Medicines & Healthcare products Regulatory Agency

Device Registrations

Reference Guide

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Logging in

Access MHRA Agency Services.

Read and Agree to Cookie Policy

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

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



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).
- 2. Click the Log in button.

Medicines & Healthcare products Regulatory Agency	
Password	
Forgot your password?	LOG IN 2
MHRA Terms & Conditions	

New Users > Change temporary password

Change Password Please complete the form to change your password.	1.	Copy a
Old Password		tempor passwo charact
New Password		email in box.
2	2.	Enter a choice i
Confirm New Password		and cor
CANCEL	3.	Click of You wi passwo now or
	3	

- . 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.
 - Click on Submit. You will be able to use the password you entered from now on.

Forgot password > resets

- 1. On the log in page, click the Forgot your password link.
- 2. Enter your username (usually firstname.lastname not your email address).
- 3. Click the Send email button. Please ensure your email address is always kept up to date on the Contacts Tab, see Editing Contacts in the Account Management Reference Guide.

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

Password		
Forgot your pass	word?	LOG
gov.uk		
MHRA Terms & O	Conditions	

Medicines & Healthcare products Regulatory Agency

Username	
Enternance and a list	ICand Emplit An ampliful he contact
Enter your username and click the email address associated in the email to reset your pass	K "Send Email". An email will be sent to with your user account. Follow the link sword.

MHRA Agency Services

This service allows you to submit registrations for devices (GMDN[®] Code or Term) and products (brand or trade name, model/version, catalogue/reference, UDI DI and DI data). You can also update your registrations, add importers, link them to registered manufacturers and order Certificates of Free sale, if required. If you are a UK Responsible Person (UKRP) or an Authorised Representative (in Northern Ireland only) you can add represented manufacturers and devices, update their details and manage device registrations on behalf of your represented manufacturers.

1. On the Landing (home) page **click** the Enter button under Device Registrations and Certificates of Free Sale for medical devices.



Organisations

- 1. This organisation is the one that the account was setup for. **Click** on the manufacturer name to register or manage devices that you manufacture.
- Note that the organisation in this example is 'Not registered'. If the status is 'Not Registered' this will remain the case if this organisation is acting purely as a UK Responsible Person (UKRP) in the UK or an Authorised Representative (in Northern Ireland) and has not registered devices of their own.
- The UK Responsible Person (UKRP) of a non-UK manufacturer or an Authorised Representative (in Northern Ireland) of a manufacturer based outside the UK or EU may click this button to <u>'Add New Manufacturers'</u>. This button is to be used when you are ready to make device registrations on behalf of another organisation.
- 4. If either your organisation or an organisation that you represent as a UK Responsible Person (UKRP) or Authorised Representative (in Northern Ireland) imports medical devices into the UK, you must use this link to <u>Add New Importer</u> details.
- 5. UK Responsible Persons (UKRP) in the UK or Authorised Representatives (in Northern Ireland) who have added represented organisations will see them in the Manufacturers you represent table.
- 6. UK Responsible Persons (UKRP) in the UK or Authorised Representatives (in Northern Ireland) who have added Importers will see them in the List of Importers table.

Your Organisa	tion						
Name	Address			Country		Devices (Products)	Registration
MHRA DEMO	10 South Color	nnade, Canary Wharf, London, E14 4PU		England, United Kin;	gdom	0 (0)	0
Key Segistered ONo	t Registered 🗢 U	Inregistered 🕕 Suspended					
found from the Applica Only use the ADD NEW already registered the r registered the manufac register additional devi	tions list. MANUFACTURER represented manuf turer, please use th ces on the existing	function if you have not facturer. If you have he Add Devices function to account.	ers can be				NEW MANUFACTURER
	er name:		SEARCH				
Name	rer name:	t Address	SEARCH	Country	Devices (Products)	Relationship	Registration Status
Name DEMO Represented O	rer name: Irganisation	Address	SEARCH Boston, 12345	Country United States	Devices (Products)	Relationship UK Responsible Person	Registration Status
Name DEMO Represented O Key Registered O No List of Import Name	rganisation t Registered	t Address 123 Street, Sea View Industrial Estate, Unregistered ① Suspended × Rej Iress	Boston, 12345	Country United States Country	Devices (Products)	Relationship UK Responsible Person Relationship	Registration Status
Name DEMO Represented O Key Registered O No List of Import Name Demo Importer	rrganisation t Registered t Registered t Add Unit	Address 123 Street, Sea View Industrial Estate, Unregistered ① Suspended × Rej Iress 765, Waterloo Crescent, Harbour House,	Boston, 12345 ected	Country United States Country U England, Unit	Devices (Products) 1 (1) ted Kingdom	Relationship UK Responsible Person Relationship UK Responsible Person	Registration Status
Name DEMO Represented C Key Registered O No List of Importer Demo Importer DEMO TWO Importer	rganisation t Registered	t Address 123 Street, Sea View Industrial Estate, Unregistered ① Suspended × Rej Iress 765, Waterloo Crescent, Harbour House, Haven Road, Industrial Estate, Rochester,	Boston, 12345 Jected	Country United States Country U England, United States	Devices (Products) 1 (1) ted Kingdom ted Kingdom	Relationship UK Responsible Person Relationship UK Responsible Person UK Responsible Person UK Responsible Person	Registration Status

Determine if your account is migrated or re-registered

Some accounts have been migrated from our old system and some organisations who held account/s on our old system/s have been asked to re-register.

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

To determine the migration/re-registration status of your account please:

- 1. Review the summary page after clicking on the manufacturer name.
- 2. If the Created Date is before 01 July 2018, your account has been migrated.

If the Created Date is between **01 July 2018 and 23 July 2019** your account is either a new account for an organisation not previously registered with MHRA or a previously registered account where the organisation name and/or address was different to your original MHRA registration in our old system.

If the Created Date is on or after **29 July 2019** your account has been re-registered or is a new account for an organisation not previously registered with MHRA.

SENCY SERVICES APPLICAT	ONS ACCOUNT MANAGEMENT		
◄ Back to DR&CFS Servi	ces		
MHRA Dem	D	Edit Organisation Details Corder Registered Devices/Products	CFS Add Devices Manage Devices Up Renew Registration Excent Devices Data to Excel Fi
	NS RELATED ORGANISATIONS DEVICES	PRODUCTS CONTACTS OTHER ADDRESSES E	DOCUMENTS NEWS
Summary			
() Your registration of determined by the data being suspended. A so the competent author	vith the MHRA must be reviewed and rei te your account was created with the Mi uspended account means you will not be rity (MHRA). It is an offence to place a no.	newed one year after the anniversary date ar IRA. Your Registration Renewal is 01/01/2022 able to place new devices on the market giv n-compliant device on the market in the UK.	nd every two years subsequently. The anniversary date is 2. Failure to renew your registration will result in your acco en it is a legal requirement to hold an active registration w
Basic Information			
Account Number	0000009132	Registration Status	Registered
EU Single Registration Number (SRN)		PARD Options	 Publish UK Responsible Person Name Publish UK Responsible Person Address Publish Organisation's Name
Role / Account Type	Manufacturer UK Responsible Person		 Publish Organisation's Address
Company Type	Limited Company	Company	654321
VAT Number	123456	Registration Number	
2 Created Date	19 September 2019	2017 MDRs	NO
Organisation Deta	ils		
Organisation	Dental laboratory	Telephone	N/A
Description	 Manufacturer of Medical device softwa Other 	re Fax	N/A
Registered Address	10 South Colonnade, 10th Floor Area 7 Canary Wharf London Greater London E14 4PU England, United Kingdom	Website	N/A
Contact Details			
Full Name	Peter Smith	Email	devices.transformation@mhra.gov.uk
Job Title	Regulatory Affairs Manager	Telephone	02030806000
Customer Service	Contact		
Telephone No.	02030806000	Email Address	devices.transformation@mhra.gov.uk

Registering new devices

1. Click on the name of the manufacturer of the device as appropriate, this may be your organisation or your represented organisation.

Please note:

- Devices must always be added to the organisation who is the **legal manufacturer** of the device.
- Check that the manufacturer information is correct (see <u>Updating Registrations</u>).

Your Organisati	on					
Name	Address		Country		Devices (Products)	Registratio Status
MHRA DEMO	10 South Colonn	ade, Canary Wharf, London, E14 4PU	England, United Kin	gdom	0 (0)	0
Key	egistered 🗢 Ur	registered 🕕 Suspended				
 a base above an all above and all a second and a second above ab second above above	and the second sec	sheet of the second			40	D NEW IMPORTED
already registered the repr registered the manufacturr register additional devices Search by manufacturer (resented manufa er, please use the on the existing a name:	struction in you have 2 Add Devices function to account.			AS	D NEW IMPORTE
already registered the repr registered the manufacture registere additional devices Search by manufacturer r Name	resented manufa er, please use the on the existing a name:	Address	Country	Devices (Products)	Relationship	o new IMPORTE Registratic Status
already registered the repr registered the manufacture registered the manufacture Search by manufacturer n Mame DEMO Represented Orga Key	resented manufa er, please use the on the existing a name: t nisation	Address Address I23 Street, Sea View Industrial Estate, Boston, 12345	Country United States	Devices (Products)	Relationship UK Responsible Person	Registratic Status
already registered the repr registered the manufacture registere additional devices Search by manufacturer r Mame DEMO Represented Orga Key Registered O Not R List of Importers Name	resented manufa er, please use the on the existing a name: tristation tegistered © L S t Addro	Address SEARCH Address I23 Street, Sea View Industrial Estate, Boston, 12345 Unregistered ① Suspended × Rejected	Country United States Country	Devices (Products)	Relationship UK Responsible Person Relationship Relationship	Registratic Status
already registered the repr registered the manufacturer registered the manufacturer Search by manufacturer r DEMO Represented Orga Key Registered O Not R List of Importers Name Demo Importer	resented manufa er, please use the on the existing a name: t nisation t s t Addr Unit 7	Address Address 123 Street, Sea View Industrial Estate, Boston, 12345 Inregistered Suspended Rejected Ess 165, Waterloo Crescent, Harbour House, DOVER, CT17 9B	Country United States	Devices (Products) 1 (1) ted Kingdom	Relationship UK Responsible Person Relationship UK Responsible Person	Registratic Status

2. Click the Devices tab to review devices you have already registered and the device status.

Please note that previously GMDN[®] Codes were only be displayed if you entered the GMDN[®] Code when adding your device. We now display both the GMDN[®] Code and the Term.

 ✓ Back to MHR SUMMARY Devices → Show 	DR&CFS Services A DEMO Y APPLICATIONS RE	2 Corder CFS Manage Devices A LATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRES	dd Devices Vpdate Registered Devices/Product
Status	GMDN Code	Term Name 1	Device Type
Status	GMDN Code	Term Name 1 Abdominal aorta endovascular stent-graft	Device Type General Medical Device - Class III
Status ©	GMDN Code 	Term Name 1 Abdominal aorta endovascular stent-graft 1 General external orthopaedic fixation system implantation kit, single-use 1	Device Type General Medical Device - Class III System or Procedure Pack
Status ©	GMDN Code 35596	Term Name 1 Abdominal aorta endovascular stent-graft 1 General external orthopaedic fixation system implantation kit, single-use 1 Vascular clamp, reusable 1	Device Type General Medical Device - Class III System or Procedure Pack General Medical Device - Class IIa

3. Click the Show Filters link to search for specific devices.

Devices				
🗕 Hide Filters				
Device Type / Class	Device Registered Dat	e GMDN Code / Term	Custom Made	Regulation/Directive:
Select device type 🔻	dd/mm/yyyy	Name		
Is Sterile?	Is Measuring	Is Single-use?	Is Reprocessed single-	Custom-made SPP
🔻			vuse?	
Reusable Surgical	Is Active?	Is Implantable?	ls Intended to	Intended purpose other
Instruments?			Administer/remove medicinal product?	than medical(Annex XVI)
Is CFS Ready	Presence of Medicinal/Herbal	Presence of Blood/Plasma	Has a Clinical investigation been	Basic UDI-DI Issuing Entity
		 ✓ 	• •	· · · ·
Basic UDI-DI Number	Device Registration	Is Device Updated?		Show
	status Select device statu	•	SEARCH CLEAR	10 per page 🔹

4. Click the Add Devices link to add new devices.

Please note that if you need to manage devices e.g. add new product to an existing device or link a new Conformity Assessment Certificate/Self-certification conformity declaration, please refer to the <u>Manage registered devices</u> section.

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

Add devices using GMDN®

- 1. Select the appropriate device type for the medical device to be registered.
- Entering appropriate words into the Global Medical Device Nomenclature GMDN[®] Code/Term text box will give you a list of GMDN[®] Terms to choose from. Entering more words into the box will reduce the list.

GMDN[®] Members may enter a GMDN[®] Code into this box. Please note The GMDN Agency provides a free enquiry service if you are in doubt about the correct GMDN[®] Term to select for your device

3. Click on a Term name to make your selection. You must pick a GMDN[®] Term from the list.

	Jaconena	
	Declare devices	
1	What type of device is it? General Medical Device In Vitro Diagnostic Device Active implantable device (Directive 90/385/EEC only) System or Procedure Pack GMDN Code/Term stend	
	Term name 1	
3	Abdominal aorta endovascular stent-graft	
	Abdominal aorta endovascular stent-graft deployment aid	
	Antibody-coated coronary artery stent	
	Aortic arch branch vessel endovascular stent-graft	
	Aortic arch endovascular stent-graft	
	< 1-5 of 87 >	
	- View all GMDN terms and definitions	
	CONTINUE SAVE & EXIT	ETE APPLICATION

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

4		- View all GMDN terms and definitions)	
	T	CONTINUE SAVE & EXIT		DELETE APPLICATION

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

aortic stent Search G	efinition here
Term name	1 Term definition
Aortic arch branch vessel endovascular stent-graft	A sterile non-bioabsorbable tubular device intended for endovascular implantation within an a branch vessel to allow unrestricted blood flow to the aortic arch branch vessel during implanta endovascular stent-graft within the aortic arch; it includes an animal-derived heparin surface to thrombosis. It is typically made of a metal alloy that forms an outer mesh structure with an inn polymer tube (endovascular graft) and is intended to be attached to the parent endovascular s (not included). It is percutaneously inserted via the femoral artery to the site of implantation ar in situ; disposable implantation devices may be included.
Aortic arch endovascular stent-graft	A sterile non-bioabsorbable tubular device intended for endovascular implantation, in a modul configuration, to repair lesions of the aortic arch and descending thoracic aorta. It is typically m metal alloy (e.g., nickel-titanium alloy (Nithol)) that forms an outer mesh structure with an inne polymer tube (endovascular graft). It includes a docking portal(s) for attachment of an ancillary endovascular stent-graft(s) [not included] to occupy and allow flow to an aortic arch branch wes percutaneously inserted via the femoral artery to the site of implantation and expanded in situ devices ascortated with insolantation may be included.

6. Answer all the mandatory questions that appear after you have selected the appropriate GMDN[®] Code or Term. These will differ depending on the device type you have selected.

Please note Failure to declare compliance the correct regulation or directive that you are certified for will result in your registration becoming invalid and you will be charged a further <u>statutory fee</u> to make the relevant changes.

Concerned Marilian	ite is nor
Un Vitro Diamon	
Active Implantation	le Device
System or Proce	
CMDN Cada (Tarre	
27940 Castilana	
- View all CMDN	
Is it custom made	
What risk classific	ation applies to this device?
Click here to know	about risk classification.
Which directive/re	gulation does this device comply with?
UK MDR 2002 (S	2002 No 618 as amended), Part II
O Directive 93/42/	EC
EU medical devi	tes regulations 2017/745
○ Yes ○ No	
Single-use device?	
○ No	
Reprocessed single-use	device?
○ Yes	
Are any of the products	related to this device active?
⊖ Yes	
○ No	inistar and/or ramova madicinal product?
Yes	maxes anotes remove meaning produce:
○ No	
Are any of the products Yes	related to this device measuring?
○ No	
Basic UDI-DI Issuing	
Please Select	•
Presence of a substance	which, if used separately, may be considered to be a medicinal/herbal medicinal product (optional) ρ
Diana Salat	
ridase belect	
Presence of a substance plasma (optional) 🝞	which, if used separately, may be considered to be a medicinal product derived from human blood or human
Please Select	•
Has a Clinical investigat	ion been conducted? (optional)

- 7. Click either the Continue button to proceed to the next page or the Save & Exit button to save and exit and resume application before submitting to MHRA. The Continue button will not be enabled until you have answered all the mandatory questions.
- 8. You can Delete Application at any stage before submitting to MHRA. This will delete all devices in the application.

Upload Self-certification conformity declarations

- If your device does not require a Conformity Assessment certificate issued by a UK Approved Body or EU Notified Body, you must upload a Self-certification conformity declaration. The document required will depend on the device type and Directive/Regulation your device complies with as follows:
 - Declaration of Conformity Class I medical devices and General IVDs that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, nonmeasuring, non-reprocessed, not a re-usable surgical instrument. Find out more about <u>Declaration of Conformity</u> / <u>EU regulations</u>
 - Declaration for all system or procedure packs and assemblers to UK MDR 2002 Regulation 14, Article 12 of Directive 93/42/EEC, or Article 22 of EU Regulation 2017/745, as appropriate. Find out more about <u>UK MDR 2002 Regulation 14</u> / <u>EU</u> regulations
 - Declaration for Performance Evaluation to UK MDR 2002 Regulation 43 Statement, Annex VIII of Directive 98/79/EC) or Part A of Annex XIII of EU regulation 2017/746, as appropriate. Find out more about <u>Performance Evaluation</u> / <u>EU regulations</u>

Custom-Made Statement – for each custom-made device (GMDN[®] Code or Term), that does not require a Conformity Assessment certificate, you need to upload a Custom-made Statement. Find out more about <u>Custom made statement</u> and see important information below concerning legislation for custom-made devices.

Details of the content of the custom-made statement can be found in the relevant directive/regulation that applies to your device:

- Regulation 15 of UK Medical Devices Regulations 2002 (S.I. No. 618, as amended), Part II
- Regulation 28 of UK Medical Devices Regulations 2002 (S.I. No. 618, as amended), Part III
- Annex XIII of Medical Devices Regulation (EU) 2017/745

Important information:

GB market:

Custom-made devices under the EU MDD (93/42/EEC) or EU AIMDD (90/385/EEC) can no longer be registered for the purposes of placing on the GB market.

You can register your custom-made device under UK MDR Part II or Part III (which is currently consistent with EU medical devices directive requirements) for the GB market only, with a suitable accompanying custom-made statement.

Northern Ireland market:

Only custom-made devices consistent with EU MDR 2017/745 can be placed on the Northern Ireland market.

However, custom-made devices registered under the EU MDD or EU AIMDD and placed on the market in an EU member state other than Northern Ireland, <u>prior</u> to 26 May 2021, can still be registered with MHRA for the purposes of placing on the NI market only. The content of the custom-made statement needs to have been drawn up <u>prior</u> to 26 May 2021 and be consistent with:

- Annex VIII of Medical Devices Directive 93/42/EEC
- Annex 6 of Active Implantable Medical Devices Directive 90/385/EEC

Please note that the statement that you upload to our system must **not** contain any patient identifiers e.g. patient name, NHS or hospital number etc. as this would contravene the General Data Protection Regulation (GDPR).

However, the statement you provide to the patient/clinician with the device, **does** need to include the patient name. Please refer to our online guidance on statements at https://www.gov.uk/government/publications/custom-made-medical-devices

2. Important note concerning CE UKNI-MDR/IVDR option.

You must **not** select the CE UKNI-MDR/IVDR option for self-certification conformity assessment type. This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medicaldevices-in-northern-ireland Click the Upload button and select the relevant Self-certification conformity declaration file stored on your system.



- 4. Select the Conformity assessment that your device complies with from the dropdown.
- Add a Document Reference of your choice. This must not contain any special characters other than hyphen (-) or underscore (_) otherwise the document will not upload. You will be able to search devices by reference when managing your devices.

- 6. Click the Upload Document button to confirm details. Repeat the process to add more documents. You can select from these as you add more devices (GMDN[®]).
- 7. Click the Continue button to proceed to the next page or the Save & Exit button to <u>save and</u> <u>exit and resume application</u>.

Select from existing Self-certification conformity declarations

- If you have already uploaded documents previously, from the Select from existing Selfcertification conformity declaration area ensure that the correct document is selected. Tick the check box to the left of the filename to select the document.
- 2. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

UKCA – MDD/IVDD/AIMD CE (UK NI) – MDD/AIMD/IVDD CE (UK NI) – MDR/IVDR

Please note if you have just uploaded a Self-certification conformity declaration it will automatically be **selected**.

3. Click the 'Continue' button.

Add New Devices for MHRA Demo - TEMP20230418142616

	Manufacturer	Device	Self-certification conformity declarations	Products Review	Payment
e	lf-certification	conformity	y declarations: 35310-	Orthodontic retainer	
Dec edic	claration of Conformity – Class	s I medical devices that o certification by a UK App	do not require certification by a UK Approved B roved Body or EU Notified Body.	dy or EU Notified Body i.e. non-sterile, non-measuri	ng, non-reprocessed. General IVD
Cust	tom-Made Statement – All cu	stom-made devices.			
Dec	laration for all system or pro	cedure packs and asse	mblers - to UK MDR 2002 Regulation 14 (Articl	12 of Directive 93/42/EEC) or Article 22 of EU Regula	ation 2017/745.
Dec	laration for Performance Eva	aluation - to UK MDR 20	002 Regulation 43 Statement (Annex VIII of Dire	tive 98/79/EC) or Part A of Annex XIII of EU regulatio	n 2017/746.
ік мі	DR 2002/ Medical Devices Dir	ective 93/42 EEC & Med	lical Devices Regulation (EU) 2017/745	Conformity Assessment Type	
Sele	ect from existing S	elf-certificatio	n conformity declarations	ALL	-
	Filename		Document Reference	Conformity Assessment Type	
	Custom-made Statement - O	rthodontic Retainer	UKCA_Retainer v01	UKCA - UK MDR 2002 Part II/Part III/Part IV	×
	Custom-made Statement 1		Custom1	CE - MDD/IVDD/AIMD	
UPLO UPLO	OAD Drop file here ce limit should not exceed 15MB. if, png. odt	tification confo	ormity declaration		
Uple UPL File siz jpg, ti Filena We m popera	Oad a new Self-cer OAD D Drap file here the limit should not exceed 15MB. if, prg. odt ame must not contain any sp hay request further technical hay requirem tects conform to the requirem ate with our requests we will	tification confe Only the following file form ecial characters other documentation from y ents of the Medical De consider using our enf	ormity declaration		
UPLI UPLI File siz jpg, .ti Filena We m produ opera	Oad a new Self-cer OAD D Drop file here the limit should not exceed 15MB. if, prg. odt ame must not contain any sp hay request further technical ucts conform to the requirem ate with our requests we will irmity assessment	tification confe Only the following file form ecial characters other documentation from y tents of the Medical De consider using our enf	ormity declaration		
UPLI UPLI File siz jpg, .ti Filena We m produ opera Confor Pleas	Oad a new Self-cer OAD Drop file here elimit should not exceed 15MB. if, .png. odt ame must not contain any sp hay request further technical ucts conform to the requirem ate with our requests we will wrmity assessment se select are providing Self-certification cor up have appointed an EU Authoris	tification confe Only the following file form ecial characters other documentation from y ents of the Medical De consider using our enf	ormity declaration nats are acceptable: .doc, .docs, .pdf, than hyphen (-) or underscore (_). rou that demonstrates your vice Regulations. If you fail to co- orcement powers.		
UPL UPL File siz File siz Filena Ve m produ opera Confor Pleas f you a hat yo Northe Find on Regula	Doad a new Self-cer Doad a new Self-cer Doad a prop file here elimit should not exceed 15MB. if, prg. odt ame must not contain any sp hay request further technical ucts conform to the requirem ate with our requests we will rmity assessment se select are providing Self-certification cor un have appointed an EU Authoris rri Ireland ut more about Declaration of C ion 14 / Performance Evaluat	tification confe Only the following file form ecial characters other documentation from y tents of the Medical De consider using our enf informity declarations for C ed Representative (EC Rep Conformity / Custom macion on / EU regulations	ormity declaration nats are acceptable: .doc, .docx, .pdf, than hyphen (-) or underscore (.). rou that demonstrates your wice Regulations. If you fail to co- orcement powers. E marked devices, you must ensure) in one of the EU 27 countries or in de statement / UK MDR 2002		
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3

Upload Conformity Assessment Certificates (if applicable)

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

Important note concerning CE UKNI-MDR/IVDR option.

This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

- 2. Select the correct Certificate Type from the dropdown menu.
 - Enter the correct Certificate Expiry date.
 - Add the Certificate reference. This must not contain any special characters other than hyphen (-) or underscore (_) otherwise the document will not upload. You will be able to search devices by reference when managing your devices.
 - Select the correct UK Approved Body/EU Notified Body designation type
- 3. Select the correct UK Approved or EU Notified Body from the list. If it does not appear on the list, click Other and Search using key words to find the correct one.
- 4. Click the Upload Certificate button to confirm details.

UPLOAD	🗋 Drop file here
File size limit .tif, .png, .odt	should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, t
We may rec products co operate wit	quest further technical documentation from you that demonstrates your onform to the requirements of the Medical Device Regulations. If you fail to co- th our requests we will consider using our enforcement powers.
Certificate	type
Please sele	ect ·
Expiry date	
dd/mm/yyy	W
Certificate	reference number
UK Approve	ed Body designation/European Notified Body
Please sele	ect .
lf you are pro Representati	oviding CE certificates, you must ensure that you have appointed an EU Authorised we (EC Rep) in one of the EU 27 countries or in Northern Ireland
Select UK A	pproved Body or EU Notified Body
O BSI	and Vienations Limited
	RNATIONAL (UK) I TD

5. A table will appear on the page showing the uploaded Certificate, this will be preselected. Repeat the process to upload more Certificates as necessary for the device. As you upload more certificates, they will appear in the table for you to select from when you next add devices. 6. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

UKCA – MDD/IVDD/AIMD CE (UK NI) – MDD/AIMD/IVDD CE (UK NI) – MDR/IVDR

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

		Se	ect fro	6 om ex	kisting	Confor ALL g cer	mity As	ssessn ates	nent Tj	уре		 Certificate S ALL 	Status		
			Filenan	ilename Reference Expiry no date			Certificate type UK Approved B Body		UK Approved Body/EU Noti Body	Body/EU Notified Conformity Assessment Type					
) (~	CE Certi 3	ificate	CE4567		31/03	/2022		Full Quality Assurance (Annex II excluding Section 4)		TÜV NORD CERT GmbH		CE - MDD/IVDD/AIMD	×
			CE Certi 3	ificate	AIMD1		31/07	/2021	0	Full Quality Assurance (Annex II excluding Section 4)		BSI		CE - MDD/IVDD/AIMD	×
[CE C 1	ertificate	CE12	3	31/05	/2021	۵	Full Q exclu	uality Assurance (Annex II ding Section 4)	BSI		CE - N	MDD/IVDD/AIMD ×	

8. Click the Continue button to proceed to next page or the Save & Exit button to save and exit and resume application.

Please note if you have selected an expired certificate or if any expired certificates are still linked to a device the Continue button will not be enabled. Unlink expired Certificates and upload new ones or link device to an active certificate.



DELETE APPLICATION

Select from existing Conformity Assessment Certificates

- From the Select from existing certificates area ensure that the correct Certificate is selected. Select the Certificate by ticking the check box to the left of the certificate filename.
- 2. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

UKCA – MDD/IVDD/AIMD CE (UK NI) – MDD/AIMD/IVDD CE (UK NI) – MDR/IVDR

3. You can filter by Certificate Status of All, Active and Expired. If you can't see the expired certificates under the 'All' filter, select 'Expired'.

sele	ect from existing certificate	es						
	Filename	Reference no	Expiry date		Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type	
	UKCA Certificate 2	UKCA_BSI_54321	30/04/2028		Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	
	UKCA Certificate 1	UKCA_BSI_12345	30/04/2028		Design Examination Certificate (Annex II with Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	
	MDR Assessment of Technical Documentation Annex IX Chapter II	EUMDR_321	30/04/2024		Technical Assessment (MDR Annex IX, Chapter II)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	
	MDR CE Certificate 1 Quality Management System Annex IX Chapters I and III	EUMDR_123	30/04/2024		Quality Management System (MDR Annex IX, Chapters I, III)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	
	CE Certificate 7	CE7	31/10/2022	0	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	
•	CE Certificate 5	UKCA1	31/10/2021	8	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	UKCA - MDD/IVDD/AIMD	
	CE Certificate 4	CE123456	31/12/2019	8	Type Examination (Annex V)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	
	CE Certificate 1	CE123	31/12/2019	۲	Full Quality Assurance (Annex IV)	TÜV SÜD Product Service GmbH	CE - MDD/IVDD/AIMD	
	CE Certificate 3	CE12345	31/12/2019	8	Production Quality Assurance limited to sterile aspects (Annex V)	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	CE - MDD/IVDD/AIMD	
	CE Certificate 2	CE1234	31/12/2019	۲	Design Examination (Annex IV with Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	

4

Select the certificates with the correct conformity assessment type

- 4. If you have selected a certificate with incorrect Conformity Assessment Type a warning message will appear and the Continue button will not be enabled. If you have selected an expired certificate the Continue button will not be enabled .Unlink expired or incorrect Certificates and upload new ones or link device to an active/correct certificate.
- 5. Click the 'Continue' button or follow the <u>Upload Conformity Assessment Certificate</u> instructions to add another certificate.



Uploading expired CE certificates that are valid under EU MDR

See the latest guidance on our website, including a template to complete and upload at:

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registrationof-certain-medical-devices-that-have-expired expiring-ce-certificates

and

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registrationof-certain-medical-devices-which-are-eu-mdd-class-i-reusable-surgical-instruments-or-eumdd-class-i-medical-devices-upclassified-from-class-i

The guidance has intentionally not been included in this Reference Guide as this may change.

Please sign up for email updates by following the link on our webpage:



Adding products individually

1. Add the product details – this is the product-specific information including brand or trade name, model/version and/or catalogue/reference and UDI DI and DI data, where applicable.

Please note:

- Answer all the mandatory questions that appear. These will differ depending on the device type and legislation you have selected.
- At least one product must be added per device group (GMDN[®] Code or Term).
- Model/Version and Catalogue/Reference data cannot be the same. You must enter either Model/Version or Catalogue/Reference or both. You cannot select No for both fields.
- We strongly recommend that you also populate all optional fields, where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.
- UDI DI and DI data must be unique for each product and for each field within each product.

Product information follows guidelines set by the <u>International Medical Device</u> <u>Regulators Forum</u> in their document <u>Common Data Elements for Medical Device</u> <u>Identification</u>

	Add products one by one	You can also upload product information in bulk using our template. This is how
	Medical Device Name (Brand/Trade/Proprietary or Common name)	Tou can also upload produce information in build using our template. This is now
	A name used to assist in the identification of the regulated medical device. It can be a	1. Download our product template-always download a new template to ensure
	brand, trade, proprietary or common name.	you have the latest version.
		2. Enable editing and/or content on the template. 3. Populate the template with your product information
		 Do not paste formulas from other Excel documents and ensure text does no
	Is Model/Version applicable?	exceed maximum length specified for each field.
	Plance Calast	Ensure 'Ready to validate' message appears on the template.
	Please Select	Click for primary validation and correct any errors identified.
		 Ensure 'Ready for upload and validation. The validation will fail if you have completed the template correctly 'message appears on the template.
	Is Catalogue/Reference applicable?	 Upload vour completed template using the "upload" button below.
	•	9. Click the Confirm Bulk Upload and Preview products button (below) - limite
ć.	Diease Calact	
N	Please Select	preview will be available – ensure all fields are correct in the template.
	Please Select	preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention
	Piease Select UDI Issuing Entity (optional)	preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.
	Piease Select UDI Issuing Entity (optional) Gast AISBL	preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention. UPLOAD D D D D D D D D D D D D D D D D D D D
	Piease Select UDI Issuing Entity (optional) GS1 AISBL HIBCC	 preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention. UPLOAD Drop file here
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	Piease Select UDI Issuing Entity (optional) GS1 AISBL HIBCC ICCBBA IFA GmbH	preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention. UPLOAD Drop file here CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS
	Piease Select UDI Issuing Entity (optional) GS1 AISBL HIBCC ICCBBA IFA GmbH UDI not assigned	preview will be available – ensure all fields are correct in the template. 10. If secondary validations fails, you will see an error message indicating which columns in the template require attention. UPLOAD Drop file here CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

2. Certificates of Free Sale (CFS) customers, please note:

Only the data you enter in the Medical Device Name, Model/Version, Catalogue/Reference, Basic UDI DI and Conformity Assessment Certificate Reference fields will appear on the CFS certificate or schedule. 3. Continue populating the fields on the screen. We recommend that you also populate all optional fields, where possible. This cannot be done in bulk at a later stage.

Type of UDI-PI (optional) 😧	
Lot or Batch Number	
Serial Number	
Manufacturing date	
Expiration date	
Software version	
Does the device incorporate human cells or tissues, or their derivative (optional)	es
Please Select	
Does the device incorporate animal cells or tissues, or their derivative (optional)	es
Please Select	
Are storage/handling conditions specified in the label/instructions for (optional)	r use
Please Select	
Quantity per package configuration (optional)	
Need for sterilisation before use (optional) 🚱	
Please Select	
What MRI safety information does the labelling contain? (optional)	
Please Select	
Does the label/instruction for use include Critical warnings or contra- indications (optional)	
Please Select	
Containing latex (optional)	
Please Select	
Clinical size applicable (optional) 🕑	
Please Select	
UDI-DI from secondary entity (optional) 🚱	
Please Select	
Endocrine disruptor (optional) 😧	
Please Select	
Additional product description (optional)	
Additional product description (optional) 🛛	

4. Once you have answered, at minimum, all the mandatory questions, **click** the Add Product button – if you don't your data won't be saved.

5. The Product preveiw table will appear at the bottom of the page with limited details. To add more products individually go to the top of the page and repeat the process. If you have many products to add, consider <u>adding products in bulk</u>, using a template

	(Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
DE	LETE SELECTED 7					6 items

- 6. If you wish to remove a product you have just added, tick the box next to the Product Status in the Product Preview table at the bottom of the screen.
- 7. Click Delete Selected to remove the products.

Please note you must add at least one product to enable the Continue button.

- 8. Once you have added all your products, click the Continue button to proceed.
- 9. If you Delete Application, all devices in the application will be deleted.

Add products in bulk – product template

You can add multiple products (model/version detail, catalogue/reference, UDI DI and DI data etc.) for a device using the product template.

Please note that uploading a template will clear all products previously added to this GMDN[®] in <u>this application</u>. Products uploaded in bulk will append to products previously accepted by MHRA.

1. Read the instructions and click the link to Download our product template.

Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment
Add products					
Here you can add product infor	mation for the device:				
62573-Aortic arch endovascular	stent-graft				
Medical Device Regulators Foru Medical Device Identification.	m in their document Co	ommon Data Elements for			
Add products one by one	9		Add products in bull	¢	
Medical Device Name (Brand/	Trade/Proprietary or	Common name)	You can also upload produ	uct information in bulk using o	ur template. This is how
A name used to assist in the ide brand, trade, proprietary or con	entification of the regul mmon name.	ated medical device. It can be a	 Download our production you have the latest very 2. Enable editing and/or 3. Populate the template the templa	ct template-always download a ersion. • content on the template. e with your product informatic	a new template to ensure
Is Model/Version applicable?			 Exceed maximum len Ensure 'Ready to valid 	gth specified for each field.	template
Please Select		•	 Click for primary valid Ensure 'Ready for unit 	lation and correct any errors in	dentified. tion will fail if you have not
Is Catalogue/Reference applic	able?		 Ensure Ready for up completed the templa Upload your complet 	ate correctly.' message appear ed template using the "upload	s on the template. " button below.
Please Select		•	 Click the Confirm Bull preview will be availa If secondary validatio 	k opioad and Preview product ble – ensure all fields are corre ns fails, you will see an error n	ect in the template. nessage indicating which
	0		columns in the templ	ate require attention.	
UDI Issuing Entity (optional)					
ODI Issuing Entity (optional)			UPLOAD 🔓 Drop file he	ere	

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

AutoSave 💽 🖪 🥍 < 🥄 👻 🤝 🔻	Product Bulk Upload Templat	e - General Medical Device - Protected View - E	ixcel Kerwick, Elke 😣	· □ /×
File Home Insert Draw Page Layou	ut Formulas Data Review View	v Help	_ 2	3 Share 🖓 Comments
PROTECTED VIEW Be careful—files from the Intern	net can contain viruses. Unless you need to edit, it's	safer to stay in Protected View. Enable Edit	ting	×
B26 - : × √ fx				~
General Medical Device Product Deta	ils		Click for primary v	validation
You need to provide Medical Device Name, ModelVersion and Catalogue Referenc Unique Device Identifier (UCD) if available. Product information follows guidelines = Regulators Forum in their document: Commo Data Elements for Ide- In the Edds that require Vasilio response, entering anything often than YeaR/e will dropdown sulates, entering any value doet that no options in the dropdown	ce (REF) for each product. Please enter set by the international Medical Device dical Device identification. be recorded as "No" in fields that have i will result in validation failure.		There are errors within this	file. Please check all columns to ensure
Presse encuel that you dreck all these carefully before upocading particularly your how the sector sector is the birefact.com. Sector	dav dopše uno pastel drib ne kriguta registrative david se se na mali direktor se na mali direktor se provinci se	attal) Catalogue/Baltereare (2017) The state given by the 1011 Inte Republic Chry locatify the south resolution medical approace. In Finites to the formet function and process. The values should apply to see specific medical decice only within that Republied Enthy's device range. Catalogue/Befference is sometimes (Republic Version) and the second second second Republic Version of the second second second Catalogue/Beference applicable? Question. (Mammum Characters: 255)	samig Cathy (Upload) if yok hae asigned UDIs you must seled the UD	Internet Deprice Meentering (100) (1) device Meenter (UDNE) and pro- prou have assigned 651 UD-Dis 14-agit tream. The CTN a bhould assigned HBCC UD-Dis to your Check Charader

3. Enable Content before you complete and save the template on your system.

The red warning box will appear at the top of the template indicating that it is not ready for upload.

		Product Bulk	Upload Template - General I	viedical Device - Read-Only - I	Excel	C Kerwick, Elke	KE E3 -	- <u> </u>
le Home Insert	Draw Page Layout	Formulas Data Re	view View Help				🖻 Share	Comments
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SECURITY WARNING Mac	ros have been disabled.	Enable Content	3					×
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						Click	for primary vali	dation
Unique Device Identifier (UDI) if avai. Regulators Forum in the	lame, Model/Version and Catalogue/Refere lable. Product information follows guideline eir document: Common Data Elements for I	as set by the International Medical Device Medical Device Identification.				1	ere are errors within this file. I	Please check all column
Vol need to provide Medical Device + Unique Device Identifier (UDI) if avai Regulators Forum in the In the fields that require Yes/No respo dropdowns values, entering Please answer that run check of fields	kame, Model/Version and Catalogue/Refere lable. Product information follows guideline if document. Common Data Elements for I onse, entering anything other than Yes/No v any value other than options in the dropdo cash it is holdow unloading nadiculated if yo	ence (RCP) for each product, Prease enter as set by the International Medical Device Medical Device Identification. will be recorded as "No", in fields that have wn will result in validation failure. In these certical and nacted into the familiate				Th	ere are errors within this file. I	Please check all column
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4. Key points to note when completing template:

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

- You need to use a separate template for each device (GMDN[®] Code or Term).
- The templates are different and depend on the device type. You must use the correct template for the device type.
- One row per product when completing product template.
- Model/Version and Catalogue/Reference data cannot be the same. You must enter either Model/Version or Catalogue/Reference or both. You cannot select No for both fields.
- We strongly recommend that you also populate all optional fields, where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.
- UDI DI and DI data must be unique for each product and for each field within each product, with the exception of Unit of Use UDI DI – see below.
- We are aware that Unit of Use UDI DI can be same across multiple products, however the bulk upload template does not curently permit this. You can omit the Unit of Use UDI DI from the template and then add the duplicated Unit of Use UDI DI by using the <u>Update Registered Devcies and Products</u> function. We are working to resolve this issue on the template.
- Note the maximum characters for each field.
- Where dropdown options exist, select from the dropdown do not paste data into these fields as secondary validation will fail.

- Do not make any changes to the layout of the template otherwise it won't upload.
- A maximum of 1000 products can be added to the template. If you have more than 1000 products for a single GMDN[®], upload 1000, create separate templates for the remainder and upload in <u>separate</u> applications. There is currently no fee to add products to registered devices.
- Use the "Paste Values" option in Excel if you need to copy product information from another spreadsheet into the bulk upload template.
- We can only accept information about your products if they are entered one by one in the system or by using the bulk upload template.
- You must complete all the mandatory fields until the red box at the top of the template turns amber and states '**Ready to Validate**.
- We strongly recommend that you also populate all optional fields where possible, and particularly UDI DI and DI, as updating fields at a later stage cannot be done in bulk.
- Certificates of Free Sale (CFS) customers, please note: only the product information you enter in the first three columns of the template (Medical Device Name, Model/Version and/or Catalogue/Reference) will appear on the CFS certificate or schedule.

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

AutoSave 💽 off)	୰ୖଡ଼ ୖୢୖୖୖୖୖୢୖୖୖୖ ₹	Stent Graft 6 Prod	ucts Bulk Upload Template - G	eneral Medical Device_FEB 2022 v3 Val	d - Excel 🛛 🔎 🔍 Kr	erwick, Elke 🣧 —	o x
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D6 - : ×	√ <i>f</i> x 2.5mm						6
<u>General Medical D</u>	evice Product Deta	ails				Click for primary valid	ation
You need to provide Medical Device Na Unique Device Identifier (UDI) if availab Regulators Forum in their	me, Model/Version and Catalogue/Referer ole. Product information follows guidelines document: Common Data Elements for M	ice (REF) for each product. Please enter set by the International Medical Device ledical Device Identification				Ready to validate	
In the fields that require Yes/No respon- dropdowns values, entering a Please ensure that you check all fie	se, entering anything other than Yes/No w ny value other than options in the dropdow lds carefully before uploading particularly	ill be recorded as "No". In fields that have m will result in validation failure. if you have copied and pasted into the			5		
Medical Device Name (Required): A name uset to assist in the identification of the regulated medical device. It came to a brand, trade, proprietary or common name. (Maximum Characters: 255)	In Model/Version applicable? [Required]: Select Yea/No from the dropdown options.	ModelWersion: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select. No for Is Model/Version applicable? question.(Maximum Characters: 100)	Is Cataloguerreference applicable? [Required] Setect Yea/No from the dropdrein options.	Catalogue/Reference (REF): The value given by the Regulated Efficity to identify the spacefic medical device as at induites to its formit, function and medical device only which that Regulated Entity's device range. Catalogue/Reference is sometimes indemical by which that Regulated Entity's device range. Catalogue/Reference associations (Catalogue/Reference aspic.table') question. (Maximum Character: 255)	IUDI Issuing: the second secon	have assigned UDIs you must select the UDI	Unique Device Idei comprised of device registering with MHR always be communic make up to 14 digits flag (+), Asterisks (*)
PremiumS [™] Stent A	Yes	25mm	Yes	S87878	GS1 AISBL		04250274702216
PremiumS ^{IM} Steet A	Yes	2.5mm	Yes	S35445 946466	GS1 AISBL		04250274702193
PremiumS [™] Stent B	Yes	3mm	Yes	\$64646	GS1 AISBL		04250274704753
PremiumS [™] Stent A Plus	Yes	4mm	Yes	S35454	GS1 AISBL		04250274704777

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

AutoSave 💽 😗 🖫	9×° %× ** =	Stent Graft 6 Prod	ucts Bulk Upload Templat	te - General Medical Device_FEB 2022 v3	3 Valid - Excel	🔎 Kerwick, Elke	KE 🖻 –	X/
File Home Inser	rt Draw Page Layou	Formulas Data	Review View H	Help			d Share	Comments
Paste ♥ B I U	• 11 • A^ A' ! • I = • <u>A</u> • <u>A</u> •	===*** * * * *	œ • % 9 50 .0	Conditional Format as Cell Formatting ~ Table ~ Styles ~	Insert → Delete → Format →	$ \begin{array}{cccc} & & & & & \\ & & & & \\ \hline & & & & \\ \hline & & & \\ & & & \\ \hline \\ \hline$	Ideas Sensitivity	
Clipboard 😼	Font 🔤	Alignment 🗔	Number	r₃ Styles	Cells	Editing	Ideas Sensitivity	^
General Medical D	c √ ƒx 2.5mm Device Product Det	ails 7			[Click	for primary valid	v lation
You need to provide Medical Device Na Unique Device Identifier (UDI) if availat Regulators Forum in their In the fields that require Yes/No respons dropdowns values, entering a Please ensure that you check all fie	me, Model/Version and Catalogue/Referen ble. Product information follows guidelines document: Common Data Elements for M se, entering anything other than Yes/No w ny value other than options in the dropdow lds carefully before uploading particularly	Ice (REF) for each product. Please enter set by the International Medic D edical Device Identification. Ill be recorded as "No". In fices ti m will result in validation fail e. f you have copied and pasts int	ing		×	Ready to	ə validate	
Medical Device Name (Requind): A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name. (Maximum Characters: 255)	In Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Varsion: The value used represent one medical develor of devices to group many vitatis have shared characteristic. If y not allocated a model/version applic ble? question.(Maximum Chara ers	Text in cells highlight length - refer to max	ed in BLUE exceeds maximum character imum length in column headers.	JDT1 wing En	tity (Optional): If you have assigned (on the dropdown options.	IDIs you must select the UDI	Unique Device Idei comprised of device registering with MHR always be communic make up to 14 digits flag (+). Asterisks (*)
D	Mar		N	047678	0.01 1/0.01			
Premium5 [™] Stent A PremiumS [™] Stent B	Yes	2.5mm	Yes	S35445	GS1 AISBL			04250274702216
PremiumS [™] Stent A	Yes	exceeds character limit exceeds character limit	Yes	S46465	GS1 AISBL			04250274704739
PremiumS™ Stent B	Yes	3mm	Yes	S64646	GS1 AISBL			04250274704753
Premiums ** Stert A Plus	Yes	14mm	Yes	335454 946466	GS1 AISBL			04250274704777
Chemicano Chemic A Files				010100	GGT NODL			04200214100040

9

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

General Medical D	evice Product Deta	ils			Click for p
You need to provide Medical Device Name Device Identifier (UDI) if available. Product in their docume	Model/Version and Catalogue/Reference (information follows guidelines set by the Internet. Common Data Elements for Medical Dev	REF) for each product. Please enter Unique emational Medical Device Regulators Forum ice identification.			Ready to valid:
In the fields that require Yes/No respon dropdowns values, entering a Please ensure that you check all fields of	nse, entering anything other than Yes/No wil any value other than options in the dropdow arefully before uploading particularly if you	I be recorded as "No". In fields that have n will result in validation failure. have copied and pasted into the template.			
Medical Device Nome (Required): A manual manual do assist in the identification of the regulated medical device. It can be a brand, trade, projectary or common name (Maximum Characters: 255)	In Model/Version applicable? (Recurred) Sect VeNto from the dropdown options.	ModelPression: The value used to represent one medical device or a family of devices to group many variations that have hande characteristics. If you have not allocated a modelversion select 1% of rs Model/Version algoitable? question (Maximum Characters: 10)	Is Cataloquerrefrence applicable? (Required) Sector VeNilo from the dropdown options.	Catalogue-Reference (REF): The value given by the Regulated Entity to identify the specific medical device as it relates to its formit, function and process. The value should apply to one specific medical device only whith that Regulated Entity's device range. Catalogue-Reference is sometimes referred to by other terms such as SkU (Stock Keeping Unit) if you have not alocated a Catalogue-Reference applicate/? question. (Maxmum Characters: 255)	UDI Insuing Entity (Optional) If you have assigned UDIs you mut Entity from the dropdown options.
PremiumS™ Stent A	Yes	2 6mm	Yes	S87878	GS1 AISBL
PremiumS [™] Stent B	Yes	2.5mm	05	\$35445	GS1 AISBL
PremiumS™ Stent A	Yes	exceeds character limit exceeds character limit ex	es	\$46465	GS1 AISBL
PremiumS™ Stent B	Yes	13mm	es	S64646	GS1 AISBL
PremiumS™ Stent A Plus	Yes	4mm	Yes	S35454	GS1 AISBL
PremiumS [™] Stent A Plus	Yes	5mm	Yes	S45466	GS1 AISBL

- 9. Click for primary validation again.
- 10. If primary validation passes the 'Ready for uploading to MHRA' message appears click OK.

General Medical Do	evice Product Deta	<u>ils</u>	10					Click for primary va	lidation
You need to provide Medical Device Nan Unique Device Identifier (UDI) if availab Regulators Forum in their o	ne, Model/Version and Catalogue/Referen ile. Product information follows guidelines document. Common Data Elements for Me	ce (REF) for each product. Please enter set by the International Medical Device idical Device Identification.						Ready to validate	
In the fields that require Yes/No respons dropdowns values, entering ar Please ensure that you check all fields ca	e, entering anything other than Yes/No wil ny value other than options in the dropdow wefully before uploading particularly if you	be recorded as "No". In fields that have will result in validation failure. have copied and pasted into the template.		Microsoft E	cel	×			
edical Device Name (Required): A me used to assist in the identification the regulated medical device. It can be rand, trade, proprietary or common ime. (Maximum Characters: 255)	Is Model/Version applicable? (Required): Select Yes/No from the dropdown options.	Model/Version: The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'Ne' for is Model/Version applicable? question (Maximum Characters: 100)	Is Catalogue/refer nce (Required): Select es/ dropdown options	Ready for u	ploading to MHRA	alue bific ncti on ula ± is SKL	piven by the nedical n and specific d Entity's ometimes (Stock	TOD Issuing Entity (Optional): Byou have assigned UDIs you must select the UDI Issuing Entity from the dropdown options.	Unique Device Identifier (UDI) (if a device identifier (UDI-DI) and prod you have assigned GS1 UDI-DIs (14-digit format. The GTIN should assigned HIBCC UDI-DIs to your Check Character
					OK	teo 7	stion.		
emiumS™ Stent A	Yes	2.5mm	Yes		S87878			GS1 AISBL	04250274702216
emiumS [™] Stent B	Yes	2.5mm	Yes		S35445			GS1 AISBL	04250274702193
emiumS™ Stent A	Yes	3mm	Yes		S46465			GS1 ASBL	04250274704739
emiumS [™] Stent B	Yes	3mm	Yes		S64646			GS1 AISBL	04250274704753
emiumS™ Stent A Plus	Yes	4mm	Yes		S35454			GS1 AISBL	04250274704777
emiumS TM Stent & Plus	Yes	5mm	Yes		S45466			GS1 AISBL	04250274705545

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

Please note that it is possible for the template to be 'Ready for upload and validation' but still contain errors, for example if you have pasted data in dropdown fields. We can't stop this happening in Excel, so we have introduced secondary validation in the system to alert you to errors.

<u>General Medical D</u>	evice Product Deta	ails				Click for primary valid	lation	11
You need to provide Medical Device M	Name, Model/Version and Catalogue/Re	ference (REF) for each product. Please				Production and and address The a	alidadan adl fad faan kana aasa	
Medical Device Regulators Forum in	n their document: Common Data Eleme	ts for Medical Device Identification.				Ready for upload and validation. The v	and attorn will rail if you have not e	ompieted the template correctly.
In the fields that require Yes/No respo dropdowns values, entering any	nse, entering anything other than Yes/N have value other than options in the dropdor	o will be recorded as "No". In fields that an will result in validation failure.	I. Carelana la factoria	Parlane (NEP). The star				T. T. IV.
Medical Llovice Name (Elevative): A name used to assist in the identification of the regulated medic proprietation or onnew, made, proprietation common name. (Maimum Characters: 255)	La Modert Version applicatue (Direquired): Select Yes No from the disp down options.	Productive store: Intervalia used o family of devices to group many characteristics (synchronous production) allocated a modeliversion select 10°, allocated a modeliversion select 10°, guestion (Maximum Characters: 100)	Is Cataloguénérerené applicable ? (Regined), Select YealNofrom the dropdown options.	Calaboptic References (RET): The American Sector References (RET): The American Sector References and References (RET) References (RET): References (RET) References (RET): References (RET) Calaboptic References (RET) References (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RET): REFERENCES (RE	UDI Issuing Ently from the o	lionait - pourae asgredute pouraut secone	Unapue Device Standbritter (UDI) Un compared of device identifier (UDI-UD) registrating with MPRA II you have any nonalies upon V Agest II you have any HBCC Reg(H), Americks (1) or the Mod	and provide the control of the contr
PremiumS [™] Stent A	Yes	2.5mm	Yes	587878	GS1 AISBL		04250274702216	
Premiums ** stent B	Tes	2.0mm	Tes	530440	OS1 AISBL		04250274702193	
Premiumo - otent A	1 83	Jimm	145	540400	GS1 AISBL		04200274704739	
Premiumo - oversi B	1 to	den en	1 WD	004040	001 1000		04200214104703	
Premiumo - oteni A Plus	Yes.		1 mil	0.00404	GOT NOR		04200274704777	
Premiumo - otent A Plus	19	omm	105	846466	US1 AISBL		04200274700040	

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

				5240			
Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment		
Add products							
Here you can add product info	ormation for the device:						
2573-Aortic arch endovascula	ar stent-graft						
for each product. Product info Medical Device Regulators For Medical Device Identification.	ormation follows guideling	es set by the International mmon Data Elements for					
Add products one by or	ne		Add products in bulk				
Medical Device Name (Brand	d/Trade/Proprietary or	Common name)	You can also upload produc	t information in bulk using o	ur template. This is how		
<i>\ name used to assist in the id brand, trade, proprietary or co</i>	dentification of the regula ommon name.	ated medical device. It can be a	 Download our product you have the latest ven Enable editing and/or of Populate the template 	template-always download a sion. content on the template. with your product informatio	a new template to ensure		
s Model/Version applicable	?		 Do not paste formulas exceed maximum leng 	from other Excel documents th specified for each field.	and ensure text does not		
Please Select		•	 Ensure 'Ready to valida Click for primary valida 	te' message appears on the t tion and correct any errors io	template. dentified.		
ls Catalogue/Reference appl	icable?		 Ensure 'Ready for uplo completed the templat Upload your completed 	ad and validation. The validat e correctly.' message appear d template using the "upload	tion will fail if you have not s on the template. " button below.		
Please Select		•	 Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template 				
	0		 If secondary validations columns in the templat 	s fails, you will see an error n e require attention.	nessage indicating which		
JDI Issuing Entity (optional)							
UDI Issuing Entity (optional) GS1 AISBL	-	12	UPLOAD Drop file her	2			
UDI Issuing Entity (optional) GS1 AISBL HIBCC	-	12	UPLOAD 📮 Drop file her	e			
UDI Issuing Entity (optional) GS1 AISBL HIBCC ICCBBA		12	UPLOAD C Drop file her	e AND PREVIEW PRODUCTS			

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

Add products one by one	Add products in bulk
Medical Device Name (Brand/Trade/Proprietary or Common name)	You can also upload product information in bulk using our template. This is how
A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.	 Download our product template-always download a new template to ensure you have the latest version. Enable editing and/or content on the template. Populate the template with your product information.
Is Model/Version applicable?	Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
Please Select V	 Ensure 'Ready to validate' message appears on the template. Click for primary validation and correct any errors identified. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctiv' message appears on the template.
Is Catalogue/Reference applicable?	 Upload your completed template using the "upload" button below.
Please Select *	 Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template. If secondary validations fails, you will see an error message indicating which columns in the template require attention.
	Stept Graft 6 Products Bulk Unload Template - General
насс	XLSM - 526.83 KB
о іссвва 13	CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS
IFA GmbH	

14. The confirmation box will appear, **click** Yes to continue and wait for secondary validation to complete or No to cancel the upload.

Add New Devices for N	Wait until validation is complete then check preview of the products at the bottom of the screen. Clicking No will cancel your	0	
Manufacturer Device	upload.	Review	Payment
Add products	NO	14	
Here you can add product information for the de 62573-Aortic arch endovascular stent-graft	rice:		

15. If you have uploaded an incorrect template (e.g. wrong device type), invalid template (e.g. previous version), not completed all mandatory fields, not Clicked for primary validation or saved the template before uploading, you will see an error message.

Add products one by one	Add products in bulk
Medical Device Name (Brand/Trade/Proprietary or Common name)	You can also upload product information in bulk using our template. This is how
A name used to assist in the identification of the regulated medical device. It can brand, trade, proprietary or common name.	 Download our product template-always download a new template to ensure you have the latest version. Enable editing and/or content on the template. Populate the template with your product information. Do not paste formulas from other Event documents and ensure text does not
Is Model/Version applicable?	exceed maximum length specified for each field.
Please Select	5. Ensure 'Ready to validate' message appears on the template. 6. Click for primary validation and correct any errors identified. 7. Ensure 'Ready for unload and validation. The validation will fail if you have not
Is Catalogue/Reference applicable?	completed the template correctly.' message appears on the template. 8. Upload your completed template using the "upload" button below.
Please Select	 Click the Confirm Bulk Upload and Preview products button (below) – limited preview will be available – ensure all fields are correct in the template.
UDI Issuing Entity (optional) 😧	 If secondary validations fails, you will see an error message indicating which columns in the template require attention.
GS1 AISBL 16	Formaldehyde 7 products Annex II List A IVD Device v3 a
НІВСС	KLSM - 569.05 KB
ICCBBA	You have used an incorrect template or template is not ready to upload. Please ensure you have clicked on validate.
IFA GmbH	
UDI not assigned	CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

- **16.** If the template has failed secondary validation:
 - a) **Hover** over the document reference until the **X** appears and **click** the **X** to remove the template you have just uploaded.
 - b) Select the correct template or make any necessary amendments to the bulk upload template, click for primary validation, save it and upload again.
- 17. If the template has passed secondary validation in the system, you will see the **Validation Complete** message.



15

18. The products will be visible in the Preview table at the bottom of the screen.

	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
DEL	LETE SELECTED 20					6 items

- **19.** If you wish to remove a product you have just added, **tick** the box next to the Product Status in the Product Preview table at the bottom of the screen.
- 20. Click Delete Selected to remove the products.

Please note you must add at least one product to enable the Continue button.

- **21.** If you Delete Application, **all** devices in the application will be deleted.
- 22. Once you have added all your products, click the Continue button to proceed.
- 23. If the products do not preview correctly or you have uploaded an incorrect template:
 - a) Hover over the document reference until the X appears and click the X to remove all products you have just uploaded.
 - b) Make any make any necessary amendments to the bulk upload template, click for primary validation, save it and upload again.



24. Once you have successfully uploaded and previewed the product information click the Continue button to move to the next page, or BACK to the conformity document screen. Clicking the Delete Application button will delete all devices in the application.



Adding System or Procedure Packs (SPP)

1. Enter the GMDN[®] Code if you know it or search using multiple words.

System or Procedure Packs (SPP) Terms can often be found by **searching** GMDN[®] Code/Term box with the word 'Kit'.

Assemblers should search for an appropriate term e.g. 'Spectacles', if you don't know the $\mathsf{GMDN}^{\$}$ Code.

MHRA cannot advise you on which GMDN[®] Code or Term to select for your device.

	Device	Self-certification conformity declarations	Products	Review	Payment
Declare device	S				
What type of device is it?					
General Medical Device					
🔵 In Vitro Diagnostic Device					
Active implantable device (Di	rective 90/385/EEC on	ly)			
System or Procedure Pack					
GMDN Code/Term					
orthopaedic kit					
Term name		t			
44758 - General external ortho	opaedic fixation syster	n implantation kit, reusable			
61467 General external orth	opaedic fixation syster	n implantation kit, single-use			
01407 - General external ortho		- Incode and the state			
44759 - General internal ortho	paedic fixation system	implantation kit			
44759 - General internal ortho 44896 - Growth-correction orth	paedic fixation system				
44759 - General internal ortho 44896 - Growth-correction orth 45253 - Orthopaedic cement p	opaedic fixation system hopaedic fixation plate preparation/delivery ki	t			

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

	Declare devices
	What tune of flavica is it?
	Mark type of denies is to
	Artive Implantable Device
	System on Proceedure Back
	GMNN Code/Term
	Aubs - General Surgical procedure xt, non-medicated, reusable
	- View all GMDN terms and definitions
	Which directive/regulation does this device comply with?
	O WINIDK 2002 (S) 2002 NO 618 as amended), Part III
	O Directive 35/42 EEL
	C eu medical devices regulations 2017/145
	() MHRA will only accept registrations for sterile System & Procedure Packs under (EU)2017/745 if the EU Notified Body is designated under the EU Medical Devices Regulation 2017/745.
	Basic UDI-DI Issuing Entity(optional)
	Please Select
	Device labelled as sterile?
2)	⊖ Yes
	O No
	Sinele-use device?
	⊖ Yes
	O No
	Reprocessed sinzle-use device?
	⊖ Yes
	○ No
	Does the System or Procedure Park incomposate a custom-made medical device that is not required to bear a UKCA/CF/CF (UK NI) markine?
	O Yes
	Are the chosen combination of medical devices compatible in view of their original intended use?
	Ves
	Concesses of a substance which if used seasantely, may be considered to be a medicinal (force) medicinal product (optional)
	Please Select
	Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma (optional) 😡
	Please Select
	Has a Clinical investigation been conducted? (optional)
	Please Select 🔹
3	CONTINUE SAVE & EXIT

3. Click the Continue button, this will not be enabled until you have answered all mandatory questions.

You will be taken to either the <u>Upload Conformity Assessment Certificate</u> page or the <u>Self-certification conformity declaration</u> page depending on the details you have added at Declare Devices stage (GMDN[®] Code or Term level).

- 4. Once you have uploaded or linked to an existing document Enter the product details, this is the brand or trade name, model/version, catalogue/reference and other details.
 - You need to add a minimum of one product per SPP (GMDN[®] Term).
 - You must enter either a Model/Version or a Catalogue/Reference or both. Model/Version and Catalogue/Reference data cannot be the same. You cannot select No for both fields.
 - There is no bulk product upload function for SPPs.
 - Answer all the mandatory questions
 - We strongly recommend that you also populate all optional fields, where possible, as updating fields at a later stage cannot be done in bulk.

Add products Here you can add product information for the device: 44054-Orthopaedic surgical procedure kit, non-medicated, reusable You need to provide medical device name, model/version and catals for each product. Product information follows guidelines set by the Medical Device Regulators Forum in their document Common Data Medical Device Regulators Forum in their document Common Data Medical Device Name (Brand/Trade/Proprietary or Common na A name used to assist in the identification of the regulated medical brand, trade, proprietary or common name. Orthokit1 Is Model/Version applicable?Please Select Is Catalogue/Reference applicable?	ngue/reference nternational Elements for me) device. It can be a		
Here you can add product information for the device: 44054-Orthopaedic surgical procedure kit, non-medicated, reusable You need to provide medical device name, model/version and catak for each product. Product: nformation follows guidelines set by the Medical Device Regulators Forum in their document Common Data Medical Device Regulators Forum in their document Common Data Medical Device Name (Brand/Trade/Proprietary or Common na A name used to assist in the identification of the regulated medical brand, trade, proprietary or common name. Orthokit1 Is Model/Version applicable?Please Select Is Catalogue/Reference applicable?	nternational IElements for ne) device. It can be a		
44054-Orthopaedic surgical procedure kit, non-medicated, reusable You need to provide medical device name, model/version and catals for each product. Product information follows guidelines set by the Medical Device Regulators Forum in their document Common Data Medical Device Name (Brand/Trade/Proprietary or Common na A name used to assist in the identification of the regulated medical brand, trade, proprietary or common name. Orthokit1 Is Model/Version applicable?Please Select Is Catalogue/Reference applicable?Please Select	ngue/reference nternational Elements for me) device. It can be a		
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Is Model/Version applicable?Please Select Is Catalogue/Reference applicable?Please Select IIDI Issuing Entity (optional)	•		
Please Select Is Catalogue/Reference applicable?Please Select IIDI Issuing Entity (optional)	-		
Is Catalogue/Reference applicable?Please Select UDL Issuing Entity (optional)			
Please Select			
IIDI Issuing Entity (ontional)	•		
obi issuing chucy (optional)			
⊖ GS1 AISBL			
○ нівсс			
◯ ICCBBA			
O IFA GmbH			
O UDI not assigned			

5. Click the link to Download our content list template, complete and save the template on your system.

	Please tell us about the contents of the system/procedure pack using the template below
5	Download our content list template J. Hill in the template with details of each item within the system/procedure pack J. Upload your completed template using the "upload" button below
	UPLOAD C Drop file here

- One row per product.
- At least 2 products (contents) must be entered otherwise the template will not upload
- The size of the contents list file must be minimum 36KB, if it is less than this enter 'Contents may vary' in the line/s under last product until file size is 36KB.
- We do not need the GMDN[®] Code or Term for each of the listed contents.
- You do not need to register the contents by individual GMDN[®] Term unless you manufacture these devices and place them individually on the UK market.
- You need to use a separate contents list template for each product (Medical Device name and Model/Version, Catalogue/reference etc.).

Please note if you have multiple products covered by a single GMDN[®] and these include a combination of similar products please add one product and upload <u>one</u> SPP content list that covers all possible contents of products under the GMDN[®] plus the wording '**Contents may vary but are available on request**' on the last line of the contents template. See example below.
5

Systems and Procedure Packs Content List

You will need to provide Medical Device Name for each product within the System or Procedure Pack. Product information follows guidelines set by the International Medical Device Regulators Forum in their document: Common Data Elements for Medical Device Identification. Model and Catalog/Reference (REF) are optional for this list.

Medical Device Name (required): A name used to	Model (optional): The value used to represent one	Catalog/Reference (REF)(optional): The value given by the
assist in the identification of the regulated medical	medical device or a family of devices to group many	regulated entity to identify the specific medical device as it relates
device. It can be a brand, trade, proprietary or	variations that have shared characteristics.	to its form, fit, function and process.
common name.		
ARTERY FORCEP CURVED	Model 001	SKU 001
ARTERY FORCEPS STRAIGHT 1-2 TEETH	Model 002	SKU 002
BLOCK END DISSECTING FORCEP	Model 003	SKU 003
BONE CUTTER	Model 004	SKU 004
BONE ELEVATOR	Model 005	SKU 005
BONE HOOK	Model 006	SKU 006
BONE LEVER	Model 007	SKU 007
CURETTE DOUBLE ENDED	Model 008	SKU 008
DIATHERMY DISSECTING FORCEPS	Model 009	SKU 009
DIATHERMY LEADS	Model 010	SKU 010
Contents may vary but are available on request		

6. Upload the completed template. Click the Upload button and select the saved template from your system.

	Please tell us about the contents of the system/procedure pack using the template below
	 Download our content list template Fill in the template with details of each item within the system/procedure pack Upload your completed template using the "upload" button below
6	UPLOAD

7. Continue answering all the mandatory questions. We strongly recommend that you also populate all optional fields, where possible, as updating fields at a later stage cannot be done in bulk:

Type of UDI-PI (optional) 🚱	
Lot or Batch Number	
Serial Number	
Manufacturing date	
Expiration date	
Software version	
Does the device incorporate human cells or tissues, or their derivatives (optional)	
Please Select	-
Does the device incorporate animal cells or tissues, or their derivatives (optional)	
Please Select	•
Are storage/handling conditions specified in the label/instructions for us (optional)	e
Please Select	•
Quantity per package configuration (optional)	
Need for sterilisation before use (optional) 😡	
Please Select	-
What MRI safety information does the labelling contain? (optional)	
Please Select	-
Does the label/instruction for use include Critical warnings or contra- indications (optional)	
Please Select	•
Containing latex (optional)	

	Clinical size applicable (optional) 🕑	
	Please Select 💌	
	UDI-DI from secondary entity (optional) 🕑	
	Please Select	
	Endocrine disruptor (optional) 🕑	
	Please Select	
	Additional product description (optional) 🥹	
8	ADD PRODUCT	
		Show
		10 per page

- 8. Click the Add Product button if you don't your product won't be saved. Repeat the process from the top of the Add Products page to add more products.
- 9. Preview the product/s you have added in the Preview table. Only limited fields display.

						Show			
						10 per page	•		
	Product preview (produc	ts: 1)							
	Preview only displays limited fields								
	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status			
9	Orthokit1	Not Applicable	001/Ortho/876	UDI not assigned		On the GB & NI market	$\overline{}$	10	I
11	CONTINUE SAVE & EXIT BACK					DELETE APPLIC	ATION		

- 10. If you wish to remove any of the products **click** the red **X** to remove. The Continue button will not be enabled until you have added at least one product.
- **11. Click** the Continue button to proceed to the Review page.

Review information prior to making payment

Please **review** all information prior to making payment. Once payment has been made applications are non-refundable. See our Terms and Conditions.

- 1. Click the chevrons to view and check that the information is correct. The Review page has separate links to view:
- 2. Device Details

Only the fields you have populated will appear on the review screen e.g. if you have not entered Basic UDI DI or Clinical Investigation details there will be no information here. **Please note** Making **any** changes at GMDN[®] Term or Code level in an application will result in the product information being removed and you will need to add product again, either individually or in bulk.

3. Confomity Assessment Certificates/Self-certification Conformity Declarations These can be amended before submitting application.

4. Products

Products can be added or removed before submitting application. Follow the <u>Adding</u> <u>products individually</u> and <u>Adding products in bulk</u> instructions – these also include instructions on removing products from an application.

Manufacturer Device Selef-certification conformity deciarations Products Review Payment Review Pevice Review Device Beala Conformity Assessment Certificates Products Products Device Details No Class III Class III Device Details No Class III Class III Device Details No Class IIII Revice Details Device Device III No Class IIII Revice Device Device IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII			,105007			
Review Performer	Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment
Perices 2 ens nucleus manipulator Conformity Assessment Certificates Perice type Conformity Assessment Certificates Center and Medical Device No Seriels Custom made? Seriels Method of Sterilisation Resultation Directive? Resultation Reprocessed single-use device? Annex XVI? No No No No Implantable Products? Active Products? No No Period Control Directive? On the device will device and straining registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical devices regulational devices regulational devices regulational devices regulational devices in the device will device and you will need to re-enter them Annex XVI? No No No Entro Device Output:	Review					
Device Details Conformity Assessment Certificates Products Device type Custom made? Risk classification General Medical Device No Class III Sterile? Method of Sterilisation Reusable surgical instruments? Yes Radiation, Gamma or Electron Beam Yes Regulative/Directive? Reprocessed single-use device? Annex XVI? No No No Implantable Products? Active Products? Administer/Remove medicinal Product? No No No No EDIT DEVICE DELETE DEVICE Ves ************************************	Devices	2		3		
Device type Custom made? Risk classification General Medical Device No Class Ila Sterile? Method of Sterilisation Reusable surgical instruments? Yes Radiation, Gamma or Electron Beam Yes Regulative/Directive? Results of the sterilisation or Electron Beam Yes Regrocessed single-use device? Annex XVI? No No No No Implantable Products? Active Products? Administer/Remove medicinal Product? No No No No EDT DEVICE DELETE DEVICE Versent of the sterilization on of the sterilization or of the sterilization conformity desaessment documents and products (model/version) for that device and you will need to re-enter them ADD ANOTHER DEVICE You are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical device assemantial require anter, where applicable of the relevant medical device location conformity desailability of the chincinal and trianal data for each device. Device requirements, where applicable of the relevant medical device classing sterilization, including the vanilability of the chincinal and trianal data for each device. Device requirements, where appl	Device Details	<u> </u>	Conformity Assessme	nt Certificates	P	roducts
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Yes Radiation, Gamma or Electron Beam Yes Regulator/Directive? Regulator/Directive? Second Sec	Sterile?		Method of Sterilisation	R	eusable surgical instruments?	
Regulative/Directive? European medical devices regulations EU 2017/745 Reprocessed single-use device? Annex XVI? No No No Implantable Products? Active Products? Administer/Remove medicinal Product? No No No Implantable Products? Active Products? Administer/Remove medicinal Product? No No No Implantable Products? Active Products? Administer/Remove medicinal Product? Oto EURT DEVICE DELETE DEVICE f clints the device will remove or unlink all conformity assessment decuments and products (incide/version) for that device and you will need to re-enter them XOD ANOTHER DEVICE You are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical de informity general safety and performance requirements, where applicable) of the relevant medical devices legislation, including the availability of technical and clinical data for each device. Devices require Vau are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical de informity declaration, including the availability of technical and clinical data for each device. Devices require Vau are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical de informity declaration, including the availability of technical and clinical data for each device. Devices require Fauther to register applicability of the relevant medical devices legislation, including the availability of technical and clinical data for each device. Devices require applicant the on the market in the UK the manufacturer must provide a signed Self-certificate. There are also additional legal requirements which must be met, ind which assemblers of systems and procedure packs specifically shutle ensure they meet before marketing such products. F	Yes		Radiation, Gamma or Electron Beam	Y	es	
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No No No EDIT DEVICE DELETE DEVICE C C C C C C C C C C C C C C C C C C	Implantable Products?		Active Products?	А	dminister/Remove medicinal P	roduct?
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Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant or NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying the environ types, are compliant with the optional building. MIRO have the factor for compose contractations. In the manufactor is used and or their devices legislation in the UK.	Further information on the legal requirem Medical devices and in-vitro diagnostic de	ents is available at the follo vices regulations.	owing links in relation to the UK Medic	al Devices Regulations 2002 (in th	e form that they exist on 1 Jan	uary 2021) and also rega
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Please tick to confirm you have read and understood the above requirements and that you agree to our terms and conditions.		indepiteed the above requi	rements and that you agree to our ter	ms and conditions		

 Click the Add Another Device button if required. You can add up to 100 devices (GMDN[®] Term) in a single application with a cumulative maximum of 20,000 products (brand or trade name, model/version and catalogue/reference details etc.).

Please note if you have more than 1000 products for a single GMDN[®] Term, upload 1000 then create separate templates for the remainder and upload in separate applications <u>after</u> the original application has been accepted by MHRA. There is currently no fee to add additional products to a registered device. Please follow the <u>Manage Registered Devices</u> instructions to do this once your application to register the device (GMDN[®]) has been completed and the device is registered.

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

		declarations	Products	Review	Payment
Review					
Devices					
✓Lens nucleus manipul	ator				
Device De	tails	Conformity Assessmen	nt Certificates	Proc	ducts
Device type General Medical Device		Custom made?		Risk classification	
Sterile?		Method of Sterilisation		Reusable surgical instruments?	
Yes		Radiation, Gamma or Electron Beam		Yes	
Regulative/Directive?	11 2017/745				
caropean meanar actives regained as					
Reprocessed single-use device?		Annex XVI?			
No		No			
Implantable Products?		Active Products?		Administer/Remove medicinal Pro	duct?
No		No		No	
EDIT DEVICE DELETE DEVICE					
Editing the device will remove or un	link all conformity assessme	nt documents and products (model/version) for	that device and you will nee	ed to re-enter them	
ADD ANOTHER DEVICE					
You are about to register/update an placing them on the market in the U general safety and performance request conformity assessments to be carrie which assemblars of system and an and the system and the system and the system and and the system and the system and the system and system and sy	existing registration as (or K the manufacturer must p airements, where applicab d out by a UK approved bo produre necks energiation	on behalf of) a manufacturer or an assemble rovide a signed Self-certification conformity (e) of the relevant medical devices legislation dy/ EU notified body must provide a valid UKC hould enurge they meat before more there	r of systems and/or proce declaration stating that e , including the availability CA/CE certificate. There are the products	edure packs. Before applying the UKCA/C ach medical device has met the appropri r of technical and clinical data for each d e also additional legal requirements whi	E mark to medical devices or iate essential requirements (o evice. Devices requiring ch must be met, including the
which assemblers or systems and pr	uirements is available at th	ne following links in relation to the UK Medica	al Devices Regulations 200	2 (in the form that they exist on 1 Januar	ry 2021) and also regarding th
Further information on the legal req Medical devices and in-vitro diagnos	tic devices regulations.				
Further information on the legal req Medical devices and in-vitro diagnos Failure to declare compliance with th	tic devices regulations.	t you are certified for will result in your regis	tration becoming invalid a	and you will be charged a further £100 to	make the relevant changes.

- 6. Please **read** the requirements and terms and conditions. Once you have done so, **tick** the 'I have read and agree to the terms and conditions' check box.
- 7. Click the 'Continue' button to proceed to payment.

Making Payments

1. Choose billing address.

Please Note see Managing Shipping, Billing, Manufacturing Site addresses in the MHRA Account Management Reference Guide.

2. Choose payment method by clicking on either worldpay or the BACS/CHAPS button.

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

Manufacturer Det	tails	Device Details	Review	Payment
oose a Billing address	and then related	payment method. See instruction	ons below on how to add a new Bi	lling address if required.
ayment detai	ls			
Devices Fee :	£100.00			
Total:	£100.00			
Address details	5			
Choose Billing address				
hoose Billing address Registered Address - 15	1, Buckingham P	'alace Road 👻		
Choose Billing address Registered Address - 15 Please choose a Billing add	1, Buckingham P	valace Road 🔹		
Choose Billing address Registered Address - 15 Please choose a Billing add 151, Buckingham Palace	1, Buckingham P Iress matching you Road, London	alace Road 🗸		
Choose Billing address Registered Address - 15 Please choose a Billing add 151, Buckingham Palace SW1W 9SZ, United Kingdo	1, Buckingham P Iress matching you Road, London om	ralace Road 🗸		
Choose Billing address Registered Address - 15 Please choose a Billing add 151, Buckingham Palace SW1W 9SZ, United Kingdo O You can add other ad Addresses' in your orgni	1, Buckingham P ress matching you Road, London om dresses by going sation's 'Related	ralace Road ur payment card. g to ' Manage Other Actions' tab.		

	Payment method Choose payment method	
2	≫worldpay	
	SUBMIT APPLICATION SAVE AND EXIT BACK	DELETE APPLICATION

Paying with worldpay

1. Click on the Pay with worldpay button.

	Click here to download the Proforma.
	You can click above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit to complete payment)
	Payment method
	Choose payment method
	⊗worldpay
1	Please proceed to pay with worldpay (opens in new window). Come back to 'Complete application' once payment is processed.

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



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



4. Select the payment method.

4

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

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Medicines & Healthcare products
Regulatory Agency

			-	
Payment reference:	DR28663190	510142214		
Description:	Medical devic registration	e registration/Updat	e to an existing medic	cal devid
Amount (GBP):	£100.00			
Select payment metho	d	AMERICAN	United Kingdom	
Select payment metho VISA Masterca	nd ard. Trd Maestro.	AMERICAN EXPRESS AMEX	United Kingdom	Masterpas Learn mo
Select payment metho VISA Masterca Kasterca	nd ard. Trd Maestro.		United Kingdom	Masterpa Masterpa Learn mo

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

VISA VISA Back
Cardholder's name *
Jane Smith
Security code * 123 Last 3 digits on the back of card
PU, United Kingdom
F

6. Click the Submit Aplication 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.

	Payme	ent com	olete		
6	Your payment	t completed succe	ssfully. Please submit your apj	plication	
Ŭ	SUBMIT APP	PLICATION			

7. A confirmation screen will appear. Click the Close button.

Application co	nplete	
Your reference number		
201905100012472	1	
What happens next	••	
We have sent you a confirmation	email and your application has been sent to an officer at MHRA.	
We will contact you again within	the next 2 -5 working days to let you know of our decision, or to ask for	more information if its needed.

8. Please note if you do not click the Close button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been -submitted. Click on the OK button.

Application complete	▲ The Task Could Not Be Submitted
Your reference number	The task has already been submitted.
2019052202171218	ок
What happens next	
We have sent you a confirmation email and your application has been	sent to an officer at MHRA.
We will contact you again within the next 2 -5 working days to let you k	know of our decision, or to ask for more information if its needed.

9. Click on the Applications Tab to see your submitted application.

10. You will receive a confirmation email from Woldpay.

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

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

NA	MHRA <do-not-reply@worldpay.coi< th=""><th>15:40</th></do-not-reply@worldpay.coi<>	15:40
	TEST. MHRA payment	~
Transac	tion Confirmation	
Please ret	ain for your records	
Thank you		
Your transaction	has been processed by WorldPay, on behalf of MHRA.	
Transactio	on details	
Transaction for t	he value of: GBP 100.00	
Description: Med	lical device registration/Update to an existing medical device registration	
Worldpay's trans	action ID: 3135822828	
This is not a tax r	eceipt	
Enquires		
This confirmation order has been a	n 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 ccepted, and to deliver any goods or services you have ordered.	
If you have any o	uestions about your order, please email MHRA at: Device.accounts@mhra.gov.uk , with the transaction details listed above.	
Your payment is	securely processed by WorldPay.	

- 11. You will also receive a confirmation email from MHRA.
- 12. Close the separate window that was opened when you were directed to the worldpay site.



Pay by BACS/CHAPS

- Click on the click here link to download a proforma invoice if you need an invoice to enable your accounting department to process payment of the device registration <u>statutory fee</u>.
- 2. Click the BACS/CHAPS button and make your BACS/CHAPS payment using the MHRA account details.

Please note you <u>must</u> quote the 'Reference number' You are able to <u>Save and Exit</u> your application and resume completion at a later time (See <u>Save and Exit:Resume Applications</u>).

- 3. Once payment is made upload your proof of payment.
- 4. Submit application.

1 Click here You can cli	to download the Proforma. Ick above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit o
Pavm	ent method
Choose p	payment method 2
3 V	worldpay
🌖 The a	pplication will be completed only after the tranfer is complete. This usually takes 5 days.
When ma the MHRA	king a payment via BACS or CHAPS you must quote the reference number below. Failure to do so will result in delay or rejectic A. The MHRA review of your application will only be completed once payment has been made and proof of payment has been r
Referenc	e number
17101908	220192042
For BACS	/CHAPS payments please use the following details:
Ac	count name: MHRA
Acco	unt number: 10004386
	Sort code: 60-70-80
	Swift code: NWBKGB2L
	IBAN: GB68NWBK60708010004386
	Bank: National Westminster Bank
	RBS, London Corporate Service Centre, 2nd Floor
	280 Bishopsgate
	London - EC2M 4RB
3 Please up	load your proof of payment. This can be a copy of a bank statement indicating the payment date, amount and payee
	oof_of_payment DCX - 11.38 KB
4 SUBMIT	APPLICATION SAVE AND EXIT BACK

Complete Application

5. Note the Application reference number.

	AGENCY SERVICES		CCOUNT MANAGEMENT		\bigcirc
	Applic	ation co	mplete		
5	Your refere	nce number			
	201805	200177128			
	What ha	ppens next	t		
	We have sent	you a confirmatio	on email and your applicatio	on has been sent to an officer at MHRA.	
	We will contai	t you again withii	n the next 2 -5 working days	s to let you know of our decision, or to ask for more information if its needed.	
6	CLOSE				

- 6. Select the Close button.
- 7. Please note if you do not click the Close button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been auto-submitted. Click on the OK button.

A The Task Could Not Be Submitted
The task has already been submitted.
•
has been sent to an officer at MHRA.

8. Click on the Applications tab and hover over the status icon tab to see the progress of your submitted applicaton.

∽Submitted Applica	tions			
Search by organisation name o	r reference number			
	SEARCH	Show All Types	Show	10 per pa 💌
Reference	Manufacturer	Application Type	Submitted on	Status
2022021801215061	MHRA Demo	New device	18 February 2022	8) 💿
2021102602208215	DEMO Represented Organisation	CFS Order	26 October 2021	•
2021102500208210	DEMO Represented Organisation	Registration Renewal	25 October 2021	٥

Application received email

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

We've received your New device application on 18 February 2022.

Application reference number: 2022021801215061

Manufacturer name(s) MHRA Demo

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

Access your MHRA account.

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

Yours sincerely,

Device registrations service

Within 5 working days from submission you should receive an email confirming the outcome of the application. Some devices may be registered, some may be rejected. This may take longer at peak times or if we require further information from you.

In the meantime, you can check the status of your application in the Applications Tab.

		NAGEMENT								
Applications										
 Draft Application 	ons									
TEMP applications will be vithin 90 days of 'Last saved	automatically delete l on' date in below t	ed 90 days from last s able. Once deleted Ti	aved on date	e. Please ensure that y ons cannot be reinsta	ou regulai ted.	'ly review yo	our TEMP application	s and subm	it to MH	IRA
earch by manufacturer n	ame or reference r	number								
	SEARCH	Service	All Types	•	Show	All Types	-	Show	10 pe	rpa 🔻
Reference		Manufacturer		Application Type			Last saved on		Ļ	Status
TEMP20220217151705		MHRA Demo		New device			17 February 2022			
•Submitted App earch by organisation na	me or reference nu	umber			Show	All Types	•	Show	10 pe	rpa… ▼
Reference	Manufactur	er		Application Ty	/pe		Submitted on		Statu	s
Reference 2022021801215061	Manufactur MHRA Demo	er D		Application Ty New device	/pe		Submitted on 18 February 2022		Statu ©	5
Reference 2022021801215061 2021102602208215	Manufactur MHRA Demo DEMO Repre	er Sented Organisation		Application Ty New device CFS Order	/pe		Submitted on 18 February 2022 26 October 2021		Statu ©	s

Registration Complete

 You will receive an email with a pdf attachment confirming the outcome of your application. Please note a pdf will only be attached to New Device, Device Amendment/Upate and Device/Manufacturer applications. Please retain all emails and pdfs for your records.



2. The manufacturer will now have a Registration Status of Registered.

evice R	egistration & Certificates of F	ree Sale		
our Organ	isation			
ame	Address	Country	Devices (Products)	Registration Status
IHRA Demo	10 South Colonnade, 10th Floor Area 7, Canary Wharf, London, Greater London, F14 4PU	England, United Kingdom	2 (27)	۰

Public Access Registration Database (PARD)

Completed registrations will appear on the <u>Public Access Registration Database (PARD)</u>, usually the week after completion.

In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database. These devices are not placed on the market.

If your registration account is suspended, your organisation will not appear on PARD, please see Renew Registration and Uploading new Letter of Designation in the Account Management Reference Guide.

If your registration is not displaying on PARD or your devices are displaying as '**Devices pending update by manufacturer**' or '**Conformity Assessment Certificate Expired**', please access your account review your devices, and follow the <u>Manage Registered devices</u> instructions to take any necessary action to bring your registration up to date. Please also see <u>Removing migrated Pseudo GMDN[®] Terms</u>.

Updating Registrations

Editing organisation details

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

Adding new devices

See steps for <u>Add device using GMDN[®].</u>

Export devices data to Excel file

Device R	egistrati	on & Certificates of	Free Sale			
Your Organ	isation					
Name	Address		Country		Devices (Products)	Registration Status
MHRA DEMO	10 South Cold	onnade, Canary Wharf, London, E14 4PU	England, United	Kingdom	0 (0)	0
Key 📀 Registered 🔘	Not Registered	Unregistered 0 Suspended				
Manufactu	rers you re	present				
Only registered ma	nufacturers appea	ar here. Newly submitted and draft			ADD N	EW MANUFACTURE
Only use the ADD NE	w MANUFACTURER	function if you have not				
already registered the registered the manufi	represented manuf acturer, please use th	acturer. If you have 1e Add Devices function to			ADD	NEW IMPORTER
register additional dev	vices on the existing	account.			ADD NEW IMPOR	TER
Search by manufa	cturer name:					
		SE/	RCH			
Name		Address	Country	Devices (Product	s) Relationship	Registration Status
DEMO Represent	ed Organisation	123 Street, Sea View Industrial Estate, Boston, 12345	United States	1 (1)	UK Responsible Person	۲
Key Registered ON Click on Exp(ot Registered 🗢 🕽	Unregistered [©] Suspended × Rejected	nk.			
Key Registered ON Slick on Exp(Back to DR&CFS Services VIHRA Demo: 1		Unregistered O Suspended × Rejected	nk.	Details 📑 Order Cl	75 a Add Devices Manage D Ster Manufacturer	Devices
Key Registered ON Click on Exp(Back to DR&CFS Services WHRA Demo: I Drganisation	ot Registered OI	Unregistered O Suspended × Rejected es Data to Excel File li resented	NK. Z Edit Organisation Registered Devices/	Details 🔋 Order Cl Products X Unregi	S Add Devices Manage D Ster Manufacturer Export Dev	Devices Z ices Data to Exce
Key Registered ON Click on Exp(Back to DR&CFS Services WHRA Demo: I Organisation SUMMARY APPLICATIONS	ot Registered C	Unregistered ^① Suspended × Rejected PS Data to Excel File li presented CONTACTS OTHER ADDRESSES DOCUMENTS N	DK. Edit Organisation Registered Devices/	Details 🔳 Order Cl Products 🗙 Unregi	S 🔲 Add Devices 🗮 Manage D ster Manufacturer 🔲 Export Dev	Devices
Key Registered ON Click on Exp(Back to DR&CFS Services WHRA Demo: I Drganisation	ot Registered C	Unregistered [©] Suspended × Rejected Son Data to Excel File Ii Presented CONTACTS OTHER ADDRESSES DOCUMENTS N	Edit Organisation Registered Devices/	Details 🔋 Order Cl Products X Unregi	S 🔲 Add Devices 🗐 Manage D ster Manufacturer 🧕 Export Dev	Vevices
Key Registered ON Click on Expension Reack to DR&CFS Services WHRA Demo: I Drganisation SUMMARY APPLICATIONS I Summary O Your registration we determined by the A sus being summer by the A sus being s	ot Registered CI	Unregistered ^① Suspended × Rejected Des Data to Excel File li presented CONTACTS OTHER ADDRESSES DOCUMENTS N st be reviewed and renewed one year aft as created with the MHRA. Your Registerut remeans you will not be able to place new to offence to place a non-compliant device	nk. Edit Organisation Registered Devices/ EWS er the anniversary di ion Renewal is 01/01 devices on the mark	Details Order Cl Products X Unregu ate and every two /2022. Failure to n et given it is a lega e UK.	3 • Add Devices Manage D ster Manufacture • Export Dev ears subsequently. The anniw enew your registration will resu	evices ices Data to Exce ersary date is ult in your acc a registration
Key Registered ON Click on Exp(Back to DR&CFS Services WHRA Demo: I Drganisation SUMMARY APPLICATIONS I SUMMARY APPLICATIONS I Summary O Your registration widdetermined by the data being suspended. A sus the competent authorit Basic Information	ot Registered C	Unregistered ^① Suspended × Rejected ES Data to Excel File li Dresented CONTACTS OTHER ADDRESSES DOCUMENTS N st be reviewed and renewed one year aft as created with the MHRA. Your Registrat "means you will not be able to place new offence to place a non-compliant device	Control of the second s	Details Order Cl Products Unregi ate and every two V2022. Failure to r et given it is a lega UK.	75 Add Devices Manage D ster Manufacturer Export Dev vears subsequently. The anniva enew your registration will result i requirement to hold an active	ersary date is ult in your acc

2

3. Click on Download Data to Excel File link.



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

Please note the maximum number of characters for an organisation name in the file name is 25 therefore you may not see the full name but can also identify the organisation by the account number that is also included in the file name.

Summary 9 Your registration determined by the being suspended. A	n with the MHRA must be reviewed and renewed date your account was created with the MHRA. Yo A suspended account means you will not be able to	one year after the anniversary date a ur Registration Renewal is 01/01/20, o place new devices on the market g	and every two ye 22. Failure to ren ven it is a legal r	ears subsequently. The anniversary date is new your registration will result in your accour requirement to hold an active registration with	nt h
Basic Information	nonty (wind), it is an onence to place a non-comp	nant device on the market in the or			
Account Number	0000009133	Registration Status	legistered		
EU Single Registration Number (SRN)		PARD Options	 Publish UK Resport Publish UK Resport Publish Organisat 	onsible Person Name onsible Person Address tion's Name	
Role / Account Type	Manufacturer		 Publish Organisati 	tion'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	2017 MDRs	10		
Organisation Detai	ils				
Organisation	 Maxillofacial technology organisation 	Telephone 3	145365655		
Description	Manufacturer of prosthetic devices Other	Fax 1	4/A		
Registered Address	123 Road, Sea View	Website N	4/A		
-	Boston				
	12345				

5. The Excel dialogue box will open. Open or save the file as required. You will need to Enable Editing to save the file.

Au	toSave 💽 Off	89	~ (~ ?		All Devices Data	for DEMC	Represente	d Organisa	a 9133 on 22	2_09_20	21 12_37 8	BST - Protected View	w - Excel 🔎
File	e Home	Insert	Draw	Page Layout	Formulas	Data	Review	View	Help				
0	PROTECTED V	IEW Be care	eful—files fr	om the Internet c	an contain viruse	es. Unless y	ou need to	edit, it's sa	fer to stay in	Protec	ted View.	Enable Editing	5
A1	~	: ×	√ fx	GMDN_Terr	m_Name								
		А			В			С				D	
1 0	MDN_Term_	Name		GMDN_Code		1	Device_Reg	istration_	Status	C	ustom_N	/lade	Custom
2 0	artilage knife					1	Registered			N	lo		
2 (artilago knifo						Posistarad			N			

Using filters to search for devices and products

Filter options are available to enable searches for specific devices and products. These can be found on the Devices screen, Products screen and Manage Devices screen. You can use multiple filters to refine your search.

- 1. When devices have been deleted, they will no longer appear in the table when you search for specific devices, you must filter for them by using the Device Registration status filter and selecting option No Longer Registered.
- 2. The Reason for Deletion will be displayed. Devices may have been deleted by MHRA, for example due to non-compliance or incorrect data provided. You will receive email confirmation when MHRA deletes a device from your account including the reason for deletion.

Please note reason for deletion will only appear for devices deleted after 21 August 2021.

SUMMARY APPLICATIONS RELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS

)evice Ti	vpe / Class	Device Registered Date	GMDN Cod	e / Term Name	Custom Made		Regulation/Directive:
- Select	: device type / Clas.	• dd/mm/yyyy			-	-	
s Sterile	?	Is Measuring	Is Single-us	se?	Is Reprocessed single-	use?	Custom-made SPP
-		• _ •		•	-	•	_ *
leusable	e Surgical	Is Active?	is implanta	able?	ls intended to		Intended purpose other than
nstrume	ents?	- •		•	Administer/remove		medical(Annex XVI)
		•				•	- •
s CFS Re	adv	Presence of Medicinal/Herba	Presence o	f Blood/Plasma	Has a Clinical investig	ation	Basic UDI-DI Issuing Entity
_		substance	substance		been conducted		
		- •		•	-	•	
Basic UD	I-DI Number	Device Registration status	Is Device U	pdated?			Show
		No Longer Registered 🔹	-	-			10 per page 🔹
							Clear Filters
Status	GMDN Code	Term Name	Ť	Device Type		Reas	son For Deletion
٥	41349	Allergen-specific immunoglobulin E (IVD, control	(IgE) antibody	In Vitro Diagnostic I	Device - IVD General	Ente	red in error
8	-	Alpha-fetoprotein (AFP) IVD, kit, enzy immunoassay (EIA)	/me	In Vitro Diagnostic I	Device - IVD General		
	90000186	Alphafetoprotein		In Vitro Diagnostic I	Device - IVD General		
	90000202	Anti-Streptolysin/Anti-Streptolysin O	(qualitative)	In Vitro Diagnostic I	Device - IVD General		
	90000227	antinuclear antibody (enzyme-labele control	d), antigen,	In Vitro Diagnostic I	Device - IVD General		
0	-	Beta-haemolytic Streptococcus serol grouping IVD, kit, agglutination	logical	In Vitro Diagnostic I	Device - IVD General		
۲	-	Boiling water sterilizer		General Medical De	vice - Class l	No lo	onger placed on the market
	90000213	Brucella		In Vitro Diagnostic I	Device - IVD General		
٥	63236	Brucella abortus total antibody IVD, agglutination	kit,	In Vitro Diagnostic I	Device - IVD General	No lo	onger placed on the market
0	63239	Brucella melitensis total antibody IVI agglutination	D, kit,	In Vitro Diagnostic I	Device - IVD General	Dele	ted By MHRA
							(1-10 of 101))

3. To view when device was deleted and by whom, click on the GMDN[®] Term of the deleted device.

		3		
Status	GMDN Code	Term Name	Device Type	Reason For Deletion
8	41349	Allergen-specific immunoglobulin E (lgE) antibody IVD, control	In Vitro Diagnostic Device - IVD General	Entered in error
8		Alpha-fetoprotein (AFP) IVD, kit, enzyme immunoassay (EIA)	In Vitro Diagnostic Device - IVD General	
	90000186	Alphafetoprotein	In Vitro Diagnostic Device - IVD General	

4. The device details will appear, and the deletion history will be displayed under Device History.

Please note Device History will only be populated for devices deleted after 21 August 2021.

¥4134	9 - Allerg	en-specific imm	unoglobulir	n E (IgE) antibody I	VD, contro	1	
	Device Type	In Vitro Diagnostic Device	-				
GMDN	description	A material which is used to specific immunoglobulin E (verify the perform (IgE) antibody in a c	ance of an assay intended to b linical specimen.	e used for the qu	alitative and/or quantitative	detection of an allerge
directiv doe	Which e/regulation s this device comply with?	Directive 98/79/EC					
Risk o	lassification	IVD General					
ls this de to p	evice subject performance	Yes					
Filenam	ne	or conformity/cu	Document F	Reference	Conformit	y Assessment Type	
Declara	tion of Conforn	hity 1	DOC1		CE - MDD/	IVDD/AIMD	
		ils					
~Proc	luct Deta						
✓ Proc Preview C	luct Deta only displays lin	nited fields					
✓ Proc Preview of Status	iuct Deta only displays lin Medical Devi (Brand/Trade Common na	nited fields ce Name e/Proprietary or me)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
✓ Proc Preview of Status	duct Deta anly displays lin Medical Devi (Brand/Trade Common nat Allergen 1	nited fields ce Name //Proprietary or me)	Model/Version Allergen 1	Catalogue/Reference (REF) AL/01/865473	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status On the GB & NI market

Manage registered devices

Please use the Manage Devices function to:

- manage (upload, link and unlink) Conformity Assessment Certificates and Selfcertification conformity declarations
- add or remove products (model or version)
- delete devices (GMDN®) and all linked products
- there is currently no fee to do this

Please note you cannot update obsolete GMDN[®] or other device details e.g. Substances, Clinical Investigations etc. or products e.g. populate fields you did not complete at registrations stage from this screen – please see Update registered devices and products.

- Go to Agency services > Enter Device Registrations and Certificates of Free Sale for medical devices.
- 2. Select the manufacturer (Legal Entity) of the devices/s you want to manage.

Device Keg	Sistiation					
Your Organisa	ation					
Name	Address		Country	D	evices (Products)	Registratio Status
MHRA DEMO	10 South Colonnad	de, Canary Wharf, London, E14 4PU	England, United Kir	ngdom 4	(9)	۲
Only use the ADD NEW M already registered the rep registered the manufactur register additional devices	found from the App IANUFACTURER function presented manufacture rer, please use the Ado s on the existing accou	lications list. ion if you have not er. If you have d Devices function to nt.			IN DDA	EW MANUFACTUR NEW IMPORTE TER
Only use the ADD NEW M Irready registered the rep egistered the manufactu egister additional devices Search by manufactu	found from the App IANUFACTURER funct rer, please use the Add s on the existing accou irer name:	lications list. ion if you have not r. If you have J Devices function to int.	SEARCH		IN DOL	EW MANUFACTUR
Only use the ADD NEW M already registered the rep registered the manufactur register additional devices Search by manufactu Name	found from the App IANUFACTURER funct rer, please use the Add s on the existing accou irer name:	lications list. Ion if you have not er. If you have J Devices function to int.	SEARCH Country	Devices (Products)	ADD NEW IMPORT	EW MANUFACTUR NEW IMPORTE TER Registratii Status
Only use the ADD NEW M already registered the rep registered the manufactur register additional devices Search by manufactur Name Demo represented or	found from the App IANUFACTURER funct rer, please use the Add s on the existing accou irrer name: t rg Three	Ilcations list. Ion if you have not tri Hyou have d Devices function to Int. Address 167 Bella Bista, East Side Compour Medtech Drive, Sea View Industrial Santa Barbara, CA, 98765	SEARCH Country d, 1000 Zone, United States	Devices (Products) 20 (21)	ADD NEW IMPORT	ew MANUFACTUR NEW IMPORTE TER Registratio Status
Only use the ADD NEW M already registered the rep registered the manufactur register additional devices Search by manufactur Name Demo represented of DEMO Represented O	found from the App IANUFACTURER funct rer, please use the Add s on the existing accou irrer name: f rg Three Drganisation	Ilcations list. Ion if you have not trif you have d Devices function to Int. Address 167 Bella Bista, East Side Compour Medtech Drive, Sea View Industrial Santa Barbara, CA, 98765 123 Street, Sea View Industrial Esta Boston, MA, 12345	SEARCH Country nd, 1000 Zone, United States ste, United States	Devices (Products) 20 (21) 3 (10)	ADD NEW IMPORT	ew manufactur new importe ter Registratii Status
Only use the ADD NEW M already registered the rep registered the manufactur register additional devices Search by manufactur Name Demo represented of DEMO Represented O DEMO Represented O	found from the App IANUFACTURER funct rer, please use the Add s on the existing accou- irer name: f rg Three Drganisation Drganisation Two	Ilcations list. Ion if you have not devices function to nt. Address 167 Bella Bista, East Side Compour Medtech Drive, Sea View Industrial Santa Barbara, CA, 98765 123 Street, Sea View Industrial Esta Boston, MA, 12345 234 Avenida Escala, Cancun, Yukat 43231	SEARCH Country nd, 1000 Zone, United States atte, United States an, Mexico	Devices (Products) 20 (21) 3 (10) 1 (1)	ADD NEW IMPORT ADD NEW IMPORT UK Responsible Person UK Responsible Person UK Responsible Person	ew MANUFACTUE NEW IMPORTE TER Registratio Status

3. Click on the Manage Devices link.

AGENCY SERVICES						
A Back to DR&C MHRA D C MHRA D C	FS Services		Z Edit Organisati Registered	on Details 🥫 Order Devices/Products 🖀	CFS Rene	Add Devices Manage Devices Jupdate Ewpert Content of the Excel File
SUMMARY AP	PLICATIONS	RELATED ORGANISATIONS	DEVICES PRODUCTS	CONTACTS OTHER A	DDRESS	SSES DOCUMENTS NEWS
• Your registri determined by being suspende the competent	ation with the the date your . ed. A suspende authority (MH	MHRA must be reviewed al account was created with ti ed account means you will I RAJ. It is an offence to place	nd renewed one year a he MHRA. Your Registr oot be able to place ne a non-compliant devi	after the anniversary da iation Renewal is 01/01, w devices on the marke ice on the market in the	te and e 2022. Fi et given UK.	t every two years subsequently. The anniversary date is Failure to renew your registration will result in your account n it is a legal requirement to hold an active registration with
Account N	lumber 0000	009132		Registration	status	Registered
EL Registration N	J Single lumber (SRN)			PARD O	otions	Publish UK Responsible Person Name Publish UK Responsible Person Address Publish Organisation's Name
Role / Accou	nt Type Man	ufacturer UK Responsible	Person			 Publish Organisation's Address

4. If you have many devices, use the available filters to **search** for a specific device. See Using Filters to search for devices and products.

emoved immediately, adding n you need to add new GMDN te	r delete produ ew product/s erms (devices	ucts (medical devi s will create an app s), please go back t	ce name and mo plication for MHR to Devices and pr	dei/version etc.), UKC/ A review. roducts and click "Add	device" butto	i) certifica n.	tes,Self-cerl	itication conformity d	ieclarat	ions and Others. An	iy deletions will be
earch by GMDN Code / Term:	Dev	vice Type:		Device Sub Type:		Ŀ	s Custom N	lade:	R	Regulation/Direct	tive:
GMDN Code / Term	De	evice type	•	Device sub type		*	Custom ma	de	-		
Sterile:	ls Measuri	ing:	Is Single-u	se?	Is Reproces	sed singl	e-use?	Custom-made SPP		Performanc	e Evaluation
Sterile 🔹	Measurin	E	▼ Single-use	•	Reprocesse	ed single-u	use 🔹	Custom-made SPP		Studies:	
										Performant	ce Evaluation 🔹
eusable Surgical Instruments	s: Is A	ictive?	_	Is Implantable?		-	Sasic UDI-D	I Issuing Entity:	-	Basic UDI-DI Numi	ber:
Reusable surgical instruments	AC	DVE	•	Impiantable	-	•	UDI-DI ISSU	ng Enuty	•	UDI-DI Number	
CFS Ready:	Intended medical(A	purpose other th innex XVI):	an Is Intende Administe	d to r/remove	Presence of Medicinal/H	t Herbal su	bstance:	Presence of Blood/ substance:	Plasma	a Has a Clinic been condu	al investigation icted:
.rs neauy	Annex XV	1	 medicinal 	product?	Medicinal/A	Herbal	-	Blood/Plasma		Clinical inve	estigation
			mm/dd/y								
				99							
Status		GMDN	GMDN term	1	Products	Device T	Гуре	5 Remark			CFS-
Status		GMDN Code	GMDN term	1	Products	Device T	Гуре	5 Remark	_		CFS- ready
Status Registered		GMDN Code 	GMDN term Abdominal aorta stent-graft	297 † a endovascular	Products 5	Device T General Class III	Type Medical De	5 Remark			CFS- ready Yes
Status Registered Conformity Assessment (Expired	Certificate	GMDN Code 	GMDN term Abdominal aort. stent-graft Angiography kit	22 ⁷ †	Products 5	Device T General Class III System o	Type Medical De or Procedur	5 Remark vice - e Pack			CFS- ready Yes No
Status Registered Conformity Assessment (Expired Registered	Certificate	GMDN Code 	GMDN term Abdominal aort: stent-graft Angiography kit General externa fixation system single-use	1 orthopædic implantation kit,	Products 5 1 1	Device T General Class III System o System o	Type Medical De or Procedur	5 Remark vice - e Pack e Pack			CFS- ready Yes No Yes
Status Registered Conformity Assessment of Expired Registered Registered	Certificate	GMDN Code 	GMDN term Abdominal aort: stent-graft Angiography kit General externa fixation system single-use Vascular clamp,	1 orthopaedic implantation kit, reusable	Products 5 1 1 1 1	Device T General Class III System o System o General Class IIa	Type Medical De or Procedur or Procedur Medical De	5 Remark vice - e Pack e Pack vice - GMDN is Documer	Obsole	ete;Conformity es soon	CFS- ready Yes No Yes Yes

5. Check the Remark column for action required to bring the registration up to date.

6. Click on the GMDN[®] Term of the device to manage.

	Status	GMDN Code	GMDN term	Products	Device Type	Remark		CFS- ready
	Registered	-	Abdominal aorta endovascular stent-graft	5	General Medical Device - Class III			Yes
	Conformity Assessment Certificate Expired		Angiography kit	1	System or Procedure Pack			No
	Registered		General external orthopaedic fixation system implantation kit, single-use	1	System or Procedure Pack			Yes
	Registered	35596	Vascular clamp, reusable	1	General Medical Device - Class Ila	GMDN is O	bsolete	Yes
	Registered	6	Vascular clamp, reusable	1	General Medical Device - Class Ila	GMDN is Obsolete;Co Document e	onformity expires soon	Yes
								5 items
BAC	к						DELETE SELECT	ED DEVICES

7. The details of the GMDN[®] Term you have selected will open to enable you to view device details. If you want to delete the device, click the Back to Manage Devices button and see the <u>Delete Devices</u> instructions.

General Medical Dev Sterile? Yes Regulative/Directive Directive 93/42/EEC Single use device? Yes Reprocessed single No	ice e? -use device?		Cu No Et	stom made? sthod of Sterilisation nylene Oxide		Risk classification Class III	
Implantable Produ Yes	tts?		Ac No	tive Products?		Administer/Remove medic No	inal Product?
Conformity A	Assessment tificates have alrea	Certificates dy expired or will e	s expire soon.				
Ellonomo	Reference	Expire date	Certifi	rate type	UK Approved Bo	dy/EU Notified Body	Conformity Assessment Typ
Filename		enquity unice		and type			
CE Certificate 5	UKCA1	31/10/2021	O Full Qu	allity Assurance (Annex II excluding Section 4)	BSI		UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY A Products (6) Preview only display Medical Device Na Common name)	UKCA1 UKCA1 simited fields me (Brand/Trade/	31/10/2021	Full Q	allity Assurance (Annex II excluding Section 4) Catalogue/Reference (REF)	DDI Issuing Entity	UDI Device Identifier (UDI-DI	UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY A Products (6) Preview only display Medical Device Na Common name) Premium Stent A	UKCA1 UKCA1 stimited fields me (Brand/Trade/	31/10/2021	Generation Generation Generation Generation Generation	ality Assurance (Annex II excluding Section 4) Catalogue/Reference (REF) U S87878 C	DDI Issuing Entity	UDI Device Identifier (UDI-D) 04250274702216	UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY A Products (6) Medical Device Na Common name) Premium Stent A Premium Stent B	UKCA1 SSESSMENT CERTIFI s limited fields me (Brand/Trade/	31/10/2021 CATES	Model/Version	Image: State Spectrum allity Assurance (Annex II excluding Section 4) Catalogue/Reference (REF) S87878 S35445	DDI Issuing Entity	UDI Device Identifier (UDI-DI 04250274702216 04250274702193	UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY # Products (6) Preview anly display Medical Device Na Concal Device Na Concal Device Na Premium Stent A Premium Stent B Premium Stent A	UKCA1 SSESSMENT CERTIFI s limited fields me (Brand/Trade/	31/10/2021 CATES	Full Que Model/Version 14F 14F 17F	Image: Answer of the section of th	DDI Issuing Entity SST AISBL SST AISBL	UDI Device Identifier (UDI-DI 04250274702216 04250274702193 04250274704739	UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY # Products (6) Preview only display Medical Device Na Common name Premium Stent A Premium Stent B Premium Stent A Premium Stent B	UKCA1 UKCA1 stimited fields me (Brand/Trade/	Proprietary or	Model/Version 14F 17F 17F	ality Assurance (Annex II excluding Section 4) ality Assurance (Annex II excluding Section 4) S87878 S86465 S64646	DDI Issuing Entity ST AISBL ST AISBL ST AISBL	UDI Device Identifier (UDI-DI 04250274702216 04250274702193 04250274704739 04250274704753	UKCA - MDD/IVDD/AIMD
CE Certificate 5 EDIT CONFORMITY A Products (6) Preview only display Medical Device Na Common name) Premium Stent A Premium Stent A Premium Stent B Premium Stent A Premium Stent A	UKCA1 UKCA1 SSESSMENT CERTIFI s limited fields me (Brand/Trade/	Proprietary or	Model/Version 14F 14F 17F 18F	ality Assurance (Annex II excluding Section 4) ality Assurance (Annex II excluding Section 4) S87878 S87878 S35445 S46465 S64646 S33454	BSI BSI BSI BSI BSI BSI BSI BSI	UDI Device Identifier (UDI-Di 04250274702216 04250274702193 04250274704739 04250274704739 04250274704753 04250274704777	UKCA - MDD/IVDD/AIMD

Manage Conformity documents

Please note if your conformity assessment document expires this will be published on the <u>Public Access Registration Database</u> (PARD). The GMDN[®] term for your registered devices will be appended with the wording **'Conformity Assessment Certificate Expired'** until the certificate has been updated. This message can remain for up to a week after you have uploaded a new certificate as PARD is usually updated on Monday.

You will receive reminder emails at 3 months, 2 months and 1 month before expiry of conformity assessment certificates. Please ensure that you act on these to avoid unnecessary status changes to your devices on the <u>Public Access Registration</u> <u>Database (PARD)</u>.

You will also be unable to order Certificates of Free Sale until valid conformity assessment certificates have been uploaded and linked to all relevant devices.

 To Add new Conformity Assessment Certificates/Self-certification conformity declarations and unlink expired ones, click the Edit Conformity Assessment Certificates or Edit Self-certification Conformity Documents button and unlink the old certificate or document.



Follow the <u>upload Conformity Assessment Certificates</u> and <u>upload Self-certification</u> <u>conformity declarations</u> instructions or the <u>select from upload Conformity Assessment</u> <u>Certificates</u> and <u>select from Self-certification conformity declarations</u> instructions.

Please note you cannot delete Conformity Assessment Certificates/Self-certification conformity declarations from the system so ensure you unlink devices from any documents that have expired, are incorrect, or are no longer appropriate.

Important note concerning CE UKNI-MDR/IVDR option.

This type of assessment can only be undertaken by a UK Notified Body. See further information under the **UKNI Indication** section at:

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

2. You can filter by Conformity Assessment Type. All types will be displayed to enable you to unlink any incorrect or no longer valid types. Please note that the following types are no longer valid:

UKCA – MDD/IVDD/AIMD CE (UK NI) – MDD/AIMD/IVDD CE (UK NI) – MDR/IVDR 3. You can filter by Certificate Status of All, Active and Expired.

	Filename	Reference no	Expiry		Certificate type	LIK Approved Body/ELI Notified Body	Conformity Assessment	
			date		contract office		Туре	
	UKCA Certificate 2	UKCA_BSI_54321	30/04/2028		Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	
	UKCA Certificate 1	UKCA_BSI_12345	30/04/2028		Design Examination Certificate (Annex II with Section 4)	BSI Assurance UK Ltd	CE UKNI - MDR/IVDR	
	MDR Assessment of Technical Documentation Annex IX Chapter II	EUMDR_321	30/04/2024		Technical Assessment (MDR Annex IX, Chapter II)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	
	MDR CE Certificate 1 Quality Management System Annex IX Chapters I and III	EUMDR_123	30/04/2024		Quality Management System (MDR Annex IX, Chapters I, III)	RISE Research Institutes of Sweden AB	CE - MDR/IVDR	
	CE Certificate 7	CE7	31/10/2022	۵	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	
~	CE Certificate 5	UKCA1	31/10/2021	8	Full Quality Assurance (Annex II excluding Section 4)	BSI Assurance UK Ltd	UKCA - MDD/IVDD/AIMD	
	CE Certificate 4	CE123456	31/12/2019	۲	Type Examination (Annex V)	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	
	CE Certificate 1	CE123	31/12/2019	8	Full Quality Assurance (Annex IV)	TÜV SÜD Product Service GmbH	CE - MDD/IVDD/AIMD	
	CE Certificate 3	CE12345	31/12/2019	۲	Production Quality Assurance limited to sterile aspects (Annex V)	LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088)	CE - MDD/IVDD/AIMD	
	CE Certificate 2	CE1234	31/12/2019		Design Examination (Annex IV with	BSI Assurance UK Ltd	CE - MDD/IVDD/AIMD	

- 4. If you have selected a certificate with incorrect Conformity Assessment Type a warning message will appear and the Apply Changes button will not be enabled. If you have selected an expired certificate the Apply Changes button will not be enabled .Unlink expired or incorrect Certificates and upload new ones or link device to an active/correct certificate.
- 5. Click the 'Apply Changes button or follow the <u>Upload Conformity Assessment Certificate</u> instructions to add another certificate.



Managing expired CE certificates that are valid under EU MDR

See the latest guidance on our website, including a template to complete and upload at:

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registrationof-certain-medical-devices-that-have-expired expiring-ce-certificates

and

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#registrationof-certain-medical-devices-which-are-eu-mdd-class-i-reusable-surgical-instruments-or-eumdd-class-i-medical-devices-upclassified-from-class-i

The guidance has intentionally not been included in this Reference Guide as this may change.

Please sign up for email updates by following the link on our webpage:



Add/remove products

- Click the Export Products Data to Excel link to download all product details for review, prior to adding/removing. Please note once changes applied and application submitted you cannot reinstate the product/s. If you delete a product in error, you will need to add it again.
- 2. To Add or remove products (model or version) click the Add/Remove product button.

Products (6) Preview only displays limited fields					
Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI market
PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI market
PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI market
PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI market
					6 items
				(1)	Export Products Data to Excel
ADD/ REMOVE PRODUCTS					

- 3. To add more products follow the instructions for <u>Adding products individually</u> or <u>Adding</u> products in bulk.
- 4. You can delete up to 20 products in a single application. You will be asked for a reason for deletion. The same reason will apply to all deleted products in the application. If the reasons are different, please create separate applications.

Important note: You cannot **delete** products that you have <u>just added in this manage</u> <u>devices & products application</u>. If you attempt to, you will see an error message. This is expected system behaviour.

To delete products you have just added or uploaded in this application, you need to either:

Hover over the bulk upload template until the X appears next to the template file name and click the X, this will remove all the products just uploaded.



Validation Complete

Then **remove** the relevant products from the template and re-upload it.

Or

2

BACK TO MANAGE DEVICES

Click the Cancel button to discard all changes in this application and start again.

APPLY CHANGES CANCEL

5. To remove products previously registered, select the box/es next to the Medical Device Name/s in the Product preview table. You must always have at least one product linked to a device so if you attempt to remove the last product the Apply changes button will not be enabled.

						10 per page
Proc	duct preview (products: 6)					
Preview	w only displays limited fields					
	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI
	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI
	PremiumS™ Stent B	3mm	Not Applicable			On the GB & NI
	PremiumS™ Stent A	3mm	Not Applicable			On the GB & NI
	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & NI
	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & NI

- 6. The number of products selected for deletion will display in the counter.
- 7. Click the Delete Selected button

Med	ical device name: Model/versio	on:	Catalogue/reference:	וט-וטו:		SEARCH
0 v	When deleting products, you will be asked for a reason	for deletion - the same	reason will apply to all deleted prod	icts in the application. If the	reasons are different please create se	parate applications. You ca
up to	o 20 products in a single application.					Show
						10 per page
Pro	oduct preview (products: 6)					
Prev	iew only displays limited fields					
	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & NI mar
	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & NI mar
	PremiumS [™] Stent B	3mm	Not Applicable			On the GB & NI mar
	PremiumS [™] Stent A	3mm	Not Applicable			On the GB & NI mar
	PremiumS [™] Stent B	2.5mm	Not Applicable			On the GB & NI mar
	PremiumS [™] Stent A	2.5mm	Not Applicable			On the GB & NI mar
						(

8. A warning message will appear asking if you are sure you want to remove the selected products. Click Yes or No as appropriate.

9. If you select Yes, the Reason for Deletion options will appear. If you select No longer placed on the market, you will be asked for the End of Distribution date.

	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
~	PremiumS™ Stent A Plus	5mm	Not Applicable			On the GB & N
~	PremiumS™ Stent A Plus	4mm	Not Applicable			On the GB & N
	PremiumS™ Stent B	3mm	Not Applicable			On the GB & N
	PremiumS™ Stent A	3mm	Not Applicable			On the GB & N
	PremiumS™ Stent B	2.5mm	Not Applicable			On the GB & N
	PremiumS™ Stent A	2.5mm	Not Applicable			On the GB & N
	ason for deletion					
Re N C End	Vo longer placed on the market nformation updated/ existing data no longer valid intered in error of distribution date					

10. Click the Apply Changes button to confirm removal of the product/s.

Please note once changes applied and application submitted you cannot reinstate the product/s. If you delete a product in error, you will need to **add** it again. There is currently no fee to add products.

Delete device/s

To delete device/s, you must be on the Manage Devices and products screen. If you
have opened the device details to review, click the Back to Manage Devices button to
display the Manage Devices and products screen.



2. Tick the box next to Status column of the device/s your wish to delete.

Please note if you select multiple devices for deletion, they must all have the same reason for deletion. If they have different reasons, you must delete the devices individually.

Please note if GMDN[®] is obsolete you can update the GMDN[®] to a valid Code/Term, you do not have to delete the device. See <u>Update Registered devices and products</u>.

3. Click the Delete Selected Devices button to remove the device/s and all underlying products of the device.

Please note You cannot manage and delete the same device in the same application. If you manage device and/or products the Delete Selected Devices button will be disabled

	s (devices), please (go back to Devices	eview. and products a	and click "Add device"	button.				Pogul	ation/Directiv	
Search by GMDN Code / Term:	Device Ty	ype:		Device Sub Type:		Is	Custom N	lade:	Regul	ation/Directiv	с.
GMDN Code / Term	Device t	ype	•	Device sub type		•	Custom ma	de 🔻			
ls Sterile:	Is Measuring:		Is Single-use	?	Is Reprocess	ed single-u	ise?	Custom-made SPP		Performance E Studies:	valuatio
Sterile	Measuring	•	Single-use	•	Reprocesse	d single-use	•	Custom-made SPP	•	Performance E	valuation
Reusable Surgical Instruments:	Is Active	?		Is Implantable?		Ва	asic UDI-D	I Issuing Entity:	Basic	: UDI-DI Number:	
Reusable surgical instruments			•	Implantable		-	UDI-DI Issu	ing Entity 🔹	UDI	-DI Number	
Is CFS Ready:	Intended purpo medical(Annex)	se other than XVI):	ls Intended Administer/	to remove medicinal	Presence of substance:	Medicinal/	Herbal	Presence of Blood/Plasma substance:	1	Has a Clinical i been conducte	nvestiga d:
CFS Ready •	Annex XVI	•	product?		Medicinal/H	lerbal	-	Blood/Plasma	•	Clinical investig	zation
Self-certification conformity declarations:	UKCA/ CE/ CE (U Certificate:	K NI)	UKCA/ CE/ C Date: mm/dd/yyyy	E (UK NI) Expiry	Device Regis	stration Sta stration Stati	atus: us •			I	SEARCH
0											
Status		GMDN Code	GMDN terr	m	t	Products	Devic	е Туре	Rer	mark	CFS-
Registered			Abdominal	l aorta endovascular s	tent-graft	5	Gene	ral Medical Device - Class III			Yes
Conformity Assessment Cert	tificate Expired	-	Angiograph	hy kit		1	System	m or Procedure Pack			No
Registered			General ex implantatio	ternal orthopaedic fix on kit, single-use	ation system	1	Syster	m or Procedure Pack			Yes
											_

4. Select a Reason for deletion. If device is no longer placed on the market, provide End of Distribution date.

Please note if you select multiple devices for deletion, they must **all** have the same reason for deletion. If they have different reasons, you must delete the devices individually.

immediately, adding new product/s will cre If you need to add new GMDN terms (devic	oducts (medical device name and model/vers eate an application for MHRA review. ces), please go back to Devices and products	ion etc.), UKCA/CE/CE (UK NI) certificates,Self-certification conformity de and click "Add device" button.	eclarations and Others. Any deletions will be remo	ved
You have made the following changes w	hich need to be submitted to MHRA for a	pproval.		
GMDN term	Products modified	CE certificates/Documents modifed	Device deleted	
Vascular clamp, reusable	No	No	Yes	
No longer placed on the market Information updated/ existing data no lo Entered in error	onger valid			
End of distribution date *				

- 5. Click the Remove Device(s) button.
- A warning message will appear, click YES to proceed or NO to cancel deletion.
 Please note once deleted you cannot reinstate the device. You will need to add it again and pay the statutory fee.

Manage Devices &	Products for M Are you sure want to remove selected device? This will remove the selected devices (and underlying products) from the manufacturer. b commits declarations and Others. Any deletions will be removed		s. Any deletions will be removed	
If you need to add new GMDN terms (de	vices), please go back to Devices a	NO		
Search by GMDN Code / Term:	Device Type:		ade:	Is 2017 Regulations:
GMDN Code / Term	Device type	Device sub-tune	me de 👻	2017 Regulations 🔹

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

conformity declarations
Device deleted
No
No
Yes
nformity assessments uding those which egarding the EU Medic
nformity assessments uding those which egarding the EU Medic nd you will be charged
nformity assessments uding those which regarding the EU Medic nd you will be charged UK. Manufacturers are agistrations, both comply with the relevant
1

- 8. When you are ready to submit the application, **Read** the on-screen information and terms and conditions, **click** the 'I have read and agree to the terms and conditions box'
- **9.** Click the Submit button to complete the application or the Clear All button to clear all changes made in this application.

Please note there is no Save & Exit function on this page, so you need to either Submit your changes or Clear All and start again if you are not ready to submit.

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

	AGENCY SERVICES		ACCOUNT MANAGEMENT	r	
	Applic	ation co	mplete		· · · · · · · · · · · · · · · · · · ·
10	Your refere	ence number			
	201906 What ha	170217136	8		
	We have sent	you a confirmatio	 n email and your applicati	tion has been sent to an officer at MHRA.	
	We will conta	ct you again withir	n the next 2 -5 working day	ys to let you know of our decision, or to ask for more information if its needed.	
11	CLOSE				

- **11. Click** on the Close button.
- 12. Please note if you do not click the Close button within 2 minutes of completing your application, the button will time out and you will see the following message. Your application is not affected and has been auto-submitted. Click on the OK button.

You will receive email confirmation of your submitted application and the review outcome.

Application complete	▲ The Task Could Not Be Submitted
Your reference number	
2019052202171218	ОК
What happens next	
Ne have sent you a confirmation email and your applicat	ion has been sent to an officer at MHRA.
We will contact you again within the next 2 -5 working day	ys to let you know of our decision, or to ask for more information if its needed.

Update registered devices and products

Use this function if GMDN[®] is now obsolete or device and/or products (model or version detail) need to be **updated** because the details have changed, or the field/s were optional, and you did not populate them at the time of registration.

Please note only certain fields can be updated. These will be enabled on the update screen to allow you to add or update data. GMDN[®] Codes/Terms can only be updated in cases where the existing GMDN[®] has been made obsolete. Changes made on this screen do not currently incur a fee.

If you need to update active GMDN[®] Codes or Terms or any fields that are not enabled on the screen, you must remove the Device via the Manage Devices link. All underlying products will also be removed. You need to add the device and products again using the <u>Add Device</u> function to add new GMDN[®] Code or Term, and pay the <u>statutory fee</u>.

If products need to be added or removed from an existing registered device, or Conformity Assessment Certificates/Self-certification conformity declarations need to be uploaded, linked, or unlinked from existing registered devices this can be done via the Manage Devices link.

 Go to Agency services > Enter Device Registrations and Certificates of Free Sale for medical devices.

Device Re	egistration	& Certificates of Fr	ee Sale				
Your Organia	sation						
Name	Address		Country		Devices (Products)	Registratio Status	
MHRA DEMO	10 South Colonnad	e, Canary Wharf, London, E14 4PU	England, United Kir	ngdom	4 (9)	۲	
manufacturers can b Only use the ADD NEW already registered the registered the manufac register additional devi Search by manufact	the found from the Appl MANUFACTURER function represented manufacture cturer, please use the Add ices on the existing account turer name:	 Newly Submitted and draft lications list. for if you have not er. If you have d Devices function to int. 			ADD N ADD ADD NEW IMPOR	EW MANUFACTURE	
manufacturers can b Only use the ADD NEW already registered the registered the manufac register additional dev Search by manufact	the found from the Appl VMANUFACTURER functi represented manufacture cturer, please use the Add ices on the existing account turer name:	Newly Submitted and draft ications list. ion if you have not er. If you have i Devices function to int. SEARC	•		ADD N	EW MANUFACTURE	
manufacturers can b Only use the ADD NEW already registered the registered the manufa- register additional devi Search by manufact	te found from the Appl V MANUFACTURER functi represented manufacture cturer, please use the Add ices on the existing accou turer name:	Newly submitted and draft ications list. ion if you have not er. If you have 1 Devices function to int. SEARC Address	H Country	Devices (Product	ADD N ADD NEW IMPOR	EW MANUFACTURE NEW IMPORTER TER Registration Status	
manufacturers can b Only use the ADD NEW already registered the registered the manufact Search by manufact Name Demo represented	te found from the Appl VMANUFACTURER funct represented manufacture curver, please use the Add loces on the existing account turer name: 1 org Three	A Newly Submitted and draft ications list. Ion if you have not er. If you have Devices function to int. Address 167 Bella Bista, East Side Compound, 10 Medtech Drive, Sea View Industrial Zone Santa Barbara, CA, 98765	H Country O United States	Devices (Product 20 (21)	ADD NEW IMPOR ADD NEW IMPOR S) Relationship UK Responsible Person	EW MANUFACTURE	
manufacturers can b Only use the ADD NEW already registered the manufact registered the manufact Search by manufact Name Demo represented DEMO Represented	te found from the Appl VMANUFACTURER functi represented manufacture curver, please use the Add loces on the existing account turer name: 1 org Three d Organisation	A Newly Submitted and draft ications list. Ications list. Ications list. Ications list. Ications list. Ications list. Ications function to Ications Ication	4 Country 00 United States United States	Devices (Product 20 (21) 3 (10)	ADD NEW IMPOR ADD NEW IMPOR ADD NEW IMPOR ADD NEW IMPOR ADD NEW IMPOR ADD NEW IMPOR	EW MANUFACTURE	

2. Select the organisation (Legal Entity) of the devices/products you want to update.

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

NCY SERVICES			
A Back to DR&CI	S Services		3 File Organization Dataile CondenCCC Deductors Add Devices Manage Devices Vupdate Registered Devices/Products Detroites Data to Excel File
SUMMARY APP	LICATIONS	RELATED ORGANISATIONS	DEVICES PRODUCTS CONTACTS OTHER ADDRESSES DOCUMENTS NEWS
Summary			
() Your registra determined by a account being s registration with	ation with the the date your uspended. A s the compete	MHRA must be reviewed a account was created with t suspended account means ent authority (MHRA). It is a	nd renewed one year after the anniversary date and every two years subsequently. The anniversary date is he MHRA. Your Registration Renewal is 01/01/2025. Failure to renew your registration will result in your you will not be able to place new devices on the market given it is a legal requirement to hold an active n offence to place a non-compliant device on the market in the UK.
Basic Inform	ation		
Account N	umber 0000	0009132	Registration Status Registered
EU Registration N	Single umber		PARD Options Publish UK Responsible Person Name Publish UK Responsible Person Address Publish UK Responsible Person Address
Registration N	(SRN)		Publish Organisation's Name

4. Use the available filters to search for a specific device.

Please note only registered devices will be visible on the Update Registered Devices & Products screen. If the conformity assessment document has expired you must update this before you can update GMDN[®], device details or products. See <u>Manage conformity</u> <u>documents</u>.

5. Click on the GMDN[®] Term of the device/product to update.

Device Ty	/pe / Class	Device Registered Date	GMDN Code / Term Name	0	Custom Made	Regulation/Directive:	
Select	device type / Class ▼	mm/dd/yyyy			•		
ls Sterile	?	Is Measuring	Is Single-use?	I	Is Reprocessed single-use?	Custom-made SPP	
	•		•	•	•	-	
Reusable Surgical Instruments?		Is Active?	is implantable?	I	is intended to	Intended purpose other al medical(Annex XVI)	
		-	•	• F	Administer/remove medicinal product?		
					•	_	
Is CFS Ready		Presence of Medicinal/Her	bal Presence of Blood/Plasma	ŀ	Has a Clinical investigation	Basic UDI-DI Issuing Ent	
	•		v	• ·		-	
Basic UD	I-DI Number	Is Device Updated?				Show	
			•			10 per page	
·						Clea	
Status	GMDN Code	Term Name			Device Type		
	chipri code	Abdominal aarta ondouar	ular stort graft		Conoral Madical Davisa	(lass III	
•	-	Abdominal aorta endovaso	ular stent-grait		General Medical Device	- Class III	
 	- 5	General external orthopae	dic fixation system implantation ki	, single-	System or Procedure Page	ck	
•	-	Vascular clamp, reusable			General Medical Device -	· Class lla	
	35596	Vascular clamp, reusable			General Medical Device -	Class Ila	

- 6. The details of the GMDN[®] Term you have selected will open to enable you to:
 - Update obsolete GMDN[®] and device data you cannot update products at the same time as updating obsolete GMDN[®], you will need to do this in two applications – currently no fee applies.
 - Update selected device and/or product fields if you are not updating obsolete GMDN[®]

Update Obsolete GMDN

1. If GMDN[®] is now obsolete a box will appear to enable you to either enter a valid GMDN[®] Code if you know it, or search for a suitable GMDN Term using multiple words.

Please note you cannot update the GMDN[®] **and** products in the same application, if you are going to update an obsolete GMDN[®] you <u>must do this first</u> and submit the application and then update products once the first application is complete. If you update the products first and then attempt to update the obsolete GMDN[®] in the same application, you will lose all the product data you entered.



Update Device Details

 If any other fields can be updated these will be enabled. If you need to make changes to a field that is not enabled you must delete the device and products via the <u>Manage</u> registered devices function and add the device again, the <u>statutory fee</u> will be payable.



2. The Conformity Assessment Certificates or Self-certification conformity declarations table will also be visible for your information. You cannot make changes to documents on this screen. Please follow the <u>Manage registered devices</u> instructions to update conformity documents.

~ Conformi	ty Assess	ment Cert	ific	ates		
lf you wish to mana	ge Conformity As	ssessment docume	ent(s) i	use the Manage Devices function		
Filename	Reference	Expiry date		Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
CE Certificate 3	AIMD1	31/07/2021	0	Full Quality Assurance (Annex II excluding Section 4)	BSI	CE - MDD/IVDD/AIMD

Update products individually

1. The Product Details table will appear. Use the filters to search for the product.

Please note if you have updated an obsolete GMDN[®] you will not be able to update products in the same application and the Medical Device Name link will not be enabled. You must update product/s in a separate application, <u>after</u> the obsolete GMDN[®] application has been submitted and completed.

- 2. You can either update products individually, or update multiple products. You must **not** update products both individually and in multiples in the same application. Please create separate applications.
- 3. Click on the Medical Device Name to update the product.

	cal device nan	ie:		Model/version:		Catalogue/refer	ence:		_			
											SEA	RCI
									10 pe	r page		
0 To	update produc	ts individu	ally, click on the M	ledical Device Nam	e of the product. Update	s made individually will n	ot be reflecte	d in the prod	uct table belo	w until after t	he applicatio	on
subn	nitted. Please ch	ieck your i	<i>updates on the Rev</i>	iew screen before	submitting application.							
To prod	update multipl uct table below	e products You can u	s, select the produce pdate a maximum	cts you wish to upo n of 500 products in	date by selecting the chec n a single application.	kbox next to the Medical	Device Name	of the releva	nt products.	The updates v	vill be visible	e in
1 Yo	u must not upd	ate produ	cts both individual	ly and in multiples	in the same application. I	Please create separate ap	plications.					
Total	updated produ	cts:0										
							UDI	UDI Device	Unit of	ls the Device	Direct	
	Medical Device	Status	ls Model/Version	Model/Version	ls Catalogue/Reference	Catalogue/Reference	Issuing	Identifier (UDI-DI)	use UDI-	directly Marked	Marking DI	
	Name	20002	applicable?	modeli refatori	applicable?	(REF) 📀	(optional)	(if	(optional)	with UDI- DI	different from	
							°.	o assigned)	v	(optional)	UDI-DI	
)	Safehandle		Yes	Safe/01	Yes	SH-001/123						
	Safehandle-		Yes	B Version	Yes	SH02/B/001						
	Safehandle- B version											
	Safehandle- B version											

APPLY CHANGES SAVE AND EXIT

CANCEL DELETE APPLICATION

4. All fields that can be updated will be **enabled**. If you need to make changes to a field that is not enabled you need to delete the products via the <u>Manage registered devices</u> function and add them again, there is currently no fee to add/remove products.

i i ouuce iii	formation	
Medical Device Name	Clamp	
ls Model/Version applicable?	Yes 🔹	
Model/Version	Clamp	
ls Catalogue/Reference applicable?	Please Select	
Catalogue/Reference (REF) 🕐		
UDI Issuing Entity (optional) 😧	GS1 AISBL HIBCC ICCBBA IFA GmbH UDI not assigned	
Product Status 😧	Please Select Please update the oroduct status	
URL for additional information		
	Type of UDI-PI	Lot or Batch Number
-----	--------------------------------	---------------------
	(optional) 😮	Serial Number
		Manufacturing date
		Expiration date
		Software version
	Does the device	Please Select ¥
	cells or tissues, or	
	their derivatives	
	(optional)	
	Does the device	Please Select
	incorporate animal	
	their derivatives	
(4)	(optional)	
	Are storage/handling	Please Select
	conditions specified	
	in the	
	for use (optional)	
	Quantity per	
	configuration	
	(optional)	
	Need for	Please Select
	sterilisation before	
	use (optional) 😯	
	What MRI safety	Please Select •
	information does the	
	(optional)	
	Deceshe	
	label/instruction for	Please Select
	use include Critical	
	warnings or contra-	
	(optional)	
	Containing latex (optional)	Please Select ¥
	Clinical size	Please Select 👻
	apprentie (optional)	
	UDLDI from	Diassa Salart
	secondary entity	• Pieze Select •••
	(optional) 😮	
	Endocrine disruptor	Please Select
	(optional) 😧	
	Additional product	
	description	
	(optional) 📀	
5	APPLY CHANGES	

CANCEL 5

5. Once all fields have been updated, **click** the Apply Changes button or Cancel to discard changes.

Update multiple products

1. The Product Details table will appear. Use the filters to search for products.

Please note if you have updated an obsolete GMDN[®] you will not be able to update products in the same application and the Medical Device Name link will not be enabled. You must update product/s in a separate application, <u>after</u> the obsolete GMDN[®] application has been submitted and completed.

- 2. You can either update products individually, or update multiple products. You must **not** update products both individually and in multiples in the same application. Please create separate applications.
- 3. Select the tick box next to the Medical Device Names of the products you wish to update.

								1	0 per page		
O To	update produc itted. Please ch	ts individu eck vour i	ially, click on the N indates on the Re	ledical Device Nam	e of the product. Update submitting application	s made individually will n	ot be reflected in the p	roduct table	below until a	fter the application	1 has
• To	update multipl	e products	s, select the produ	cts you wish to upo	date by selecting the chec	kbox next to the Medical	Device Name of the re	levant produ	icts. The upda	ites will be visible i	in the
You	i must not upd	te produ	indate a maximun cts both individua	ly and in multiples	in the same application.	Please create separate ap	plications.				
Total	updated produ	cts : 0									
v	Medical Device Name	Status	ls Model/Version applicable?	Model/Version	ls Catalogue/Reference applicable?	Catalogue/Reference (REF) O	UDI Issuing Entity (optional) 🛛	UDI Device Identifier (UDI-DI) (if assigned)	Unit of use UDI- DI (optional)	Is the Device directly Marked with UDI-DI (optional) O	Di Ma dif UI
	Safehandle		Yes 🔹	Safe/01	Yes 👻	SH-001/123	Select UDI Entity 💌			Please Select 💌	Ple
v	Safehandle-		Yes 💌	B Version	Yes 💌	SH02/B/001	Select UDI Entity 💌	4		Please Select 🔻	Ple

- 4. All fields that can be updated will be enabled.
- 5. Use the scrollbar to view all data fields.

Resolving data issues

6. When updating products the same validation rules apply as when adding products. If you enter invalid data, or duplicate data, or do not add data to mandatory fields you will see a warning message under the Apply Changes button with the product name and the fields that need attention.

Safehandle Yes Safe/01 Yes Safe/01 ICCBBA Yes Yes Yes Please Select Ple	×	Medical Device Name	Status	ls Model/Version applicable?	Model/Version	ls Catalogue/Reference applicable?	Catalogue/Reference (REF) 😡	UDI Issuing Entity (optional)	UDI Device Identifier (UDI-DI) (if assigned) O	Unit of use UDI- DI (optional)	Is the Device directly Marked with UDI-DI (optional) O	Direct Marking DI different from UDI-DI	Dire Mar DI nun
Safehandie: Unique Device Identifier (UDI) Safehandie: Unique Devic	~	Safehandle		Yes 💌	Safe/01	Yes 👻	safe/01	ICCBBA 👻			Yes 👻	Yes 🗣	
Please use the scrollbar to view all product data fields. APPLY CHANGES SAVE AND EXIT Please check the following columns for data errors: Safehandie : Model/Version; Catalogue Reference Safehandie : Unique Device Identifier (UDI) Safehandie : Dinque Device Identifier (UDI) Safehandie : Dinque Device Identifier (UDI) Safehandie : Device Iden	~	Safehandle- Biversion		Yes 💌	B Version	Yes 💌	SH02/B/001	Select UDI Entity 💌			Please Select 💌	Please Select *	
	D Ple	ase use the so	ollbar to v SAVE Al	iew all product da	ta fields.							CANCEL	LETE A

Key points to note when using the update products functions

The following are data issues that will result in errors:

- Adding duplicate data in Model/Version and Catalogue/reference field
- Selecting a UDI issuing entity and not entering a valid UDI or DI data or v.v.
- Entering invalid UDI or DI data
- Selecting product status of 'No longer on the GB or Ni Market' and not adding Commercial Distribution End Date
- Selecting Yes for storage handling and not entering a description or v.v.
- Selecting Yes for Method of sterilisation and not entering method or v.v.
- Selecting Yes for Critical Warning and not entering description or v.v.
- Selecting Yes for Clinical Size and not entering size or v.v.
- Selecting yes for Secondary UDI entity and not entering valid UDI DI data or v.v.
- 7. The Apply Changes and Save and Exit buttons will not be enabled until you have resolved all data issues.

8. Once you have completed updating products, and resolved any data issues, the Apply Changes and Save and Exit buttons will be enabled.

Y	Medical Device Name	Status	ls Model/Version applicable?	Model/Version	ls Catalogue/Reference applicable?	Catalogue/Reference (REF) ●	UDI Issuing Entity (optional) 🛛	Device Identifier (UDI-DI) (if assigned)	Unit of use UDI- DI (optional)	Is the Device directly Marked with UDI-DI (optional) O	Direct Marking DI different from UDI-DI	Direct Marking DI number	Pack Num (opti
~	Safehandle		Yes 👻	Safe/01	Yes 👻	SH-001/123	IFA GmbH 🔹	44666768		No 👻	Please Select 🔻		Plea
~	Safehandle- B version		Yes 👻	B Version	Yes 👻	SH02/B/001	Select UDI Entity 🔻			Please Select 🔻	Please Select 👻		Plea
•													
O Ple	ease use the sci	rollbar to v	view all product da	ita fields.						ſ		< < 1 - 2	of 2 >

9. Click Cancel to discard the changes just made or Delete Application to delete all changes to all products that have not yet been submitted.

Review updated devices and products

1. On the Review page, click the > icon to display the Updated device details. Only fields that you have updated will display here.

AGENCY SERVICES APPLICATIO				# (
Review				
GMDN Term		Devi	ice modified	Products modified
Vascular clamp, reusable		YES		YES
Basic UDI-DI Issuing Entity ICCBBA Contains Medicinal/Herba No	y B al substance? C	Basic UDI-DI N 7576878769869 Contains Bloo No	lumber 98 d/Plasma substance?	
Basic UDI-DI Issuing Entity ICCBBA Contains Medicinal/Herba No Clinical investigation beer Yes Clinical Investigation Deta	y B 7 al substance? C n conducted? ails	Basic UDI-DI N 7576878769869 Contains Blood No	lumber ⁹⁸ d/Plasma substance?	
Basic UDI-DI Issuing Entity ICCBBA Contains Medicinal/Herba No Clinical investigation beer Yes Clinical Investigation Deta Country MHRA F	y B 7 al substance? C N n conducted? ails Reference Number IRAS	Basic UDI-DI N 7576878769869 Contains Blood No	lumber 98 d/Plasma substance? Short Title and Version Number of the Study	Clinical Investigation Plan Code Number

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

	Review			
	GMDN Code	GMDN Term	Device modified	Products modified
	12235	Scalpel handle, reusable	NO	YES
2	> Updated device details > Updated Product detail Click on Medical Device Name to view fu	Is I details		
3	Medical Device Name (Brand/Trade/P Safehandle	roprietary or Common name)	Model/Version	Catalogue/Reference

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

GMDN Code	GMDN Term		Device modified		Products modified	
12235	Scalpel handle, reusable	2	NO		YES	
> Updated device	details					
~ Updated Produ	ct details					
- Show All Products						
UDI Issuing Entity		UDI Device Identifier				
IFA GmbH		4466676878889				
Directly Marked with UDI						
No						
UDI-PI Type						
Lot or Batch Number; Manuf	facturing date					
Incorporates Human Cells		Incorporates Animal Cells	S	torage/Handl	ing	
		100	Ť	es		
Storage/Handling Descript	ion	Sterilisation Before Use				
Sterilization method		MPI Safaty		ritical Warnin		
Steam		MRUsafe	N	lo	igs	
Containing Later						
No						
UDI-DI From Secondary En	tity					
No						
Endocrine Disruptor						
No						
You are about to register/u them on the market in the (or general safety and perf conformity assessments to and procedure packs speci	update an existing registration as (UK the manufacturer must provide formance requirements, where app b be carried out by a notified body r fically should ensure they meet be	or on behalf of) a manufacturer or an asse e a signed declaration of conformity/Cust licable) of the relevant medical devices le nust provide a valid CE certificate. There a fore marketing such products.	embler of systems and/or procedure p om-made Statement stating that each gislation, including the availability of are also additional legal requirements	acks. Before a medical devi technical and which must b	pplying the CE mark to ce has met the appropria clinical data for each de met, including those w	nedical devices or placing ate essential requirements vice. Devices requiring /hich assemblers of system
Further information on the regulations.	e legal requirements is available at	the following links in relation to the med	ical devices directives and also regardi	ing the EU Me	dical devices and in-vitro	o diagnostic devices
Failure to declare complia	nce with the directive/regulation th	nat you are certified for will result in your	registration becoming invalid and you	will be charg	ed a further £100 to mak	the relevant changes.
NOTE: It is possible to select ensuring they are compliant incorrectly classified or if the	a GMDN code/term for a product tha with the relevant legislation. MHRA h ey do not comply with the relevant leg	t is not categorised as a medical device unde ave the right to remove registrations, both o islation. Under such circumstances, the £100	r medical devices legislation in the UK. M rganisations and or their devices, if we co fee is non-refundable.	lanufacturers a onsider that the	are responsible for correct e registered products are r	ly classifying their devices an not medical devices, are
Please tick to confirm you	have read and understood the abo	ve requirements and that you agree to ou	r terms and conditions.			
I have read and agree to t	the terms and conditions					
SUBMIT SAVE AND EXT						BACK CANCE

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

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

Application complete

	Your reference number
8	2023051101217988
_	What happens next
	We have sent you a confirmation email and your application has been sent to an officer at MHRA.
	We will contact you again within the next 2-5 working days to let you know of our decision, or to ask for more information if its needed.
9	SUBMIT & CLOSE SUBMIT & CONTINUE 10

- 9. You will be given two options for your next action. Submit & Close will end the transaction.
- **10.** Submit & Continue will take you back to the screen with the products that you previously selected for update but have not finished updating. The status column indicates which products have been updated.

		Medical Device Name	Status	ls Model/Version applicable?	Model/Version	ls Catalogue/Reference applicable?	Catalogue/Reference (REF) O	UDI Issuing Entity (optional)	UDI Device Identifier (UDI- DI)(if assigned)	Unit of use UDI- DI (optional)	Is the Device directly Marked with UDI- DI (optional)	Direct Marking DI different from UDI-DI	Direct Marking DI number	Package DI Number (optional)	Paci DI Nur Ieve
10		Safehandle	Updated	Yes	Safe/01	Yes	SH-001/123	IFA GmbH	4466676878889		No				
		Safehandle- B version		Yes	B Version	Yes	SH02/B/001								
															•
	O Ple	ease use the scr	ollbar to vie	w all product data	fields.									< < 1 - 2 of 2	<u>2</u> > >
	APF	LY CHANGES	SAVE ANI	DEXIT								CANO	EL DELE	TE APPLICAT	ION

Email confirmation

1. If you have updated an obsolete GMDN[®] you will receive email confirmation of your submitted application and another email confirming outcome of MHRA review. You will not receive email confirmation for updating other device and/or product fields.

Version history

Each application to update a device or product will generate a version history for the device.

1. To view the version history for a device. Search for the device using the ls device updated filter? on the Device tab.

				Regulation/Directive:	
Back to DR&CFS Services		_		Regulation/Directive.	
/HRA DEMO	(1) 🖻	Order CFS Manage Devices	Add Devices / Update		
UMMARY APPLICATIONS	RELATED ORGANISATIONS DEVICES	RODUCTS CONTACTS OTHER	ADDRESSES DOCUMENTS NEWS	5	
Devices					
Devices					
- Hide Filters					
Device Type / Class	Device Registered Date	GMDN Code / Term Name	Custom Made	Is 2017 Regulations	
- Select device type / Clas	 mm/dd/yyyy 		- •	-	٠
ls Sterile?	Is Measuring	Is Single-use?	Is Reprocessed single-use?	Custom-made SPP	
-	-	- •	- •	-	•
Reusable Surgical	Is Active?	Is Implantable?	Is Intended to	Intended purpose other th	an
Instruments?	-	- *	Administer/remove medicinal product?	medical(Annex XVI)	
-	•		_	-	٠
Is CES Doody	Processo of Medicinal/Herb	Processo of Plead/Placma	Has a Clinical investigation	Pasis UDI DI Issuing Entity	
is cr5 keauy	substance	substance	been conducted	basic obi-bi issuing chucy	
-	•	- •	•	-	•
	Device Registration status	Is Device Updated?		Show	
Basic UDI-DI Number	bevice Registration status				

2. To view the version history for a product. Search for the product using the Updated Products filter on the Product tab.

Back to DR&CFS Serv	ices					
/HRA Dem	0	2 ^{rde}	r CFS 📄 Manage Dev	vices a Add Devices	Update Regist	ered Devices/Products
SUMMARY APPLICATIO	ONS RELATED ORGANIS			OTHER ADDRESSES DOCU	IMENTS NEWS	
		Ľ				
Products					Regul	ation/Directive:
Products						
Device Type / Class:	Medical device	Registered Date:	GMDN Code / Term:	Search by	Custom Made:	Device Reg Under
Select device ty 🔻	name:	dd/mm/yyyy		model/version:		2017:
la Stavila	Is Monsuring	UDI Issuing Entitus	UDI DI Number	Containing latery	Brodust Status	
- *	- *	- *	obron Number.	- *		sterilisation before
						•
Product Registration	Intended purpos	e other Endocrine d	lisruptor: MRI safe	ty information: Huma	an cells or tissues:	Animal cells or tissues:
Status:	than medical(An XVI):	nex		-	-	•
	-	•				

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

	ELATED ORGANISATIONS	S PRODUCTS CONTACT	IS OTHER A	ADDRESSES DOCUMENTS NEW	/S
Devices					
← Hide Filters					
Device Type / Class	Device Registered Date	GMDN Code / Term	Name	Custom Made	Is 2017 Regulations
– Select device type / Clas 🝷	dd/mm/yyyy			- •	Regulation/Directive:
ls Sterile?	Is Measuring	Is Single-use?		Is Reprocessed single-use?	
- •		•	-	•	- •
Reusable Surgical	Is Active?	is implantable?		Is Intended to	Intended purpose other that
- *	-	▼	•	medicinal product?	
				•	
ls CFS Ready	Presence of Medicinal/Her substance	bal Presence of Blood/P substance	lasma	Has a Clinical investigation been conducted	Basic UDI-DI Issuing Entity
- *	-	•	-	*	-
Basic UDI-DI Number	Device Registration status	Is Device Updated?			Show
	Select device status	▼ Yes	-		10 per page
					Clear Filter
Status GMDN Code	Term Name	3	t	Device Type	
62470	Surgical bulldog clamp,	, reusable		General Medical Device - Class	lla

4. An Update History table will appear with a version entry for each update application submitted for the device, indicating when the device was modified and by whom.

4	∨ Update Histo	pry		
	Version	Term Name	Modified On 4	Modified By
	Version 3	Surgical bulldog clamp, reusable	13/08/2021 15:05 BST	Peter Smith
5	Version 2	Surgical bulldog clamp, reusable	13/08/2021 15:03 BST	Peter Smith
	Version 1	Vascular clamp, reusable	13/08/2021 14:39 BST	Peter Smith

5. Click on each version to view updates made to the device.

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

	✓Update History
	Device information
	Reference
6	2021081301207935
	GMDN Term
	Surgical buildog clamp, reusable
	Basic UDI-DI Issuing Entity
	IFA GmbH
	Basic UDI-DI Number
	654856456485
	Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product
	No
	Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma
	No
	Has a Clinical investigation been conducted?
	N/A
$\left(7\right)$	PACK

- 7. Click the Back button to go back to the Update History table and view other versions.
- 8. To view the version history for a product. Search for the product using the Updated Products filter on the Products tab.

Products						
Products						
Device Type / Class:	Medical device	Registered Date:	GMDN Code / Term:	Search by	Custom Made:	Device Reg Under
Select device ty 💌	name:	dd/mm/yyyy		model/version:	- •	2017:
s Sterile:	Is Measuring:	UDI Issuing Entity:	UDI-DI Number:	Containing latex:	Product Status:	Regulation/Directive
- •	- •	- •		- •	- •	
Product Registration	Intended purpo	se other Endocrine di	sruptor: MRI safet	y information: Huma	an cells or tissues:	Animal cells or tissue
	FID DID 100001001001001	nev				

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

UMMARY	APPLICATION	NS RELATED ORGANI	SATIONS	DEVICES PRO	DUCTS CONTACTS	OTHER	ADDRESSES	DOCUN	MENTS NEWS		
Products											
Produ Device Ty Select de	ICTS ype / Class: evice ty 🔻	Medical device name:	Registe	red Date: ත්හුහු	GMDN Code / Terr	n: Se m	earch by odel/version	:	Custom Made:	•	Device Reg Unde 2017:
Sterile:	•	Is Measuring:	UDI Issu	uing Entity: •	UDI-DI Number:	Co	ontaining late	ex: •	Product Status:	F	Regulation/Directiv
roduct l tatus:	Registration	Intended purpo than medical(Ar XVI):	se other nnex	Endocrine dis	ruptor: MRI sa	fety inf	formation: •	Humar	n cells or tissues: •	An	imal cells or tissu
roduct l tatus: Init of u	Registration se UDI-DI:	Intended purpos than medical(Ar XVI): - Is the Device dir Marked with UD	se other nnex • rectly DI-DI:	Endocrine dis	ruptor: MRI sa 	fety inf	formation: T	Humar 	n cells or tissues: •	An 	imal cells or tissu
Product I itatus: Init of u	Registration se UDI-DI:	Intended purpos than medical(Ar XVI): - Is the Device dir Marked with UD -	se other nnex rectly DI-DI:	Endocrine dis	ruptor: MRI sa	fety inf	formation:	Humar 	n cells or tissues: •	An 	SEARCH CLE
Product I itatus: Init of u Status	Registration se UDI-DI: GMDN Code	Intended purpos than medical(Ar XVI): - Is the Device dir Marked with UD - Term Name	se other nnex rectly DI-DI:	Endocrine dis	MRI se MRI se - ucts: Medical Device Nar	fety inf	formation:	Humar 	n cells or tissues: • •	An 	SEARCH CLE

10. Click on the Medical Device Name of the product

~Prod	luct Details					
Preview o	only displays limited fields					
Status	Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
•	Clamp1 10	Clamp/R/001	545757767			On the GB market
(ey 🥑 Regist	tered 🔿 Not Registered ጰ No Longer	Registered 🗙 R	ejected			

11. An Update History table will appear with a version entry for each update application submitted for the product, indicating when the product was modified and by whom. Click on each version to view updates made to the product.

(∨ Update His	story		
	Version	Medical Device Name	Modified On	Modified By
11	Version 3	Clamp1	13/08/2021 14:48 BST	Peter Smith
	Version 2	Clamp1	13/08/2021 14:45 BST	Peter Smith
	Version 1	Clamp1	13/08/2021 14:34 BST	Peter Smith

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

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

13. Click the Back button to go back to the Update History table and view other versions.

Removing migrated Pseudo GMDN[®] Terms

This section applies to Migrated customers **only**. Please see <u>Determine if your account is</u> <u>migrated or re-registered</u>. These are invalid terms and you cannot update these devices.

You will need to **add** all the devices you manufacture <u>first</u> and then **remove** the Pseudo GMDN[®] Terms.

Migrated Pseudo GMDN[®] Terms do not appear on the <u>Public Access Registration Database</u> (<u>PARD</u>). If you only have Migrated Pseudo GMDN[®] Terms on your account, PARD will display the following message in the device field: '**Devices pending update by manufacturer**'.

- 1. Click the Devices tab
- 2. Check if you have any migrated Pseudo GMDN[®] Terms in your list of devices these can be identified by the following symbol:

I Back to I	DR&CFS Services		
₹egre	ession Tes	t	Order CFS Manage Devices Add Device
SUMMARY	APPLICATIONS RE	ELATED ORGANISATIONS DEVICES PRODUCTS CONTACTS OTHER ADDI	RESSES DOCUMENTS NEWS
Devices			
Device	20		
→ Show F	Filters		
→ Show F	GMDN Code	Term Name	Device Type
→ Show F Status	GMDN Code	Term Name Electrode gel	Device Type General Medical Device - Class I
→ Show I Status	GMDN Code 11425 90003720	Term Name Electrode gel Examination/Treatment Couches And Leg/Arm Rests	Device Type General Medical Device - Class I General Medical Device - Class I
Status	GMDN Code 11425 90003720 42893	Term Name Electrode gel Examination/Treatment Couches And Leg/Arm Rests General-purpose bowl, reusable	t Device Type General Medical Device - Class I General Medical Device - Class I General Medical Device - Class I
Show I Status C C C C C C C C C C C C C C C C C C	GMDN Code 11425 90003720 42893 90004871	Term Name Electrode gel Examination/Treatment Couches And Leg/Arm Rests General-purpose bowl, reusable Rehabilitation Equipment	Device Type General Medical Device - Class I
→ Show I Status 0 2 2 2	GMDN Code 11425 90003720 42893 90004871 90004872	Term Name Electrode gel Examination/Treatment Couches And Leg/Arm Rests General-purpose bowl, reusable Rehabilitation Equipment Treatment Chairs (Chiropody/Dental/Ophthalmic)	Device Type General Medical Device - Class I General Medical Device - Class I

- 3. After following all the <u>Add Devices using GMDN[®]</u> instructions to add all the devices you manufactuer:
- 4. Click on the Manage Devices link.

CY SERVICES		ACCOUNT MANAGEMENT							
A Back to D	R&CFS Services	ost				Order CFS 📃	4 Manage Devices	Add Devices	
SUMMARY	APPLICATIONS	RELATED ORGANISATIONS DEV	PRODUCTS	CONTACTS	OTHER ADDRESSE	5 DOCUMENTS	NEWS		
Devices									
→ Show F	Ilters								
Status	GMDN Code	Term Name			t	Device Type			

5. Select all the Pseudo GMDN[®] Terms migrated from our old system. You can identify these in your manage devices list by either searching for the device using filters or searching all devices that are **not** CFS ready by using the Is CFS ready? filter, the Remark column will indicate 'Invalid GMDN Term'.

Click	each GMDN te	erm to add or delete products (medic	al device	name and m	nodel etc.) and CE certificates. Any	deletions will be removed immediately, add	ling new
prod If you	uct/s will creat I need to add I	e an application for MHRA review. new GMDN terms (devices), please go	back to	Devices and	products and click "Add device" bu	utton.	
Sear	ch by GMDN (Code / Term :	Devic	е Туре:		Device Sub Type:	
GM	DN Code / Terr	77	Gene	eral Medical (Device	✓ Class I	
ls Cu	stom Made:		Is Ste	rile:		Is Measuring:	
Cus	tom made	•	Steri	le		Measuring	
ls CF	S Ready:		CE Cei	rtificate:			SEARCH CLEA
CFS	Ready	•					
	Status	GMDN term	t	Products	Device Type	Remark	CFS- ready
	Registered	Assistive scissors		0	General Medical Device - Class	PRODUCT INFORMATION IS REQUIRED	No
	Registered	Electrode gel		0	General Medical Device - Class	PRODUCT INFORMATION IS REQUIRED	No
•	Registered	Examination/Treatment Couches A Leg/Arm Rests	nd	0	General Medical Device - Class	PRODUCT INFORMATION IS REQUIRED INVALID GMDN TERM	No
~	Registered	Rehabilitation Equipment		0	General Medical Device - Class	PRODUCT INFORMATION IS REQUIRED INVALID GMDN TERM	No
•	Registered	Treatment Chairs (Chiropody/Dental/Ophthalmic)		0	General Medical Device - Class	PRODUCT INFORMATION IS REQUIRED INVALID GMDN TERM	No

6. Click the Delete Selected Devices button.

7. Select option Information updated/existing data no longer valid for Reason for deletion. The selecetd option will be applied to all the deleted devices. If the reasons for deletion are different, please create separate applications.

Reason for deletion

No longer placed on the market

Information updated/ existing data no longer valid
 Entered in error

8. See <u>Using filters to search for devices and products</u> to search for deleted devices.

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

1. Click the Enter button on the Landing Page.



2. Click on the Add New Manufacturer button.

Please note. Only UK Responsible Persons (of manufacturers outside the UK) or NIbased Authorised Representatives (of manufacturers outside the EU) may **click** this button to 'Add New Manufacturers'. This button is to be used when you are ready to make device registrations on behalf of a represented manufacturer.

If you have already registered the represented manufacturer, please manage their existing account. Do not create multiple accounts for the same represented manufacturer, this results in additional unnecessary work and fees.

Device Registration & Certificates of Free Sale Your Organisation Registration Country Name Address Devices (Products) Status 10 South Colonnade, 10th Floor Area 7, Canary MHRA Demo England, United Kingdom 1 (27) Wharf, London, Greater London, E14 4PU Key 🥑 Registered 🔘 Not Registered 😄 Unregistered 🕕 Suspended 🗙 Rejected Manufacturers you represent Only registered manufacturers appear here. Newly submitted and NEW MANUFACTURE 2 raft manufacturers can be found from the Applications list Only use the ADD NEW MANUFACTURER function if you have not already registered the represented manufacturer. If you have registered the manufacturer, please use the Add Devices function to egister additional devices on the existing account.

3.	 Enter manufacturer details: Select to confirm I wish to represent this manufacturer as UK Responsible Person, or I wish to represent this organisation as an Authorised Representative (the
	Authorised Representative option will only appear if you are based in Northern Ireland).
	 Select up to three options to describe the organisation. Complete all the mandatory fields otherwise you won't be able to proceed.
	AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT
	Manufacturer and Device Registration - TEMP202001030124106
	Manufacturer Device CE certificates/ Products Review Payment Declaration of
3	Provide Manufacturer Details
	Organisation details
	Organisation name
	Describe your organisation by selecting up to three options below -Select-
	I wish to represent this manufacturer as
	VIK Responsible Person Address Details
	Enter address details for the organisation
	Select International Address
	Address line 1
	Address line 2 (optional)
4.	Enter details of the contact at the represented organisation – please do not enter your contact details here.

details).	
Please provide details of	f how we can contact the manufacturer.
Title (optional)	
- Select	
First name	
Last name	
Job title (optional)	
Fmail	

5. Upload the Letter of Designation.

Please note This must be a legal contract, stating that you are the exclusive UK Responsible Person or Northern Ireland Authorised Representative, acting for the manufacturer and specifying the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contract for UKRPs can be found in our <u>regulatory guidance for UK Responsible</u> <u>Persons</u>. For Authorised Representatives in Northern Ireland the requirements can be found in the <u>guidance for Authorised Representatives</u>.

From Date	To Date	
dd/mm/yyyy	dd/mm/yyyy	
Description of document (ptional)	

6. Enter the Letter of Designation validity dates

Please note you will receive email reminders 3, 2 and 1 month prior to expiry of your Letter of designation. If you do not upload a new Letter of Designation before the expiry of the existing one, your account will be suspended until you upload a valid letter. A suspended account means you are no longer lawfully allowed to place devices on to the UK market. It is a legal requirement to hold an active registration with the UK competent authority (MHRA). It is an offence to place a non-compliant device on the UK market. Your details will also be removed from the <u>Public Access</u> <u>Registration Database (PARD)</u>. See Uploading New Letter of Designation in the Account Management Reference Guide to update Letter of Designation.

From Date *	To Date *	
30/10/2020	31/12/2021	
scription of document (onal)	
1		
1		
I		

 Click the Continue button to go to the Add Devices page and follow the instructions as for <u>Registering New Devices</u> or click the Save & Exit button if you wish to save a draft application.

Adding Importers

You must add the details of all importers that import medical devices into the UK for your organisation or any of the organisations that you represent as a UK Responsible Person (of manufacturers outside the UK) or Northern Ireland-based Authorised Representative (of manufacturers outside the EU).

1. Click the Enter button on the Landing Page.



2. Click on the Add New Importer button.



- 3. Enter the importer details:
 - Select to confirm I am associated with this organisation as UK Responsible Person and/or Manufacturer and/or Authorised Representative (the Authorised Representative option will only appear if you are based in Northern Ireland).

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

- Multiple associations can be ticked e.g. if you have a dual or triple role and also use the importer for your represented manufacturers in your capacity as UKRP or Northern Ireland Authorised Representative.
- Complete all the mandatory fields otherwise you won't be able to proceed.

	AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT	# ()
	Importer Registration - TEMP20210722165614	
3	Provide Importer Details Organisation details	
	Organisation name	
	Big Shipping UK Limited	
	I am associated with this organisation as UK Responsible Person Manufacturer	

4. Select from the list of Registered Manufacturers you represent. Multiple manufacturers can be selected.

Please note if you have selected that **you** are associated with this importer as a manufacturer, your organisation will automatically be included and will not appear in the List of Registered Manufactuers.



5. Enter all mandatory address fields for the importer

Postcode lookup		
CT17 9BU	FIND UK ADDRESS	
Pick an address		
Waterloo Crescent, Harbour Hou	se, Dover, Kent, CT17 9BU	
Enter address manually		
Address line 1		
Unit 561		
Address line 2 (optional)		
Waterloo Crescent		
Address line 3 (optional)		
Harbour House		
Address line 4 (optional)		
State/County/Province (optiona	D	
Kent		
City/Town		
Dover		
Country *		
England, United Kingdom 🗙		
Post code		
CT17 9BU		
Telephone		
1234567		
Fax (untional)		

6. Enter the importer's contact details- please do not enter your contact details here.

Please provide details of how we can contact the importer.			
Title (optional)			
- Select	•		
First name			
Peter			
Last name			
James			
Job title (optional)			
Import Manager			
Email			
pete@bigshipping.co.uk			
Telephone			
1245676			

5. Click the Continue button.

- 6. Click the Complete Application button. Add New Importer - TEMP202001030154509 Payment is not required for the application. Please click on complete application to finish. 6 COMPLETE APPLICATION DELETE APPLICATION BACK 7. Click the Close button. Application complete Your reference number 202010300115416 What happens next... We have sent you a confirmation email and your application has been sent to an officer at MHRA. We will contact you again within the next 2-5 working days to let you know of our decision, or to ask for more information if its needed. 7 CLOSE
- 8. The importer will appear in the List of Importers on the Organisation page. If you are no longer associated with an importer please see <u>Deactivating Importers</u>.

Device Regist	ration & Cer	tificates of Free Sale						
Your Organisatio	n							
Name	Address		Cou	intry		De	vices (Products)	Registratio Status
MHRA DEMO	10 South Colonnade, Ca	nary Wharf, London, E14 4PU	Eng	land, United Kingdom	n	4 (9)	۲
Registered Not Reg Manufacturers y Only registered manufacture the Applications list. Only use the AD NeW MANURA Alived y registered the represent gestere different devices on the Search by manufacturer ne Name Demo represented org Thin	e Unregistered our epresent sappear here. Newly sub trueRR function if you have in fmanufacturer. If you have to use the Add Devices function setting account. me: 1	Suspended × Rejected itted and draft manufacturers can be found from or n to Address 167 Bella Bista, East Side Compound, 1000 Medice Draw, Saa View Industrial Zone, Senta Barbara C	H	Country United States	Device 20 (21	es (Products)	Relationship	DD NEW MANUFACTUR
DEMO Represented Organi	ation	123 Street, Sea View Industrial Estate, Boston, MA	, 12345	United States	3 (10)		UK Responsible Person	۲
DEMO Represented Organi	ation Two	234 Avenida Escala, Cancun, Yukatan, 43231		Mexico	1 (1)		UK Responsible Person	۰
	ation Three	60 Strand Street, Douglas, Isle Of Man, IM1 2EL		Isle of Man	0 (0)		UK Responsible Person	0
DEMO Represented Organi								
DEMO Represented Organi Key Registered O Not Reg List of Importers Name	stered Cunregistered	Suspended X Rejected	Country			Relationship		Status
DEMO Represented Organi Key Registered Not Reg List of Importers Name Big Shipping UK Limited	Address Unit 561, Wate 98U	Suspended X Rejected rloo Crescent, Harbour House, Dover, Kent, CT17	Country England,	United Kingdom		Relationship UK Responsible Pe	rson ; Manufacturer	Status
DEMO Represented Organi Key Registered Not Reg List of Importers Name Big Shipping UK Limited Demo Importer	Address Unit 561, Wate Unit 765, Wate C117 98U	Suspended X Rejected	Country England, I	United Kingdom United Kingdom		Relationship UK Responsible Pe UK Responsible Pe	rson ; Manufacturer	Status o

9. Click on the importer name in the List of Importers on the Organisation page.

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

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

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

Back to DR&CFS Servi	 O: Big Shipping UK			Deactivate Importer
imited				
UMMARY APPLICATIO	NS NEWS			
Summary				
Basic Information				
Account Number	0000007097	Registration Status Active		
Role / Account Type	Importer	2		
Organisation Name	MHRA DEMO			
Relationship	Manufacturer UK Responsible Person			
Created Date	22 July 2021			
Organisation Deta	ils			
Registered Address	Unit 561, Waterloo Crescent	Telephone 1234567		
	Harbour House Dover	Fax N/A		
	Kent CT17 9BU England, United Kingdom	Website N/A		
Contact Details				
Full Name	Peter James	Email pete@bigsh	ipping.co.uk	
Job Title	Import Manager	Telephone 12345676		
Associated Manufa	acturers			
Name		Address	Country	Registration Status
Demo represented o	orgThree	167 Bella Bista, East Side Compound, 1000 Medtech Drive, Sea Viev Industrial Zone, Santa Barbara, CA, 98765	V United States	٢
DEMO Represented	Organisation	123 Street, Sea View Industrial Estate, Boston, MA, 12345	United States	•
DEMO Represented	Organisation Two	234 Avenida Escala, Cancun, Yukatan, 43231	Mexico	٢
		10 South Colonnade, Canary Wharf, London, . E14 4PU	England, United	٢

Deactivating Importers

1. Click on the name of the importer you want to deactivate in the List of Importers table.

Please note if you need to make any changes to association between Importer and Manufacturers you must **deactivate** the importer, **add** them again and link the appropriate associated manufacturers. It is not currently possible to remove associated manufacturers from an importer record.

Your Organisa	ation					
Name	Address			Country	Devices (Products)	Registratio Status
MHRA DEMO	10 South Colonnade	, Canary Wharf, London, E14 4	4PU	England, United Kingdom	0 (0)	0
Only registered manufa	acturers appear here. Ne	ewly submitted and draft man	ufacturers can be			
Yound from the Applica Donly use the ADD NEW Wready registered the manufact registered the manufact register additional device Search by manufactur Name	ations list MANUFACTURER funct epresented manufacturi turer, please use the Ad- ces on the existing accou- rer name: Address	ion if you have not er. If you have d Devices function to int. Country	SEARCH Devices (F	Products)	Relationship	ADD NEW MANUFACTURE
found from the Applica Only use the ADD NEW Micrady registered the n registered the manufact egister additional devic Search by manufactur Name	ations list. MANUFACTURER funct epresented manufactur turer, please use the Ad ces on the existing accou- rer name: Address	ion if you have not er. If you have d Devices function to int.	SEARCH Devices (F No manufactures	Products) rs are available	Relationship	ADD NEW IMPORTER ADD NEW IMPORTER Registration Status
Found from the Applica Only use the ADD NEW Wready registered the manufact egister additional devic Search by manufactur Name 1 Name 1 Key Registered O No List of Import	ations list. MANUFACTURER funct genesented manufactur turer, please use the Ad- ces on the existing accou- rer name: t Address ot Registered O Unr ers	ion if you have not er. If you have d Devices function to int. Country egistered ① Suspended	SEARCH Devices (F No manufactures X Rejected	Products) rs are available	Relationship	ADD NEW IMPORTER
found from the Applica Only use the ADD NEW Miready registered the n egistered the manufact egister additional devic Search by manufactur I Name 1 Key Registered Name	ations list: MANUFACTURER functe epresented manufactur turer, please use the Ad- ces on the existing accou- rer name: 1 Address 1 Address	ion if you have not er. If you have d Devices function to int. Country egistered ① Suspended	SEARCH Devices (F No manufactures × Rejected	Products) rs are available Country	Relationship	ADD NEW IMPORTER ADD NEW IMPORTER Registration Status Status

2. Click on the Deactivate Importer button.

 ■ Back to DR&CFS Servi MHRA DEM SUMMARY 	œs O: Demo Importer		Deactivate Importer 2
Summary			
	000005322	Registration Status Active	
Role / Account Type	Importer	Registration status Active	
UK Responsible Person	MHRA DEMO		
Created Date	30 October 2020		

3. Click the Yes button to deactivate or the No button to cancel the action.

Please note once the importer has been deactivated you will not be able to reactivate/reinstate the record. You will need to add the importer again, if required.

	AGENCY SERVICES			
	Are you sure wa	ant to deactivate	the Importer?	
3	YES NO)		

4. The status of the importer will change to Inactive on the Summary page and in the List of Importers.

Registration	Status Inactive	4	
Registration	Status Inactive	4	
Registration	Status Inactive	4	
Registration	Status Inactive	4	
Registration	Status Inactive	4	
Registration	Status Inactive	4	
Registration	Status Inactive	4	
Tele	phone 01304 123	456	
	Fax N/A		
v	lebsite N/A		
	Email james@de	mo.com	
Tele	phone 01304 123	456	
	Tele	Fax N/A Website N/A Email james@de Telephone 01304123	Fax N/A Website N/A Email james@demo.com Telephone 01304 123456



Active O Inactive

9BU

Save and exit: resume applications

When completing an application, you may save, exit and return to completing the application from where you left off. This creates a TEMP (draft) application.

Please note TEMP applications will be automatically deleted 90 days from last saved on date. Please ensure that you regularly review your TEMP applications and submit to MHRA within 90 days of 'Last saved on' date indicated in the Applications table. Once deleted TEMP applications cannot be reinstated.

1. Click the Save and Exit button (if available on the page that you are on).



2. Confirm that you want to Save and Exit.

evice	Are you sure you want to "Save and Exit" the application? If Yes, Your application will be saved and closed.
ayment met	NO YES d.

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

AGENCY SERVICES APPLICATIONS ACCOUNT MANAGEMENT	
Application saved	
Your application has been saved successfully.	
Your draft application reference number: TEMP20190510134111	
CLOSE	
AG	Application saved Your application has been saved successfully. Your draft application reference number: TEMP20190510134111 CLOSE

4. Click the Close button.

5. Click on the Applications tab on the home page or the Applications link on the Organisation page. This will display all the applications for your organisation and all of your represented organisations (if applicable).

our Organ	isation			
Name	Address	Country	Devices (Products)	Registration Status
MHRA DEMO	10 South Colonnade, Canary Wharf, London, E14 4PU	England, United Kingdom	0 (0)	0
Nanufactur nly registered ma anufacturers can	Not Registered Unregistered USuspended X Rejected Yers you represent nufacturers appear here. Newly submitted and draft be found from the Applications list.			DD NEW MANUFACTURER
Negistered III Manufactur nly registered ma anufacturers can nly use the ADD NE ready registered the gistered the manufa gister additional de	Not Registered Unregistered USuspended X Rejected Cers you represent nufacturers appear here. Newly submitted and draft be found from the Applications list. V MANUFACTURER function if you have not represented manufacturer. If you have icturer, please use the Add Devices function to ices on the existing account.			DD NEW MANUFACTURER

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

AGENCY SERVICES		ACCOUNT MANAGEMENT			
 ■ Back to DR&C MHRA E SUMMARY Summary 	EFS Services Demo PLICATIONS	6 ELATED ORGANISATIONS	Edit Organisation Det	ails a Order CF Registered Do TS OTHER ADDRES	S Add Devices Manage Devices Update evices/Products Export Devices Data to Excel File SES DOCUMENTS NEWS
Vour registra determined by the being suspende the competent a	ation with the N the date your a ed. A suspended authority (MHR	IHRA must be reviewed an ccount was created with th 1 account means you will n 4). It is an offence to place	nd renewed one year after the ar ne MHRA. Your Registration Rene ot be able to place new devices of a non-compliant device on the r	niversary date and wal is 01/01/2022. I on the market given narket in the UK.	every two years subsequently. The anniversary date is Failure to renew your registration will result in your account it is a legal requirement to hold an active registration with
Basic Inform	nation				
Account N	lumber 00000	09132	F	legistration Status	Registered
EL Registration N	J Single lumber (SRN)			PARD Options	Publish UK Responsible Person Name Publish UK Responsible Person Address Publish Organisation's Name
Role / Accou	nt Type Manu	facturer UK Responsible	Person		Publish Organisation's Address
Compar	n y Type Limite	d Company		Company	654321
VATIN	lumber 12345	6	Re	gistration Number	
Create	ed Date 19 Se	otember 2019		Registered under 2017 MDRs	No

7. Click on the TEMP (draft) application's Reference to open it. TEMP applications will be automatically deleted 90 days from Last saved on date. Please ensure that you regularly review your TEMP applications and submit to MHRA within 90 days of 'Last saved on' date in below table. Once deleted TEMP applications cannot be reinstated.

		NAGEMENT								(
Applications										
✓Draft Application	ons									
OTEMP applications will be within 90 days of 'Last saver	automatically delet l on' date in below t	ed 90 days from last : able. Once deleted T	saved on date. EMP applicatio	Please ensure that y ns cannot be reinsta	you regula ated.	arly review yo	our TEMP applications	and subm	it to MI	1RA
Search by manufacturer n	ame or reference	number								
	SEARCH	Service	All Types	•	Show	All Types	-	Show	10 pe	er pa 🔻
Reference		Manufacturer		Application Type	e		Last saved on		Ţ	Status
TEMP20220217151705		MHRA Demo		New device			17 February 2022			-
Submitted App Search by organisation na	me or reference n	umber			Show	All Types	•	Show	10 pe	er pa 🖣
Reference	Manufactur	er		Application T	уре		Submitted on		Statu	S
2022021801215061	MHRA Dem	2		New device			18 February 2022		G	
2022021801215061 2021102602208215	DEMO Repr	e esented Organisation	1	New device CFS Order			18 February 2022 26 October 2021		0	

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

Manufacturer	Device	Self-certification	Products	Review	Payment
Manaracturer	Device	conformity declarations	FIGUELS	NEVIEW	Fayinen
Add products					
lere you can add product inforr	mation for the device:				
4054-Orthopaedic surgical pro	cedure kit, non-medic	ated, reusable			
'ou need to provide medical de or each product. Product inforn Aedical Device Regulators Forur Aedical Device Identification.	vice name, model/vers nation follows guidelir m in their document C	sion and catalogue/reference nes set by the International ommon Data Elements for			
Add products one by one					
Medical Device Name (Brand/	Trade/Proprietary or	Common name)			
	otification of the reau	lated medical device. It can be a			

9. If you have multiple users on your account your will need to Click on the Accept task button in order to continue with the application or Click on the Go Back button to go back to the Applications list. All TEMP applications will be visible and accesible to all users on the account with the exception of applications saved on the Payments page and applications created before a user was given access to the account.

Please note if you have clicked Save and Exit on the Payments page only **you** will be able to see the TEMP application in the Applications Tab. If you want your colleagues to be able to view the application please **Click** the Back button to the Review page and then **Click** on the Save and Exit button.

	ACCOUNT MANAGEM	ENT			(
You must accept this task bef	ore completing it			9	ACCEPT GO BACK
Add New Devi	ces for MH	RA Demo - TEMF	2022021715	51705	
Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment
Add products					
Here you can add product infor	mation for the device:				
44054-Orthopaedic surgical pro	ocedure kit, non-medica	ted, reusable			
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Add products one by one	Ð				
Medical Device Name (Brand	/Trade/Proprietary or	Common name)			
A name used to assist in the ide brand, trade, proprietary or con	entification of the regul mmon name.	ated medical device. It can be a			
Is Model/Version applicable?					
Please Select		•			
ls Catalogue/Deference appli	rable?				
Diesse Selert	Labic:				

Annex I – Workflow

