Medicines & Healthcare products Regulatory Agency

Certificates of Free Sale

Reference Guide

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

Contents – Certificates of Free Sale

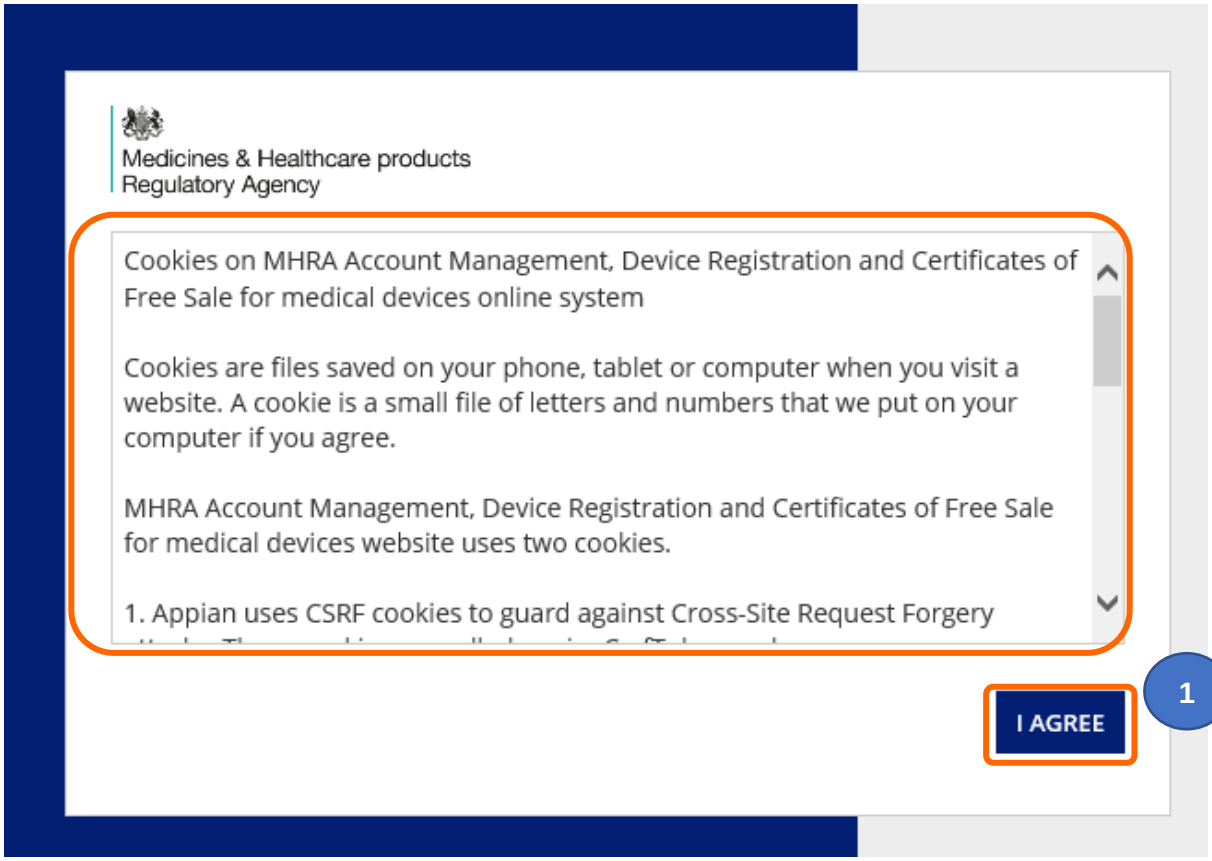
Logging in

Access MHRA Agency Services for Device Registrations and Certificates of Free Sale for medical devices.

Agree to Cookie Policy

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

1. When you have read the Cookie Policy, **click** the **'I Agree'** button.



Username and Password

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

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

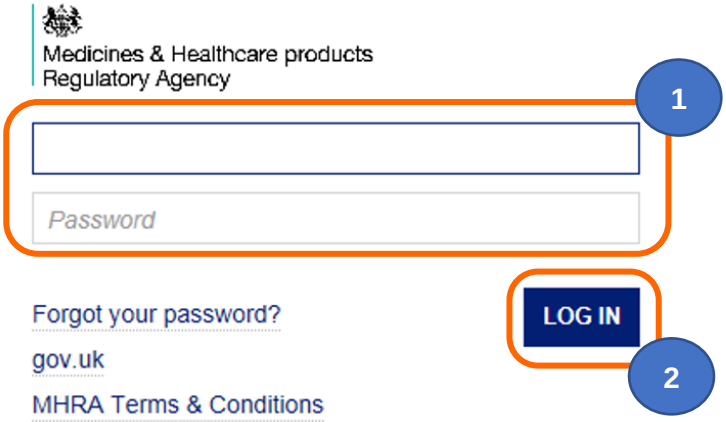
2. A separate email with subject line **MHRA Portal account creation** from email address admin@mhrabpm.appiancloud.com containing your username (usually firstname.lastname), a temporary password and a link to the system

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

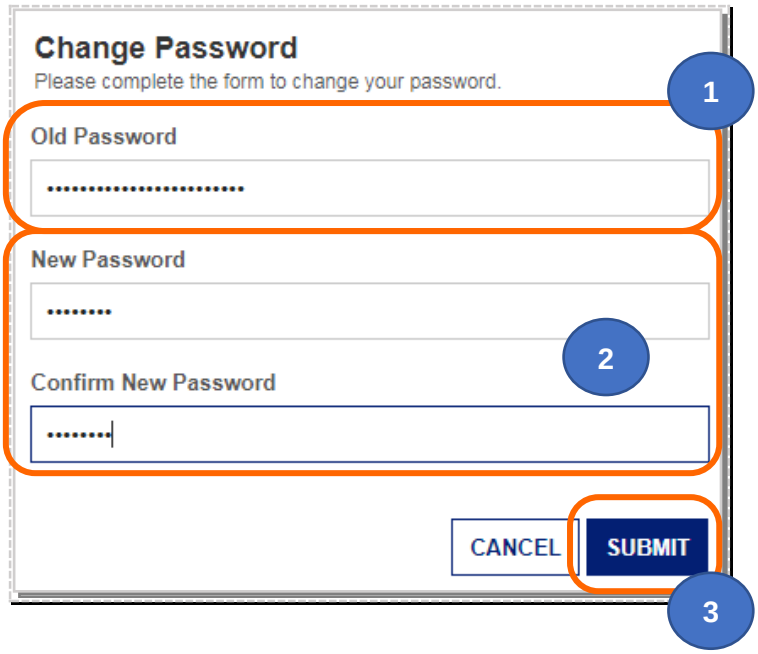
If the welcome email or the username and temporary password email have not been received this is usually due to your system blocking the originating email address. Please add the above email addresses to your **safe senders** list, usually via settings in your email system and email device.registrations@mhra.gov.uk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

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

2. **Click** the 'Log in' button.



New Users > Change temporary password

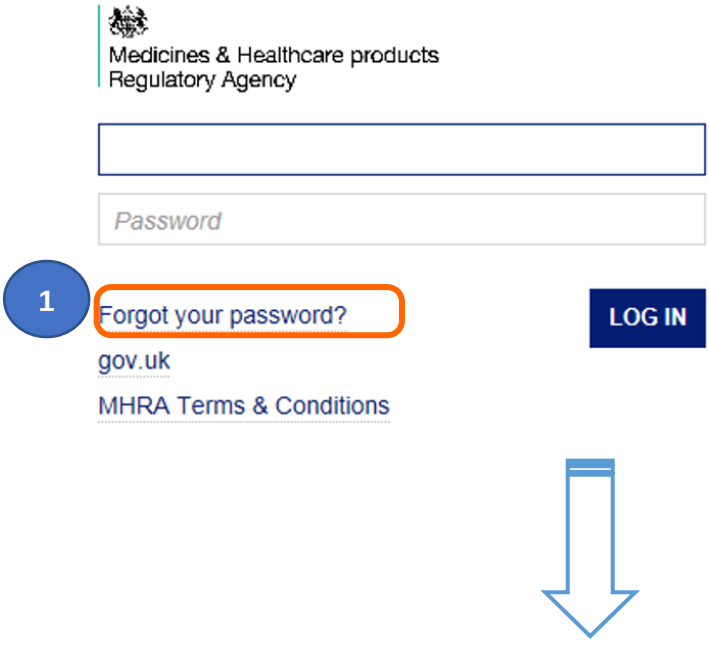


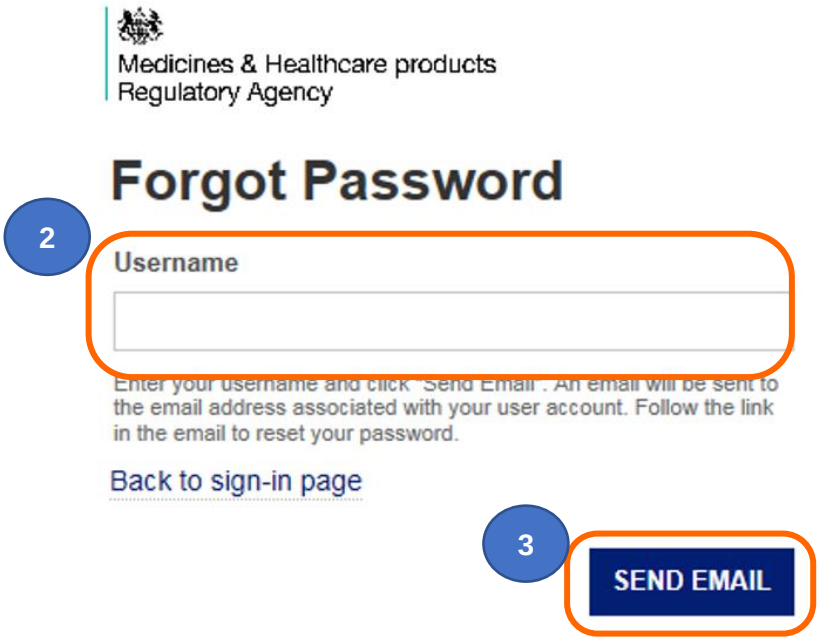
1. **Copy** and **paste** the temporary password (long password with multiple characters) sent to you via email into the old password box.
2. **Enter** a password of your choice into the new password and confirmation boxes.
3. **Click** on Submit.
   You will be able to use the password you entered from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

Forgot password > resets

1. On the log in page, **click** the 'Forgot your password' link.
2. **Enter** your username (usually firstname.lastname – not your email address).
3. **Click** the 'Send email' button.

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




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

Certificates of Free Sale (CFS) Service

This service enables UK based manufacturers, UK Responsible Persons and Authorised Representatives in Northern Ireland to apply for Certificates of Free Sale for medical device products that have been registered with MHRA.

Please follow all the instructions in the **Device Registration Reference Guide** to register devices for your organisation or manufacturers you represent.

Please note the important information in the above guide on adding product (model/version Catalogue/Reference and UDI DI etc.) data – only the Medical Device Name, Model/Version and Catalogue/Reference, Basic UDI DI and UKCA or CE Certificate Reference No. data that you enter will appear on the Certificate of Free Sale.

in vitro diagnostic medical devices for performance evaluation cannot be included on CFS orders.

It is your responsibility to check with the receiving country that they will accept the CFS **before** your make payment for your order. You will be given the option to download a preview sample that you can email to the country. Please note the formatting on the preview sample may not match the final certificate formatting.

CFS order applications are **non-refundable** – please see our terms and conditions. You must preview the CFS Certificate and Schedule **before** making payment to ensure it meets your needs and **before** you pay.

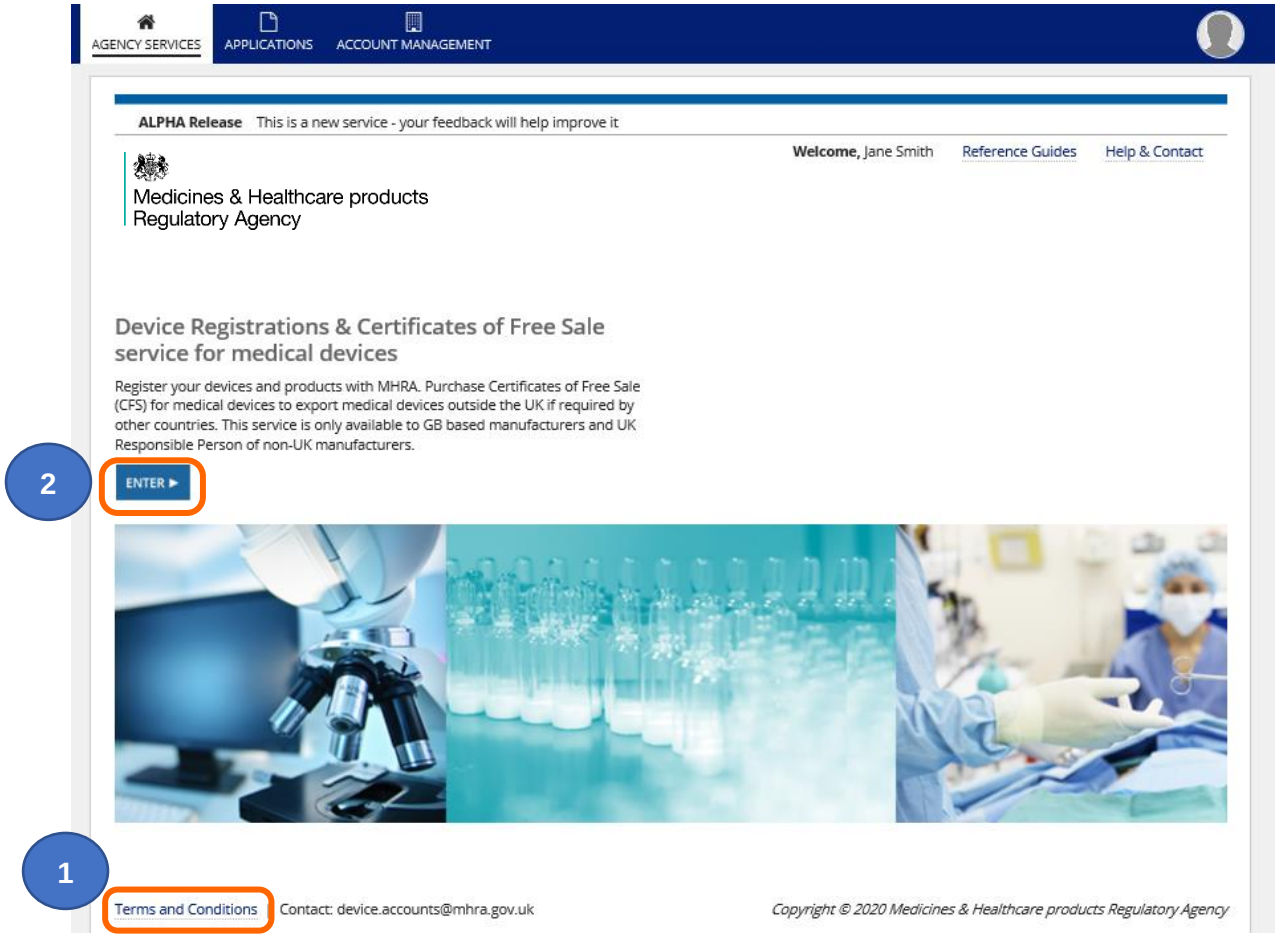
Since 01 January 2021 new medical device regulations have applied in the UK. Depending on your location and the type of Conformity Assessment that your registered device(s) comply with, the CFS certificate will state that the devices can be placed on either the GB (England, Scotland, Wales) market, or the UK (England, Scotland, Wales and Northern Ireland) market. For Northern Ireland-based manufacturers and Authorised Representatives with devices that are CE marked, the CFS certificate will also state that devices can be placed on the EU/EEA market. Please ensure that you download the preview and check with the recipient country **before** placing your order.

CFS for medical devices are issued as pdf documents with electronic signature. Hard copies with wet signature are no longer issued. We will try to process your order within 10 working days from date of receipt. During busy periods orders may take longer. Please order as far in advance as possible.

Please note that the Foreign, Commonwealth & Development Office will not apostille pdf documents directly from MHRA. You will need a Notary to carry out checks on the certificates with MHRA to ascertain their authenticity, and can then notarise the certificates, if required by the recipient country. Once notarised, the Foreign, Commonwealth & Development Office will apostille the documents.

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate. In issuing Certificates of Free Sale, the MHRA does not assess or verify that the product complies with relevant export requirements and restrictions. It is the applicant's responsibility to ensure compliance with these requirements and restrictions.

1. **Read** our terms and conditions. Certificate of Free Sale orders are non-refundable.
2. **Click** the Enter button on the Landing page.

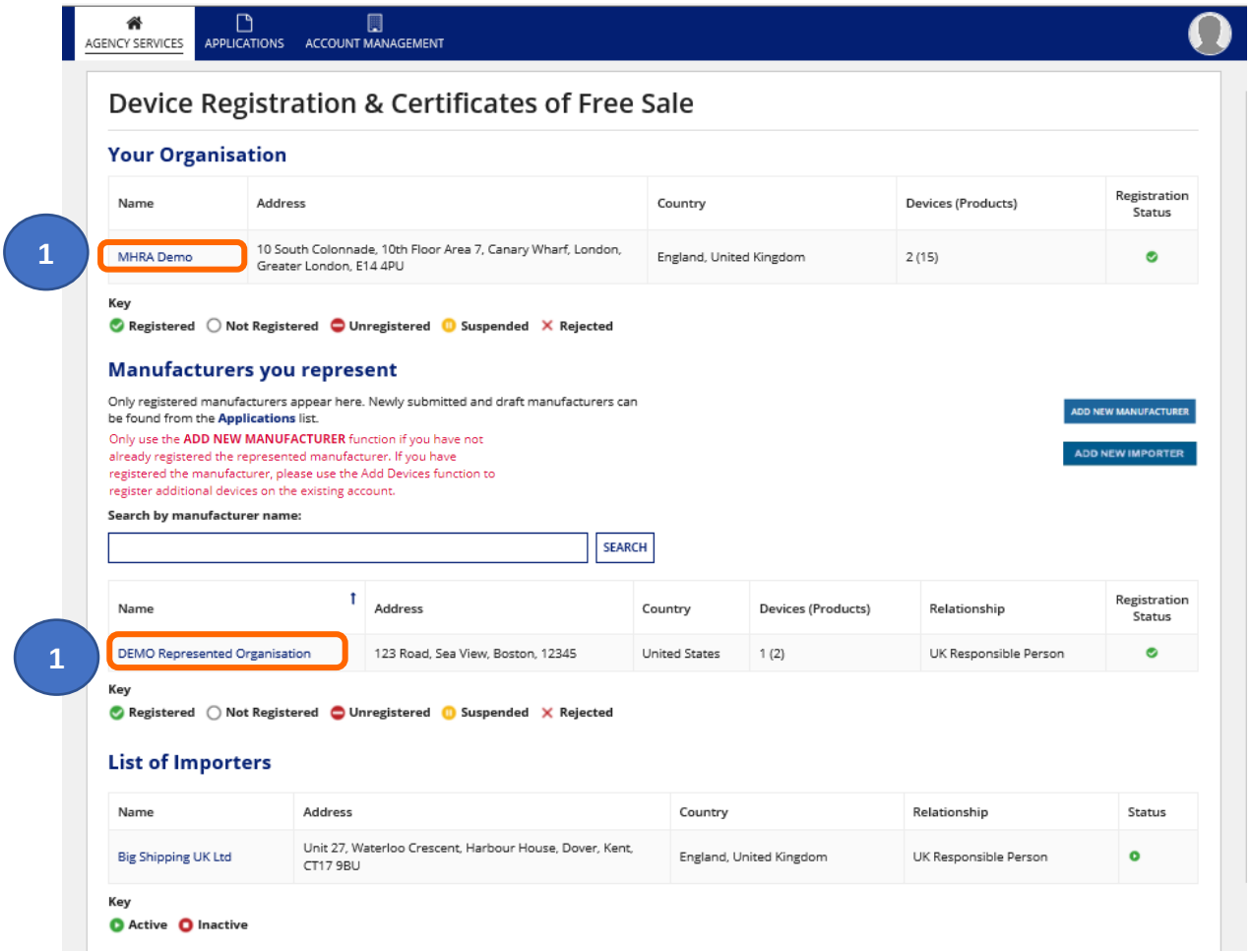


Organisations

Organisation page

1. **Click** on the name to select the manufacturer that you want to order a CFS for. This could be Your Organisation if you are a manufacturer or a Represented Manufacturer if you are a UK Responsible Person in the UK or an Authorised Representative in Northern Ireland.

   Please note you can only order Certificates of Free Sale for registered devices, *in vitro diagnostic* medical devices for performance evaluation cannot be included on CFS orders. Follow all the instructions in the **Device Registration Reference Guide** to Add devices for your organisation or to Add manufacturers that you represent.



Check organisation information

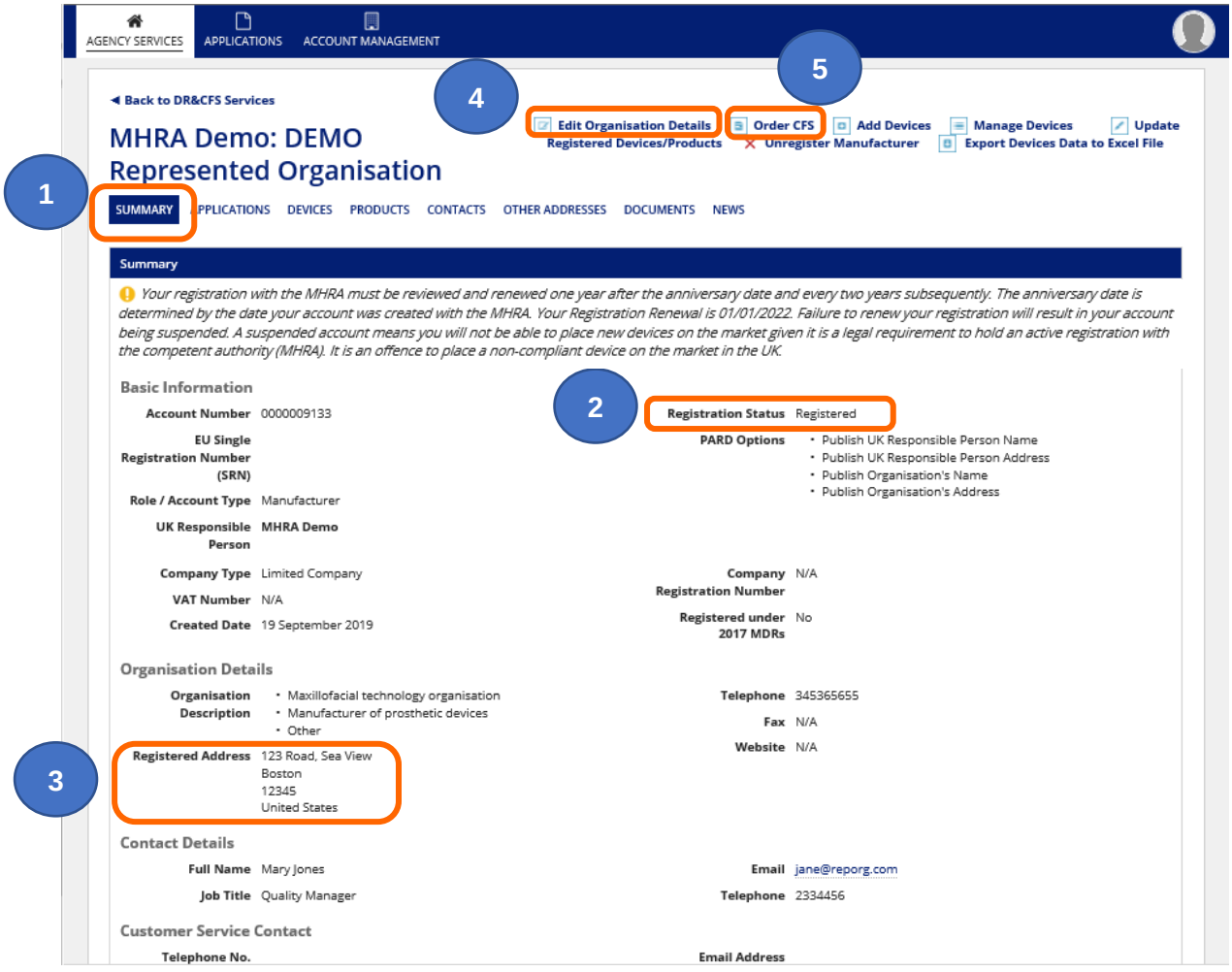
1. **Check** that the organisation information is correct on the Summary page.

2. Check Registration status. CFS can only be ordered for manufacturers with a registration status of 'Registered'. If account status is 'Suspended' you must first either renew registration or submit updated Letter of Designation, as appropriate. See the the **Account Management Reference Guide.**

3. The Registered Address displayed here will be the address printed as the Legal Manufactuer on the Certificate of Free Sale.

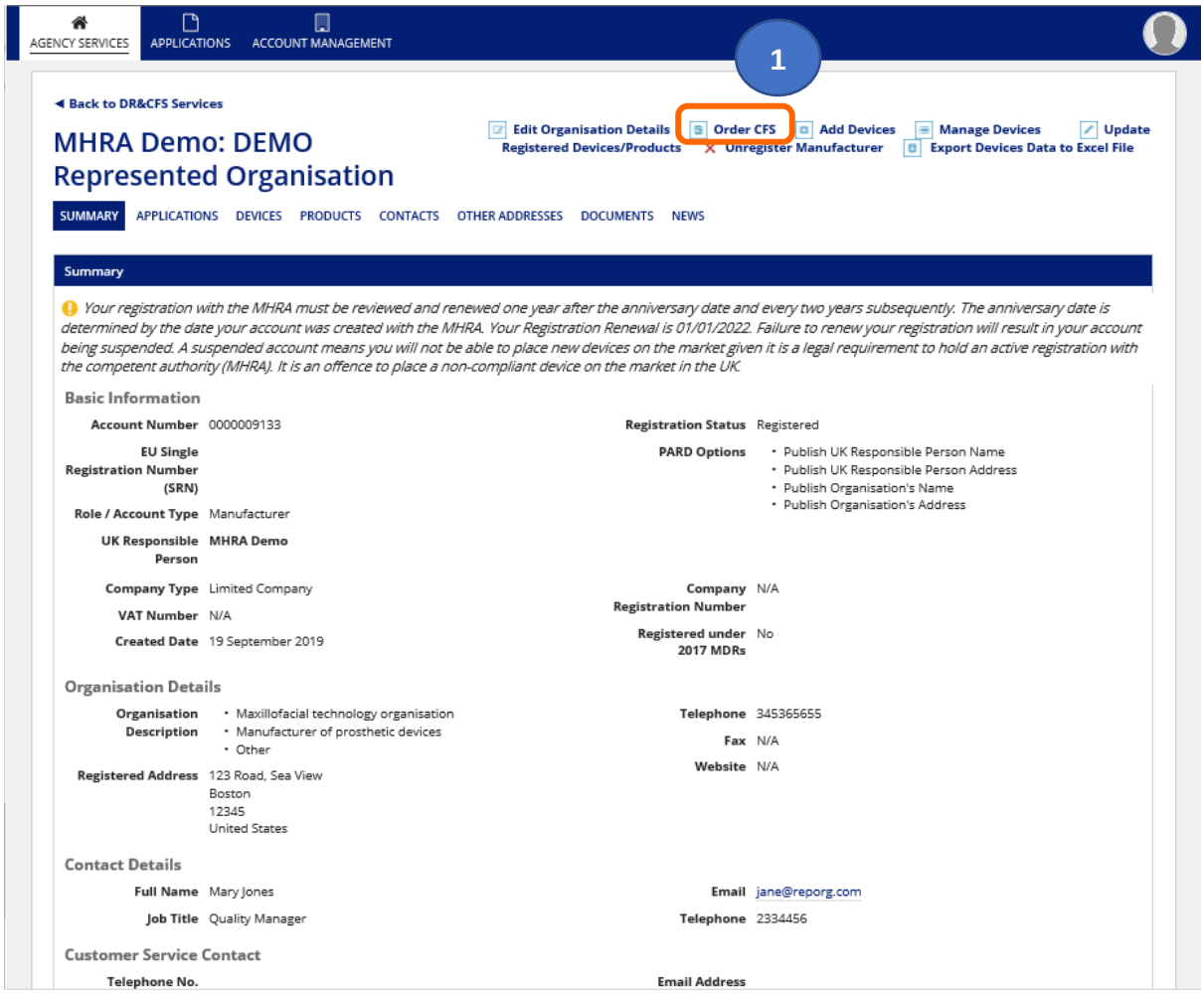
4. If you need to edit organisation details, see the Editing Organisation Details section of the **Account Management Reference Guide**. Statutory fees apply to edit organisation details.

5. If you have already registered devices you will see the option to Order CFS, *in vitro diagnostic* medical devices for performance evaluation cannot be included on CFS orders. If no devices and products have been added, follow all the instructions in the **Device Registration Reference Guide** to Add devices for your organisation or a manufacturer that you represent as a UK Responsible Person in the UK or an Authorised Representative in Northern Ireland.



Ordering a CFS

1. **Click** the Order CFS button.



Completing the CFS Application

Adding products to your CFS order

1. Use the filters to **search** for specific products. Only products that are CFS Ready will display, *in vitro diagnostic* medical devices for performance evaluation cannot be included on CFS orders so will not appear in the product table. If the conformity assessment document linked to the devices has expired, you cannot order CFS for the underlying products.

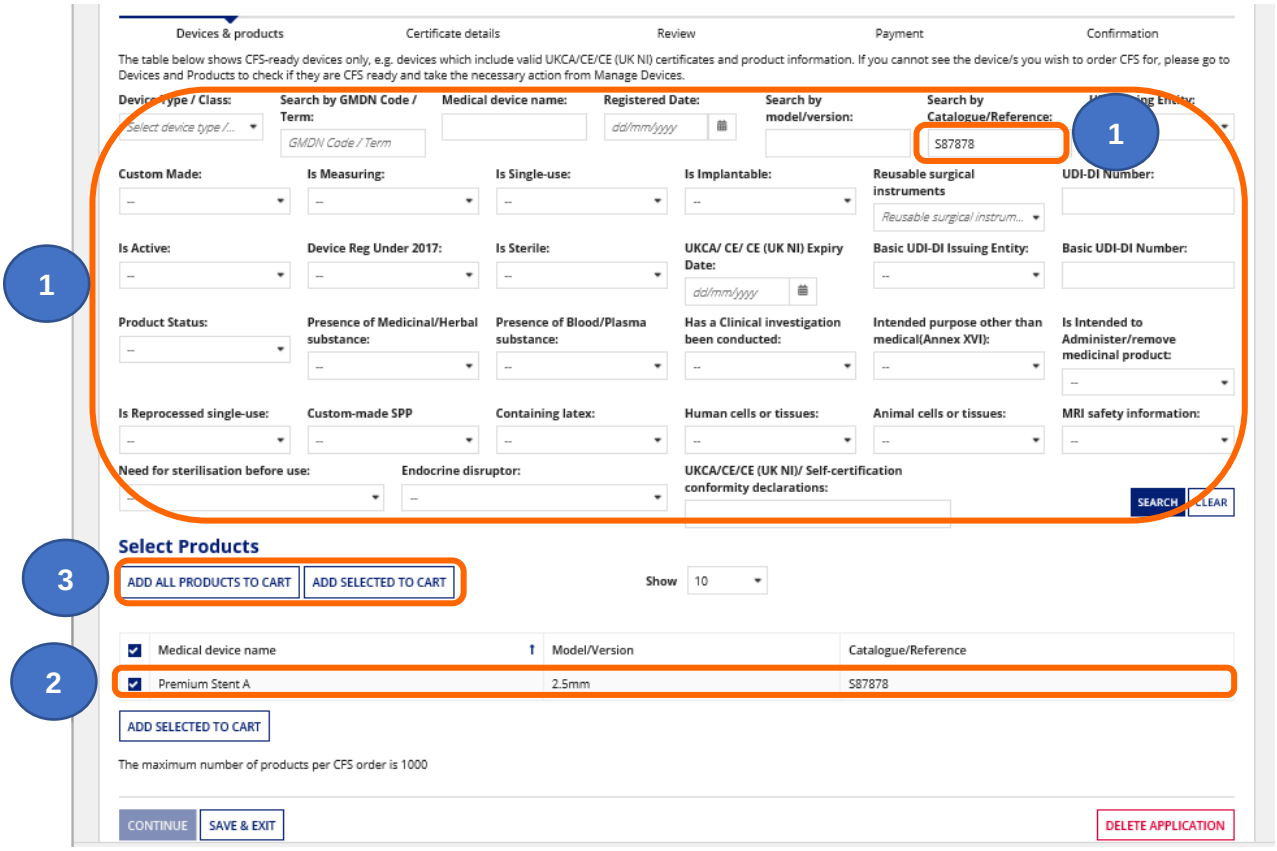
   Please note if products you are expecting to see do not appear, check if conformity assessment document has expired - see Manage registered devices in the **Device Registration Reference Guide**.

   If product information is incorrect see Updating registered devices and products in the **Device Registration Reference Guide**. You may need to remove the product and add it again.

2. **Select** the products which are to appear on the Certificate of Free Sale. **A maximum of 1000 products can be added to the order.**

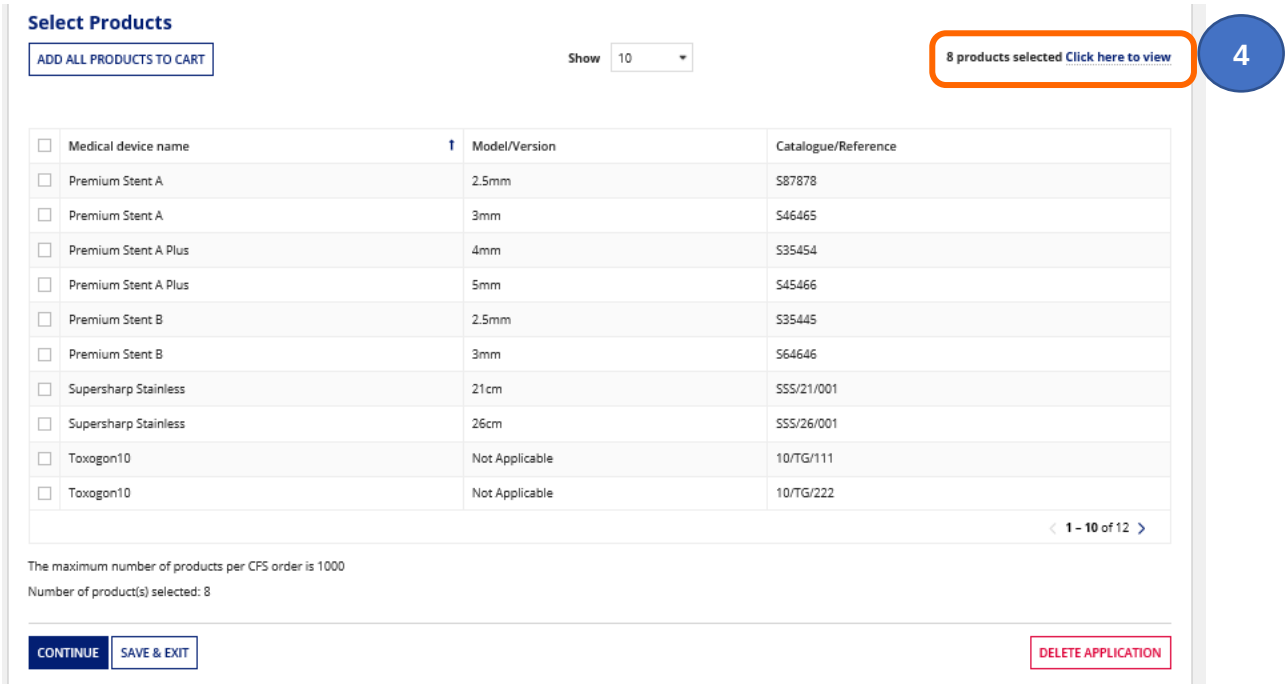
3. Use the Add to Cart function to add your selected products. If you have 1000 products or less, you can Add all products to cart. If you select more than one product, your products will appear on the Schedule attached to the CFS Certificate.

   Please note it is the product data that is added to the CFS order (Medical Device Name, Model/Version and Catalogue/Reference **only**) not the device (GMDN® Code or Term).

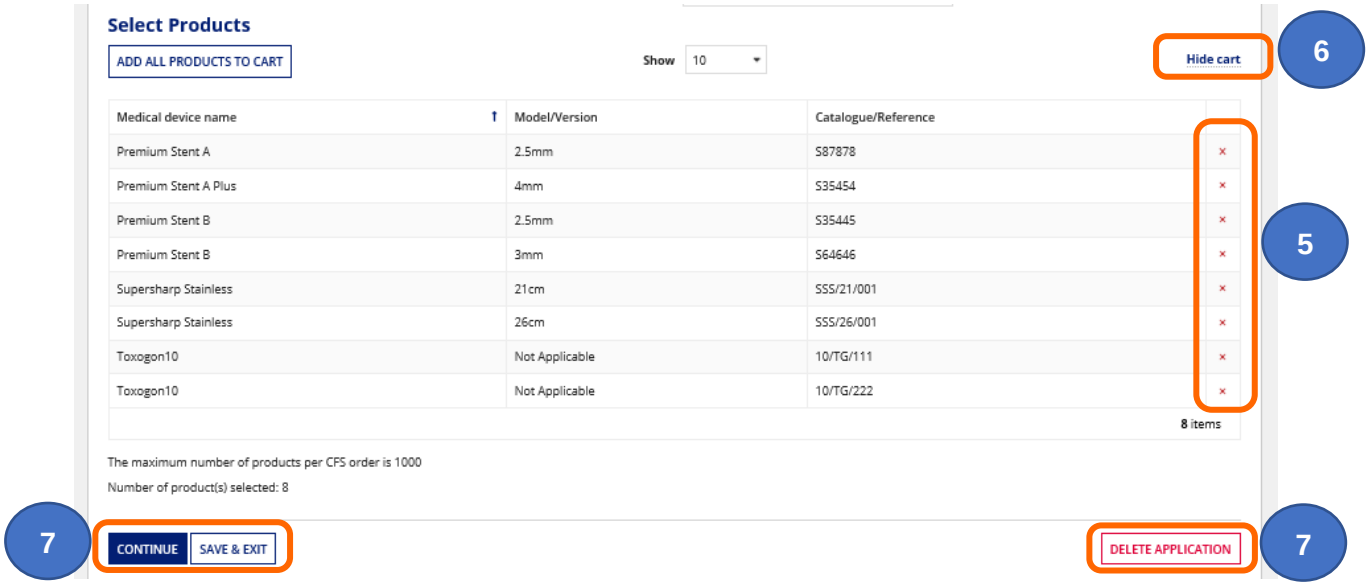


Check products in cart

4. When you have added all the required products to cart **click** to view cart.



5. The products added will display. If you want to remove any **click** the red **X** to remove.



6. **Click** the Hide cart link to add more products. If adding more products, ensure you view cart again before proceeding.

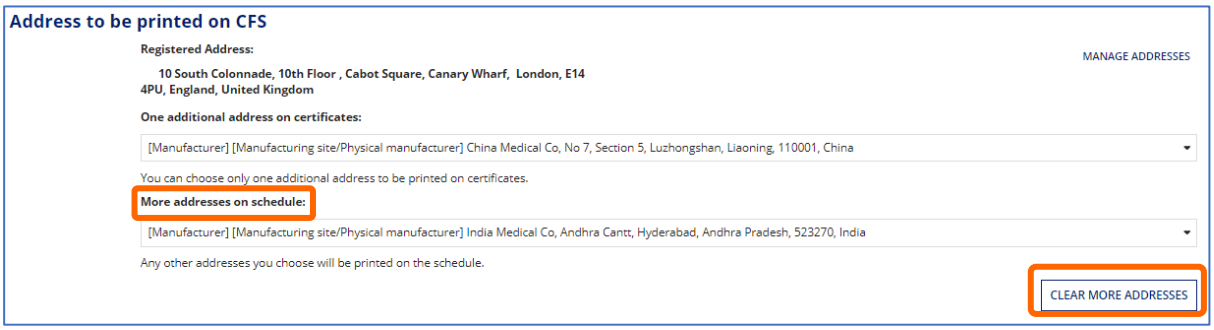
7. **Click** the Continue button to continue to Review page or Save & Exit to save a TEMP application or Delete Application to discard or start again.

Certificate details

1. You can have **one** address in addition to the legal manufacturer's address on the CFS certificate. You can select which additional address appears on the Certificate.

2. You can select more addresses to appear on the schedule. Both UKRP and Authorised Representative addresses as well as manufacturer other addresses will appear in the dropdown. Ensure that you select an address that has been added for this specific manufacturer.

   Important note: the Clear More addresses button is **not** currently working. If you select incorrect addresses you will need to **delete** the application and start again. We are working towards a fix for this issue. Please accept our apologies for any inconvenience and ensure that you **Review order and preview CFS** before making payment.



3. You can add additional addresses to the system by clicking on the Manage addresses link. Follow the steps in the Shipping, Billing, Manufacturing Site Addresses section of the MHRA **Account Management Reference Guide** to add addresses.

   Please note if you click on the Manage addresses link you will be asked to save your application. You can then proceed to Manage addresses then come back and complete your application by following the Save and exit: resume applications instructions.

4. You no longer need to select a Certificate delivery address as all CFS orders are now issued as pdf documents with electronic signature. Hard copies with wet signature are no longer issued. The pdf will be emailed to the email address of the person who placed the order.


AGENCY SERVICES
APPLICATIONS
ACCOUNT MANAGEMENT
CFS (Certificate of Free Sale) Application for DEMO Represented Organisation - TEMP20220221162325
Devices & products
Certificate details
Review
Payment
Confirmation
Address to be printed on CFS
Registered Address:
123 Road, Sea View, Boston, 12345, United States
MANAGE ADDRESSES
3
One additional address on certificates:
[UK Responsible Person] [Billing Address] MHRA Finance Dept, 10, South Colonnade, LONDON, London, E14 4PU, United Kingdom
1
You can choose only one additional address to be printed on certificates.
More addresses on schedule:
[Manufacturer] [Manufacturing site/Physical manufacturer] Mexico Medical inc, 678 Buenavista , Mexico City, Iztacalo, 00810, Mexico
2
Any other addresses you choose will be printed on the schedule.
Special formatting request (optional)
5
The only request that will be considered is for manufacturing site address/s where no schedule is generated due to only one product (model/version) on the order. You must use the 'Other Addresses' function to add manufacturing site addresses for selection on CFS orders where more than one product is added to the order and a schedule will be generated. Only the Medical Device Name, Model/Version and Catalogue/Reference columns will be included on CFS orders. All orders are sorted by Medical Device Name. Please do not ask for other formatting changes as they will not be considered and CFS orders are non-refundable.
4
Certificate delivery address
Registered address:
10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU, England, United Kingdom
MANAGE ADDRESSES
3
Alternative address:

5. **Enter** any Special Formatting Requests.

   Please note MHRA will **not**:

   - add other addresses to the Certificate or Schedule **unless** the order is for a **single** product (where no schedule is generated) – you need to add and select other addresses **before** making payment. Follow the steps in the Shipping, Billing, Manufacturing Site Addresses section of the MHRA **Account Management Reference Guide** to add other addresses

   - make **any** changes to CFS certificate or schedule including layout or text or adding additional columns

6. **Enter** the country name/s and number of certificates. If you do not want to specify a country, tick the 'Do not specify a country' box. Check that the recipient country will accept this.

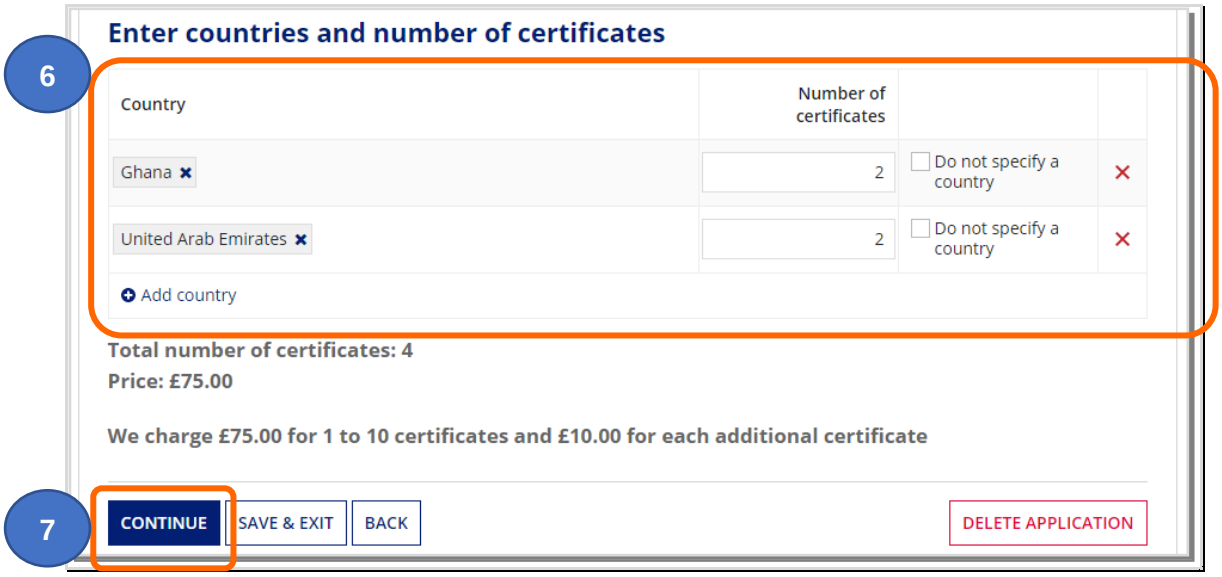
   Please note:
   You can only select from countries that appear in the Foreign, Commonwealth & Development Office's (FCDO) Geographical names index. We print the Country Name from this index on the CFS certificate e.g. for CFS requested for Venezuela we print 'Venezuela', not the Official Name e.g. 'The Bolivarian Republic of Venezuela'.

   If the country name does not appear in the dropdown in the system, or in the above index, you can still order a CFS by selecting 'Do not specify a country'. However, you must check that the recipient country will accept this, before placing your order.

   The fee is dependant on the total number of certificates.

   The expiry date on all CFS certificates will be the earliest Conformity Assessment document expiry date of any device included in the CFS order plus 365 days. For devices with Declaration of Conformity or Custom-made Statements the maximum validity will be 5 years.

7. **Click** the Continue button to review your order.



Review order and preview CFS Certificate and Schedule

1. **Review** and/or **Edit** your Order.

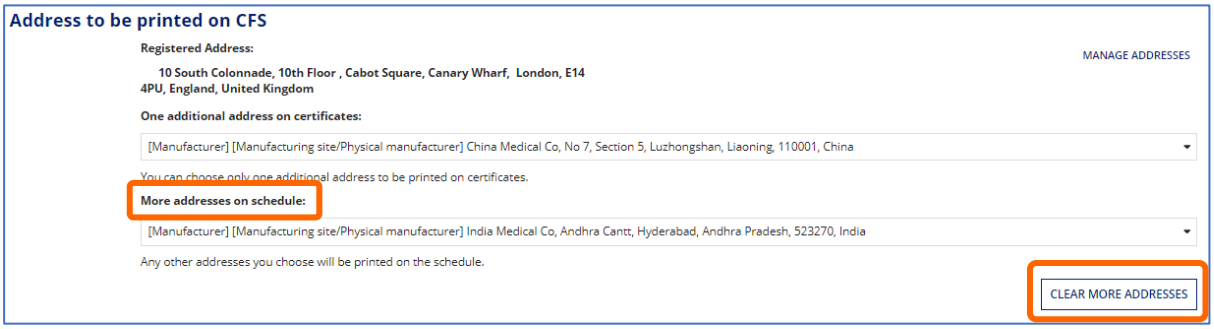
2. **Click** the Download CFS documents Preview link to view and review the CFS certificate and schedule for your order.

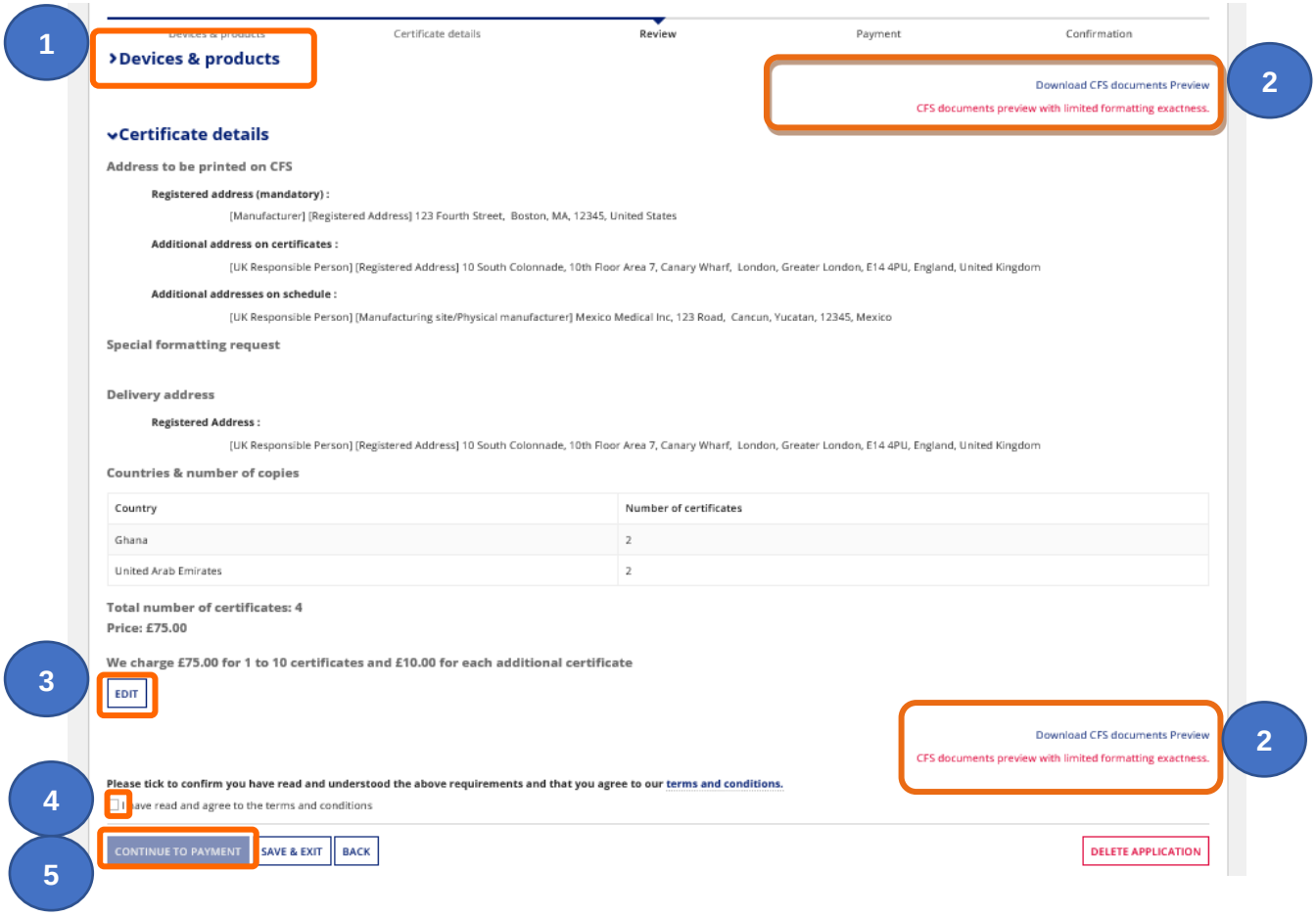
   Please note: Our system allows you to preview an order **before** submitting payment. It is your responsibility to ensure that the order is correct and acceptable to the receiving country. **CFS orders are non-refundable** – see our terms and conditions.

   If you forget to preview your schedule and certificate before you press the Continue to Payment button, and then click the Back button on the payment page, the previews will no longer be available. To preview you will need to go Back again to Order page and then **click** the continue button. The preview will then be available again.

3. If you need to make any changes click the **Edit** button.

   Important note: the Clear More addresses button is **not** currently working. If you select incorrect addresses you will need to **delete** the application and start again. We are working towards a fix for this issue. Please accept our apologies for any inconvenience and ensure that you **Review order and preview CFS** before making payment.





4. **Read & Tick** the 'I have read and agree to the terms and conditions' checkbox if you have read and agree to the terms and conditions.

5. **Click** the Continue to Payment button.

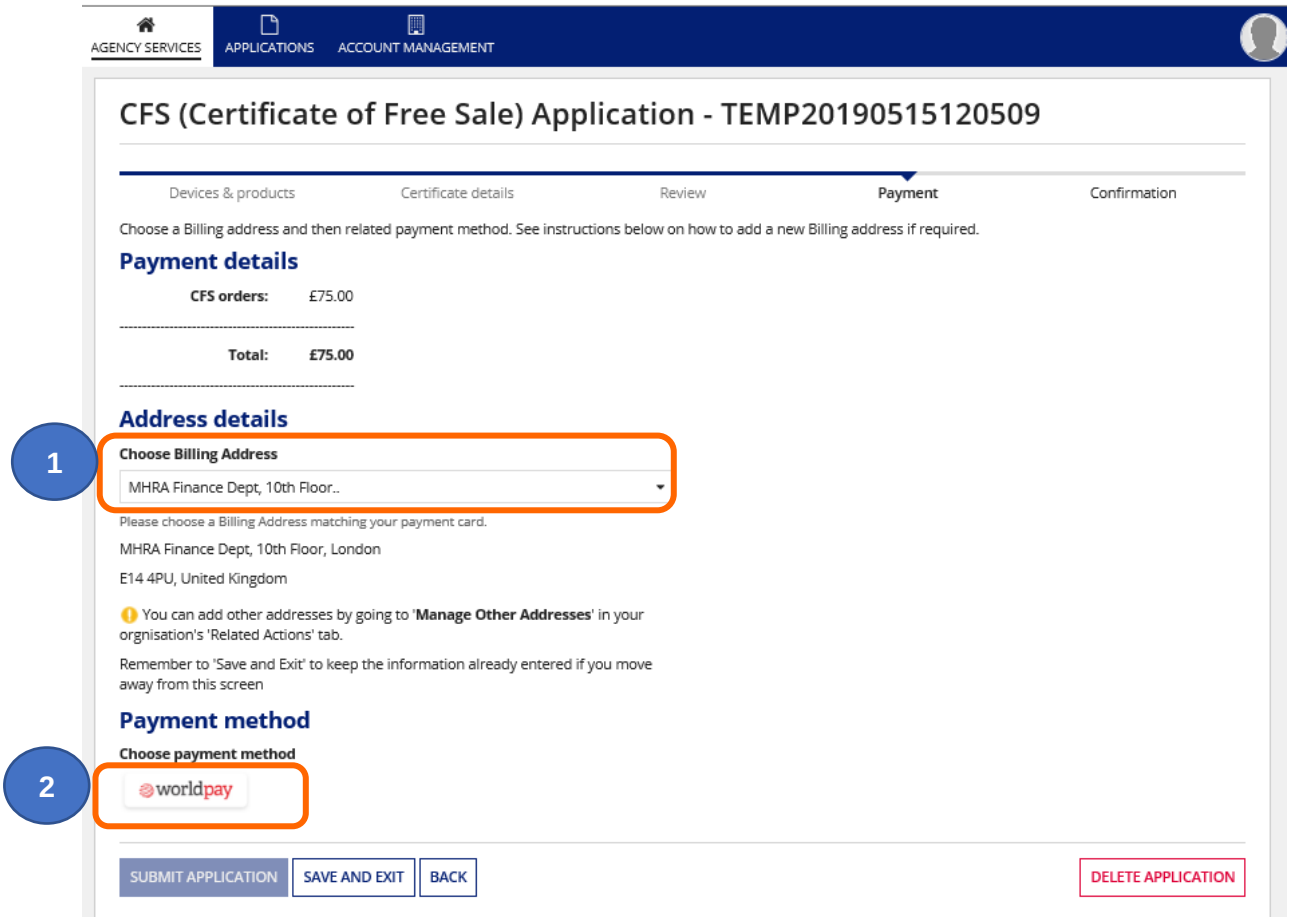
Pay for your CFS order

1. **Chose** a billing address

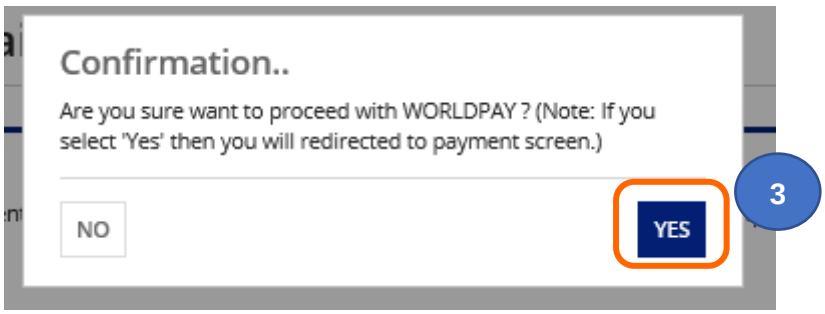
   See Managing Shipping, Billing, Manufacturing Site addresses in the **MHRA Account Management Reference Guide.**

2. **Click** on the worldpay button. We only accept payment by worldpay for CFS orders.

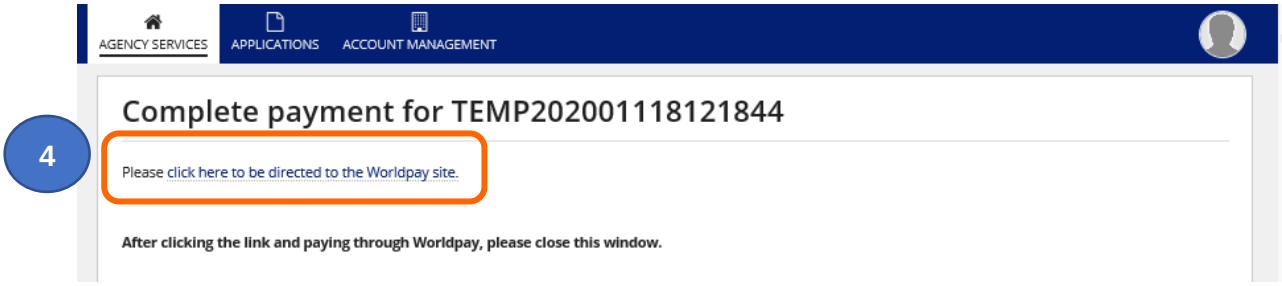
   Important note: Fee in screenshot is for illustrative purposes only. Check current fee on our website.



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

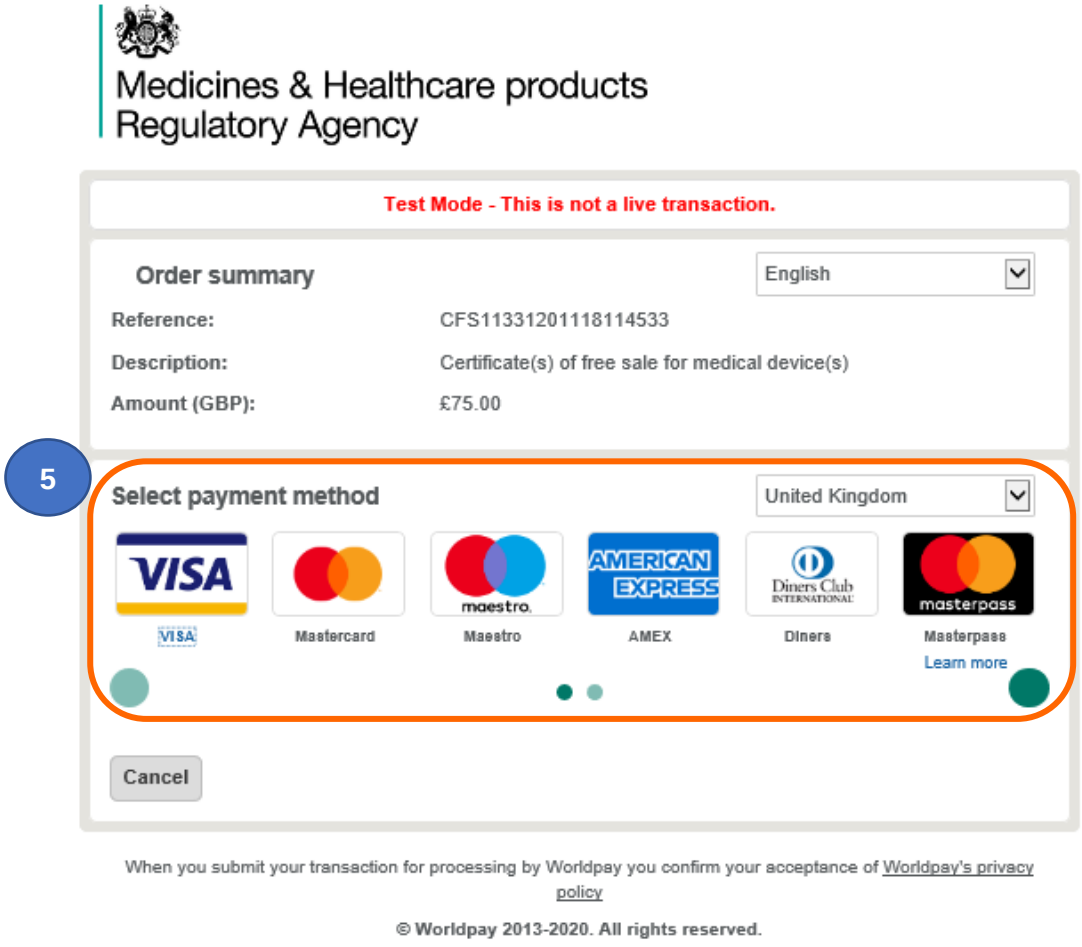


4. **Click** the link to be directed to the worldpay site.



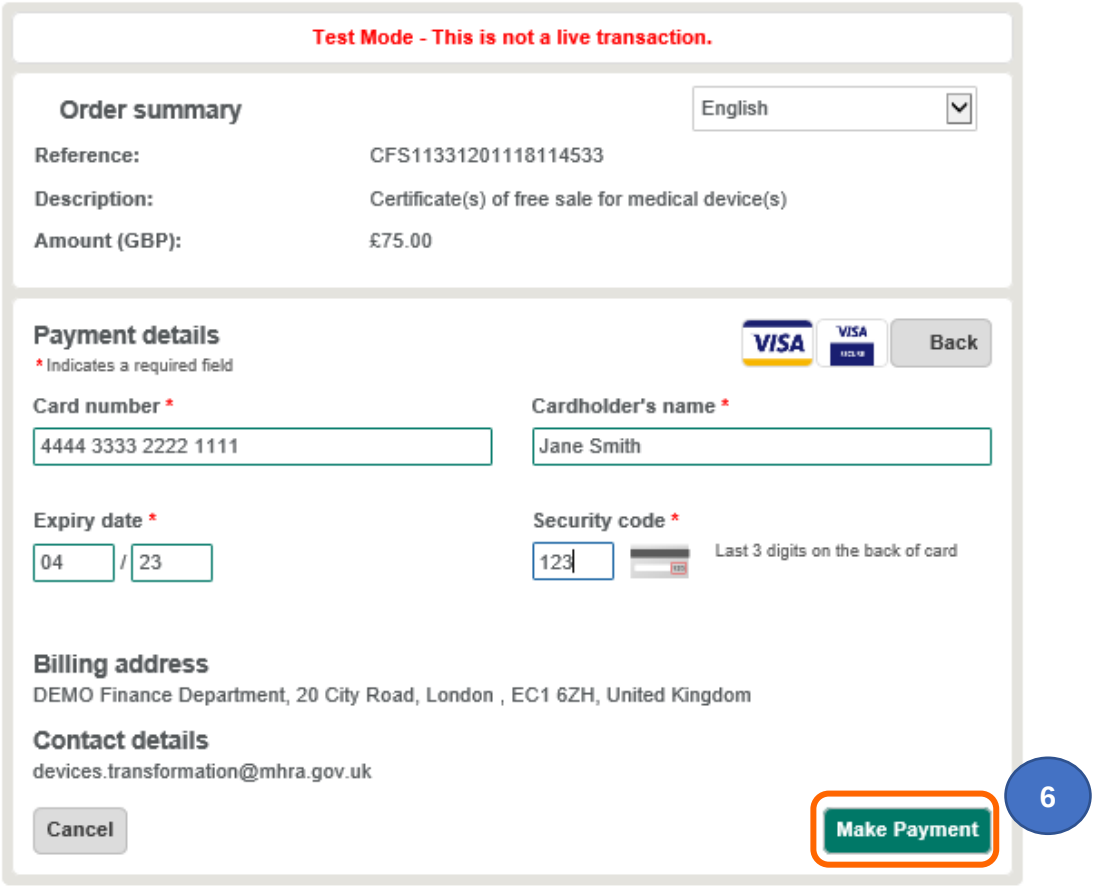
5. **Select** the payment method.

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

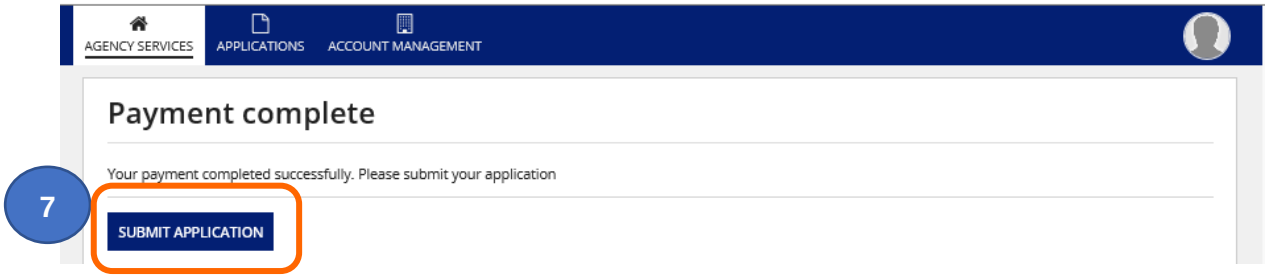


6. Enter payment details and **click** the Make payment button.

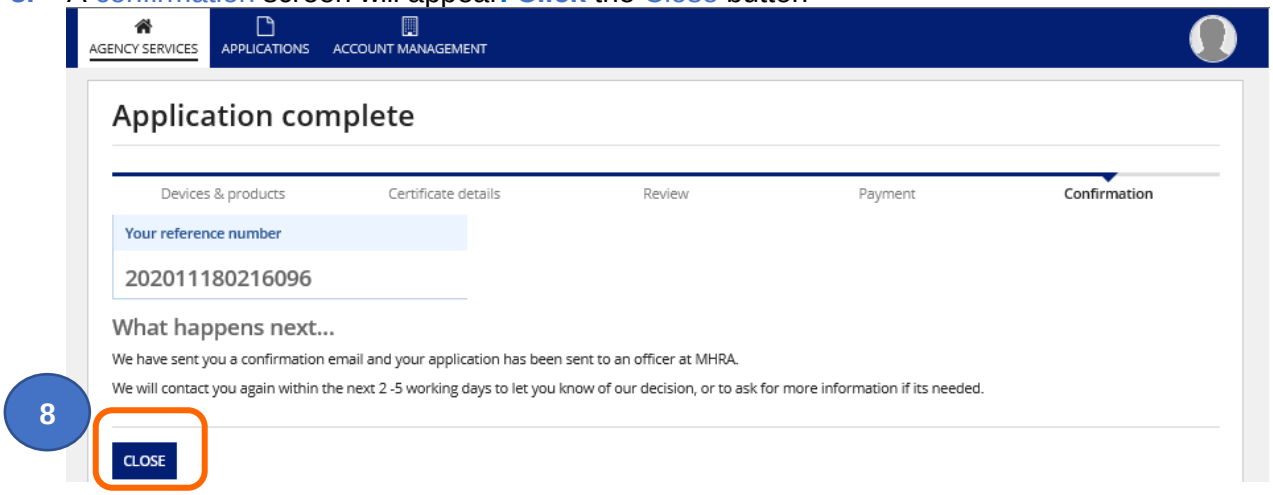
Important note: Fee in screenshot is for illustrative purposes only. Check current fee on our website.



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



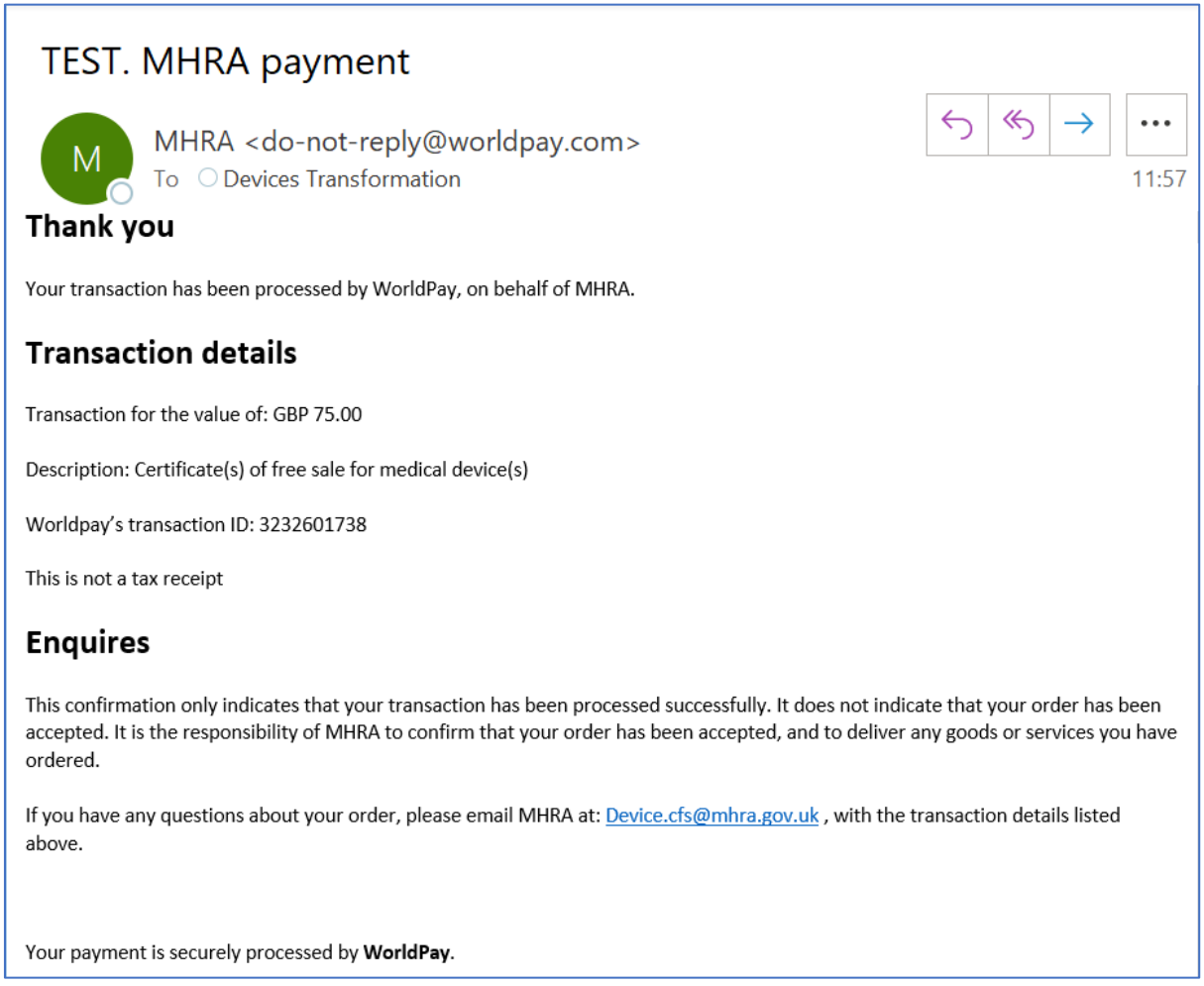
8. A confirmation screen will appear**. Click** the Close button



9. You will receive a confirmation email from worldpay.

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

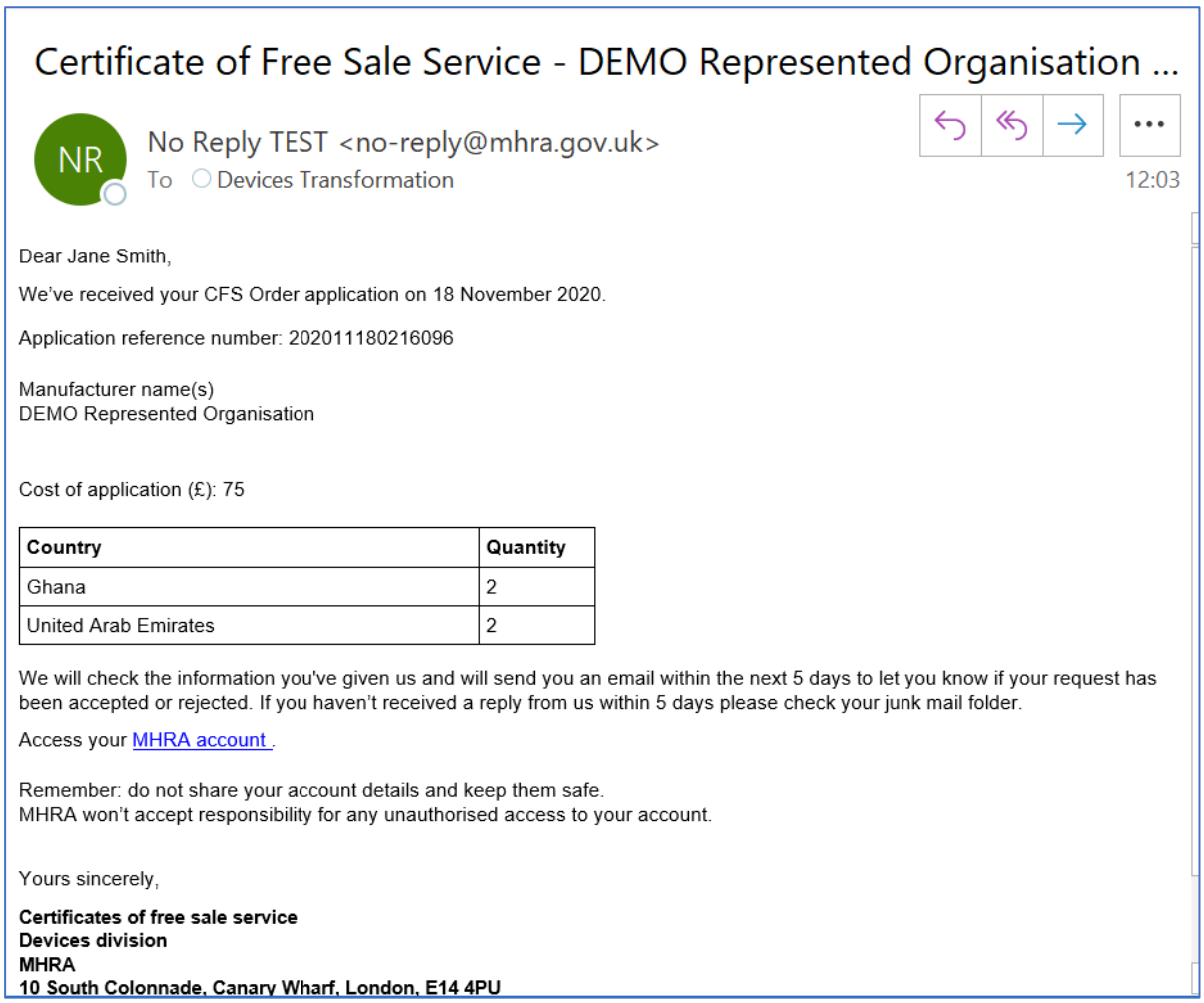
Important note: Fee in screenshot is for illustrative purposes only. Check current fee on our website.



CFS Order confirmation email

10. You will receive a confirmation email from MHRA.

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



Certificate of Free Sale Service - DEMO Represented Organisation ...

NR

No Reply TEST <no-reply@mhra.gov.uk>

To Devices Transformation

12:03

Dear Jane Smith,

We've received your CFS Order application on 18 November 2020.

Application reference number: 202011180216096

Manufacturer name(s)
DEMO Represented Organisation

Cost of application (£): 75

Country	Quantity
Ghana	2
United Arab Emirates	2

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

Access your MHRA account .

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

Yours sincerely,

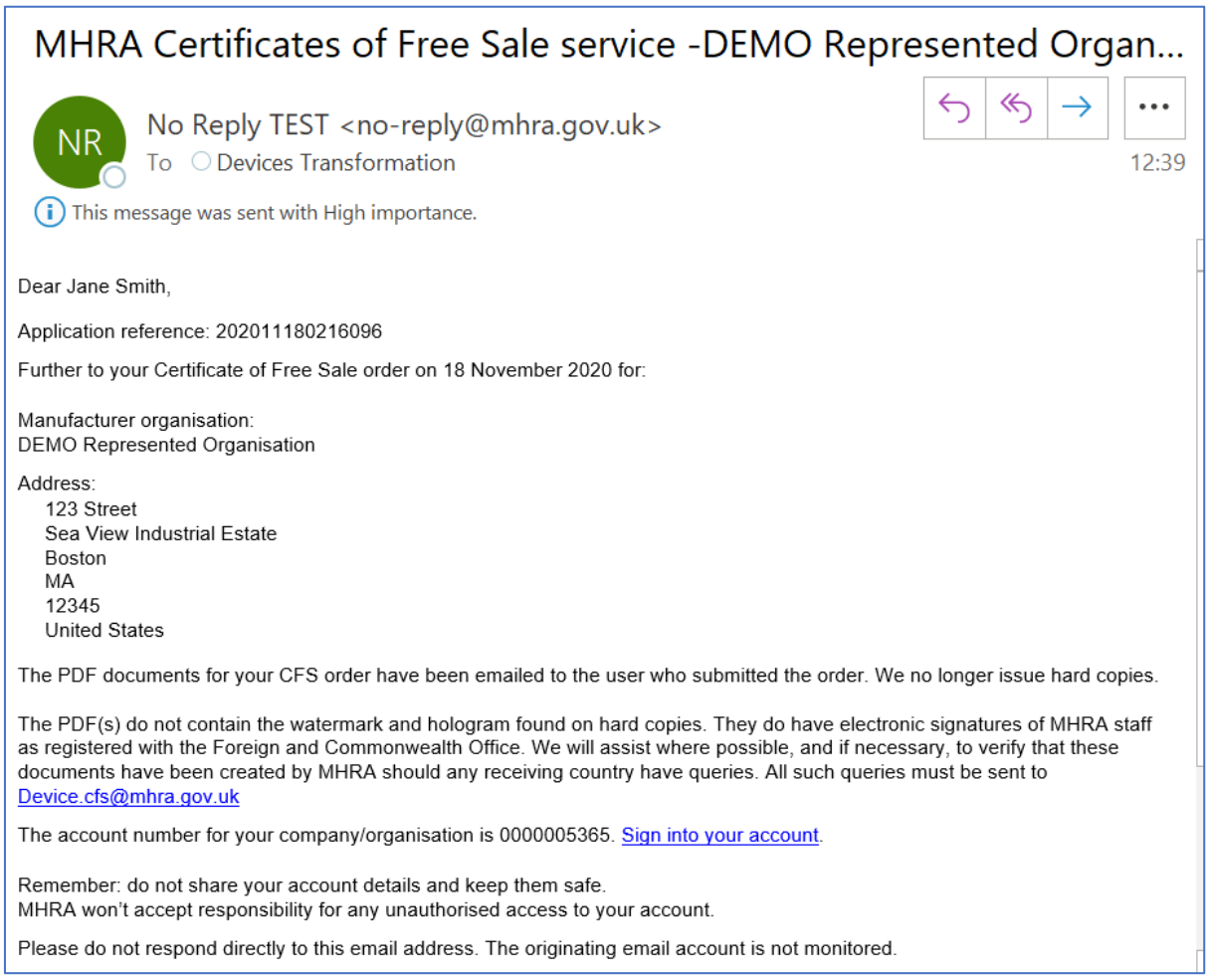
Certificates of free sale service
Devices division
MHRA
10 South Colonnade, Canary Wharf, London, E14 4PU

Order complete confirmation

11. Once we have processed and emailed the pdf documents for your order in a **separate email**, you will receive an automated confirmation email from MHRA.

Please note CFS for medical devices are issued as pdf documents with electronic signature. Hard copies with wet signature are no longer issued. We will try to process your order within 10 working days from date of receipt. During busy periods orders may take longer. Please order as far in advance as possible.

Please note that the Foreign, Commonwealth & Development Office will not apostille pdf documents directly from us. You will need a Notary who will carry out checks on the certificates with MHRA to ascertain their authenticity, and can then notarise the certificates, if required by the recipient country. Once notarised, the Foreign, Commonwealth & Development Office will apostille the documents.



MHRA Certificates of Free Sale service -DEMO Represented Organ...

NR No Reply TEST <no-reply@mhra.gov.uk>

To Devices Transformation 12:39

This message was sent with High importance.

Dear Jane Smith,

Application reference: 202011180216096

Further to your Certificate of Free Sale order on 18 November 2020 for:

Manufacturer organisation:
DEMO Represented Organisation

Address:
123 Street
Sea View Industrial Estate
Boston
MA
12345
United States

The PDF documents for your CFS order have been emailed to the user who submitted the order. We no longer issue hard copies.

The PDF(s) do not contain the watermark and hologram found on hard copies. They do have electronic signatures of MHRA staff as registered with the Foreign and Commonwealth Office. We will assist where possible, and if necessary, to verify that these documents have been created by MHRA should any receiving country have queries. All such queries must be sent to Device.cfs@mhra.gov.uk

The account number for your company/organisation is 0000005365. Sign into your account.

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

Please do not respond directly to this email address. The originating email account is not monitored.

CFS layout

Please note the expiry date on all CFS certificates will be the earliest Conformity Assessment document expiry date of any device included in the CFS order plus 365 days. For devices with Declaration of Conformity or Custom-made Statements the maximum validity will be 5 years.

Medicines & Healthcare products Regulatory Agency

Example only

10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

mhra.gov.uk

Certificate number: **2023051202218001/1**

Order date: **12/05/2023**

CFS Expiry date: **31/10/2024**

Medicines and Healthcare products Regulatory Agency

On behalf of the Secretary of State for Health and Social Care

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO

GHANA

It is hereby certified that, on the basis of information provided, and subject to approval requirements for covid tests (see below), the products named below and detailed in the attached schedule (if applicable), which are manufactured by: Legal Manufacturer: **DEMO Represented Organisation,** 123 Road, Sea View, Boston, 12345, United States UK Responsible Person: **MHRA Demo,** 10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU, England, United Kingdom have been affixed with the relevant conformity marking(s) e.g. CE under EU MDD 93/42/EEC, CE under EU IVDD 98/79/EC, UKCA under UK MDR (2002/618) Part II and may be freely sold in Great Britain (England, Scotland, Wales). In the UK, certain covid test devices must be approved by the Secretary of State before they can be freely placed on the market or put into service. UK approved tests are listed at: https://www.gov.uk/government/publications/covid-19-test-validation-approved-products.

Please see attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate. In issuing Certificates of Free Sale, the MHRA does not assess or verify that the product complies with relevant export requirements and restrictions. It is the applicant's responsibility to ensure compliance with these requirements and restrictions.

Yours sincerely,

Schedule layout

Please note only the Medical Device Name, Model/Version and Catalogue/Reference, Basic UDI DI and UKCA or CE Certificate Reference No. data will appear on the CFS certificate or schedule. If any of these fields have not been populated in the registrations system, ' 'Not applicable' or N/A' or will appear on the CFS certificate or schedule. To populate these fields, where applicable, follow the Update products instructions in the **Device Registration Reference Guide**.

If you select more than one product, your products will appear on the Schedule attached to the CFS Certificate. Please also note that it is the product that is added to the CFS order (Medical Device Name, Model/Version and Catalogue/Reference, Basic UDI DI and UKCA or CE Certificate Reference No. **only**) not the device (GMDN® Code or Term).

Certificate Reference: 20230512022180001/1
Ordered on: 12/05/2023

Directive/Regulation: CE under EU MDD 93/42/EEC, CE under EU IVDD 98/79/EC, UKCA under UK MDR (2002/618) Part II,

Manufacturer Name: DEMO Represented Organisation

CFS Expiry Date: 31/10/2024

Addresses:

[UK Responsible Person] Manufacturing site/Physical manufacturer: India Medical Co , Andhra Cantt, Hyderabad, Andhra Pradesh, 523270, India
[UK Responsible Person] Manufacturing site/Physical manufacturer: Mexico Medical Inc, 123 Road, Cancun, Yucatan, 12345, Mexico

#	Medical Device Name	Model/Version	Catalogue/ Reference	Basic UDI DI	Certificate Reference No.
1	Altmatsys	Altmatsys1	AMS/001/01	N/A	BSI_6533453
2	Custom retainer	Cusret1	Not Applicable	N/A	N/A
3	Custom retainer-child	Cusretchild1	Not Applicable	N/A	N/A
4	Premium Stent A	3mm	S46465	8788787656	67868768, 5746576567_EU MDR Art120 Extension
5	Premium Stent A	2.5mm	S87878	8788787656	67868768, 5746576567_EU MDR Art120 Extension
6	Premium Stent A Plus	5mm	S45466	8788787656	67868768, 5746576567_EU MDR Art120 Extension
7	Premium Stent A Plus	4mm	S35454	8788787656	67868768, 5746576567_EU MDR Art120 Extension
8	Premium Stent B	3mm	S64646	8788787656	67868768, 5746576567_EU MDR Art120 Extension
9	Premium Stent B	2.5mm	S35445	8788787656	67868768, 5746576567_EU MDR Art120 Extension
10	Supersharp Stainless	21cm	SSS/21/001	657668787889898	67868768
11	Supersharp Stainless	26cm	SSS/26/001	657668787889898	67868768
12	Toxogon10	Not Applicable	10/TG/444	076568548548	546576767
13	Toxogon10	Not Applicable	10/TG/333	076568548548	546576767

Page **2** of **3**

Manage registered devices

If products need to be added or removed from an existing registered device or Conformity Assessment documents certificates need to be uploaded, linked, or removed (unlinked) from existing registered devices this can be done using the Manage registered devices function. There is currently no fee to do this.

Follow the instructions in the Updating Registrations section of the **Device Registration Reference Guide** to Manage registered devices.

Update registered devices and products

If products need to be updated, for example Catalogue/Reference data has changed or was not added at the time of registration, this can be done using the Update registered devices and products function. If Medical Device Name or Model/Version needs to be updated, you will need to remove the product and add it again. There is currently no fee to do this.

If Basic UDI DI needs to be added follow the Update Device Details instructions in the **Device Registration Reference Guide**.

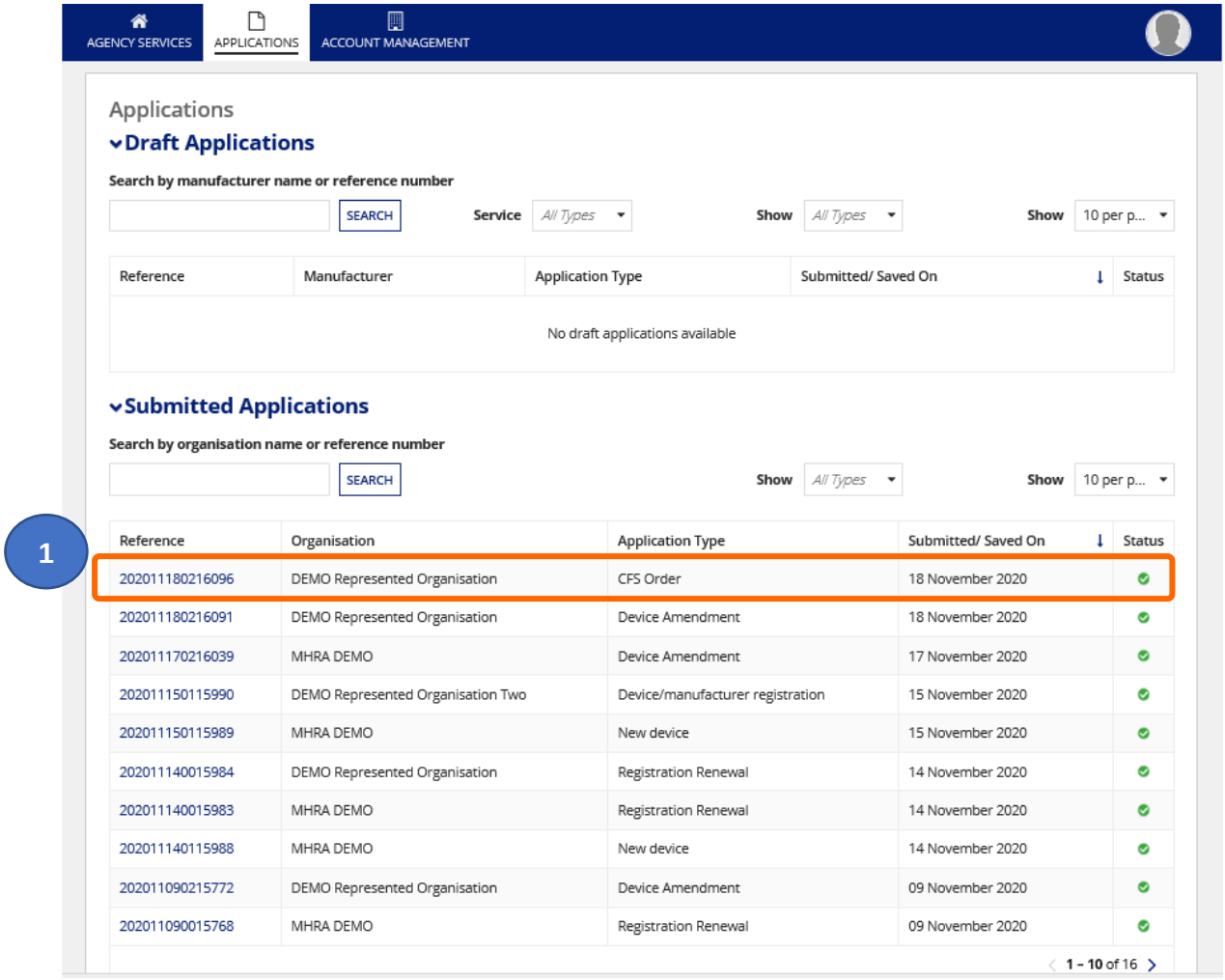
If product data needs to be updated, follow the Update products instructions in the **Device Registration Reference Guide**.

Re-ordering a CFS

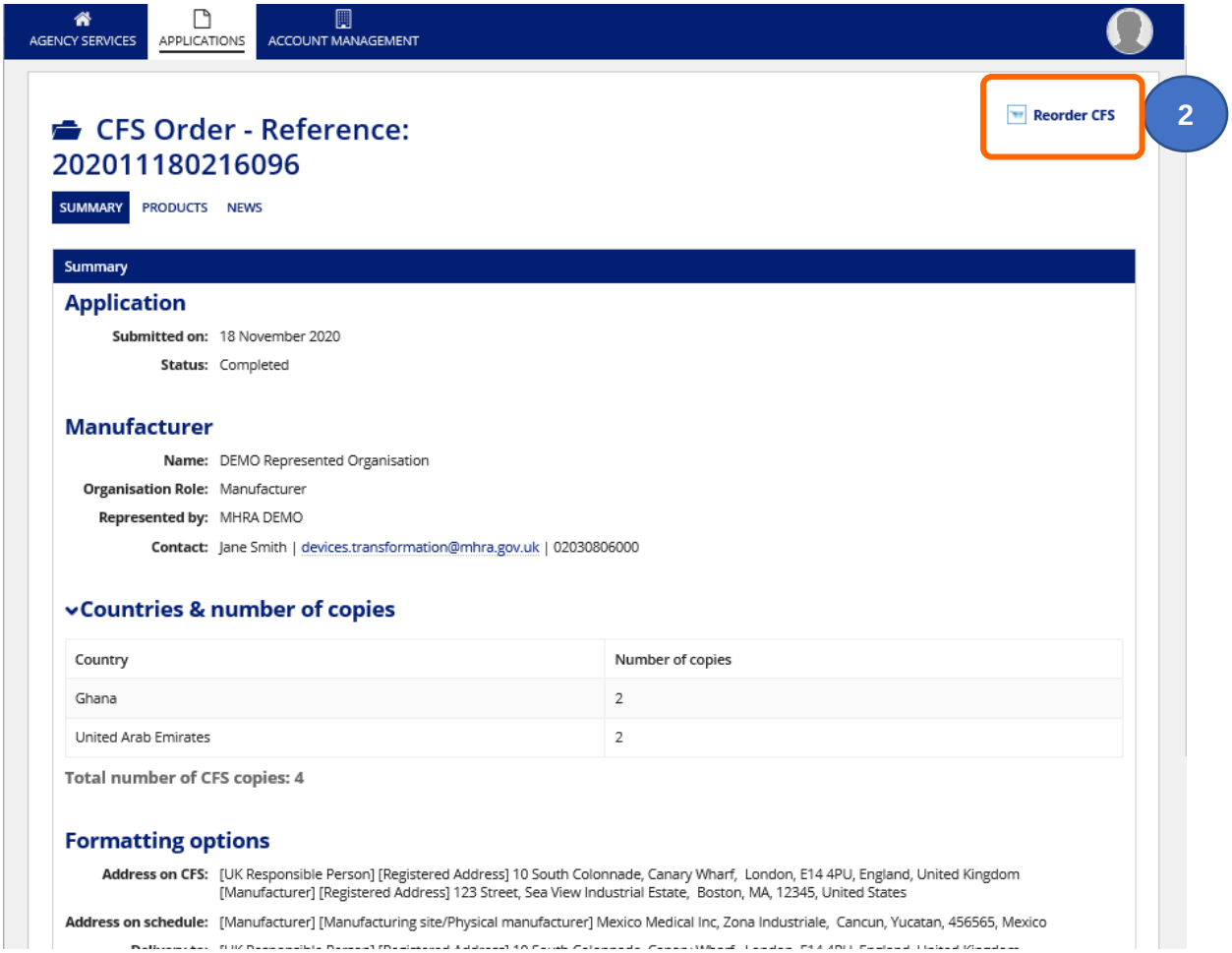
You can repeat a previous CFS order, optionally amending any of the information entered previously.

1. In your list of applications, **select** the previously completed application you would like to reorder by **clicking** on the Reference number.

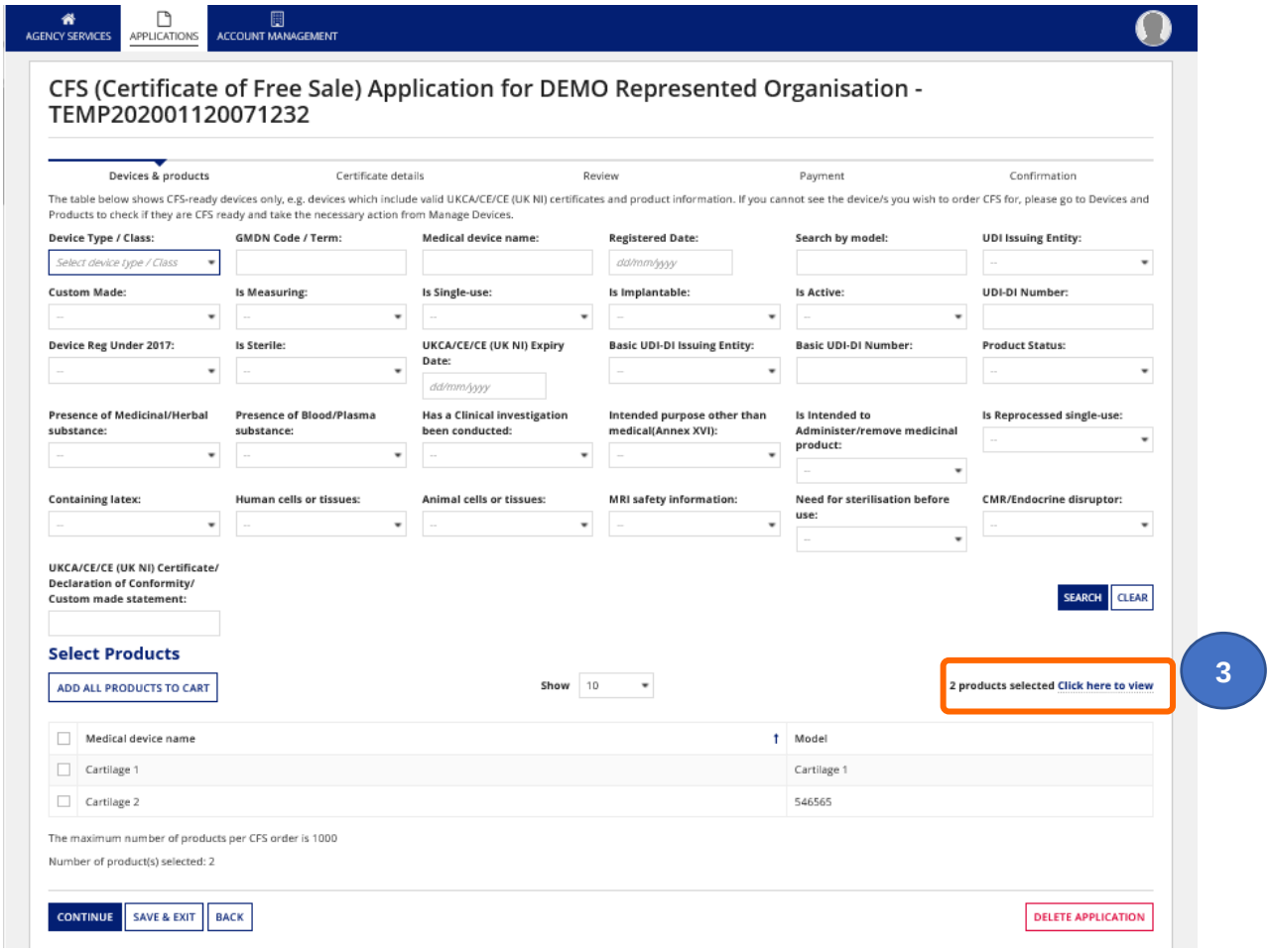
   Please note you will not be able to use the 'Reorder' functionality for any CFS orders submitted prior to 23 May 2018.



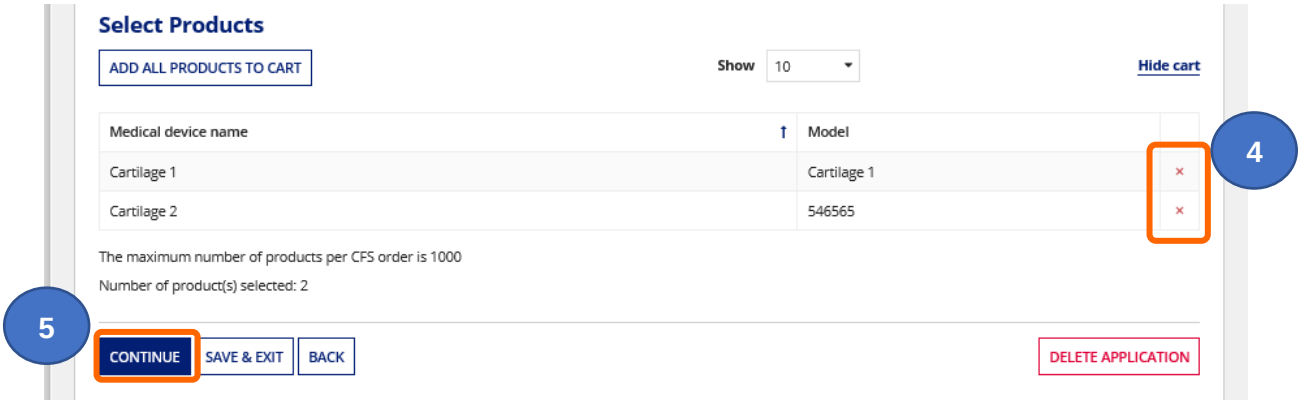
2. **Select** the Reorder CFS link in the top right corner.



3. The products and information entered on the previous order will be pre-populated, providing Conformity Assessment certificates are still valid, but you can add or remove products for the new order as required. **Select** the Click here to view link to view all products on the original order.

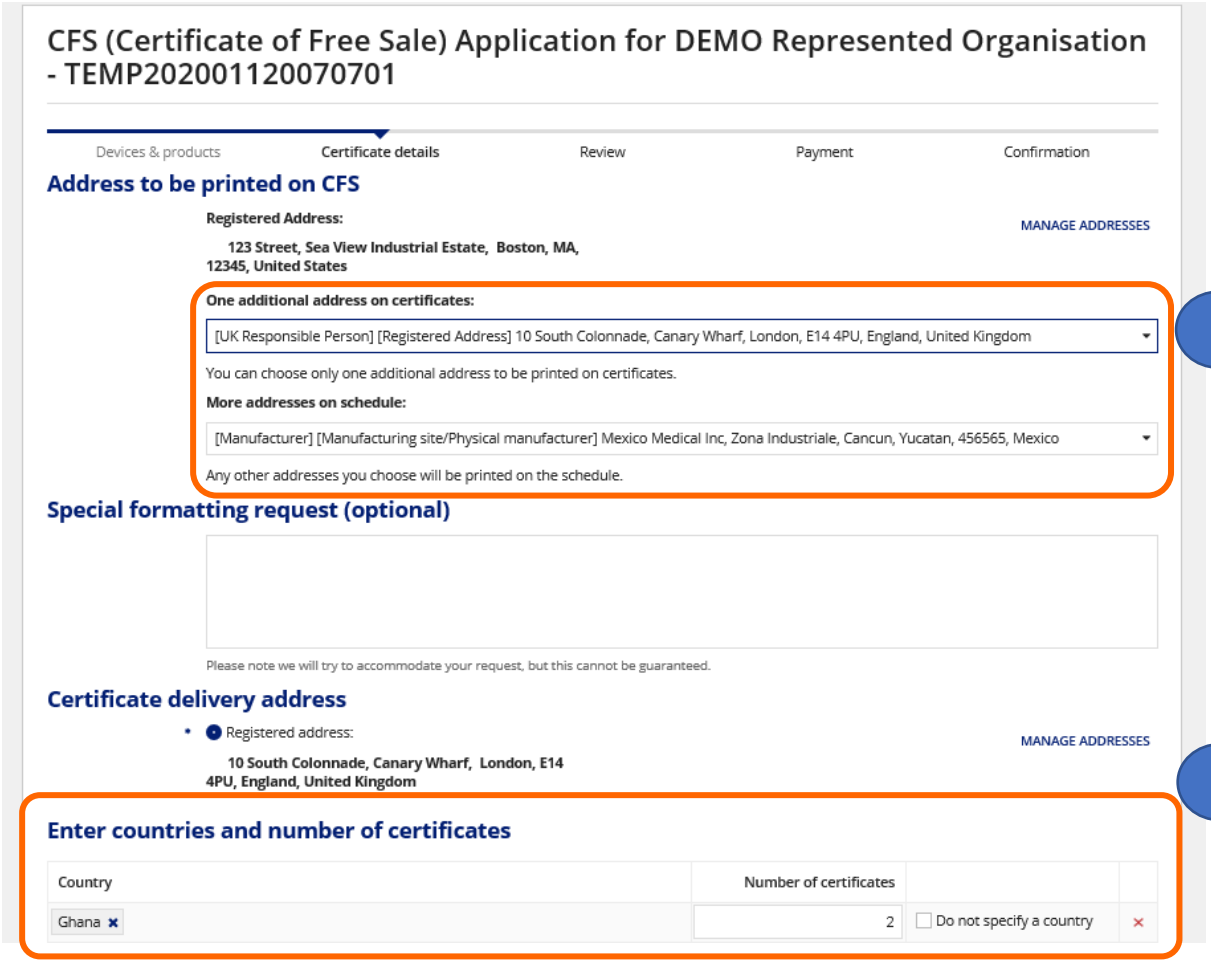


4. To remove product not required on this new order **click** the red **X** next to the product.



5. **Click** the Continue button.

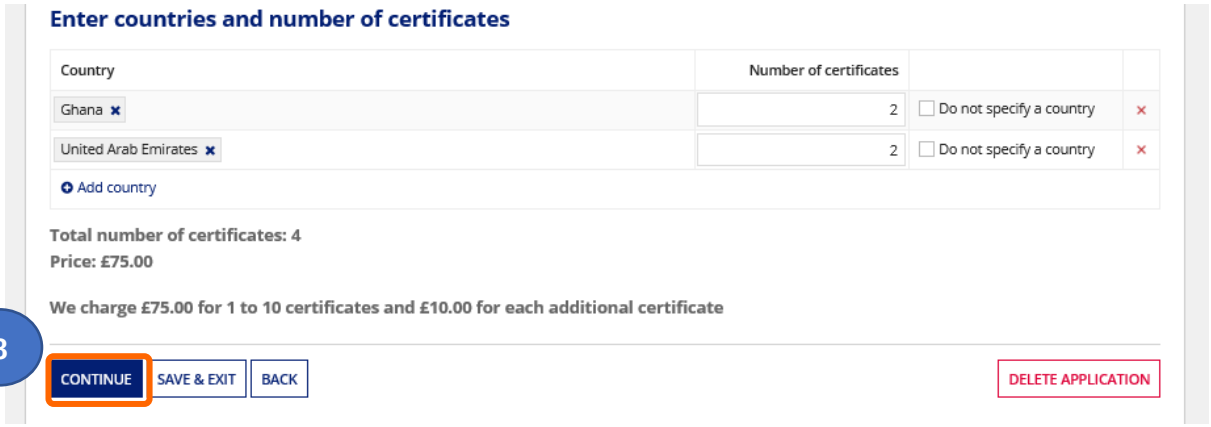
6. Make any required changes to Addresses.



7. Make any required changes to Countries and number of certificates. If you want to remove a country that was on the original order, **click** the red **X**.

8. Click continue to the review page and Review your order and preview CFS Certificate and Schedule then Pay for your CFS Order.

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



Save and exit: resume applications

When completing an application, you can save, exit and return to completing the application from where you left off. This option is not available on all screens.

Please follow the instructions in the **Device Registration Reference Guide**.

Adding a New Manufacturer (for UKRP in UK and AR in NI)

Follow the instructions in the Updating Registrations section of **the Device Registration Reference Guide** for Adding a Manufacturer. The current statutory fee will be payable.

Annex I – Workflow