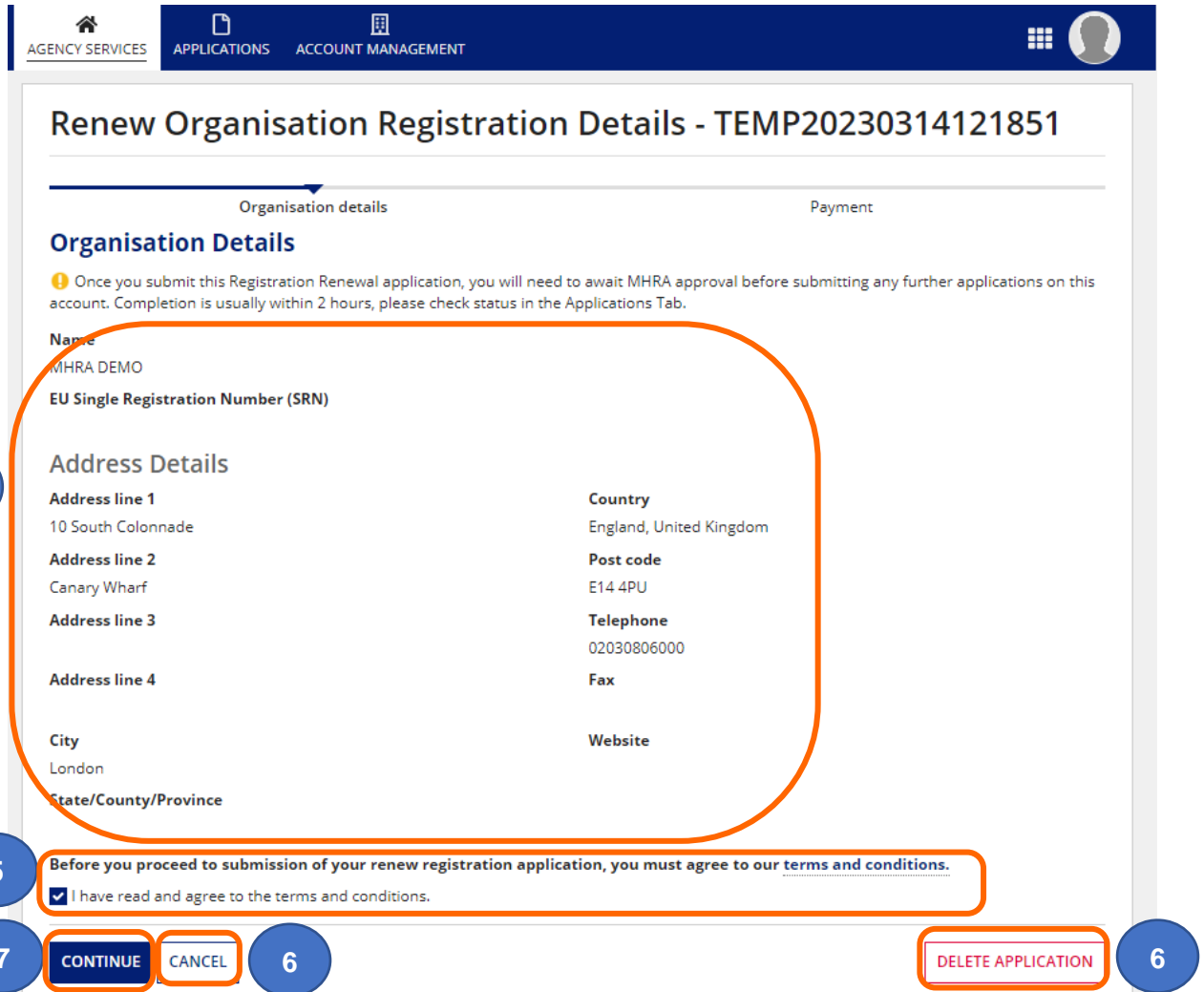
[Back to DR&CFS Services](#) [Edit Organisation Details](#) [Order CFS](#) [Add Devices](#) [Manage Devices](#) [Unregister Manufacturer](#) **Renew Registration**

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

Summary

2 **3**

4. **Check** organisation details.
5. If they are correct, read the terms and conditions and **tick** that you have read these.
6. If the organisation details are **not** correct **Click** the **Cancel** button or the **Delete application** button and follow the instructions for [Editing Organisation details](#), then Renew Registration.



Renew Organisation Registration Details - TEMP20230314121851

Organisation details | Payment

Organisation Details

⚠ Once you submit this Registration Renewal application, you will need to await MHRA approval before submitting any further applications on this account. Completion is usually within 2 hours, please check status in the Applications Tab.

Name
MHRA DEMO

EU Single Registration Number (SRN)

Address Details

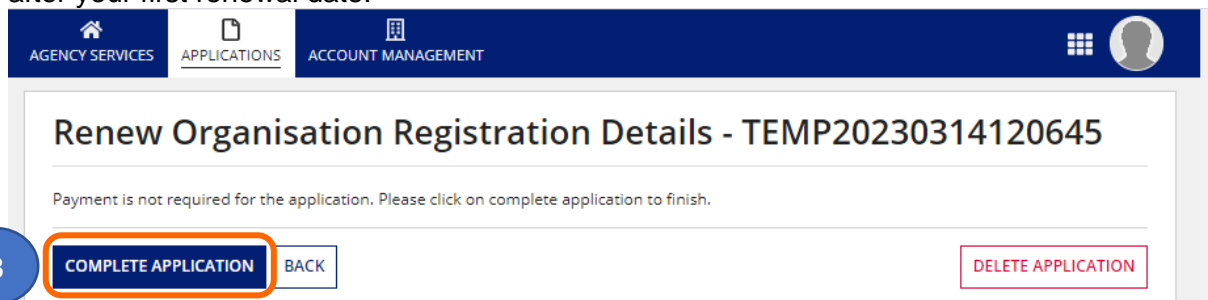
Address line 1 10 South Colonnade	Country England, United Kingdom
Address line 2 Canary Wharf	Post code E14 4PU
Address line 3	Telephone 02030806000
Address line 4	Fax
City London	Website
State/County/Province	

Before you proceed to submission of your renew registration application, you must agree to our [terms and conditions](#).

I have read and agree to the terms and conditions.

CONTINUE **CANCEL** **DELETE APPLICATION**

7. If details are correct, **Click** the **Continue** button to proceed.
8. There is currently no fee to submit the Renew registration application. **Click** the **Complete Application** button to submit. Your next renewal date will be set to two years after your first renewal date.



Renew Organisation Registration Details - TEMP20230314120645

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

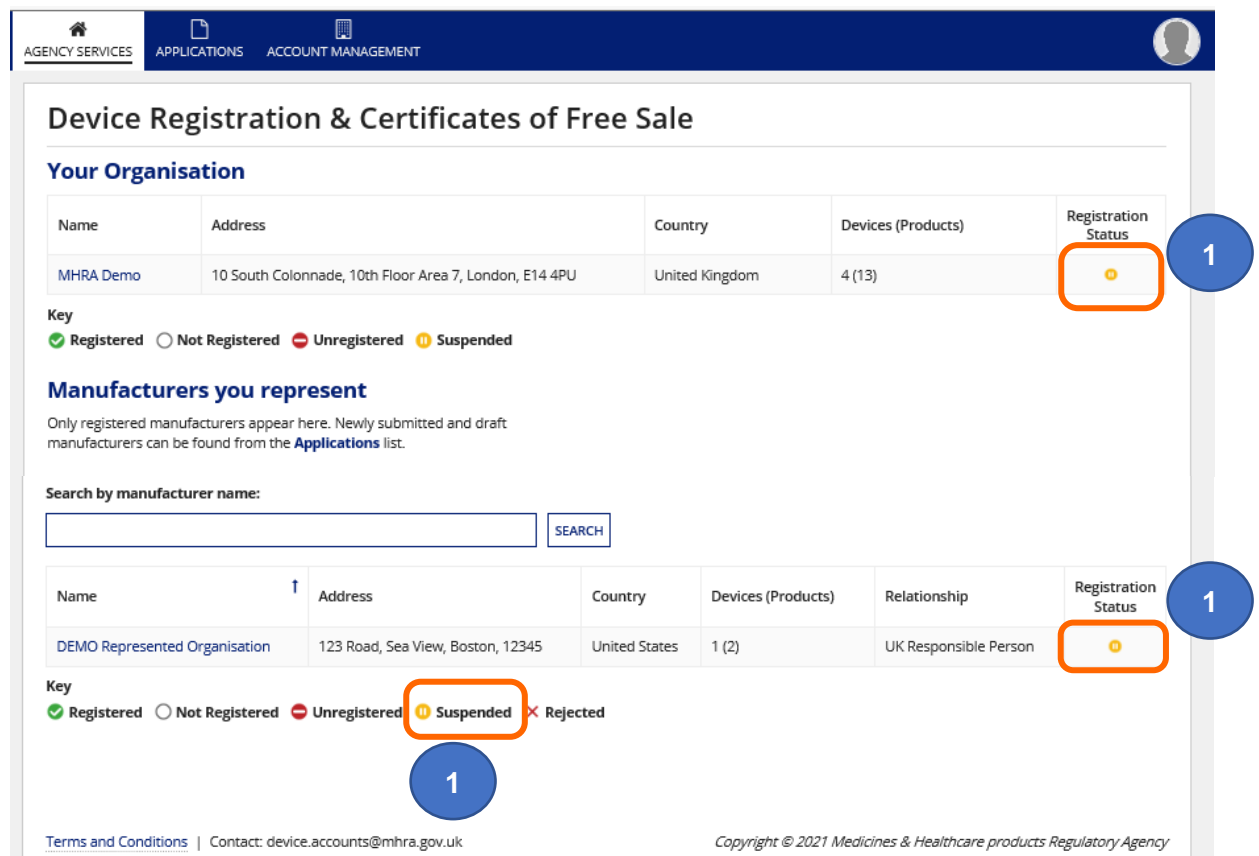
COMPLETE APPLICATION **BACK** **DELETE APPLICATION**

Account Suspension

1. If you do not [renew](#) your registration **before** the [renewal date](#) or upload a new [Letter of Designation](#) **before** the existing one expires, your account will be [suspended](#). If you are a UK Responsible Person or an Authorised Representative (in Northern Ireland) **the accounts of all your represented organisations will also be suspended**. Suspended accounts will be removed from the [Public Access Registration Database \(PARD\)](#).

You will receive reminder emails at 3 months, 2 months and 1 month before suspension of an account. Please ensure that you act on these to avoid unnecessary suspension of your account and removal of your registration from the [Public Access Registration Database \(PARD\)](#).

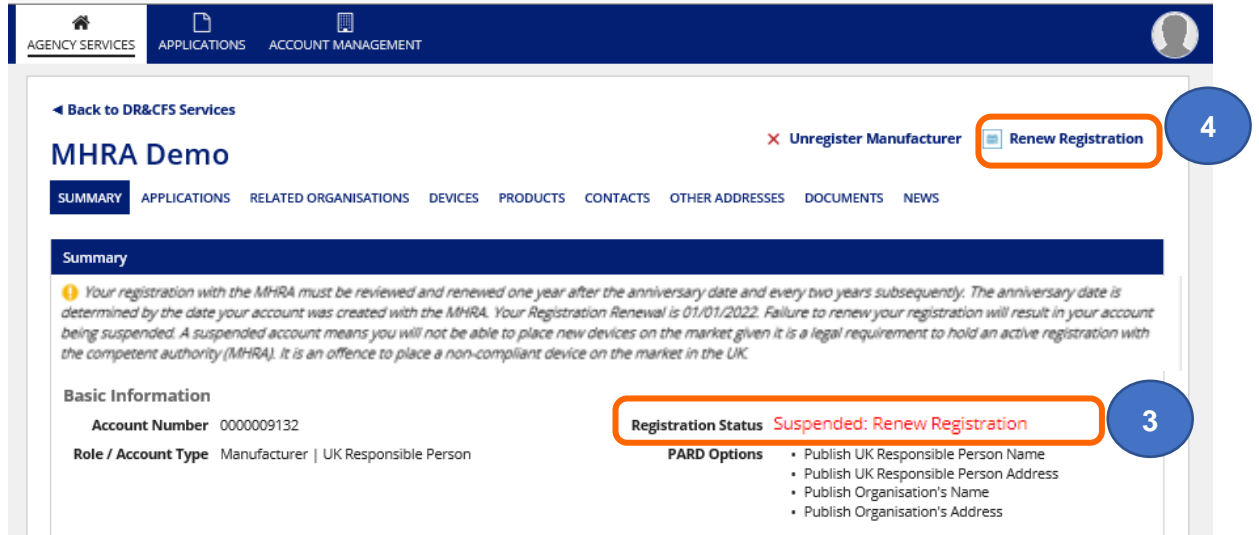
Please note if the [Renew Registration](#) and [Letter of Designation](#) renewal dates are on the **same date** for a manufacturer you represent, you must first update the Letter of Designation – see [Uploading new Letter of Designation](#). The day after your new Letter of Designation application has been reviewed by MHRA and been completed, you will see a status of Registered for the manufacturer. The day after that, the account will be suspended again due to Renew Registration, unless you have already renewed the registration.



The screenshot displays the 'Device Registration & Certificates of Free Sale' page. It features two main sections: 'Your Organisation' and 'Manufacturers you represent'. Both sections include a table listing registered entities. In the 'Your Organisation' table, the 'MHRA Demo' entry has a 'Registration Status' of 'Suspended', indicated by a yellow circle with a dot. In the 'Manufacturers you represent' table, the 'DEMO Represented Organisation' entry also has a 'Registration Status' of 'Suspended'. A key below the second table defines the status icons: a green circle with a checkmark for 'Registered', a grey circle with a slash for 'Not Registered', a red circle with a slash for 'Unregistered', a yellow circle with a dot for 'Suspended', and a red circle with an 'X' for 'Rejected'. The 'Suspended' status is highlighted with an orange box and a blue circle containing the number '1' in both tables. The page footer includes 'Terms and Conditions | Contact: device.accounts@mhra.gov.uk' and 'Copyright © 2021 Medicines & Healthcare products Regulatory Agency'.

2. If an account is suspended, you will only be able to [Renew registration](#), [upload a new Letter of Designation](#) or [unregister](#) your organisation or the manufacturers that you represent. **You will no longer be able to place new devices on the market** and your registration will be removed from the [Public Access Registration Database \(PARD\)](#).

3. Check the [reason for suspension](#) on the Summary page of the relevant organisation.
4. Follow the [Unload new Letter of Designation](#) and/or [Renew Registration](#) instructions to reinstate your account/s.



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

← Back to DR&CFS Services

MHRA Demo Unregister Manufacturer Renew Registration **4**

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

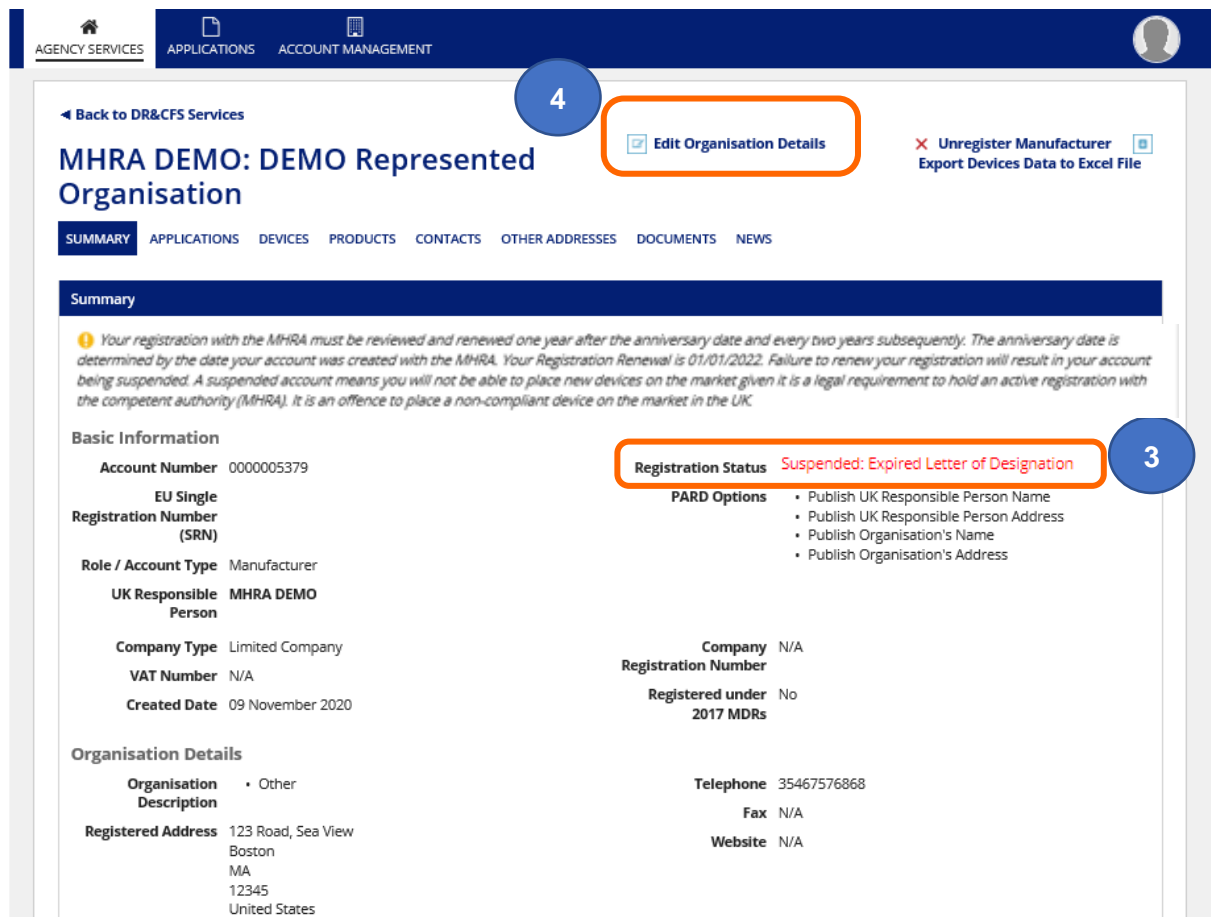
Account Number 0000009132

Role / Account Type Manufacturer | UK Responsible Person

Registration Status **Suspended: Renew Registration** **3**

PARD Options

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



AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT

← Back to DR&CFS Services

MHRA DEMO: DEMO Represented Organisation Edit Organisation Details Unregister Manufacturer Export Devices Data to Excel File **4**

SUMMARY APPLICATIONS 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 0000005379

EU Single Registration Number (SRN)

Role / Account Type Manufacturer

UK Responsible Person MHRA DEMO

Company Type Limited Company

VAT Number N/A

Created Date 09 November 2020

Registration Status **Suspended: Expired Letter of Designation** **3**

PARD Options

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

Company N/A

Registration Number

Registered under 2017 MDRs No

Organisation Details

Organisation Description • Other

Registered Address 123 Road, Sea View
Boston
MA
12345
United States

Telephone 35467576868

Fax N/A

Website N/A

Making payment for changes to organisation details

See the [Making Payments](#) section in the [Device Registration Reference Guide](#).

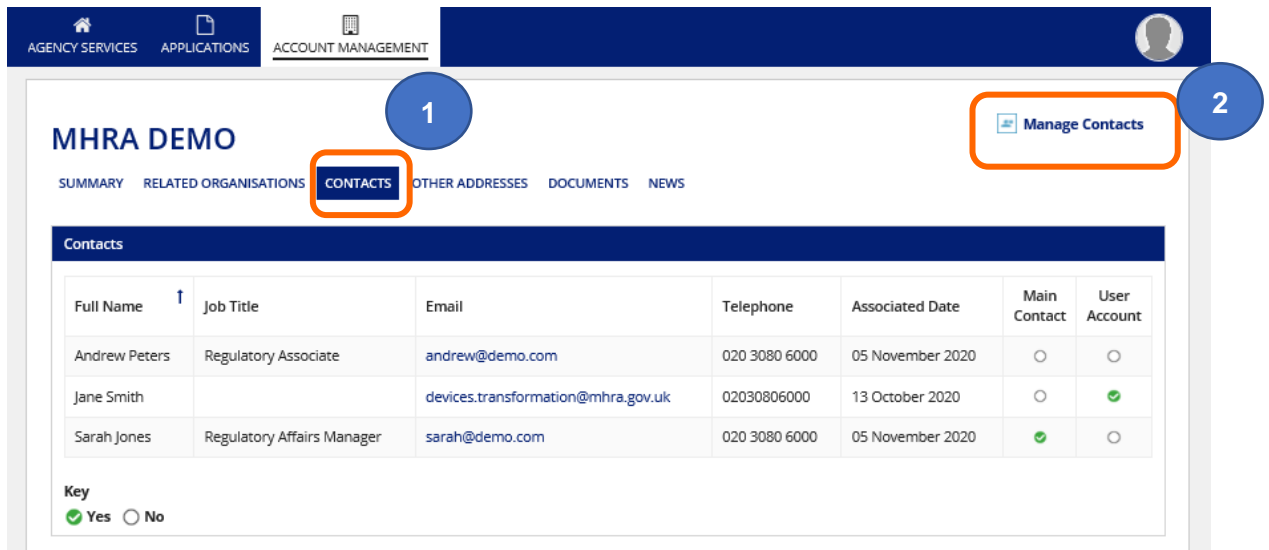
Adding contacts and users

Each [organisation](#) has a **separate** contact list. There must always be at least one main contact.

From the [Organisation page](#), **select** the [organisation](#) you would like to add a contact or user to.

Please note that [users](#) can only be added to [Your Organisation](#).

1. **Click** the [Contacts](#) tab.
2. **Click** the [Manage Contacts](#) button.

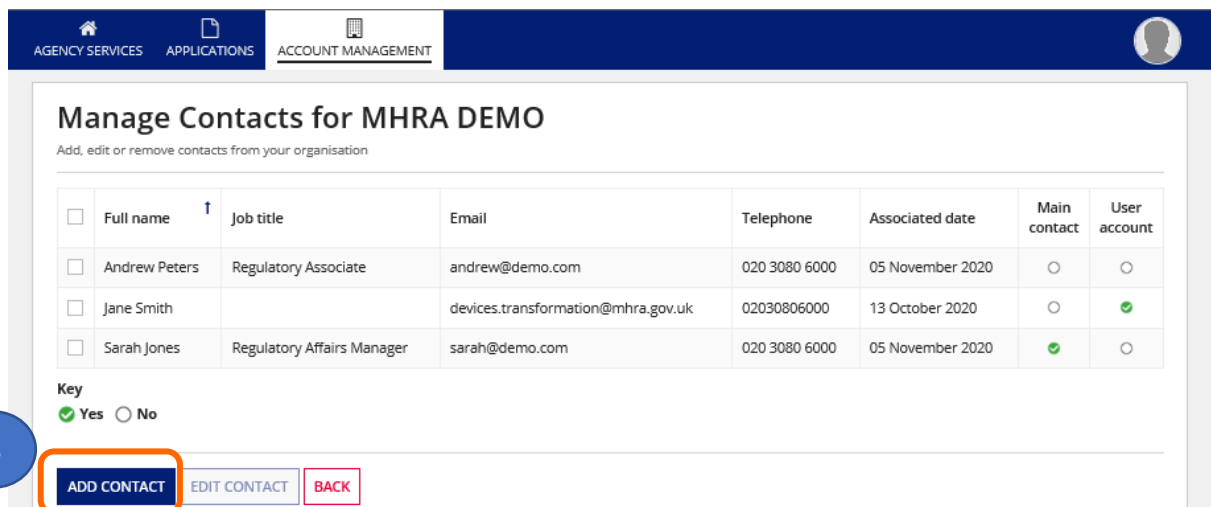


The screenshot shows the 'ACCOUNT MANAGEMENT' section of the MHRA DEMO interface. The 'CONTACTS' tab is selected and highlighted with a blue circle labeled '1'. The 'Manage Contacts' button is highlighted with an orange box and a blue circle labeled '2'. Below the tabs is a table of contacts with columns for Full Name, Job Title, Email, Telephone, Associated Date, Main Contact, and User Account. A key indicates that a green checkmark means 'Yes' and an empty circle means 'No'.

Full Name	Job Title	Email	Telephone	Associated Date	Main Contact	User Account
Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	<input type="radio"/>	<input type="radio"/>
Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	<input type="radio"/>	<input checked="" type="radio"/>
Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	<input checked="" type="radio"/>	<input type="radio"/>

Key
 Yes No

3. **Click** the [Add Contact](#) button.



The screenshot shows the 'Manage Contacts for MHRA DEMO' page. The 'ADD CONTACT' button is highlighted with an orange box and a blue circle labeled '3'. The page includes a table of contacts with checkboxes in the first column. A key indicates that a green checkmark means 'Yes' and an empty circle means 'No'.

<input type="checkbox"/>	Full name	Job title	Email	Telephone	Associated date	Main contact	User account
<input type="checkbox"/>	Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/>	Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	<input type="radio"/>	<input checked="" type="radio"/>
<input type="checkbox"/>	Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	<input checked="" type="radio"/>	<input type="radio"/>

Key
 Yes No

ADD CONTACT EDIT CONTACT BACK

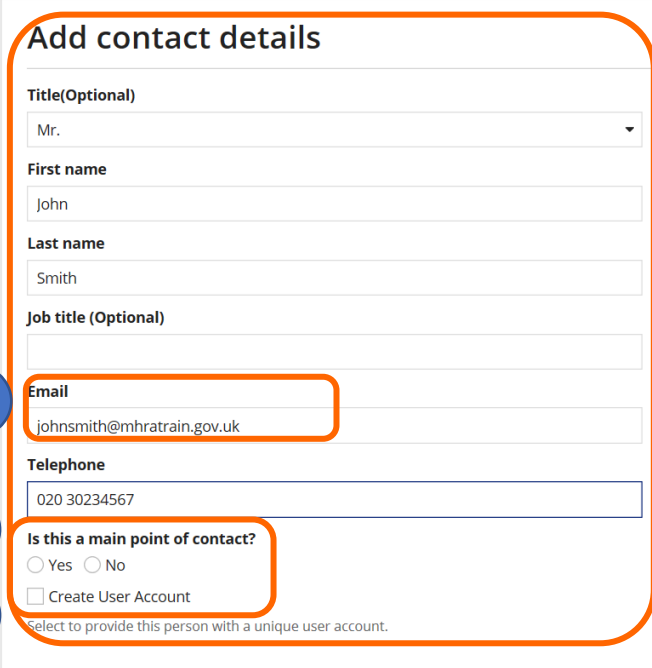
Please note:

- There must always be a **Main Contact** in the **Contacts list**. The **Main Contact** does not have to have a **User Account** but must have a valid email address so that MHRA can email with important information, if necessary.
 - You can create user accounts for other colleagues who need to access your organisation account/s. Please be aware that **all users** will be able to see and make changes to **all data** held in the account/s. There is no read-only access and it is not possible to limit access to specific areas of the system. It is your responsibility to manage internal user access.
 - There is no limit to the number of **contacts** which may be added.
 - A maximum of 15 **users** can be added to the main organisation account.
 - User accounts cannot be created for **Represented Organisations** or **Importers**.
4. Enter contact details – ensure a valid email address which the new contact has access to is entered.
 5. **Select** the appropriate **Is this a main point of contact?** answer.

Please note you must have one **main contact**, there is no limit to the number of other contacts.

6. **Tick** the ‘**create user account**’ checkbox if appropriate. A username will automatically be created – usually **firstname.lastname** – please do **not** change this.
7. **Click** on the **Save** button.

Please note once you confirm and save the user, an email will be sent to the email address of the new user inviting them to complete the user account setup process. Once the new user completes the setup process, they will be able to access the MHRA Agency account for your organisation.



Add contact details

Title(Optional)
Mr. ▼

First name
John

Last name
Smith

Job title (Optional)

4 **Email**
johnsmith@mhratrain.gov.uk

Telephone
020 30234567

5 **Is this a main point of contact?**
 Yes No

6 **Create User Account**
Select to provide this person with a unique user account.

7 **SAVE** CANCEL

8. A confirmation dialogue box will appear, **click Yes** or **No** as appropriate.

Are you sure want to add this contact ?

NO

YES

The new contact with a user account will be added to the list of contacts.

They will receive an email with their user name and a temporary password. Follow the [username and password](#) instructions.

Removing contacts

1. To remove a contact, **select** the **contact** by ticking the box to the left of the name.

Please note:

- You cannot remove your own contact details or user account.
- You must have at least one [Main Contact](#).
- If you wish to change the [Main Contact](#), please add or select another contact as your Main Contact first.

2. **Click** the **Remove contact** button

AGENCY SERVICES
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ACCOUNT MANAGEMENT
U

Manage Contacts for MHRA DEMO

Add, edit or remove contacts from your organisation

	Full name [†]	Job title	Email	Telephone	Associated date	Main contact	User account
<input checked="" type="checkbox"/>	Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/>	Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	<input type="radio"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	<input checked="" type="radio"/>	<input type="radio"/>

Key
 Yes No

ADD CONTACT
EDIT CONTACT
REMOVE CONTACT
BACK

3. A confirmation dialogue box will appear, **click Yes** or **No** as appropriate.

Removal of a contact(s) will also remove any previously granted user access (if applicable)

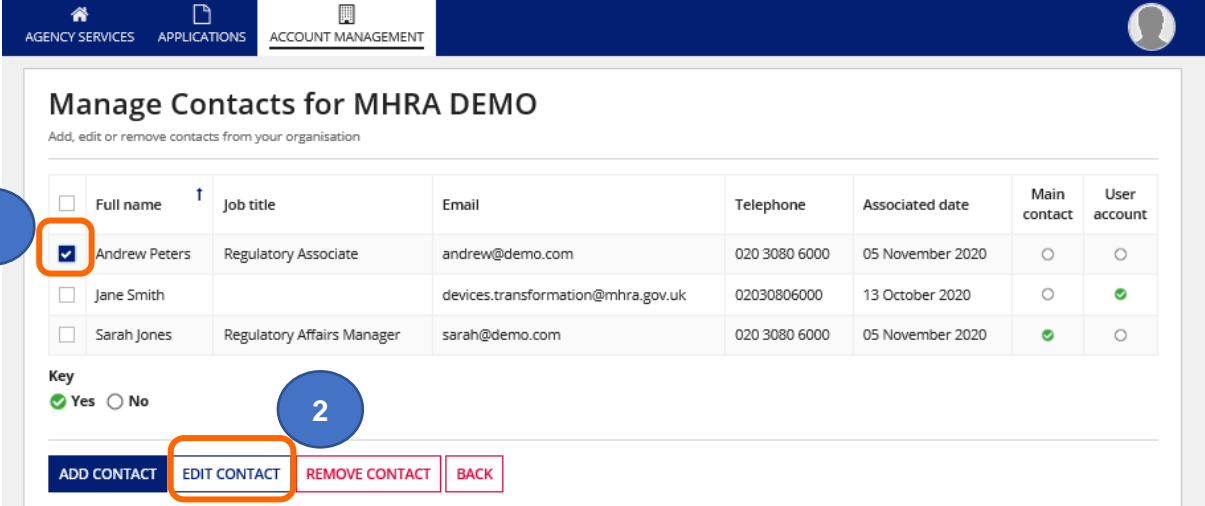
NO

YES

Editing contacts

1. To edit a contact, **select** the **contact**.
2. **Click** the **Edit contact** button.

Please note that the changes will be applied instantly – there will be no confirmation dialogue box unless you are changing this contact to a **user** account.



Manage Contacts for MHRA DEMO

Add, edit or remove contacts from your organisation

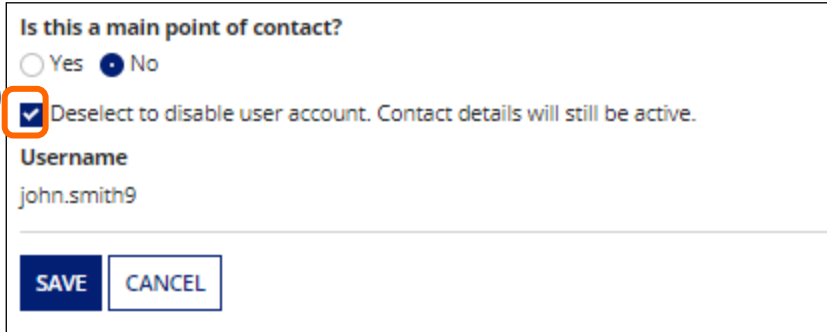
<input type="checkbox"/>	Full name ↑	Job title	Email	Telephone	Associated date	Main contact	User account
<input checked="" type="checkbox"/>	Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/>	Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	<input type="radio"/>	<input checked="" type="radio"/>
<input type="checkbox"/>	Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	<input checked="" type="radio"/>	<input type="radio"/>

Key
 Yes No

ADD CONTACT EDIT CONTACT REMOVE CONTACT BACK

Deactivating a user account

1. **Select** the **contact**.
2. **Click** the **Edit Contact** button.
3. **Untick** the **Deselect to disable user account** check box.
4. **Click** the **Save** button.



Is this a main point of contact?

Yes No

Deselect to disable user account. Contact details will still be active.

Username
john.smith9

SAVE CANCEL

5. A confirmation dialog box will appear, **Click Yes** if you wish to deactivate the user account. The contact details will remain active unless you remove the contact.



Are you sure you want to deactivate this user account?

NO YES

Billing, Shipping and Manufacturing Site addresses

The system has functionality to capture other addresses, these are intended for the following purposes:

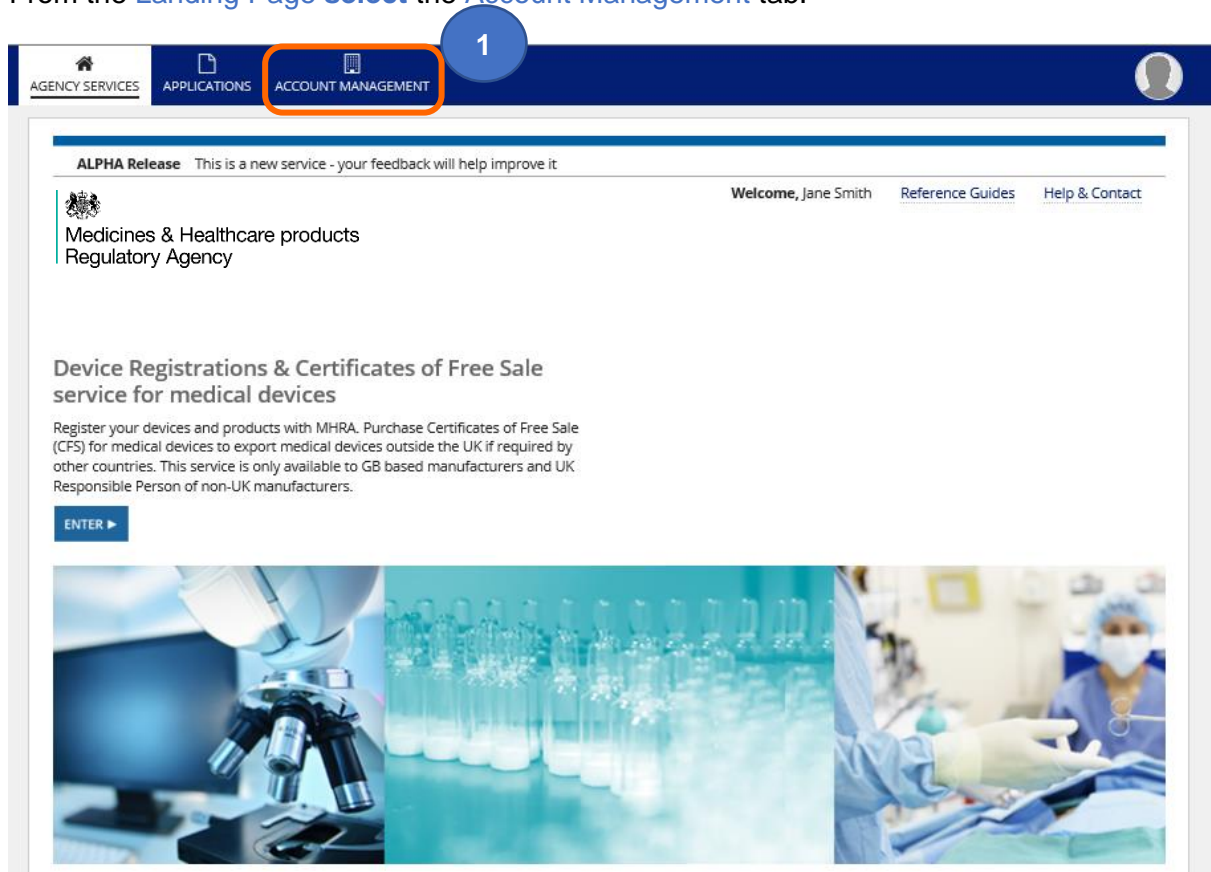
Billing: Use this option to store billing addresses to select from on the payment page.

Shipping: This option only relates to Certificates of Free Sale. As we are currently processing all CFS orders in pdf format and sending by email you do not need to use this option.

Manufacturing Site: This option is to enable customers to add manufacturing site/physical manufacturer addresses to Certificates of Free Sale if they differ from the Legal Manufacturer name and/or address. You cannot change your legal entity name and/or address here and addresses added here will not appear anywhere other than on Certificates of Free Sale.

Please note. If you need to change your registered (legal entity) name and/or address, please follow the [Editing Organisation Details](#) steps. The [statutory fee](#) will be payable.

1. From the [Landing Page](#) select the [Account Management](#) tab.



AGENCY SERVICES APPLICATIONS **ACCOUNT MANAGEMENT**

1

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

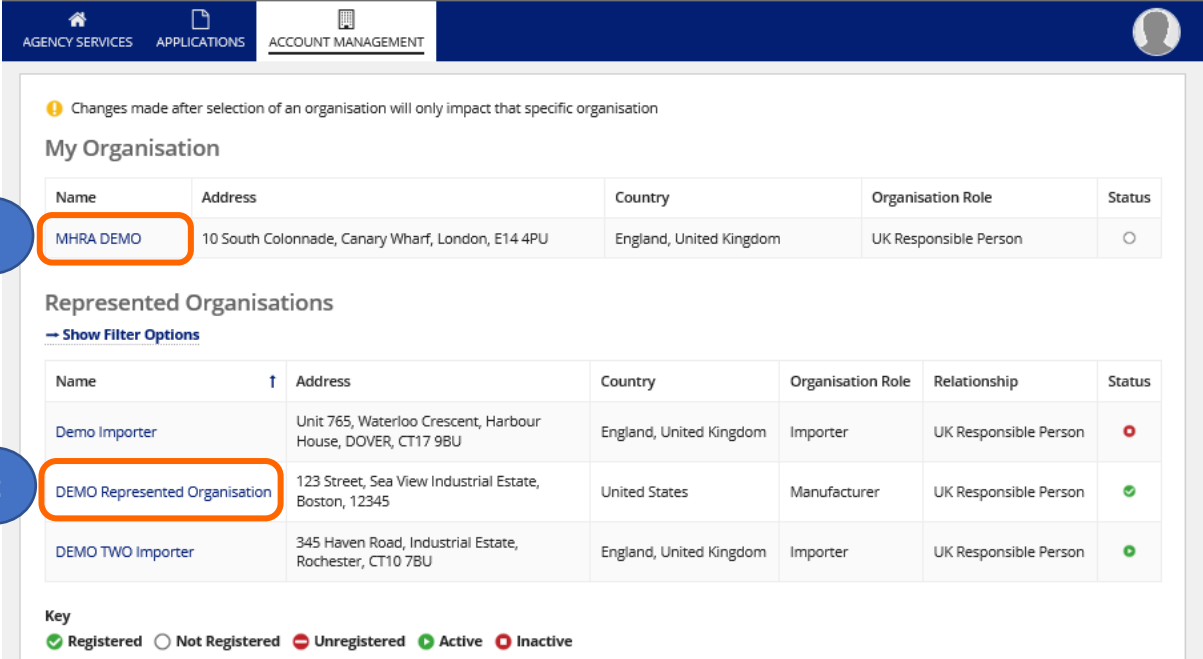
Device Registrations & Certificates of Free Sale service for medical devices

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.

ENTER ►



2. Select [your organisation](#) or the [organisation](#) that you want to add [other addresses](#) to. This function is not available for [Importers](#).



Changes made after selection of an organisation will only impact that specific organisation

My Organisation

Name	Address	Country	Organisation Role	Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	UK Responsible Person	<input type="radio"/>

Represented Organisations

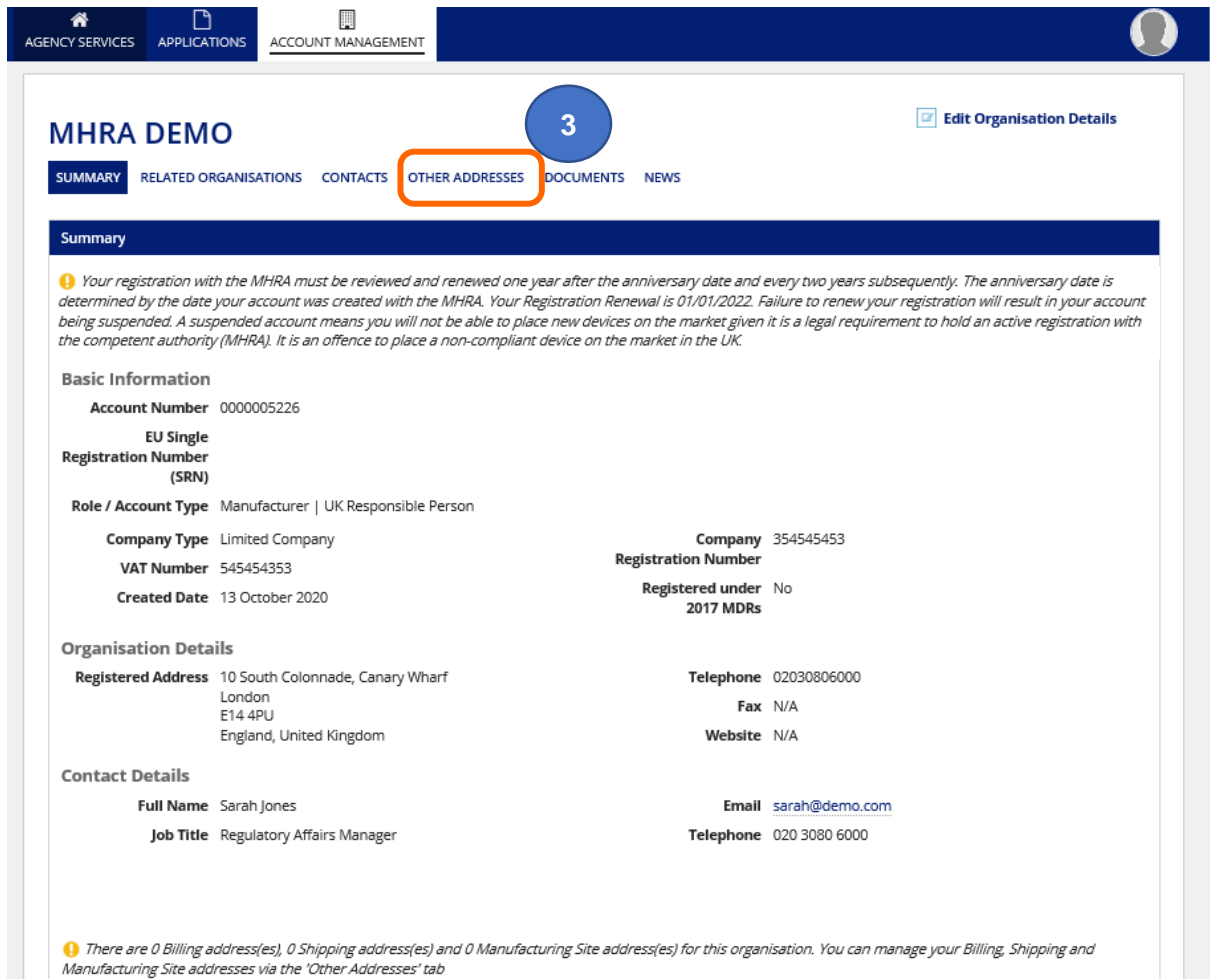
→ Show Filter Options

Name	Address	Country	Organisation Role	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	Importer	UK Responsible Person	<input type="radio"/>
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	Manufacturer	UK Responsible Person	<input checked="" type="radio"/>
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	Importer	UK Responsible Person	<input checked="" type="radio"/>

Key
 Registered
 Not Registered
 Unregistered
 Active
 Inactive

Please note. [Manufacturer site addresses](#) must only be added to the [Legal manufacturer](#) that the manufacturing site applies to. Do not add manufacturing site addresses for another organisation to your own [Other addresses](#) tab or v.v.

3. Click on 'Other Addresses' tab.



MHRA DEMO [Edit Organisation Details](#)

SUMMARY RELATED ORGANISATIONS 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 0000005226

EU Single Registration Number (SRN)

Role / Account Type Manufacturer | UK Responsible Person

Company Type Limited Company **Company Registration Number** 354545453

VAT Number 545454353 **Registered under 2017 MDRs** No

Created Date 13 October 2020

Organisation Details

Registered Address 10 South Colonnade, Canary Wharf, London, E14 4PU, England, United Kingdom

Telephone 02030806000 **Fax** N/A **Website** N/A

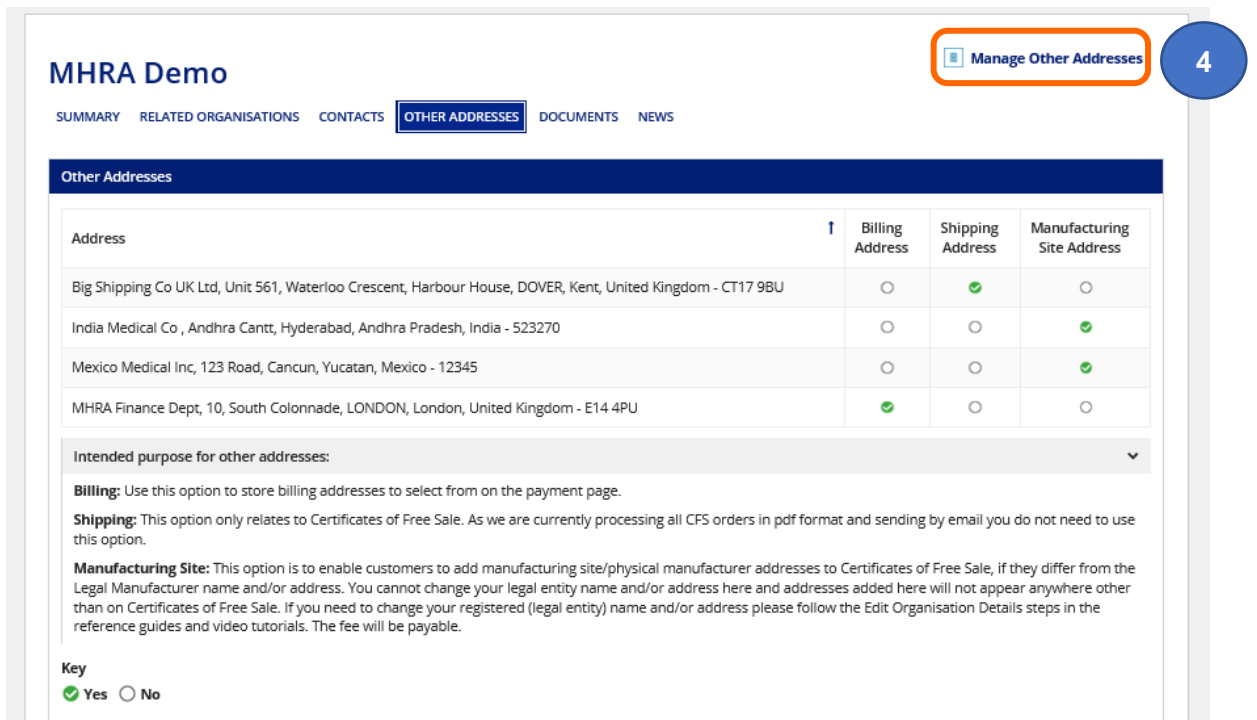
Contact Details

Full Name Sarah Jones **Email** sarah@demo.com

Job Title Regulatory Affairs Manager **Telephone** 020 3080 6000

! There are 0 Billing address(es), 0 Shipping address(es) and 0 Manufacturing Site address(es) for this organisation. You can manage your Billing, Shipping and Manufacturing Site addresses via the 'Other Addresses' tab

4. Click the Manage Other Addresses link.



MHRA Demo [Manage Other Addresses](#)

SUMMARY RELATED ORGANISATIONS CONTACTS **OTHER ADDRESSES** DOCUMENTS NEWS

Other Addresses

Address	Billing Address	Shipping Address	Manufacturing Site Address
Big Shipping Co UK Ltd, Unit 561, Waterloo Crescent, Harbour House, DOVER, Kent, United Kingdom - CT17 9BU	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
India Medical Co , Andhra Cantt, Hyderabad, Andhra Pradesh, India - 523270	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Mexico Medical Inc, 123 Road, Cancun, Yucatan, Mexico - 12345	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
MHRA Finance Dept, 10, South Colonnade, LONDON, London, United Kingdom - E14 4PU	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Intended purpose for other addresses:

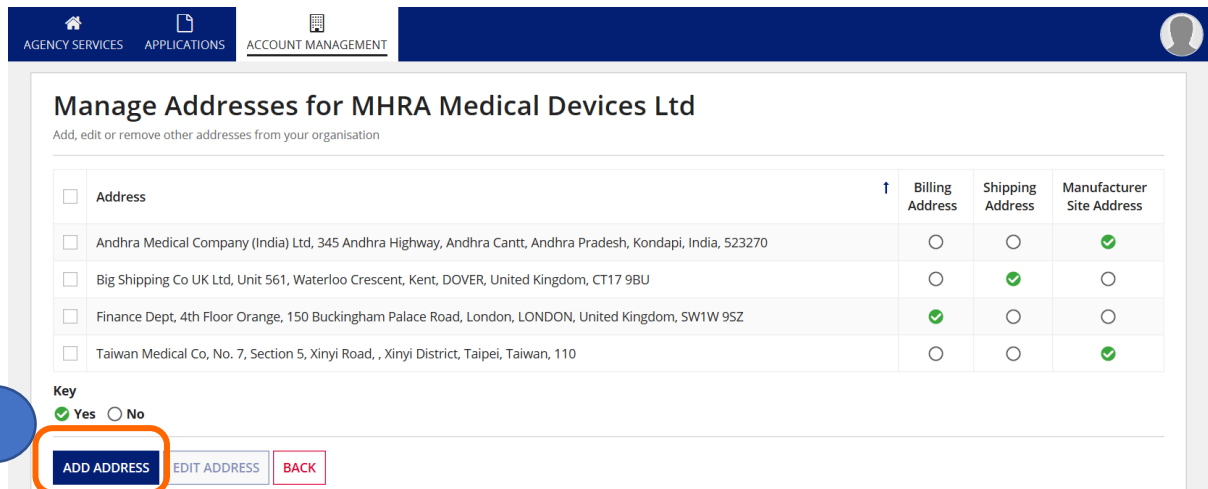
Billing: Use this option to store billing addresses to select from on the payment page.

Shipping: This option only relates to Certificates of Free Sale. As we are currently processing all CFS orders in pdf format and sending by email you do not need to use this option.

Manufacturing Site: This option is to enable customers to add manufacturing site/physical manufacturer addresses to Certificates of Free Sale, if they differ from the Legal Manufacturer name and/or address. You cannot change your legal entity name and/or address here and addresses added here will not appear anywhere other than on Certificates of Free Sale. If you need to change your registered (legal entity) name and/or address please follow the Edit Organisation Details steps in the reference guides and video tutorials. The fee will be payable.

Key
 Yes No

5. Click the **Add Address** button.



Manage Addresses for MHRA Medical Devices Ltd
Add, edit or remove other addresses from your organisation

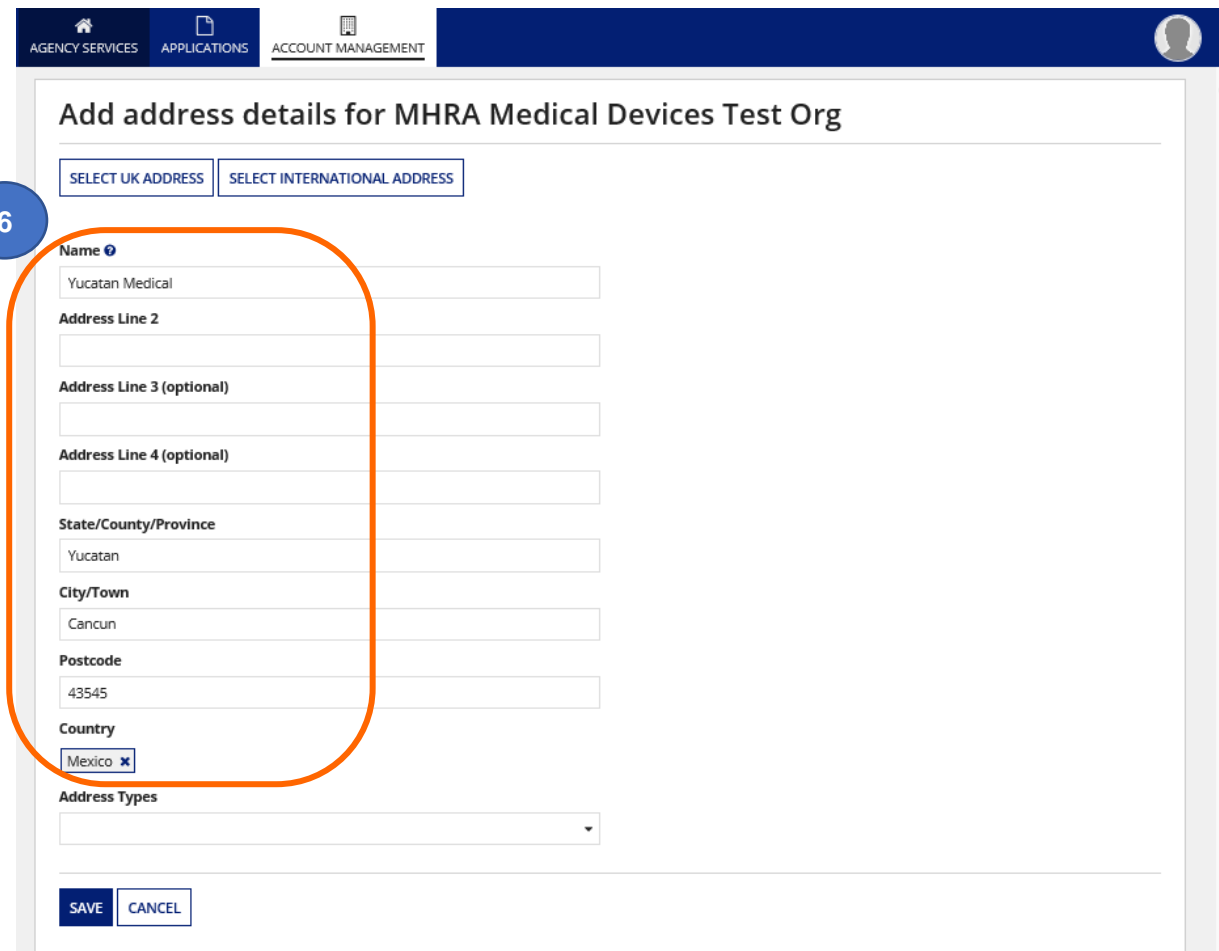
<input type="checkbox"/>	Address	Billing Address	Shipping Address	Manufacturer Site Address
<input type="checkbox"/>	Andhra Medical Company (India) Ltd, 345 Andhra Highway, Andhra Cantt, Andhra Pradesh, Kondapi, India, 523270	<input type="radio"/>	<input type="radio"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	Big Shipping Co UK Ltd, Unit 561, Waterloo Crescent, Kent, DOVER, United Kingdom, CT17 9BU	<input type="radio"/>	<input checked="" type="checkbox"/>	<input type="radio"/>
<input type="checkbox"/>	Finance Dept, 4th Floor Orange, 150 Buckingham Palace Road, London, LONDON, United Kingdom, SW1W 9SZ	<input checked="" type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/>	Taiwan Medical Co, No. 7, Section 5, Xinyi Road, , Xinyi District, Taipei, Taiwan, 110	<input type="radio"/>	<input type="radio"/>	<input checked="" type="checkbox"/>

Key
 Yes No

ADD ADDRESS EDIT ADDRESS BACK

6. Add the address details. You can do this by using the [Postcode Look up](#) facility, or manually. We prefer if you use the Postcode Look Up option, where possible.

Please note Postcode Lookup does not work for all international addresses and some address lines may appear in the wrong fields so you will need to **review** carefully and manually cut and paste them into the correct field before saving.



Add address details for MHRA Medical Devices Test Org

SELECT UK ADDRESS SELECT INTERNATIONAL ADDRESS

Name
Yucatan Medical

Address Line 2

Address Line 3 (optional)

Address Line 4 (optional)

State/County/Province
Yucatan

City/Town
Cancun

Postcode
43545

Country
Mexico

Address Types

SAVE CANCEL

7. From the **Address Types** drop down menu, **select** the address type:
 - **Shipping** – only **UK** shipping addresses can be added.
 - **Billing** - address can be worldwide.
 - **Manufacturer site address** – this is the manufacturing site/physical manufacturer if it not the same as the **legal manufacturer address** and is specific per organisation (if you are a UK Responsible Person or Authorised Representative in Northern Ireland).

City/Town

Cancun

Postcode

43545

Country

Mexico ✕

7

Address Types

Manufacturer Site Address Details

8

SAVE CANCEL

8. **Click** the **Save** button.
9. The address will now be available to select for billing, shipping or manufacturing site as appropriate.

AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT
👤

Manage Addresses for MHRA Medical Devices Test Org

Add, edit or remove other addresses from your organisation

<input type="checkbox"/> Address	↑	Billing Address	Shipping Address	Manufacturer Site Address
<input type="checkbox"/> Andhra Medical Company (India) Ltd, 345 Andhra Highway, Andhra Cantt, Andhra Pradesh, Kondapi, India, 523270	1	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
<input type="checkbox"/> Big Shipping Co UK Ltd, Unit 561, Waterloo Crescent, Kent, DOVER, United Kingdom, CT17 9BU		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Canary Wharf Finance Dept, 10, South Colonnade, London, London, United Kingdom, E14 4PU		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Finance Dept, 4th Floor Orange, 150 Buckingham Palace Road, London, LONDON, United Kingdom, SW1W 9SZ		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Taiwan Medical Co, No. 7, Section 5, Xinyi Road south, Xinyi District, Taipei, Taiwan, 110		<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
<input type="checkbox"/> Yucatan Medical, 234 Avenida San Juan, Yucatan, Cancun, Mexico, 43545		<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

1 - 6 of 6

Key
 Yes No

ADD ADDRESS
EDIT ADDRESS
BACK

Unregister Manufacturer

1. Click on the name of the [organisation](#) that you want to [unregister](#).

Please note that only [registered](#) manufacturers will display the [Unregister manufacturer](#) link.

Represented Organisations
[→ Show Filter Options](#)


Name	Address	Country	Organisation Role	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	Importer	UK Responsible Person	●
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	Manufacturer	UK Responsible Person	●
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	Importer	UK Responsible Person	●

Key
● Registered ○ Not Registered ● Unregistered ● Active ● Inactive

2. Click on the [Unregister Manufacturer](#) button.

Please note the [Unregister Manufacturer](#) link will only be visible if there are no applications in progress i.e. [TEMP](#) (draft) applications in the [Applications Tab](#) or [submitted](#) applications that have not yet been reviewed and completed by MHRA.

[AGENCY SERVICES](#) [APPLICATIONS](#) [ACCOUNT MANAGEMENT](#)



DEMO Represented Organisation

[Edit Organisation Details](#) [Unregister Manufacturer](#)

SUMMARY [RELATED ORGANISATIONS](#) [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.

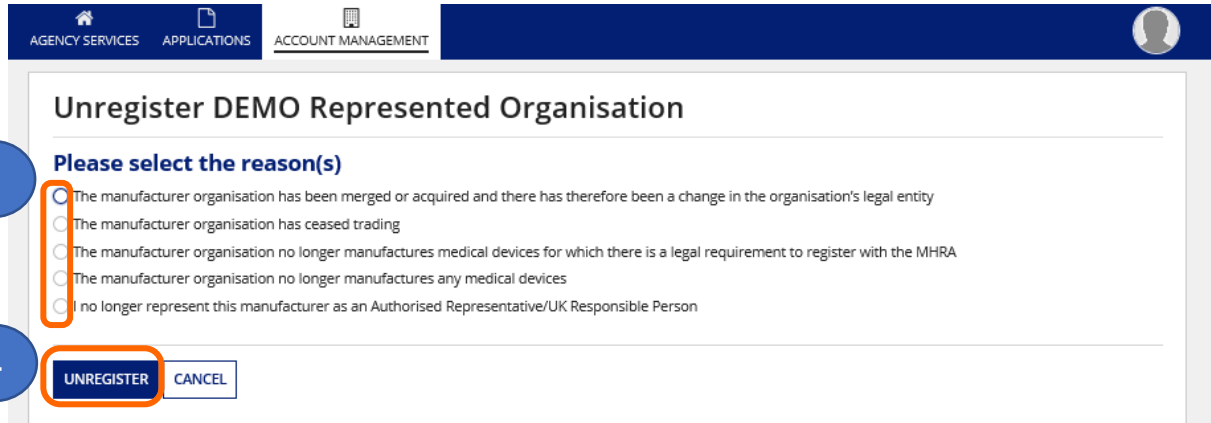
Basic Information

EU Single Registration Number (SRN)	
Role / Account Type	Manufacturer
Company Type	N/A
VAT Number	N/A
Created Date	
Company Registration Number	N/A
Registered under 2017 MDRs	No

Organisation Details

Organisation Description	• Other	Telephone	465654767676
Registered Address		Fax	N/A
		Website	N/A

3. **Select** a **reason** for unregistering the manufacturer.
4. **Click** on the **Unregister** button. Once you click this button you will not be able to undo the action, you would need to register the manufacturer again, add all their devices and pay the **statutory fee**.



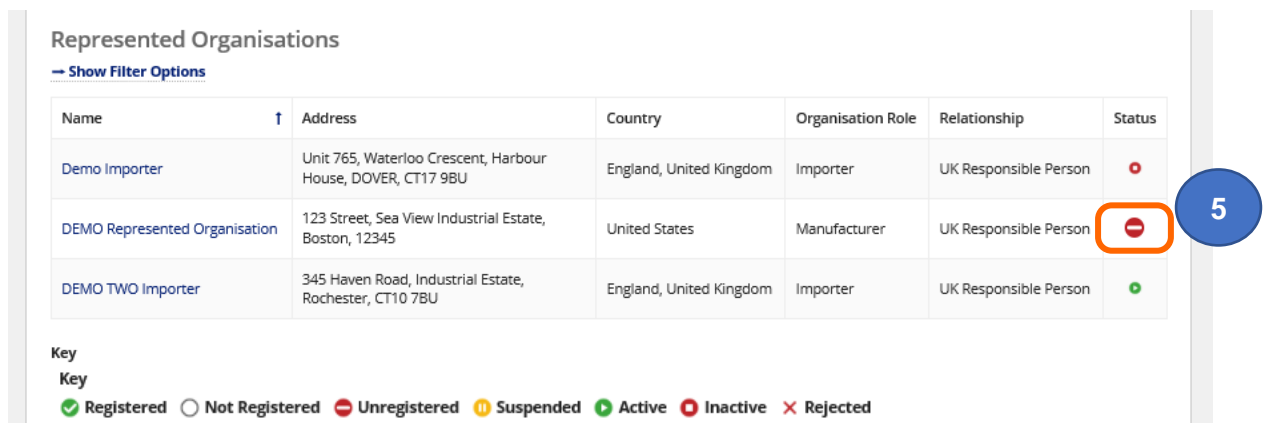
Unregister DEMO Represented Organisation

Please select the reason(s)

- The manufacturer organisation has been merged or acquired and there has therefore been a change in the organisation's legal entity
- The manufacturer organisation has ceased trading
- The manufacturer organisation no longer manufactures medical devices for which there is a legal requirement to register with the MHRA
- The manufacturer organisation no longer manufactures any medical devices
- I no longer represent this manufacturer as an Authorised Representative/UK Responsible Person

UNREGISTER **CANCEL**

5. The organisation will now have a status of **Unregistered**. An unregistered account cannot be re-instated.



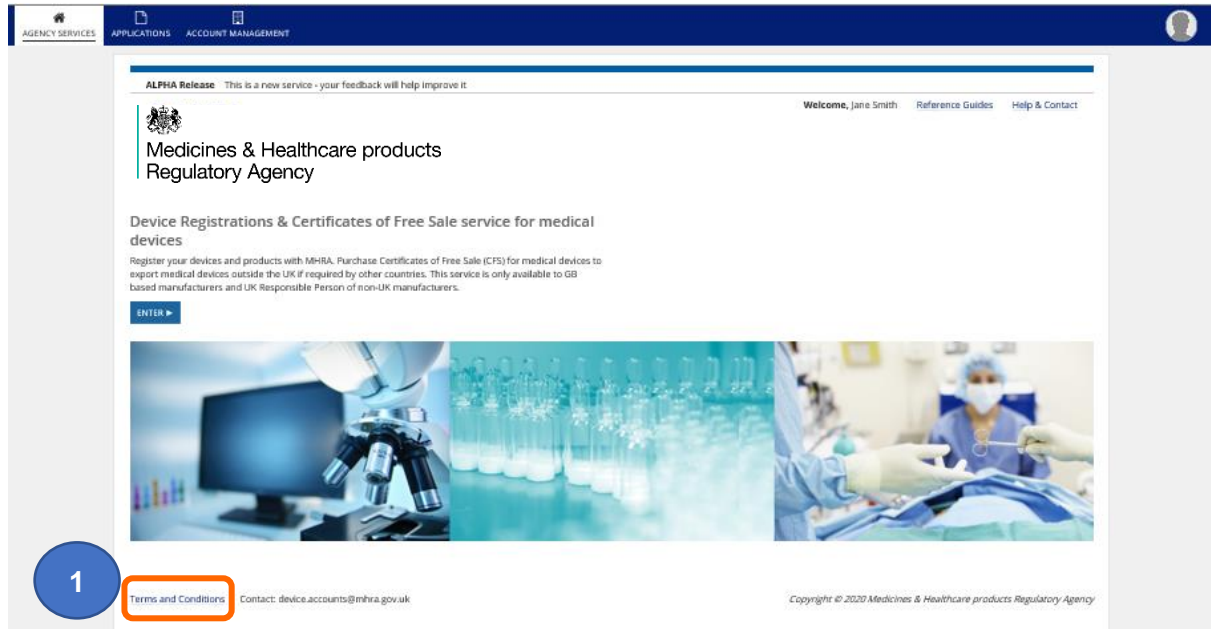
Represented Organisations
[— Show Filter Options](#)

Name	Address	Country	Organisation Role	Relationship	Status
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	Importer	UK Responsible Person	
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	Manufacturer	UK Responsible Person	
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	Importer	UK Responsible Person	

Key
Key
 Registered Not Registered Unregistered Suspended Active Inactive Rejected

Annex I – MHRA Services terms and conditions

1. Click on the [terms and conditions](#) link on the home page to view MHRA Services terms and conditions. Please only refer to the [online](#) Terms and Conditions as these will be the latest version.



Annex II – Reference Guides

1. Click on the [Reference Guides](#) link on the home page to view the most recent reference Guides. Please only refer to the [online](#) guides as these will be the latest versions.

