Medicines & Healthcare products Regulatory Agency

Certificates of Free Sale

Reference Guide

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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:

- 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 Forgot your 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 passw	vord.
Old Password	
New Password	
Confirm New Password	2
[CANCEL SUBMIT

- 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.

Regulatory Agency	
Password	
Forgot your password?	LOG
gov.uk	
MHRA Terms & Conditions	

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Medicines & Healthcare products **Regulatory Agency**

Forgot Password

2

Username

Enter your username and CICK 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



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.

Device Regi		e buie			
Your Organisat	ion				
Name	Address	Country		Devices (Products)	Registra Statu
	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, E14 4PU	England, United	d Kingdom	2 (15)	۲
© Registered O Not R Manufacturers	Registered Ourregistered OSuspended X Rejected				
Only registered manufact be found from the Applic Only use the ADD NEW M already registered the repi	urers appear here. Newly submitted and draft manufacturers of tations list. ANUFACTURER function if you have not resented manufacturer. If you have rer, please use the Add Devices function to s on the existing account. r name:	RCH			
Only registered manufact be found from the Applic Only use the ADD NEW M . already registered the repi registered the manufactur register additional devices	urers appear here. Newly submitted and draft manufacturers of tations list. ANUFACTURER function if you have not resented manufacturer. If you have rer, please use the Add Devices function to s on the existing account. r name:		Devices (Products)		D NEW IMPOR
Only registered manufact be found from the Applic Only use the ADD NEW M . already registered the repi registered the manufacturer registered additional devices Search by manufacturer Name DEMO Represented Org	viers appear here. Newly submitted and draft manufacturers of tations list. ANUFACTURER function if you have not resented manufacturer. If you have ere, please use the Add Devices function to s on the existing account. r name: SEA	IRCH	Devices (Products) 1 (2)	AD	D NEW IMPOR
Only registered manufact be found from the Applic Only use the ADD NEW M already registered the repu- registered the manufactur register additional devices Search by manufacturer Name DEMO Represented Org Key	vurers appear here. Newly submitted and draft manufacturers of tations list. ANUFACTURER function if you have not resented manufacturer. If you have tere, please use the Add Devices function to is on the existing account. r name: SEA 1 Address tanisation 123 Road, Sea View, Boston, 12345 Registered Ourregistered OSuspended X Rejected	Country		Relationship	NEW MANUFACT D NEW IMPOR Registra Statu

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.
- If you need to edit organisation details, see the Editing Organisation Details section of the Account Management Reference Guide. <u>Statutory fees</u> 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.

AGEN	CY SERVICES APPLICAT			
	I Back to DR&CFS Servi		Edit Organisation Details	CFS Add Devices Manage Devices / Update
	MHRA Dem	o: DEMO	Registered Devices/Products X Univ	
F	Represente	d Organisation		
		NS DEVICES PRODUCTS CONTACTS	OTHER ADDRESSES DOCUMENTS NEWS	
	Summary			
	determined by the da being suspended. A si	te your account was created with the M uspended account means you will not b	IHRA. Your Registration Renewal is 01/01/2022	d every two years subsequently. The anniversary date is . Failure to renew your registration will result in your account en it is a legal requirement to hold an active registration with
	Basic Information			
	Account Number	0000009133	2 Registration Status	Registered
	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 2017 MDRs	No
	Organisation Deta	ils		
	Organisation	 Maxillofacial technology organisation 	Telephone	345365655
	Description	 Manufacturer of prosthetic devices Other 	Fax	N/A
3	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
	Customer Service	Contact		
	Telephone No.		Email Address	

Ordering a CFS

1. Click the Order CFS button.

CY SERVICES APPLICAT	IONS ACCOUNT MANAGEMENT		1
Back to DR&CFS Servi	o: DEMO	Edit Organisation Details	
	d Organisation		
SUMMARY APPLICATIO	NS DEVICES PRODUCTS CONTACTS OTHER A	DDRESSES DOCUMENTS NEWS	
Summary			
determined by the dat being suspended. A su	te your account was created with the MHRA. Yo	ur Registration Renewal is 01/01/2022. p place new devices on the market give	d every two years subsequently. The anniversary date is Failure to renew your registration will result in your accoun n it is a legal requirement to hold an active registration with
Basic Information			
Account Number	0000009133	Registration Status	Registered
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 2017 MDRs	No
Organisation Deta	ils		
Organisation	 Maxillofacial technology organisation 	Telephone	345365655
Description	 Manufacturer of prosthetic devices Other 	Fax	N/A
Registered Address		Website	N/A
Contact Details			
Full Name	Mary Jones	Email	jane@reporg.com
Job Title	Quality Manager	Telephone	2334456
Customer Service	Contact		
Telephone No.		Email Address	

Completing the CFS Application

Adding products to your CFS order

 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.
- 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).

	evice Type / Class:	Search by GMDN Code /	Medica	I device name:	Registered [)ate:	Search by	Search by	ing End
	Select device type / 🔹	Term: GMDN Code / Term			dd/mm/yyyy	/ 🗰	model/version:	Catalogue/References	
9	ustom Made:	Is Measuring:		Is Single-use:		ls Implanta		Reusable surgical instruments	UDI-DI Number:
Ľ	-	•	•		•	-	•	Reusable surgical instrum 🔹	
l!	Active:	Device Reg Under 20)17:	Is Sterile:		UKCA/ CE/ Date:	CE (UK NI) Expiry	Basic UDI-DI Issuing Entity:	Basic UDI-DI Number
	-	•	•		•	dd/mm/yy	y 🗯	•	
. .	roduct Status:	Presence of Medicin substance:	al/Herbal	Presence of Bloo substance:	od/Plasma	Has a Clinio been condu	al investigation	Intended purpose other than medical(Annex XVI):	ls Intended to Administer/remove medicinal product:
L 1		-	•		-	-	•	•	
Ŀ	Reprocessed single-use	custom-made SPP		Containing lates	c	Human cel	s or tissues:	Animal cells or tissues:	MRI safety informati
	-	• -	-		-		•		-
	leed for sterilisation before the sterilisatio	fore use: End	ocrine disi	ruptor:	•		E (UK NI)/ Self-certif	fication	SEARCH
	ADD ALL PRODUCTS TO (CART ADD SELECTED TO C	ART		Shov	v 10	•		
	 Medical device nan 	ne		1 Model	/Version		Ci	talogue/Reference	
	Premium Stent A			2.5mm	1		S8	17878	
	ADD SELECTED TO CART	1							

Check products in cart

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

AD	D ALL PRODUCTS TO CART	Show 10 -	8 products selected <u>Click here to vie</u>
	Medical device name t	Model/Version	Catalogue/Reference
	Premium Stent A	2.5mm	587878
	Premium Stent A	3mm	S46465
	Premium Stent A Plus	4mm	\$35454
	Premium Stent A Plus	5mm	S45466
	Premium Stent B	2.5mm	\$35445
	Premium Stent B	3mm	S64646
	Supersharp Stainless	21cm	SSS/21/001
	Supersharp Stainless	26cm	SSS/26/001
	Toxogon10	Not Applicable	10/TG/111
	Toxogon10	Not Applicable	10/TG/222
			< 1-10 of 12 >

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

ledical device name	1 Model/Version	Catalogue/Reference	\frown	
remium Stent A	2.5mm	587878	×	
remium Stent A Plus	4mm	\$35454	×	
remium Stent B	2.5mm	\$35445	×	
remium Stent B	3mm	564646	×	
upersharp Stainless	21cm	SS5/21/001	×	
upersharp Stainless	26cm	SSS/26/001	×	
oxogon10	Not Applicable	10/TG/111	×	
oxogon10	Not Applicable	10/TG/222	×	
			8 items	

- 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 <u>Review order and preview CFS</u> before making payment.

Address to be printed on CFS	
Registered Address:	MANAGE ADDRESSES
10 South Colonnade, 10th Floor , Cabot Square, Canary Wharf, London, E14 4PU, England, United Kingdom	
One additional address on certificates:	
[Manufacturer] [Manufacturing site/Physical manufacturer] China Medical Co, No 7, Section 5, Luzhongshan, Liaoning, 110001, China	•
You can choose only one additional address to be printed on certificates.	
More addresses on schedule:	
[Manufacturer] [Manufacturing site/Physical manufacturer] India Medical Co, Andhra Cantt, Hyderabad, Andhra Pradesh, 523270, India	-
Any other addresses you choose will be printed on the schedule.	
	CLEAR MORE ADDRESSES

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 <u>Save and exit: resume applications</u> 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.

Devices & pr	
ddress to b	e printed on CFS
	Registered Address: 133 Deed, Social
	123 Road, Sea View, Boston, 12345, United States One additional address on certificates:
	[UK Responsible Person] [Billing Address] MHRA Finance Dept, 10, South Colonnade, LONDON, London, E14 4PU, United Kingdom
	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
	Any other addresses you choose will be printed on the schedule.
pecial form	atting 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.

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 <u>Foreign, Commonwealth &</u> <u>Development Office's (FCDO) Geographical names index</u>. 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, <u>before</u> 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.

Ghana 🗙	2 Do not specify a country
United Arab Emirates 🗙	2 Do not specify a country
• Add country	

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 <u>Review order and preview CFS</u> before making payment.

Address to be	printed on CFS	
	Registered Address:	MANAGE ADDRESSES
	10 South Colonnade, 10th Floor , Cabot Square, Canary Wharf, London, E14 4PU, England, United Kingdom	
	One additional address on certificates:	
	[Manufacturer] [Manufacturing site/Physical manufacturer] China Medical Co, No 7, Section 5, Luzhongshan, Liaoning, 110001, China	•
	You can choose only one additional address to be printed on certificates.	
	More addresses on schedule:	
	[Manufacturer] [Manufacturing site/Physical manufacturer] India Medical Co, Andhra Cantt, Hyderabad, Andhra Pradesh, 523270, India	-
	Any other addresses you choose will be printed on the schedule.	
		CLEAR MORE ADDRESSES

>Devices & products	Certificate details	Review	Payment	Confirmation
v Devices a products			CFS docum	Download CFS documents Prev ents preview with limited formatting exactn
✓Certificate details				
Address to be printed on CFS				
Registered address (mandatory) :				
[Manufacturer] [Regi	stered Address] 123 Fourth Street, Boston,	n, MA, 12345, United States		
Additional address on certificates	:			
[UK Responsible Pers	on] [Registered Address] 10 South Colonna	ade, 10th Floor Area 7, Canary Wharf, Londo	n, Greater London, E14 4PU, England, Un	ited Kingdom
Additional addresses on schedule :	1			
[UK Responsible Pers	on] [Manufacturing site/Physical manufact	turer] Mexico Medical Inc, 123 Road, Cancun	, Yucatan, 12345, Mexico	
Special formatting request				
Delivery address				
Registered Address :				
	on] [Registered Address] 10 South Colonna	ade, 10th Floor Area 7, Canary Wharf, Londo	n, Greater London, E14 4PU, England, Un	ited Kingdom
Countries & number of copies				
Country		Number of certificates		
-		Number of certificates		
Ghana		2		
Ghana		2		
Ghana United Arab Emirates		2		
Ghana United Arab Emirates Total number of certificates: 4	ates and £10.00 for each addition	2		
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific	ates and £10.00 for each addition	2		
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00	ates and £10.00 for each addition	2		
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific	ates and £10.00 for each addition	2		Download CFS documents Prev
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific		2 2 nal certificate		Download CFS documents Prev ents preview with limited formatting exacto
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific EDT	nderstood the above requirements and	2 2 nal certificate		
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific	nderstood the above requirements and	2 2 nal certificate		
Ghana United Arab Emirates Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certific EDIT	nderstood the above requirements and	2 2 nal certificate		

- 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 <u>fee</u> on our website.

Devices & products	Certificate details	Review	Payment	Confirmation
5	n related payment method. See instru	ttions below on how to add a ne	w Billing address if required.	
Payment details				
CFS orders: £75.	00			
Total: £75.				
I'dai. 1/5.				
Address details				
Choose Billing Address				
MHRA Finance Dept, 10th Floor.		•		
Please choose a Billing Address mate	ching your payment card.			
MHRA Finance Dept, 10th Floor, L	ondon			
without indirect bept, four floor, c				
E14 4PU, United Kingdom				
E14 4PU, United Kingdom	by going to ' Manage Other Addresse).	s' in your		
E14 4PU, United Kingdom O You can add other addresses orgnisation's 'Related Actions' tab				
E14 4PU, United Kingdom O You can add other addresses orgnisation's 'Related Actions' tab Remember to 'Save and Exit' to ke).			

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

ai	Confirmation	
Ł	Are you sure want to proceed with WORLDPAY ? (Note: If you select 'Yes' then you will redirected to payment screen.)	
ini	NO YES 3	

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 <u>fee</u> on our website.



Order summary			English	•
Reference:	CFS1133120	1118114533		
Description:	Certificate(s)	of free sale for medi	cal device(s)	
Amount (GBP):	£75.00			
		AMIERICAN EXPRESS	Diners Club	
Masterca	ird Maestro	AMEX	Diners	Masterpass Masterpass Learn more

When you submit your transaction for processing by Worldpay you confirm your acceptance of Worldpay's privacy

policy

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

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

1	est Mode - This is n	ot a live transactio	on.
Order summary			English 🗸
Reference:	CFS113312011	18114533	
Description:	Certificate(s) of	free sale for medica	al device(s)
Amount (GBP):	£75.00		
Payment details * Indicates a required field			VISA VISA Back
Card number *		Cardholder's na	me *
4444 3333 2222 1111		Jane Smith	
Expiry date *		Security code *	Last 3 digits on the back of card
Billing address DEMO Finance Department, 20	City Road, London ,	EC1 6ZH, United Ki	ngdom
Contact details devices.transformation@mhra.g	ov.uk		
Cancel			Make Payment

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

Devices & products	Certificate details	Review	Payment	Confirmation
Your reference number				
202011180216096				
What happens next				

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 <u>fee</u> on our website.

TEST. MHRA payment
MHRA <do-not-reply@worldpay.com> To ○ Devices Transformation 11:57 Thank you</do-not-reply@worldpay.com>
Your transaction has been processed by WorldPay, on behalf of MHRA.
Transaction details
Transaction for the value of: GBP 75.00
Description: Certificate(s) of free sale for medical device(s)
Worldpay's transaction ID: 3232601738
This is not a tax receipt
Enquires
This confirmation only indicates that your transaction has been processed successfully. It does not indicate that your order has been accepted. It is the responsibility of MHRA to confirm that your order has been accepted, and to deliver any goods or services you have ordered.
If you have any questions about your order, please email MHRA at: <u>Device.cfs@mhra.gov.uk</u> , with the transaction details listed above.
Your payment is securely processed by WorldPay .

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 <u>fee</u> on our website.

Certifica	ate of Free Sale Se	rvice - [
	lo Reply TEST <no-reply< th=""><td>@mhra.go</td></no-reply<>	@mhra.go
6	 O Devices Transformation 	
Dear Jane Smit		
	', your CFS Order application on 18 I	November 202
Application retei	ence number: 202011180216096	
Manufacturer na DEMO Represe	me(s) nted Organisation	
Cost of applicati	on (£): 75	
Country		Quantity
Country Ghana		Quantity 2
	irates	-
Ghana United Arab En We will check th	nirates e information you've given us and v or rejected. If you haven't received a	2 2 will send you a
Ghana United Arab En We will check th	e information you've given us and v or rejected. If you haven't received	2 2 will send you a
Ghana United Arab En We will check th been accepted of Access your MH Remember: do	e information you've given us and v or rejected. If you haven't received	2 2 will send you a a reply from us
Ghana United Arab En We will check th been accepted of Access your MH Remember: do	e information you've given us and v or rejected. If you haven't received RA account . not share your account details and	2 2 will send you a a reply from us
Ghana United Arab En We will check th been accepted of Access your MH Remember: do n MHRA won't acc	e information you've given us and y or rejected. If you haven't received a <u>IRA account</u> . not share your account details and cept responsibility for any unauthori ree sale service	2 2 will send you a a reply from us

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
No Reply TEST < no-reply@mhra.gov.uk> To ○ Devices Transformation 12:39
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 <u>Device.cfs@mhra.gov.uk</u>
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.



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: 2023051202218001/1 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

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 <u>2018</u>.

Applications	er name or reference number SEARCH Service	All Types 🔹	Show	Ali Types 🔹	Show 10 per p
Reference	Manufacturer	Application Type	Si	ubmitted/ Saved On	ţs
earch by organisation	name or reference number				
Reference	Organisation	Applicatio		All Types	Show 10 per p Saved On 4 S
Reference 202011180216096		Applicatio CFS Order			Saved On 🕴 S
	Organisation		n Type	Submitted/ S	Saved On ↓ S
202011180216096	Organisation DEMO Represented Organisation	CFS Order	n Type endment	Submitted/ S	Saved On 1 S r 2020 r r 2020
202011180216096 202011180216091	Organisation DEMO Represented Organisation DEMO Represented Organisation	CFS Order Device Am Device Am	n Type endment	Submitted/	Saved On 4 S r 2020 r 2020 r 2020
202011180216096 202011180216091 202011170216039	Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO	CFS Order Device Am Device Am	n Type endment endment nufacturer registratio	Submitted/	Saved On I S r 2020 r r r 2020 r r r 2020 r r r 2020 r r
202011180216096 202011180216091 202011170216039 202011150115990	Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation Two	CFS Order Device Am Device Am Device Am o Device/ma	n Type endment endment nufacturer registratio	Submitted/ S 18 November 18 November 17 November 15 November	Saved On I S r 2020 r r
202011180216096 202011180216091 202011170216039 202011150115990 202011150115989	Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation Two MHRA DEMO MHRA DEMO MHRA DEMO	CFS Order Device Arr Device Arr o Device/ma New device Registratio	n Type endment endment nufacturer registratio	Submitted/S 18 November 18 November 17 November 01 15 November 15 November	Saved On I S r 2020 r r
202011180216096 202011180216091 202011170216039 202011150115990 202011150115989 202011140015984	Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation Two MHRA DEMO DEMO Represented Organisation Two MHRA DEMO DEMO Represented Organisation Two DEMO Represented Organisation Two MHRA DEMO DEMO Represented Organisation Two	CFS Order Device Arr Device Arr o Device/ma New device Registratio	n Type endment endment nufacturer registratio e n Renewal n Renewal	Submitted/ S 18 November 18 November 17 November 15 November 14 November	Saved On I S r 2020 I I
202011180216096 202011180216091 202011170216039 202011150115990 202011150115989 202011140015984 202011140015983	Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation DEMO Represented Organisation DEMO Represented Organisation DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation MHRA DEMO DEMO Represented Organisation	CFS Order Device Arr Device Arr o Device/ma New device Registration	n Type endment endment nufacturer registration e n Renewal n Renewal	Submitted/S 18 November 18 November 17 November 15 November 14 November 14 November	Saved On I S r 2020 I I r 2020 I I

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

	r - Reference:		
0201118021	16096		
IMMARY PRODUCTS	NEWS		
ummary			
pplication			
Submitted on: 1	8 November 2020		
Status: C	ompleted		
/lanufacturer			
Name: D	EMO Represented Organisation		
Organisation Role: N	Aanufacturer		
Represented by: N	IHRA DEMO		
Contact: Ja	ane Smith devices.transformation@mhra.gov.uk 0203080	06000	
Countries & n	umber of copies		
Country		Number of copies	
Ghana		2	
United Arab Emirates		2	
otal number of CFS	copies: 4		
	ions		

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.

Devices & products	Certificate deta	ails Rev	riew	Payment	Confirmation
		e valid UKCA/CE/CE (UK NI) certificate	s and product information. If you car	not see the device/s you wish to orde	er CFS for, please go to Devices and
roducts to check if they are CFS re Device Type / Class:	ady and take the necessary action fro	om Manage Devices. Medical device name:	Registered Date:	Search by model:	UDI Issuing Entity:
Select device type / Class *	dividin code / Term.	medical device name.	dd/mm/yyyy	Search by model.	
ustom Made:	Is Measuring:	Is Single-use:	is implantable:	Is Active:	UDI-DI Number:
- •			- *	- *	
evice Reg Under 2017:	Is Sterile:	UKCA/CE/CE (UK NI) Expiry	Basic UDI-DI Issuing Entity:	Basic UDI-DI Number:	Product Status:
- •		Date:	- *		
		dd/mm/yyyy			
resence of Medicinal/Herbal ubstance:	Presence of Blood/Plasma substance:	Has a Clinical investigation been conducted:	Intended purpose other than medical(Annex XVI):	is intended to Administer/remove medicinal	Is Reprocessed single-use:
	- *	v	- *	product:	
				•	
ontaining latex:	Human cells or tissues:	Animal cells or tissues:	MRI safety information:	Need for sterilisation before use:	CMR/Endocrine disruptor:
- •	*	v	- *	- •	v
IXCA/CE/CE (UK NI) Certificate/ veclaration of Conformity/ ustom made statement:				C	SEARCH CLEAR
ADD ALL PRODUCTS TO CART		Show 10	•	2 pr	oducts selected <u>Click here to view</u>
Medical device name			t	Model	
Cartilage 1				Cartilage 1	
Cartilage 2				546565	

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

device name		1 Mode	I	
1		Cartila	age 1	×
2		54656	5	×
	1	2	1 Cartila 2 54656	1 Cartilage 1 2 546565

5. Click the Continue button.

6. Make any required changes to Addresses.

Devices & pro	oducts	Certificate details	Review	Payment	Confirmation
ddress to b	e printed	l on CFS			
	Registered	I Address:			MANAGE ADDRESSE
		eet, Sea View Industrial Estate, E ted States	Boston, MA,		
	One additi	ional address on certificates:			
	[UK Respo	onsible Person] [Registered Addres	s] 10 South Colonnade, Canary V	Vharf, London, E14 4PU, England, L	Inited Kingdom
	You can ch	oose only one additional address to	o be printed on certificates.		
	More addr	esses on schedule:			
	[Manufac	turer] [Manufacturing site/Physical	manufacturer] Mexico Medical I	nc, Zona Industriale, Cancun, Yucat	an, 456565, Mexico
	Any other a	addresses you choose will be printe	ed on the schedule.		
	latting re	quest (optional)			
		quest (optional)			
		we will try to accommodate your requ	uest, but this cannot be guaranteed		
	Please note	we will try to accommodate your requ	uest, but this cannot be guaranteed		
-	Please note	we will try to accommodate your requ	iest, but this cannot be guaranteed		MANAGE ADDRESSE
certificate d	Please note elivery a • • Register 10 Sout	we will try to accommodate your requ ddress	_		MANAGE ADDRESSE
Certificate d	Please note elivery at • • Register 10 Sout 4PU, Engla	we will try to accommodate your requ ddress red address: th Colonnade, Canary Wharf, Lor	ndon, E14		MANAGE ADDRESSE
Certificate d	Please note elivery at • • Register 10 Sout 4PU, Engla	we will try to accommodate your requ ddress red address: th Colonnade, Canary Wharf, Lor ind, United Kingdom	ndon, E14	Number of certificates	MANAGE ADDRESSE

- 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 <u>Review your order and preview CFS Certificate</u> and <u>Schedule</u> then <u>Pay for your CFS Order</u>.

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

Ghana x 2 Do not specify a country United Arab Emirates x 2 Do not specify a country • Add country 2 Do not specify a country • Add country 7 Total number of certificates: 4 Price: £75.00 We charge £75.00 for 1 to 10 certificates and £10.00 for each additional certificates	United Arab Emirates x 2 Do not specify a country O Add country Total number of certificates: 4 Price: £75.00	Country	Number of certificates	
• Add country Total number of certificates: 4 Price: £75.00	© Add country Total number of certificates: 4 Price: £75.00	Ghana 🗙	2	Do not specify a country
Total number of certificates: 4 Price: £75.00	Total number of certificates: 4 Price: £75.00	United Arab Emirates 🗙	2	Do not specify a country
Price: £75.00	Price: £75.00	Add country		
Price: £75.00	Price: £75.00	Total number of contificators 4		
We charge £75.00 for 1 to 10 certificates and £10.00 for each additional certificate	We charge £75.00 for 1 to 10 certificates and £10.00 for each additional certificate	Price: £75.00		
We charge £75.00 for 1 to 10 certificates and £10.00 for each additional certificate	We charge £75.00 for 1 to 10 certificates and £10.00 for each additional certificate			
			litional certificate	
		We charge £75.00 for 1 to 10 certificates and £10.00 for each add		

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 <u>statutory fee</u> will be payable.

Annex I – Workflow

