Medicines & Healthcare products Regulatory Agency

# **Account Management**

# **Reference Guide**

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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.



## 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.



### 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:

- 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
- 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 <u>device.registrations@mhra.gov.uk</u> 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).
- Medicines & Healthcare products Regulatory Agency Password Password? gov.uk MHRA Terms & Conditions
- **2.** Click the 'Log in' button.

### New Users > Change temporary password

Change Password Please complete the form to change your password	L	1.	Copy and paste the
Old Password	1		<b>temporary</b> password (long password with multiple characters) sent to you via email into the old password
New Password			box.
	2	2.	Enter a password of your choice into the new password
Confirm New Password			and confirmation boxes.
		3.	Click on Submit.
C/	ANCEL 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).
- Click the 'Send email' button. Please ensure your email address is always kept up to date on the Contacts Tab, see <u>Editing Contacts</u>.

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.

Medicines & Healthcare products Regulatory Agency	
Password	
Forgot your password?	LOG IN
gov.uk	
MHRA Terms & Conditions	

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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



2

# 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 organisation's 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



2. Click on the Profile button.



## 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.

AGENCY SERVICES		ACCOUNT		
Jane Sr	nith			
Summary	Organisations	News	Related Actions	
				44
4	Jane S	mith	3	
	EDIT PROFILE	C PHOTOS		
				Contraction of the second seco
				1 1 plan and man and
<ul> <li>devices</li> <li>0203080</li> </ul>	transformation@ 06000 ( <i>Mobile</i> )	)mhra.gov.u	ık	

- 5. Please note that only the "Blurb" can be edited (this is not a mandatory field), all other changes need to be made via <u>Edit Organisation Details function</u>.
- 6. Make any required changes, click the Save Changes button.

* First Name	Jane	Mobile Phone	02030806000
* Last Name	Smith	Office Phone	
Nickname		Address 1	
* Email	devices.transformation@mhra.gov.uk	Address 2	
Supervisor		Address 3	
Title		Town	
5 Blurb		City	
	0/140	Post Code	
		Country	

÷.

## **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. If the Account has a status of 'Suspended' please follow the instructions to <u>Renew Registration</u> and/or <u>Upload new Letter of Designation</u>, as appropriate and depending on suspension reason.
- 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.

Or Changes made after selection of My Organisation	an organisation will only impact that spe	ecific orga	anisation					
Name Address	Address			Organisation			Relationship	Status
MHRA Demo 10 South Colo London, Great	MHRA Demo 10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU			m Manufacturer			<b>(</b>	
Represented Organisa - Show Filter Options	tions		Current	0	institut Dala	Delect		Charl
Name	Address	45	Country United States	Manu	facturer	UK Res	nship ponsible Person	Status

5. Click the Show filter options link to search by represented organisation name or registration status

Represented Organis	ations	
Name	Registration Status	
	Select status	-
		SEARCH CI

## **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.

MMARY APPLICATIONS	RELATED ORGANISATIONS DEVICES PRODUCTS CONTA	CTS OTHER ADDRESSES		
ews				
Application	Activity	Action taken by	Action taken on	1
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	lane Smith	13 October 2020, 12:25 pm	

#### 2. Click on the Application number or No application link.



3. Click on Amended Devices to view details of the action taken.

Device Amendment - Reference: 2020     Amended SUMMARY AMENDED DEVICES AMENDED NEWS     Devices	011090215772
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.
- 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.



## **Editing organisation details**

- 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 <u>their</u> name, they would be
  required to pay a <u>statutory fee</u> for their own organisation plus a <u>statutory fee</u> 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 <u>before</u> making any changes to your organisation
  name. If any represented manufacturers are suspended due to <u>Renew Registration</u> or
  <u>Expired Letter of Designation</u> you will also be charged. If you no longer represent a
  manufacturer, please follow the <u>Unregister manufacturer</u> instructions.
- If a sole manufacturer (who has a registered status) wishes to change their name or address, then one <u>statutory fee</u> 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 <u>upload a new letter of</u> <u>designation</u> 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 <u>Unregister Manufacturer</u> 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 <u>before</u> making any changes to your organisation. If you no longer represent a manufacturer, please follow the <u>Unregister manufacturer</u> instructions. If any represented manufacturers are suspended due to <u>Renew</u> <u>Registration</u>, submit the Renew registration application for the suspended manufacturers <u>before</u> you change your organisation name/address.

	Name	Address		Country Organisation Role Relation			Relationship	Status		
	MHRA Demo 10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU		Englan	and, United Kingdom Manufacturer				0		
	Hume		Address	country		organisation tole		Relationship		State
) (	DEMO Represer	nted Organisation	123 Road, Sea View, Boston, 1234	15	United States	Manu	facturer	UK Resp	oonsible Person	۲

### 2. Click on the Edit Organisation Details link.

<ul> <li>Back to DR&amp;CFS Servior</li> </ul>	ces		
MHRA Dem Organisatio	o: DEMO Represented n		Export Devices Data to Excel File
SUMMARY APPLICATIO	NS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS N	EWS	
Summary			
Our registration will completed by the MHR- the market given it is a light completed by the MHR-	th the MHRA must be reviewed and renewed one year after the anniversary date at 4. Your Registration Renewal is 01/01/2026. Failure to renew your registration will ri legal requirement to hold an active registration with the competent authority (MHR	nd every two years subseque esult in your account being s A). It is an offence to place a	ently. The anniversary date is determined by the date your account request was uspended. A suspended account means you will not be able to place new devices on non-compliant device on the market in the UK.
<b>Basic Information</b>			
Account Number	0000009133	<b>Registration Status</b>	Suspended: Expired Letter of Designation
EU Single Registration Number (SRN)		PARD Options	Publish UK Responsible Person Name     Publish UK Responsible Person Address     Publish Organisation's Name
Role / Account Type	Manufacturer		Publish Organisation's Address
UK Responsible Person	MHRA Demo		
Company Type	Limited Company	Company	N/A
VAT Number	N/A	Registration Number	
Created Date	19 September 2019	Registered under EU MDR/IVDR	No
Organisation Deta	ils		
Organisation	<ul> <li>Maxillofacial technology organisation</li> </ul>	Telephone	345365655
Description	Manufacturer of prosthetic devices     Other	Fax	N/A
Registered Address	123 Road, Sea View Boston 12345 United States	Website	N/A
Contact Details			
Full Name	Mary Jones	Email	jane@reporg.com
Job Title	Quality Manager	Telephone	2334456

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 <u>statutory fee</u>. 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 <u>your</u> organisation name or address, the <u>statutory fee</u> will be payable for your organisation and for <u>each</u> 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.

Edit Organisation Details - TEMP20250306121100

Organisation details	Review	Payment
Please note that changes made via this Edit Organisation Details application do until the application is completed (and approved). This includes any previous draft information after the Edit Organisation Details application is completed (and appro- tion).	o not take effect until the application is completed (and approv applications you have saved and any other functions such as ( oved).	ed) by MHRA. All other functions will continue to use the original det [FS Orders etc. Please delete any draft applications and re-enter the
Organisation details		
Name		
DEMO Represented Organisation		
Enter the name of the organisation you represent		
Describe your organisation by selecting up to three options below*		
Maxillofacial technology organisation, Manufacturer of prosthetic devices, Other	-	
EU Single Registration Number (SRN) (optional)		
Address Details		
Select International Address		
Address line 1		
123 Road		
Address line 2 (optional)		
Sea View		
Address line 3 (ontional)		

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 manufacturers).

**Please note** This must be a legal contract, stating that you are the sole 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 <u>regulatory guidance for UK Responsible Persons</u>. For Authorised Representatives in Northern Ireland the requirements can be found in the <u>guidance for Authorised Representatives</u>.

5. Enter new letter of designation validity dates.

The Letter of Designation validity dates should match the start and end dates of your contract with the represented manufacturer. **The maximum validity is 5 years.** The \* after From Date and To Date indicates mandatory field.

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

PDF - 6.89 KB	
File size limit should not exceed 15MB. Only the fe	wing file formats are acceptable; .doc, .docx, .pdf, .jpg, .tif, .png, .odt
05/03/2025	10 Date * 05/03/2028
	Enter the expiry date of the Letter of Designation. Maximum validity is 5 years.
Description of document (optional)	
Description of document (optional)	
Description of document (optional)	'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button
Description of document (optional) Limit: 255 characters, remaining: 255. Vou can manage your 'Billing', 'Shipping' ar Desse be aware that changes to certain fit MHRA will undertake checks to verify that the	'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button s 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 s no legal entity/ownership changes

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.
- 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 - TEMP20250306121100

Organisation deta	ails	Review		Payment
Organisation Details				
Once you submit these organisation char	nges, 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 Inc				
EU Single Registration Number (SRN)				
Address Details				
Address line 1		Country		
123 Road		United States		
Address line 2		Post code		
Sea View		12345		
Address line 3		Telephone		
Address line 5		345365655		
Address line 4		Fax		
City		Website		
Boston				
State/County/Province				
Customer Service Contact [	Details			
Telenhone No		Email Address		
5656565656		demo@demo.com		
Represented Organisation I	Documents			
The below document is uploaded for repres	ented organisation			
Document	Document Type		From Date	To Date
Designation Letter	Letter Of Designation		06/03/2025	06/03/2028
and the second				



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 orgnisations you currently represent. Please take the following action to update your role from Authorised Representative to UK Responsible Person.

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

1. Check your list of existing Represented Manufacturers.

**Please note** if you will **not** be representing any of these as a UKRP please follow the instructions to <u>Unregister Manufacturer</u> **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 <u>statutory fee</u>.

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

Your Organisation				
Name	Address	Country	Devices (Products)	Registrati Status
GB Auth Rep Services	10 South Colonnade, Canary Wharf, Canary Wharf, London, E14 4PU	United Kingdom	1 (1)	۲
Registered Not Register Manufacturers you Only registered manufacturers ap manufacturers can be found from where the MANUFACTURE formed	ed Curregistered Suspended represent suppear here. Newly submitted and draft the Applications list.		ADD	NEW MANUFACTU
Registered Not Register Manufacturers you Only registered manufacturers a manufacturers can be found from Only use tha ADD NEW MANUFACTURER function f registered the manufacture, josse use the Add Dev registered the manufacture, josse use the Add Dev Search by manufacturer name:	ed Curregistered Suspended represent uppear here. Newly submitted and draft the Applications list. you have not out here test function to		ADD	NEW MANUFACTU
Registered Not Register     Not Register     Manufacturers you     Only registered manufacturers ap     manufacturers can be found from     Only use that ADD NEW MANUFACTURER function     registered the manufacture, plasse use the AdD NEW     Search by manufacturer name:	ed Curregistered Suspended  represent  uppear here. Newly submitted and draft to the Applications list.  uppear here uppear Suspect Sectoreone		DDA	NEW MANUFACTU
Registered Not Register     Manufacturers you     Only registered manufacturers ag     manufacturers can be found from     Only use tha ADD NEW MANUFACTURER function fr     registered the manufacture, plass use the Add Designed yeagered devices on the early registered     Search by manufacturer name:     Name	ed Curregistered Suspended represent upear here. Newly submitted and draft the Applications list. you have no: sub Name SEARCH Address Country D	Devices (Products)	Relationship	NEW MANUFACTU Registrati Status

- 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 Servi	p Services	4 Edit Organi Mana	sation Details ge Devices a Export Devices Data to Excel F
SUMMARY APPLICATIO	NS RELATED ORGANISATIONS DEVICES PROD	UCTS CONTACTS OTHER ADDRES	SES DOCUMENTS NEWS
Summary			
Our registration wit determined by the date being suspended. A sus the competent authority	h the MHRA must be reviewed and renewed one y your account was created with the MHRA. Your Re pended account means you will not be able to plac ('MHRA). It is an offence to place a non-compliant	ear after the anniversary date and e gistration Renewal is 01/01/2022. Fi e new devices on the market given device on the market in the UK.	very two years subsequently. The anniversary date is ailure to renew your registration will result in your acco it is a legal requirement to hold an active registration w
Basic Information			
Account Number	000003888	Registration Status	Registered
EU Single Registration Number (SRN)		PARD Options	Publish Authorised Representative Name     Publish Authorised Representative Address     Publish Organisation's Name
Role / Account Type	Authorised Representative   Manufacturer		Publish Organisation's Address
Company Type	Limited Company	Company	N/A
VAT Number	N/A	Registration Number	
Created Date	08 May 2020	Registered under 2017 MDRs	No
Organisation Deta	ils		
Registered Address	10 South Colonnade, Canary Wharf	Telephone	3534534535
	Canary Wharf London	Fax	N/A
	Greater London E14 4PU Uniced Kingdom	Website	N/A
	United Kingdom		
Contact Details	United Kingdom		

### 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 <u>statutory fee</u>.

Organisation details	Review	Payment
Please note that changes made via this Edit Organisati functions will continue to use the original details held unti any other functions such as CFS Orders etc. Please delete (and approved).	on Details application do not take effect until the applica I the application is completed (and approved). This includ any draft applications and re-enter the information after	tion is completed (and approved) by MHRA. All other des any previous draft applications you have saved an the Edit Organisation Details application is complete
Organisation details		
Name		
GB UKRP Services		
Enter the name of the organisation		
Organisation Role		
Describe your organisation by selecting up to three op	ations below *	
Select	•	
EU Single Registration Number (SRN) (optional)		
v Address Details		
✓Address Details		
✓ Address Details Postcode lookup		
✓ Address Details Postcode lookup FIND UK ADDR	1ESS	
Address Details Postcode lookup FIND UK ADDR Enter address manually	RESS	

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

England, United Kingdom 🗙		
Telephone		
0203080 6826		
Fax (optional)		
Website (optional)		
www.mhra.gov.uk		
Customer Service Contact		
This will be displayed on the Public Acces	s Registration Database (PARD), if populated	
Telephone no (optional)	Email address (optional)	
02030806000	UKRP@MHRA.GOV.UK	
() You can manage your 'Billing', 'Shij	pping' and 'Manufacturing Site' Addresses via the OTHER ADDF	RESSES TAB/VIEW - 'Manage Addresses' button
Please be aware that changes to control of the second s	ertain fields could result in a charge being applied. In addition that there is no legal entity/ownership changes	changes are only allowed if there is no change in the legal entity or ownership of the manufacturer organisatio
Changes to the telephone, fax and MHRA approval before the organisation	website details will be reflected immediately in this organisation record is updated.	on's record without the need for MHRA approval. Changes to organisation name and/or registered address wil

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

Postcode / Zipcode			
E14 4PU			
Country			
England, United Kingdom 🗙			
Telephone			
0203080 6826			
Fax (optional)			
Website (optional)			
www.mhra.gov.uk			
Customer Service Contact			
This will be displayed on the Public Access Registration Dat	abase (PARD), if populated		
Telephone no (optional)	Email address (optional)		
02030806000	UKRP@MHRA.GOV.UK		
() You can manage your 'Billing', 'Shipping' and 'Manu	facturing Site' Addresses via the OTHER ADDRESSES TA	B/VIEW - 'Manage Addresses' button	
Please be aware that changes to certain fields could MHRA will undertake checks to verify that there is no least the checks the checks to verify that there is no least the checks to verify that there is no least the checks to verify that there is no least the checks to verify that the checks to verify that the checks to verify the checks to ve	d result in a charge being applied. In addition changes a egal entity/ownership changes	ire only allowed if there is no change in the legal entity or ownership of the manufacture	er organisation. The
Changes to the telephone, fax and website details MHRA approval before the organisation record is updated and the second	will be reflected immediately in this organisation's reco ated.	rd without the need for MHRA approval. Changes to organisation name and/or registere	ed address will require
			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 sole 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 <u>regulatory guidance for UK Responsible Persons</u>. For Authorised Representatives in Northern Ireland the requirements can be found in the <u>guidance for Authorised Representatives</u>.

The Letter of Designation validity dates should match the start and end dates of your contract with the represented manufacturer. **The maximum validity is 5 years.** 

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 de 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 for the Manufacturers 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 for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represent manufacturer. The maximum validity is 5 years.  Manufacturer Name Document Type Upload Document From Date To Date DEMO Represented Organisation Letter Of Designation Letter Of Designation Letter Of Designation Definition Definite Definition Definition Definition Definition Definition Definit	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 detail 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).  Defined Letter of designation  To update the documentation for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represented manufacturer. The maximum validity is 5 years.  Manufacturer Name Document Type Upload Document Details application Details application Details application Details application Details application Details application for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represented organisation Details application Details application Details application Details application Details application for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represented organisation Details D	Organisatio	n details	Review			Payment	
Upload Letter of designation         Image: state of the state of	Upload Letter of designation            •) This change will require you to update the documentation for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the representer manufacturer. The maximum validity is 5 years.             Manufacturer Name         Decument Type         Upload Document         Etter Of Designation         Letter Of Designation         Letter Of Designation         Letter Of Designation         Designation         Letter Of Designation	Please note that changes made via until the application is completed (and information after the Edit Organisation	this Edit Organisation Details applicatio approved). This includes any previous o Details application is completed (and a	on do not take effect until the application is comp draft applications you have saved and any other approved).	leted (and approved) by MHRA. A functions such as CFS Orders etc.	All other functions v Please delete any	will continue to use the o draft applications and re	original details he ⊱enter the
This change will require you to update the documentation for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represent manufacturer. The maximum validity is 5 years.      Manufacturer Name     Document Type     Upload Document     From Date     To Date     Designation     Letter Of Designation     Letter Of Designation     Letter Of Designation     Letter Of Designation	In this change will require you to update the documentation for the Manufacturers you represent. The Letter of Designation validity dates should match the start and end dates of your contract with the represented manufacturer. The maximum validity is 5 years.   Manufacturer Name Document Type   Upload Document From Date   DEMO Represented Organisation Letter Of Designation     Letter Of Designation Designation     Upload Document From Date     To Date        DEMO Represented Organisation     Letter Of Designation	Upload Letter of design	ation					
DEMO Represented Organisation Letter Of Designation Designation Letter Of Designation Letter Of Designation Def = 6.89 KB 06/03/2025	DEMO Represented Organisation Letter Of Designation CPDF - 6.89 KB 06/03/2025	O The shares will be a descent of the second	and the state of t	The Lease C Destance	and the state of the	and the second states and	Contraction of the state of the	and the second second
		This change will require you to upd manufacturer. The maximum validity is Manufacturer Name	ate the documentation for the Manufac 5 years. Document Type	tturers you represent.The Letter of Designation	ralidity dates should match the st	art and end dates o	of your contract with the To Date	represented

Edit Organisation Details - TEMP20250306114911

9. Click the Continue button to be taken to the reveiw page.

Edit Organisation Details - TEMP20250306114911

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

Organisation details		Review	Payme	int		
Organisation Details						
() Once you submit these organisation changes, you will not be	e able to submit new applications to De	vice Registration or CFS services until this applic	ation has been reviewed by the MHR/	Α.		
Name						
GB UKRP Services						
EU Single Registration Number (SRN)						
Address Details						
Address line 1		Country				
10 South Colonnade	England, United Kingdom					
ddress line 2		Post code				
Oth Floor Area 7		E14 4PU				
Address line 3		Telephone				
Canary Wharf		02030806000	02030806000			
Address line 4	ddress line 4		Fax			
City		Website				
London						
State/County/Province						
Greater London						
Customer Service Contact Details						
Telephone No.		Email Address				
02030806000		devices.transformation@mhra.gov.uk	devices.transformation@mhra.gov.uk			
Represented Organisation Documents						
The below are the documents uploaded for all represented org	anisations					
Manufacturer Name	Document	Document Type	From Date	To Date		
DEMO Represented Organisation	Designation Letter	Letter Of Designation	06/03/2025	06/03/2028		
Before you proceed to submission of your application, you	must agree to our terms and condition	ns.				
I have read and agree to the terms and conditions.		j j				

- **11. Click** the Continue button to be taken to the payment page. The <u>statutory fee</u> will be payable for Your Organisation and each represented manufacturer. See the Making Payments section in the **Device Registration Reference Guide.**
- 12. Your role wil be updated to UKRP and your association with your represented manufacturers will be UK Responsible Person.

Manufacturers you represent						
Only registered manufacturers appear here. Newly the <b>Applications</b> list.	ADD	IEW MANUFACTURER				
Only use the <b>ADD NEW MANUFACTURER</b> 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.						NEW IMPORTER
Search by manufacturer name:	Search by manufacturer name: Registration Status:           Select status         Select status         SEARCH         CLE					
Name	t Address		Country	Devices (Products)	Relationship	Registration Status
DEMO Represented Organisation	ew, Boston, 12345	United States	1 (15)	UK Responsible Person	۲	
Key 🥑 Registered 🔵 Not Registered 🧔 Unregiste	red 🕕 Suspended	× Rejected				

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11

### **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 <u>suspended</u> 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 <u>Public</u> Access Registration Database (PARD).

1. From the Agency Services tab **click** on the name of the organisation you want to upload a new Letter of Designation for.

l		SE/	ARCH			
	Name †	Address	Country	Devices (Products)	Relationship	Registration Status
	DEMO Represented Organisation	123 Road, Sea View, Boston, 12345	United States	1 (1)	UK Responsible Person	0

2. Review the organisation details and click on the Edit Organisation Details link.

AGENCY SERVICES APPLICA			
<ul> <li>■ Back to DR&amp;CFS Serv</li> <li>MHRA DEM</li> <li>Organisatio</li> </ul>	o: DEMO Represent	ed Edit Organisation	Details X Unregister Manufacturer Export Devices Data to Excel File
SUMMARY APPLICATIO	NS DEVICES PRODUCTS CONTACTS	OTHER ADDRESSES DOCUMENTS NEWS	
9 Your registration wi determined by the date being suspended. A sus the competent authority	th the MHRA must be reviewed and renewe y your account was created with the MHRA. spended account means you will not be able y (MHRA). It is an offence to place a non-coi	d one year after the anniversary date and Your Registration Renewal is 01/01/2022. I to place new devices on the market giver npliant device on the market in the UK.	every two years subsequently. The anniversary date is Failure to renew your registration will result in your account i ti s a legal requirement to hold an active registration with
Basic Information			
Account Number	0000005379	Registration Status	Suspended: Expired Letter of Designation
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		Publish Organisation's Address
UK Responsible Person	MHRA DEMO		
Company Type	Limited Company	Company	N/A
VAT Number	N/A	Registration Number	Na
Created Date	09 November 2020	2017 MDRs	NO
Organisation Deta	ils		
Organisation Description	• Other	Telephone	35467576868
Registered Address	123 Road, Sea View Boston MA 12345 United States	rax 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 <u>statutory fee</u>.

Organisation details	Review	Payment
Please note that changes made via this Edit Organisation functions will continue to use the original details held until th any other functions such as CFS Orders etc. Please delete any (and approved).	Details application do not take effect until the applic e application is completed (and approved). This inclu y draft applications and re-enter the information afte	ation is completed (and approved) by MHRA. All other ides any previous draft applications you have saved ar er the Edit Organisation Details application is complete
Organisation details		
Name		
DEMO Represented Organisation		
Enter the name of the organisation you represent		
Describe your organisation by selecting up to three optio	ns below *	
Other		
EU Single Registration Number (SRN) (optional)		
Address Details		
Select International Address		

4. Upload the new Letter of Designation.

**Please note** This must be a legal contract, stating that you are the sole 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 <u>regulatory guidance for UK Responsible Persons</u>. For Authorised Representatives in Northern Ireland the requirements can be found in the EU <u>guidance for Authorised Representatives</u>.

UPLOAD         Drop file here           File size limit should not exceed 15MB. Only the f	owing file formats are acceptable; .doc, .docx, .pdf, .jpg, .tdf, .pngodt
From Date	To Date
dd/mm/yyyy 🗰	dd/mm/yyyy 🏙
	Enter the expiry date of the Letter of Designation. Maximum validity is 5
Description of document (optional)	years.
Description of document (optional)	years.
Description of document (optional)	years. 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button
Description of document (optional) Limit: 255 characters, remaining: 255. You can manage your 'Billing', 'Shipping' a Please be aware that changes to certain fit MHRA will undertake checks to verify that the	years. 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button is 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 organisat is no legal entity/ownership changes

### 5. Enter the new Letter of Designation validity dates.

The Letter of Designation validity dates should match the start and end dates of your contract with the represented manufacturer. **The maximum validity is 5 years.** The \* after From Date and To Date indicates mandatory field.

Upload Letter of Designation	
This is an official letter on headed paper, fro manufacturer.The Letter of Designation val	om the manufacturer stating your company's name and address, and that you as the UK Responsible Person (UKRP) of a non-UK manufacturer are acting with the consent of the dity dates should match the start and end dates of your contract with the represented manufacturer. Click here for more information on the role of UKRP.
Designation Letter PDF - 6.89 KB	
File size limit should not exceed 15MB. Only th	e following file formats are acceptable;.doc,.docc,.pdf, jpg,.tif,.png,.odt
From Date *	To Date *
05/03/2025 📾	05/03/2028
	Enter the expiry date of the Letter of Designation. Maximum validity is 5 years.
Limit: 255 characters, remaining: 255.	
Umit: 255 characters, remaining: 255.	and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button
Limit: 255 characters, remaining: 255. You can manage your 'Billing', 'Shipping Please be aware that changes to certain MHRA will undertake checks to verify that t	and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button 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 here is no legal entity/ownership changes
Limit: 255 characters, remaining: 255. You can manage your 'Billing', 'Shipping Please be aware that changes to certain MHRA will undertake checks to verify that t Changes to the telephone, fax and web MHRA approval before the organisation rec	and 'Manufacturing Site' Addresses via the OTHER ADDRESSES TAB/VIEW - 'Manage Addresses' button 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 rere is no legal entity/ownership changes site 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 requir ord is updated.

Click the Continue button to go to the Review page. Please note there is no Save & Exit
option for this application. Check the details and either click Back or Delete Application if
something is not correct.

Address Details					
Address line 1		Country			
123 Street		United States			
Address line 2		Post code			
		43434			
Address line 3		Telephone			
		3434545			
Address line 4		Fax			
City		Website			
Boston					
State/County/Province					
MA					
Customer Service Contact Details					
Telephone No.		Email Address			
Represented Organisation Documents	k				
The below document is uploaded for represented organisation	in				
Document	Document Type		From Date	To Date	
Designation Letter	Letter Of Designation		04/03/2025	04/03/2028	
Before you proceed to submission of your application, you	u must agree to our terms and conditions.				
I have read and agree to the terms and conditions.					
CONTINUE BACK	J			Γ	DELETE APPLICATION
				L	

7. Read and agree to our terms and conditions and click the Continue button to go to the payment page. Please note there is no Save & Exit option for this application. 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 <u>video tutorial</u> 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<sup>®</sup>), where applicable).

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

Please note if organisation name and/or address has changed you must update these <u>before</u> renewing your registration, you cannot do this within the Renew registration application. Follow the instructions for <u>Editing Organisation details</u>, the <u>statutory fee</u> 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 <u>suspended</u> and the accounts of any manufacturers that you represent will be <u>suspended</u>, even if their renewal dates are different. Suspended accounts are removed from the <u>Public Access Registration Database (PARD)</u> 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 <u>video tutorial.</u>

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

	IONS ACCOUNT MANAGEMENT		
MHRA Dem Organisatio	O: DEMO Represented n other addresses documents news	🖅 Edit C	Organisation Details X Unregister Manufactur
Summary			
determined by the date being suspended. A sus the competent authorit	your account was created with the MHRA. Your pended account means you will not be able to pl y (MHRA). It is an offence to place a non-complia	Registration Renewal is 01/01/2022. Fa lace new devices on the market given i nt device on the market in the UK.	t is a legal requirement to hold an active registration will
Account Number	0000009133		
EU Single Registration Number (SRN)			
EU Single Registration Number (SRN) Role / Account Type	Manufacturer		
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person	Manufacturer MHRA Demo		
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type	Manufacturer <b>MHRA Demo</b> Limited Company	Company	N/A
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type VAT Number	Manufacturer <b>MHRA Demo</b> Limited Company N/A	Company Registration Number	N/A
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type VAT Number Created Date	Manufacturer <b>MHRA Demo</b> Limited Company N/A 19 September 2019	Company Registration Number Registered under 2017 MDRs	N/A No
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type VAT Number Created Date Organisation Deta	Manufacturer MHRA Demo Limited Company N/A 19 September 2019 ils	Company Registration Number Registered under 2017 MDRs	N/A No
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type VAT Number Created Date Organisation Deta Organisation	Manufacturer MHRA Demo Limited Company N/A 19 September 2019 ils • Maxillofacial technology organisation	Company Registration Number Registered under 2017 MDRs Telephone	N/A No 345365655
EU Single Registration Number (SRN) Role / Account Type UK Responsible Person Company Type VAT Number Created Date Organisation Deta Organisation	Manufacturer MHRA Demo Limited Company N/A 19 September 2019 ils • Maxillofacial technology organisation • Manufacturer of prosthetic devices • Other	Company Registration Number Registered under 2017 MDRs Telephone Fax	N/A No 345365655 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 <u>suspended</u>. **Click** on the Renew Registration link.



- 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 <u>Editing Organisation details</u>, then Renew Registration.

Organisation details	Payment	
Organisation Details		
Once you submit this Registration Renewal applicat account. Completion is usually within 2 hours, please c	ion, you will need to await MHRA approval before submitting any further a heck status in the Applications Tab.	pplications on th
Napre		
MHRA DEMO		
EU Single Registration Number (SRN)		
Address Details		
Address line 1	Country	
	England, United Kingdom	
Capacy Wharf	F14 4PU	
Address line 3	Telephone	
	02030806000	
Address line 4	Fax	
City	Website	
State/County/Province		
ate/county/Province		
Before you proceed to submission of your renew re	gistration application, you must agree to our terms and conditions.	
I have read and agree to the terms and conditions.	o	
CONTINUE CANCEL 6	DEL	ETE APPLICATIO

Renew Organisation Re	gistration Details - TEMP20230314120645
Payment is not required for the application. Please o	lick on complete application to finish.
COMPLETE APPLICATION BACK	DELETE APPLICATIO

## Account Suspension

 If you do not renew your registration before the renewal date or upload a new Letter of Designation before the exisiting 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 manufacturers will also be suspended. Suspended accounts will be removed from the <u>Public Access Registration Database</u> (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 <u>Public Access Registration</u> <u>Database (PARD)</u>.

**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 <u>Uploading new Letter of Designation</u>. The day after your new Letter of Designation application has been reveiwed by MHRA and been completed, you will see a status of Registred for the manufacturer. The day after that, the account will be suspended again due to Renew Registration, unless you have already renewed the registration.

'our Organi	sation					
Name	Address		Cour	try	Devices (Products)	Registration Status
MHRA Demo	10 South Colon	nade, 10th Floor Area 7, London, E14 4P	U Unite	d Kingdom	4 (13)	•
Inly registered man nanufacturers can b earch by manufac	ers you repro ufacturers appear he be found from the Ap turer name:	esent ere. Newly submitted and draft pplications list.	ARCH			
only registered man nanufacturers can b earch by manufac	ers you repri ufacturers appear he pe found from the Ap turer name:	esent ere. Newly submitted and draft splications list.	Country	Devices (Products)	Relationship	Registration Status
Only registered man manufacturers can b earch by manufac Name DEMO Representer	ers you reprivufacturers appear his be found from the Ap turer name: t d Organisation	esent ere. Newly submitted and draft splications list.  Address 123 Road, Sea View, Boston, 12345	Country United States	Devices (Products) 1 (2)	Relationship UK Responsible Person	Registration Status

 If an account is suspended, you will only be able to <u>Renew registration</u>, <u>upload a new</u> <u>Letter of Designation</u> or <u>unregister</u> 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 <u>Public Access Registration Database (PARD)</u>.

- 3. Check the reason for suspension on the Summary page of the relevant organisation.
- Follow the <u>Unload new Letter of Designation</u> and/or <u>Renew Registration</u> instructions to reinstate your account/s.

lack to DR&CFS Servic	es	V 1	Inregister Manufacturer
HRA Demo	)	~ `	
MMARY APPLICATION	IS RELATED ORGANISATIONS DEVICES	PRODUCTS CONTACTS OTHER ADDRESSES	DOCUMENTS NEWS
ımmary			
Your registration with termined by the date ting suspended. A susp e competent authority	h the MHRA must be reviewed and rener your account was created with the MHR rended account means you will not be a (MHRA). It is an offence to place a non-	wed one year after the anniversary date and even A. Your Registration Renewal is 01/01/2022. Failu ble to place new devices on the market given it is compliant device on the market in the UK.	ry two years subsequently. The anniversary date is re to renew your registration will result in your account a legal requirement to hold an active registration with
asic Information			
Account Number	0000009132	Registration Status Su	spended: Renew Registration 3
Role / Account Type	Manufacturer   UK Responsible Person	PARD Options	Publish UK Responsible Person Name Publish UK Responsible Person Address Publish Organisation's Name Publish Organisation's Address
<b>*</b>			
Y SERVICES APPLICA	TIONS ACCOUNT MANAGEMENT	-	
		4	
Back to DR&CFS Serv	o: DEMO Represer	4 Inted	tails X Unregister Manufacturer Export Devices Data to Excel File
Back to DR&CFS Serv IHRA DEM Organisatio	ICCES O: DEMO Represer INS DEVICES PRODUCTS CONTACTS	4 Edit Organisation De s OTHER ADDRESSES DOCUMENTS NEWS	tails X Unregister Manufacturer Export Devices Data to Excel File
Back to DR&CFS Serv IHRA DEM Organisatio JMMARY APPLICATIO	ices O: DEMO Represer In INS DEVICES PRODUCTS CONTACTS	4 Edit Organisation De s OTHER ADDRESSES DOCUMENTS NEWS	tails X Unregister Manufacturer Export Devices Data to Excel File
Back to DR&CFS Serv HRA DEM Organisatio JMMARY APPLICATIO JMMARY APPLICATIO JMMARY Vour registration w determined by the dat being suspended. A su the competent author	Ices O: DEMO Represer On NS DEVICES PRODUCTS CONTACTS It the MHRA must be reviewed and ren by our account was created with the MH spended account means you will not be (Y(MHRA). It is an offene to place a non	4 Edit Organisation De 5 OTHER ADDRESSES DOCUMENTS NEWS evved one year after the anniversary date and eve RA. Your Registration Renewal is 01/01/2022. Failu able to place new devices on the market given it is -compliant device on the market in the UK.	tails × Unregister Manufacturer Export Devices Data to Excel File
Back to DR&CFS Serv IHRA DEM Organisatio JMMARY APPLICATIO JMMARY O Your registration w determined by the dat being suspended. A su the competent author Basic Information	ices O: DEMO Represer on NS DEVICES PRODUCTS CONTACTS ith the MHRA must be reviewed and rem by our account was created with the MH spended account means you will not be ty (MHRA). It is an offence to place a non	4 Edit Organisation De 5 OTHER ADDRESSES DOCUMENTS NEWS eweed one year after the anniversary date and eve RA. Your Registration Renewal is 01/01/2022. Fail able to place new devices on the market given it is scompliant device on the market in the UK	tails X Unregister Manufacturer Export Devices Data to Excel File
Back to DR&CFS Serv IHRA DEM Organisatio UMMARY APPLICATION MMARY APPLICATION MMARY APPLICATION MORE AND	Ices O: DEMO Represer In NS DEVICES PRODUCTS CONTACTS ith the MHRA must be reviewed and ren e your account was created with the MH spended account means you will not be ity (MHRA). It is an offence to place a non 0000005379	4 Edit Organisation De 5 OTHER ADDRESSES DOCUMENTS NEWS evved one year after the anniversary date and eve RA. Your Registration Renewal is 01/01/2022. Failu able to place new devices on the market given it is -compliant device on the market in the UK Registration Status	tails × Unregister Manufacturer Export Devices Data to Excel File
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## 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 <u>Organisation page</u>, 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.

IHRA DE	MO to organisations contacts	1 OTHER ADDRESSES DOCUMENTS NEWS		(	🖃 Manage	e Contacts
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	0	0
lane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	0	۲
,				05 May and an 2020		0

3. Click the Add Contact button.

nuu, e	concorremove contac	is from your organisation					
	Full name 1	Job title	Email	Telephone	Associated date	Main contact	User accoun
	Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	0	0
	Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	0	۲
	Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	0	0

#### **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 Manufacturers or Importers.
- 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.

	Optional)
Mr.	
First	name
Johr	1
Last	name
Smi	th
Job ti	tle (Optional)
johr Telep	ismith@mhratrain.gov.uk
020	30234567
ls thi O Ye	s a main point of contact? s     No
	este liser Account
🗌 Cr	

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



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

They wil receive an email with their user name and a temporary password. Follow the <u>username and password</u> 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

+					Main	User
Full name	Job title	Email	Telephone	Associated date	contact	account
Andrew Peters	Regulatory Associate	andrew@demo.com	020 3080 6000	05 November 2020	0	0
Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	0	۲
Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	۲	0

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

Removal of a user access (if	contact(s) will also remove any previously granted applicable)	3
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.

Add, e	dit or remove contac	s from your organisation					
	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	0	0
	Jane Smith		devices.transformation@mhra.gov.uk	02030806000	13 October 2020	0	۲
	Sarah Jones	Regulatory Affairs Manager	sarah@demo.com	020 3080 6000	05 November 2020	•	0

### 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
3	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.



## 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 <u>Editing Organisation Details</u> steps. The <u>statutory fee</u> will be payable.

1. From the Landing Page select the Account Management tab.



2. Select your organisation or the manufacturer that you want to add other addresses to. This function is not available for Importers.

	LION					
Name	Address		Country	Organi	sation Role	Stat
MHRA DEMO	10 South Col	onnade, Canary Wharf, London, E14 4PU	England, United Kingdom	UK Res	ponsible Person	0
Name	t	Address	Country	Organisation Role	Relationship	Stat
Name Demo Importer	t	Address Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	Country England, United Kingdom	Organisation Role	Relationship UK Responsible Person	Stat
Name Demo Importer DEMO Represente	t d Organisation	Address Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU 123 Street, Sea View Industrial Estate, Boston, 12345	Country England, United Kingdom United States	Organisation Role Importer Manufacturer	Relationship UK Responsible Person UK Responsible Person	Stati

**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.

Y SERVICES APPLICA			
	O	3 DOCUMENTS NEWS	<b>Edit Organisation Details</b>
Summary			
Pour registration will determined by the date being suspended. A sus the competent authorit	th the MHRA must be reviewed and renewed o your account was created with the MHRA. You pended account means you will not be able to y (MHRA). It is an offence to place a non-comp	ne year after the anniversary date and ur Registration Renewal is 01/01/2022. F place new devices on the market given liant device on the market in the UK.	every two years subsequently. The anniversary date is ailure to renew your registration will result in your account it is a legal requirement to hold an active registration with
Basic Information			
EU Single Registration Number (SRN)	000005226		
Role / Account Type	Manufacturer   UK Responsible Person		
Role / Account Type Company Type	Manufacturer   UK Responsible Person Limited Company	Company	354545453
Role / Account Type Company Type VAT Number	Manufacturer   UK Responsible Person Limited Company 545454353	Company Registration Number	354545453
Role / Account Type Company Type VAT Number Created Date	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020	Company Registration Number Registered under 2017 MDRs	354545453 No
Role / Account Type Company Type VAT Number Created Date Organisation Deta	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 iils	Company Registration Number Registered under 2017 MDRs	354545453 No
Role / Account Type Company Type VAT Number Created Date Organisation Deta Registered Address	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 ills 10 South Colonnade, Canary Wharf	Company Registration Number Registered under 2017 MDRs Telephone	354545453 No 02030806000
Role / Account Type Company Type VAT Number Created Date Organisation Deta Registered Address	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 ils 10 South Colonnade, Canary Wharf London F14 APU	Company Registration Number Registered under 2017 MDRs Telephone Fax	354545453 No 02030806000 N/A
Role / Account Type Company Type VAT Number Created Date Organisation Deta Registered Address	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 ils 10 South Colonnade, Canary Wharf London E14 4PU England, United Kingdom	Company Registration Number Registered under 2017 MDRs Telephone Fax Website	354545453 No 02030806000 N/A N/A
Role / Account Type Company Type VAT Number Created Date Organisation Deta Registered Address Contact Details	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 ils 10 South Colonnade, Canary Wharf London E14 4PU England, United Kingdom	Company Registration Number Registered under 2017 MDRs Telephone Fax Website	354545453 No 02030806000 N/A N/A
Role / Account Type Company Type VAT Number Created Date Organisation Deta Registered Address Contact Details Full Name	Manufacturer   UK Responsible Person Limited Company 545454353 13 October 2020 ils 10 South Colonnade, Canary Wharf London E14 APU England, United Kingdom Sarah Jones	Company Registration Number Registered under 2017 MDRs Telephone Fax Website Email	354545453 No 02030806000 N/A N/A sarah@demo.com

Othere 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.

MMARY RELATED ORGANISATIONS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS			
ther 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	0	۲	0
India Medical Co , Andhra Cantt, Hyderabad, Andhra Pradesh, India - 523270	0	0	۲
Mexico Medical Inc, 123 Road, Cancun, Yucatan, Mexico - 12345	0	0	۲
MHRA Finance Dept, 10, South Colonnade, LONDON, London, United Kingdom - E14 4PU	۲	0	0
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 form this option.	at and sending	g by email you	do not need to use
Manufacturing Site: This option is to enable customers to add manufacturing site/physical manufacturer addresses to Legal Manufacturer name and/or address. You cannot change your legal entity name and/or address here and address than on Certificates of Free Sale. If you need to change your registered (legal entity) name and/or address please follow reference guides and video tutorials. The fee will be pavable	Certificates of es added here the Edit Orga	of Free Sale, if i e will not appe enisation Detai	they differ from the ar anywhere other ls steps in the

5. Click the Add Address button.

Add, e	dit or remove other addresses from your organisation			
	Address 1	Billing Address	Shipping Address	Manufacture Site Address
	Andhra Medical Company (India) Ltd, 345 Andhra Highway, Andhra Cantt, Andhra Pradesh, Kondapi, India, 523270	0	0	۲
	Big Shipping Co UK Ltd, Unit 561, Waterloo Crescent, Kent, DOVER, United Kingdom, CT17 9BU	0	0	0
	Finance Dept, 4th Floor Orange, 150 Buckingham Palace Road, London, LONDON, United Kingdom, SW1W 9SZ	0	0	0
	Taiwan Medical Co, No. 7, Section 5, Xinyi Road, , Xinyi District, Taipei, Taiwan, 110	0	0	0

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.

SELECT UK ADDRESS SELEC	T INTERNATIONAL ADDRES	55		
Name 🛛				
Yucatan Medical				
Address Line 2				
Address Line 3 (optional)				
Address Line 4 (optional)				
State/County/Province				
Yucatan				
City/Town				
Cancun				
Postcode				
43343 Country				
Novice *				
Mexico ×				

- 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.

Address	t Billin Addre	g Shipp ss Addr	oing ress	Manufacturer Site Address
Andhra Medical Company (India) Ltd, 345 Andhra Highway, Andhra Cantt, Andhra Pradesh, Kondapi, India, 523270	0	C		۲
Big Shipping Co UK Ltd, Unit 561, Waterloo Crescent, Kent, DOVER, United Kingdom, CT17 9BU	0	و	•	0
Canary Wharf Finance Dept, 10, South Colonnade, London, London, United Kingdom, E14 4PU	۲	0		0
Finance Dept, 4th Floor Orange, 150 Buckingham Palace Road, London, LONDON, United Kingdom, SW1W 95Z	۲	C	)	0
Taiwan Medical Co, No. 7, Section 5, Xinyi Road south, Xinyi District, Taipei, Taiwan, 110	0	0		۲
Yucatan Medical, 234 Avenida San Juan, Yucatan, Cancun, Mexico, 43545	0	0	)	۲

## **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.

Name 1	Address	Country	Organisation Role	Relationship	Statu
Demo Importer	Unit 765, Waterloo Crescent, Harbour House, DOVER, CT17 9BU	England, United Kingdom	Importer	UK Responsible Person	0
DEMO Represented Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	Manufacturer	UK Responsible Person	۲
DEMO TWO Importer	345 Haven Road, Industrial Estate, Rochester, CT10 7BU	England, United Kingdom	Importer	UK Responsible Person	0

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 APPL			
	presented Organ	Edit O	rganisation Details X Unregister Manufacturer
Summary Your registration determined by the da being suspended. A s the competent author Basic Information EU Sing Registration Number	with the MHRA must be reviewed an te your account was created with th uspended account means you will n rity (MHRA). It is an offence to place on gle er	d renewed one year after the anniversary date and e e MHRA. Your Registration Renewal is 01/01/2022. Fe ot be able to place new devices on the market given i a non-compliant device on the market in the UK.	every two years subsequently. The anniversary date is allure to renew your registration will result in your account it is a legal requirement to hold an active registration with
(SR Role / Account Ty	<b>N)</b> pe Manufacturer		
Company Ty VAT Numb	pe N/A ver N/A	Company Registration Number	N/A
Created Da	te	Registered under 2017 MDRs	No
Organisation De	etails		
Organisati	on • Other	Telephone	465654767676
Registered Addre	:SS	Fax Website	N/A 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 <u>statutory fee</u>.

	AGENCY SERVICES				
	Unregi	ster DEN	/IO Represer	nted Organisation	
	Please se	lect the re	ason(s)		
3	The manufa	cturer organisatio	n has been merged or acc	quired and there has therefore been a change in the organisation's legal entity	
	C The manufa	cturer organisatio	n has ceased trading		
	C The manufa	cturer organisatio	n no longer manufactures	s medical devices for which there is a legal requirement to register with the MHRA	
	C The manufa	cturer organisatio	n no longer manufactures	s any medical devices	
	C I no longer i	epresent this mar	nufacturer as an Authorise	ed Representative/UK Responsible Person	
4	UNREGISTER	CANCEL			

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

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	0
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	0

## 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.

