

EUDAMED user guide Registration of Old/custommade devices in the Vigilance module

Playground v 3.11.0 2025

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1 Introduction

According to the Medical Devices legislation, Old and custom-made devices (OCM) are not to be registered in the UDI/Devices module but are to be referenced in Vigilance reports.



NOTE

Old Device: Devices placed on the market according to the medical devices Directives or the in vitro diagnostic medical devices Directive before the date of application of the MDR and IVDR or placed on the market before the Directives entered into force.

Custom-made Device: Any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

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2 Registering old/custommade devices

2.1 Step 0: Old/custom-made device registration

- 1. On the dashboard, click on Register an old/custom-made device.
- 2. Select the applicable legislation:

* Applicable Legislation
Applicable Legislation
 MDR (REGULATION (EU) 2017/745 on medical devices)
IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)
O MDD (Directive 93/42/EEC on Medical Devices)
\bigcirc AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)
O NONE
O UNKNOWN

3. If a UDI-DI is assigned, toggle the button to Yes and provide the *Issuing Entity* and the *UDI-DI code*:

UDI-DI assigned for the current old/custom-made device? Yes No	
* Issuing Entity:	* UDI-DI code:
Issuing Entity:	Basic UDI-DI:

If a UDI-DI is not assigned, toggle the button to *No* and enter the *Device code*. Then click on the **Generate** button:

JDI-DI assigned for the current old/custom-made device		
Issuing Entity:	* Device code:	
EUDAMED 🗸		
Generate an old/custom-made device identifier based on y	ur device code provided above:	
Generate		

4. The Device identifier will be displayed. Click on **Save & Next** to continue:

* Generate an old/custom-made device identifier based on your device code provided above:	
Generate	
Generated Identifier Device identifier: N-dev_ocm_ba1RL Issuing Entity: EUDAMED	
Save & Next >	_

2.2 Step 1: Old/custom-made device information

The fields displayed on this page depend on the selected option for the *Applicable legislation* field in the Step 0: Old/custom-made device registration [2] section.

- 1. Complete the fields in this section by referring to the table at the bottom of the section.
- 2. Click the **Submit** button:



3. A pop-up window is displayed. Click **Confirm** to register the old/custom-made device:

*Close Are you sure you want to submit your old/custom-made device registration request?
After submission, the old/custom-made device will have the state Registered. You may view your data by visiting 'Manage your old/custom-made devices' page.
Confirm

Your old/custom-made registration request was successfully submitted.

The following table summarises the displayed fields per applicable legislation.

Legislation/	MDR	IVDD	MDD	AIMDD	NONE	UNKNOWN
Fields						
Device is custom-made	✓ Set to Yes and non-editable	/	/	/	J	1
Is it a System or Procedure Pack which is a Device in itself?	1		1	1		
ls it a kit		1				

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Legislation/	MDR	IVDD	MDD	AIMDD	NONE	UNKNOWN
Fields						
Special device type	Mandatory if No is selected for the Is it a System or Procedure Pack which is a Device in itself? field	Mandatory if <i>No</i> is selected for the <i>Is it a kit</i> field	Mandatory if No is selected for the Is it a System or Procedure Pack which is a Device in itself? field	Mandatory if No is selected for the Is it a System or Procedure Pack which is a Device in itself? field		
Risk class	J	1	1	1		
Implantable	1		1	1		
Measuring function	J		J	J		
Reusable surgical instruments	1		1	1		
Active device	1		1	1		
Device intended to administer and/or remove medicinal product	1		1	1		
Near-patient testing		1				
Self-patient testing		1				
Companion diagnostic		1				
Reagent		1				
Instrument		1				
Professional testing		1				
Device model	1	1	1	1	1	1
Device name	1	1	1	1	1	1
Trade name	1	1	1	1	1	1
Select the language	1	1	1	1	1	1
Reference/Catalogue number	1	1	1	1	1	1
Device status	/	 Set to No longer placed on the EU market and non- editable if No is selected for the Device is custom- made field 	Set to No longer placed on the EU market and non- editable if No is selected for the Device is custom- made field	✓ Set to No longer placed on the EU market and non- editable if No is selected for the Device is custom- made field	<i>•</i>	/
Device labelled as sterile	1	1	1	1	1	1
Presence of human tissues or cells, or their derivatives	1	1	1	1	1	1
Intended purpose other than medical (Annex XVI)	1					
Presence of substance which, if used separately, may be considered to be a medical product	1		1	1		
Presence of substance which, if used separately, may be considered to be a medical product derived from human blood or human plasma	/		/	/		
Member states where the device is or is to be made available on the market	1	1	1	1	1	1

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NOTE

If *No* is selected for the *Device is custom-made* field, the user must check the box for the field *I confirm that this device has no longer been placed on the EU market after the date of the application of the MDR/IVDR* to confirm that the device is considered 'old'. Otherwise, the old/custom-made device registration will not be possible.

Old/custom-made device information



O Yes ⊛ No

I confirm that this device has no longer been placed on the EU market after the date of the application of the MDR/IVDR



NOTE

For certain mandatory fields, the user can select the *Unknown* option. When creating a new version of the old/custom-made device, these fields cannot be edited unless the *Unknown* option is selected.



3 Manage your old/custommade devices

- 1. On the dashboard, click on Manage your old/custom-made devices.
- 2. The *Old/custom-made devices management* page is displayed. Select your search criteria and click on the **Apply filters** button to view the results:

ld/custom-made devi	ces managem	nent				
Filter 🔻					Register an old/cus	tom-made device
Applicable legislation		Status		Risk class		
-	× •	-	×		×	
UDI-DI/Device identifier	Basic UDI-DI		Device Model			
Device Is custom-made	Trade name		Reference/Catalogue number			
State Draft						
Apply filters Clear all filters						
tive filters: tate: Draft <u>Clear search</u>						

N B

NOTE

By default, the system lists the old/custom-made devices in *draft* state. To retrieve other states use the filters.

3.1 Create a new version of an old/ custom-made device

Follow the steps in the Manage your old/custom-made devices [6] section to view a draft .

1. Select the option *Registered* in the *State* field and click on the **Apply filters** button:

× v DI-DI	Status	× •	Risk class	× •
× v		× •	-	× ×
DI-DI				
		Device Model		
ame		Reference/Catalogue numbe	r	
	ame	ame	ame Reference/Catalogue numbe	ame Reference/Catalogue number

2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:

Old/custom-made device	s mana	igement					
Filter 🔻					Register an o	ld/custom-made	device
Active filters:							
State: Registered Clear search							
Showing 1 to 20 of 26 entries					Show 20	✓ entries	per page
UDI-DI/Device Device Name 11 identifier 11	Risk class	Applicable legislation	Trade name #	Date 👪	UDI-DI/Device status	State	Actions
N-5454_baDX DN_BA2	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-31	On the EU market	 Registered 	
59744654421465 59744654421465	-	Unknown		2025-03-13	On the EU market	View da	ta
59744654421458 310701sanity_3.11.1_077V	-	None		2025-03-13	On the EU market	Registered	
59744654421434 59744654421434	AIMDD	AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
59744654421427 310701sanity_3.11.1_057R	Class III	MDD (Directive 93/42/EEC on Medical Devices)		2025-03-13	No longer placed on the EU market	Registered	
59744654421427 59744654421427	IVD devices for self- testing	IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)		2025-03-13	No longer placed on the EU market	Registered	
59744654421410 59744654421410	Class III	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-13	On the EU market	Registered	

3. You will see a summary of your old/custom-made device details. Click on the **Create new version** button:

Old/custom-made device N-5454_baDX						
 <u>Go back to the list</u> Old/custom-made device data 	Create new version Discard					
Version 1 [Current] Last update date: 🗮 2025-03-31						
UDI-DI/Device identifier:	N-5454_baDX					
Issuing Entity:	EUDAMED					
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)					
Manufacturer SRN:	FR-MF-000004867					
Manufacturer name:	Martin-Moreau & Fils.					
Manufacturer address:	StreetNum-\V/<>?é,à/è-i~ò.ù-â_é+i@òlû#ç/e//`ü'-EndStreetNum AddressActor-\V/<>?é,à/è-i~ò.ù-â_ê+i@òlû#ç/e/i^ü'-End- Address POBox-\V/<>é,à/è-i~ò.ù-â_ê+i@òlû#ç/e/i`ü'-EndPOBox PostCode\V/<>?é,à/è-i~ò.ù-â_ê+i@ôlû#ç/e/i`ü'- EndPostCode City-\V/<>é,à/è-i~ò.ù-â_ê+i@ôlû#ç/e/i`ü'-EndCity					
Basic UDI-DI code:						
Issuing Entity:	•					
Device is custom-made:	Yes					
Is it a System or Procedure Pack which is a Device in itself?:	No					
Special device type:	No					
Risk class:	Class IIa					
Implantable:	No					
Measuring function:	Unknown					
Reusable surgical instruments:	Unknown					
Active device:	No					
Device intended to administer and/or remove medicinal product:	Unknown					
Device Model:	BA_2DM					
Name:	DN BA2					

4. On the next screen, there are some fields that are not editable:

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Old/custom-made device N-5454_baDX
Create a new version of old/custom-made device N-5454_baDX
Actor identification <u>FR-MF-000004867</u> , Martin-Moreau & Fils.
Old/custom-made device identification Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)
UDI-DVDevice identifier: N-5454_baDX Issuing Entity: EUDAMED Basic UDI-DI: - Issuing Entity: -
Old/custom-made device information [★] Device is custom-made [●] Yes ○ No
Is it a System or Procedure Pack which is a Device in itself? Yes No Is it a System or Procedure Pack which is a Device in itself is required unless you select the option - No
Special device type Yes No Special device type is required unless you select the option - No
* Risk class: Class IIa ~

- 5. For the editable fields, consult the table presented in the Step 1: Old/custom-made device information [3] section.
- 6. When you have finished updating the desired fields, click on the **Submit new version** button:

Save	Submit new version >	Cancel

7. A pop-up window is displayed. Click **Confirm** to create a new version of the old/ custom-made device:

Create new ver	sion	× <u>Close</u>
You are about to create a ne	ew version of old/custom-made device N-5454_baDX	
Confirm	Cancel	

3.2 View historical versions of an old/ custom-made device

Follow the steps in the Manage your old/custom-made devices [6] section to view a draft old/custom-made device.

1. Select the option *Registered* in the *State* field and click on the **Apply filters** button:

	street manager	lion			
Filter V					Register an old/custom-made dev
Applicable legislation		Status		Risk class	
	×		× •		× ~
UDI-DI/Device identifier	Basic UDI-DI	De	evice Model		
Device Name	Trade name	Re	eference/Catalogue number		
Device is custom-made					
Registered	·				
Apply filters Clear all fi	Iters				

2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:

Old/custo	m-made device	s mana	gement					
Filter 🔻						Register an o	old/custom-mad	e device
tive filters:								
State: Registered	<u>Clear search</u>							
nowing 1 to 20 of 26	entries					Show 20	✓ entries	s per pag
IDI-DI/Device dentifier ‡†	Device Name 1	Risk class	Applicable legislation	Trade name ↓†	Date 🛔	UDI-DI/Device status	State	Actions
N-5454_baDX	DN_BA2	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-31	On the EU market	 Registered 	
9744654421465	59744654421465	-	Unknown		2025-03-13	On the EU market	View d	ata
9744654421458	310701sanity_3.11.1_077V	-	None		2025-03-13	On the EU market	Registered	
59744654421434	59744654421434	AIMDD	AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
9744654421427	310701sanity_3.11.1_057R	Class III	MDD (Directive 93/42/EEC on Medical Devices)		2025-03-13	No longer placed on the EU market	Registered	
9744654421427	59744654421427	IVD devices for self- testing	IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
9744654421410	59744654421410	Class III	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-13	On the EU market	Registered	

3. Click the See version history link:

Old/custom-made device N-5	5454_baDX
Co back to the list	
Old/custom-made device data	Create new version Discard
Version 2 [Current] See version history Last update date: 2025-03-31	
UDI-DI/Device identifier:	N-5454_baDX
Issuing Entity:	EUDAMED
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Manufacturer SRN:	FR-MF-000004867
Manufacturer name:	Martin-Moreau & Fils.
Manufacturer address:	StreetNum-\\/\<>?é,à/ė-i~ô.ù-âê+i@ðlù#ç\e/i″u'EndStreetNum AddressActor\\/<>?é,à/e-i~ô.ù-âê+i@ôlû#ç\e/i″u'End- Address POBox\\/<>?é,à/e-i~ô.ù-â_ê+i@ôlû#ç\e/i″u'EndPOBox PostCode\\/<>?é,à/e-i~ô.ù-â_ê+i@ôlû#ç\e/i″u' EndPostCode City\\/<>?é,à/e-i~ô.ù-â_ê+i@ôlû#ç\e/i″u'EndCity
Basic UDI-DI code:	· ·
Issuing Entity:	
Device is custom-made:	Yes
Is it a System or Procedure Pack which is a Device in itself?:	No
Special device type:	No
Risk class:	Class IIa
Implantable:	No

4. On the next screen, you will see all available versions of the selected old/custommade device. Click on the desired version to view further details:

Old/custom-made device N-5454_baDX	
Co back to the current version	
Historical version(s) for old/custom-made device N-5454_baDX	
Version 1 - Last update date: 2025-03-31	>

5. The *Old/custom-made device data* page will display details on the selected version of the old/custom-made device:

Old/custom-made device N-5	6454_baDX
Co back to the current version	
Historical version(s) for old/custom	n-made device N-5454 baDX
	-
Version 1 [History] - Last update date: 2025-03-31	
Old/custom-made device data	=See all version history.(1)
Version 1 [Registered] Last update date: 🗮 2025-03-31	
UDI-DI/Device identifier:	N-5454_baDX
Issuing Entity:	EUDAMED
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Manufacturer SRN:	FR-MF-000004867
Manufacturer name:	Martin-Moreau & Fils.
Manufacturer address:	StreetNum\\/\ é,à/è-i~ò.ù-â_ê+i@ð\û#ç\ë/"ü'EndStreetNum AddressActor\\/<?é,à/è-i~ò.ù-â_ê+i@ð\û#ç\ë/"ü'End-<br Address POBox\\/ é,à/è-i~ò.ù-â_ê+i@ð\û#ç\ë/"ü'-EndPOBox PostCode\\/<?é,à/è-i~ò.ù-â_ê+i@ð\û#ç\ë/"ü'<br EndPostCode City\\/ é,à/è-i~ò.ù-â_ê+i@ð\û#ç\ë/"ü'-EndCity</th
Basic UDI-DI code:	• ·
Issuing Entity:	
Device is custom-made:	Yes
Is it a System or Procedure Pack which is a Device in itself?:	No
Special device type:	No
Risk class:	Class IIa
Implantable:	No
Measuring function:	Unknown
Reusable surgical instruments:	Unknown
Active device:	No
Device intended to administer and/or remove medicinal product:	Unknown



NOTE

You can navigate to the existing versions of the old/custom-made device by either clicking on the *See all version history* link or the *Next version* link at the top of the page.

3.3 Discard a registered old/custom-made device

Follow the steps in the Manage your old/custom-made devices [6] section to view a draft old/custom-made device.

1. Select the option *Registered* in the *State* field and click on the **Apply filters** button:

× v DI-DI	Status	× •	Risk class	× •
× v		× •	-	× ×
DI-DI				
		Device Model		
ame		Reference/Catalogue numbe	r	
	ame	ame	ame Reference/Catalogue numbe	ame Reference/Catalogue number

2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:

Old/custom-made device	es mana	agement					
Filter ▼					Register an o	old/custom-mad	e device
Active filters:							
State: Registered Clear search							
Showing 1 to 20 of 26 entries					Show 20	✓ entries	s per page
UDI-DI/Device Device Name 11 identifier 11	Risk class	Applicable legislation	Trade name ‡†	Date ∔	UDI-DI/Device status	State	Actions
N-5454_baDX DN_BA2	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-31	On the EU market	 Registered 	
59744654421465 59744654421465	-	Unknown		2025-03-13	On the EU market	View d	ata
59744654421458 310701sanity_3.11.1_077V	-	None		2025-03-13	On the EU market	 Registered 	
59744654421434 59744654421434	AIMDD	AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
59744654421427 310701sanity_3.11.1_057R	Class III	MDD (Directive 93/42/EEC on Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
59744654421427 59744654421427	IVD devices for self- testing	IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)		2025-03-13	No longer placed on the EU market	 Registered 	
59744654421410 59744654421410	Class III	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-13	On the EU market	 Registered 	

3. You will see a summary of your old/custom-made device details. Click on the **Discard** button:

Old/custom-made device N-	5454 baDX
< <u>Go back to the list</u> Old/custom-made device data	Create new version Discard
Version 2 [Current] See version history Last update date: 2025-03-3	1
UDI-DI/Device identifier:	N-5454_baDX
Issuing Entity:	EUDAMED
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Manufacturer SRN:	FR-MF-000004867
Manufacturer name:	Martin-Moreau & Fils.
Manufacturer address:	StreetNumW/<>?é,å/é-i~ò.ù-â_é+i@ðlù#ç\e/i″ü'EndStreetNum AddressActorW/<>?é,å/é-i~ò.ù-â_é+i@ðlù#ç\e/i″ü'End- Address POBoxW/<>?é,å/é-i~ò.ù-â_é+i@ðlù#ç\e/i″ü'-EndPOBox PostCodeW/<>?é,à/é-i~ò.ù-â_ê+i@ðlû#ç\e/i″ü'- EndPostCode CityW/<>?é,à/é-i~ò.ù-â_ê+i@ðlû#ç\e/i″ü'-EndCity
Basic UDI-DI code:	•
Issuing Entity:	
Device is custom-made:	Yes
Is it a System or Procedure Pack which is a Device in itself?:	No
Special device type:	No
Risk class:	Class IIa
Implantable:	No



NOTE

When discarding an old/custom-made device that has more than one version, all the versions of that old/custom-made device will be discarded.

4. Click **Yes** in the pop-up window:

Discard old/cu	stom-made device	* <u>Close</u>
Details of the old/custom-n the operation?	ade device will be discarded (lost). The ope	eration cannot be reverted. Do you want to finalise
Yes	Cancel	

When the old/custom-made device is discarded, a red banner will appear at the top of the *Old/custom-made device data* page:

Old/custom-made device N-5	5454_baDX
Co back to the list	
This old/custom-made device has been discarded Last u	pdate: 2025-03-31
Old/custom-made device data	
Version 2 [Current] See version history Last update date: 2025-03-3	1
UDI-DI/Device identifier:	N-5454_baDX
Issuing Entity:	EUDAMED
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Manufacturer SRN:	FR-MF-000004867
Manufacturer name:	Martin-Moreau & Fils.
Manufacturer address:	StreetNum\V/<>?é,à/ė-i~ò.ù-â_ê+î@ôlû#ç\e//°ŭ′-EndStreetNum AddressActor\V/<>?é,à/è-i~ò.ù-â_ê+î@ôlû#ç\e//°ü′-End- Address POBox\V/<>?é,à/è-i-ò.ù-â_ê+î@ôlû#ç\e/í°ü′-EndPOBox PostCode\V/<>?é,à/è-i~ò.ù-â_ê+î@ôlû#ç\e/í°ü′- EndPostCode City\V/<>?é,à/è-i~ò.ù-â_ê+î@ôlû#ç\e/i″ü′-EndCity
Basic UDI-DI code:	
Issuing Entity:	
Device is custom-made:	Yes
Is it a System or Procedure Pack which is a Device in itself?:	No
Special device type:	No
Risk class:	Class IIa
Implantable:	No
Measuring function:	Yes

3.4 Edit a draft old/custom-made device

Follow the steps in the Manage your old/custom-made devices [6] section to view a draft old/custom-made device.

1. Select the desired old/custom-made device and click on *Edit data* under the three dots:

Old/custom-made devices management							
Filter 🔻						Register an o	ld/custom-made device
Active filters: State: Draft <u>Clear search</u>	I						
Showing 1 to 2 of 2 entries						Show 20	✓ entries per page
UDI-DI/Device identifier It	Device Name ↓†	Risk class	Applicable legislation	Trade name ↓†	Date 🔒	UDI-DI/Device status	State Actions
N-dev_ocm_ba1RL		-	MDR (REGULATION (EU) 2017/745 on medical devices)		-	-	• 1st Draft ····
5747547475	et353	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)	3525gr	2025-02-14	On the EU market	 <u>View data</u> Edit data
Alternatively, o	click on	View	data under the three do	ots:			

Old/custom-ı	made dev	vices r	management				
Filter T						Register an	old/custom-made device
Active filters: State: Draft Clear search							
Showing 1 to 2 of 2 entries UDI-DI/Device identifier	Device Name	Risk class	Applicable legislation	Trade name It	Date 🔒	Show 20 UDI-DI/Device status	entries per page State Actions
Showing 1 to 2 of 2 entries UDI-DI/Device identifier If N-dev_ocm_ba1RL	Device Name 41	Risk class	Applicable legislation MDR (REGULATION (EU) 2017/745 on medical devices)	Trade name ↓†	Date 🖺	Show 20 UDI-DI/Device status	entries per page State Actions Ist Draft ···

The Old/custom-made device data page is displayed. Click on the Edit button:

Old/custom-made device N-dev_ocm_ba1RL				
Co back to the list	Edit Delete			
UDI-DI/Device identifier:	N-dev_ocm_ba1RL			
Issuing Entity:	EUDAMED			
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)			
Manufacturer SRN:	FR-MF-000004867			
Manufacturer name:	Martin-Moreau & Fils.			
Manufacturer address:	StreetNum-\V/<>?é,à/é-i~ò.ù-â_ê+î@ôlû#ç/a/"ü'-EndStreetNum AddressActor-\V/<>?é,à/é-i~ò.ù-â_ê+i@ôlû#ç/a/"ü'-End- Address POBox-\V/<>?é,à/é-i~ò.ù-â_ê+i@ôlû#ç/a/"ü'-EndPOBox PostCode\V/<>?é,à/é-i~ò.ù-â_ê+i@ôlû#ç/a/"ü'- EndPostCode City\V/<>?é,à/é-i~ò.ù-â_ê+i@ôlû#ç/a/"ü'-EndCity			
Basic UDI-DI code:				
Issuing Entity:	- ·			
Device is custom-made:	· ·			
Is it a System or Procedure Pack which is a Device in itself?:	No			
Risk class:	· ·			
Implantable:				
Measuring function:	·			
Reusable surgical instruments:	-			
Active device:	·			
Device intended to administer and/or remove medicinal product:				
Device Model:				
Name:				
Trade name:	•			

2. Update the desired fields.



NOTE

Refer to the table in the Step 1: Old/custom-made device information [3] section to see which fields you can edit based on the *Applicable legislation* of your draft old/custom-made device.

3.5 Delete a draft old/custom-made device

Follow the steps in the Manage your old/custom-made devices [6] section to view a draft old/custom-made device.

1. Select the desired old/custom-made device and click on *View data* under the three dots:

Old/custom-i	made dev	vices r	management				
Filter 🔻						Register an o	old/custom-made device
Active filters: State: Draft Clear searce	h						
Showing 1 to 2 of 2 entries						Show 20	✓ entries per page
UDI-DI/Device identifier It	Device Name ∔t	Risk class	Applicable legislation	Trade name ∔t	Date 11	UDI-DI/Device status	State Actions
N-dev_ocm_ba1RL		-	MDR (REGULATION (EU) 2017/745 on medical devices)		-	-	• 1st Draft 🛛 •••
5747547475	et353	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)	3525gr	2025-02-14	On the EU market	 <u>View data</u> Edit data

2. The Old/custom-made device data page is displayed. Click on the **Delete** button:

Old/custom-made device N-dev_ocm_ba1RL				
Go back to the list				
	Edit Delete			
UDI-DI/Device identifier:	N-dev_ocm_ba1RL			
Issuing Entity:	EUDAMED			
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)			
Manufacturer SRN:	FR-MF-000004867			
Manufacturer name:	Martin-Moreau & Fils.			
Manufacturer address:	StreetNum\// é,à/ė-i~ò.ù-â_ê+i@ðlü#ç\e/i″ü′EndStreetNum AddressActor\//<?é,à/è-i~ò.ù-â_ê+i@ðlü#ç\e/i″ü′End-<br Address POBox\// é,à/è-i~ò.ù-â_ê+i@ðlü#ç\e/i″ü′EndPOBox PostCode\//<?é,à/è-i~ò.ù-â_ê+i@ðlû#ç\e/i″ü′<br EndPostCode City\// é,à/è-i~ò.ù-â_ê+i@ðlû#ç\e/i″ü′EndCity</td			
Basic UDI-DI code:				
Issuing Entity:				
Device is custom-made:	·			
Is it a System or Procedure Pack which is a Device in itself?:	No			
Risk class:	•			
Implantable:				
Measuring function:	·			
Reusable surgical instruments:	-			
Active device:				
Device intended to administer and/or remove medicinal product:	•			
Device Model:	·			
Name:				
Trade name:	· ·			

playground

NOTE A yellow banner appears w made device:	hen viewing a draft version of the selected old/custom-
Old/custom-made device 574	7547475
▲ Go back to the list	
Old/custom-made device data	Edit Delete
Version 2 [Draff] Last update date: 🗮 2025-02-14	
UDI-DI/Device identifier:	5747547475
Issuing Entity:	ICCBBA
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Manufacturer SRN:	FR-MF-000004867
Manufacturer name:	Martin-Moreau & Fils.
Manufacturer address:	StreetNum-W é,á/é-i~ô,ù-á_é+i@0lů#çie/ï'ű-EndStreetNum AddressActor-W<?é,á/é-i~ô,ù-á_é+i@0lů#çie/ïŭ-End-<br Address POBox-W é,á/é-i~ô,ù-á_é+i@0lů#çie/ïŭ-EndPOBox PostCode-W<?é,á/é-i~ô,ù-á_é+i@0lů#çie/ïŭ-<br EndPostCode City-W é,á/é-i~ô,ù-â_é+i@0lů#çie/ïŭ-EndCity</th
Basic UDI-DI code:	4364375ZB
Issuing Entity:	GS1
Device is custom-made:	Yes
Is it a System or Procedure Pack which is a Device in itself?:	No
Special device type:	No
Risk class:	Class IIa
Implantable:	No

3. Click **Confirm** in the pop-up window to delete the draft old/custom-made device:

*CI Delete old/custom-made device Delete the Draft version of the old/custom-made device?				
Yes	Cancel			

Playground

