EUDAMED user guide

Registration of Old/custom-made 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.

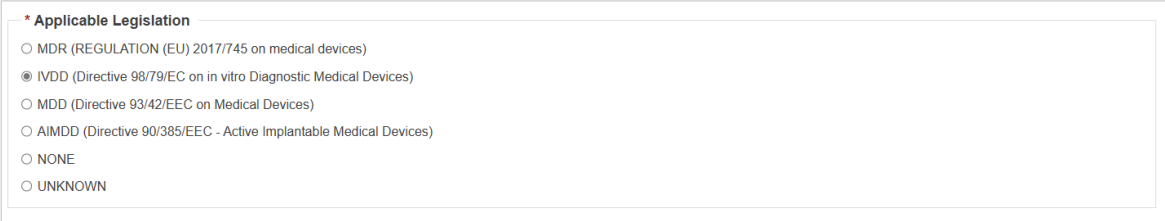
Custom-made Device: Any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use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

2 Registering old/custom-made devices

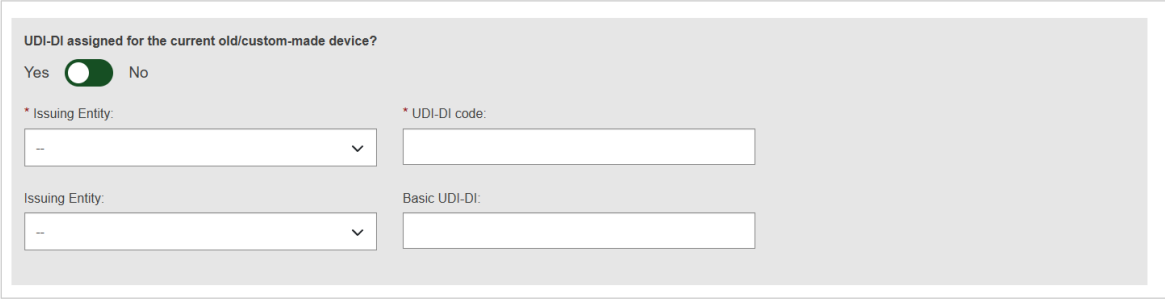
2.1 Step 0: Old/custom-made device registration

1. On the dashboard, click on *Register an old/custom-made device*.

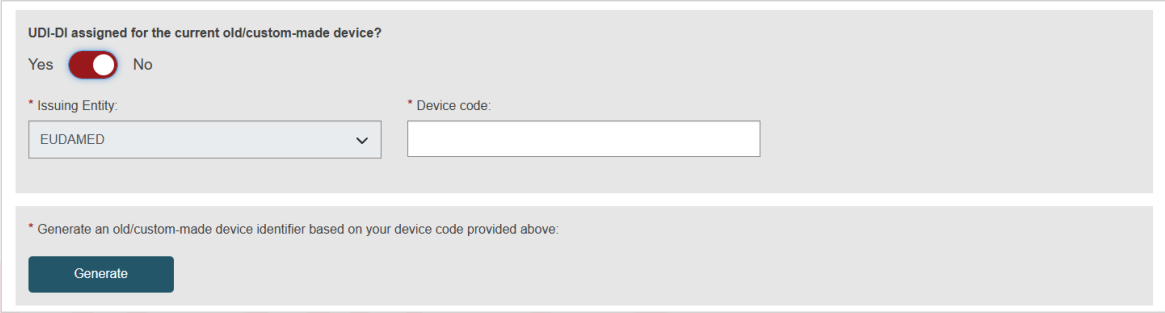
2. Select the applicable legislation:



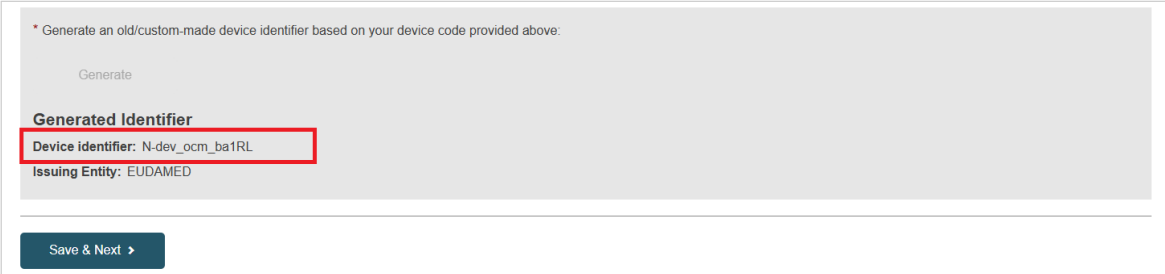
3. If a UDI-DI is assigned, toggle the button to *Yes* and provide the *Issuing Entity* and the *UDI-DI code*:



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



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



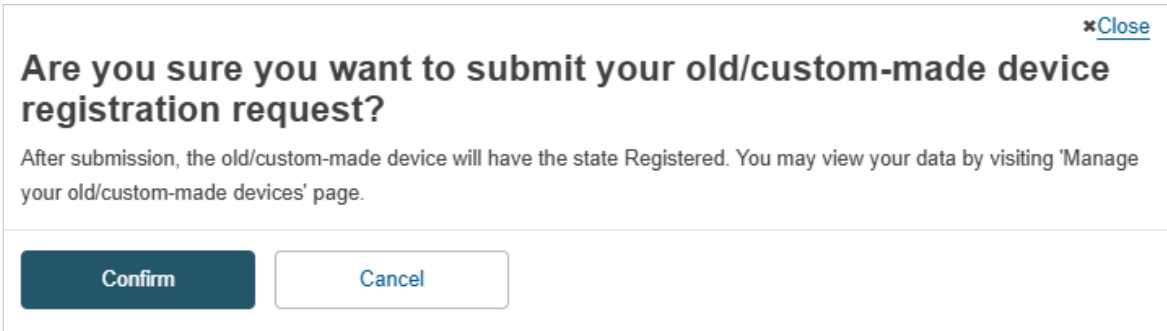
2.2 Step 1: Old/custom-made device information

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:



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

The following table summarises the displayed fields per applicable legislation.

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

Legislation/ Fields	**MDR**	**IVDD**	**MDD**	**AIMDD**	**NONE**	**UNKNOWN**
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 *No* is selected for the *Is it a kit* 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	✓	✓	✓	✓		
Implantable	✓		✓	✓		
Measuring function	✓		✓	✓		
Reusable surgical instruments	✓		✓	✓		
Active device	✓		✓	✓		
Device intended to administer and/or remove medicinal product	✓		✓	✓		
Near-patient testing		✓				
Self-patient testing		✓				
Companion diagnostic		✓				
Reagent		✓				
Instrument		✓				
Professional testing		✓				
Device model	✓	✓	✓	✓	✓	✓
Device name	✓	✓	✓	✓	✓	✓
Trade name	✓	✓	✓	✓	✓	✓
Select the language	✓	✓	✓	✓	✓	✓
Reference/Catalogue number	✓	✓	✓	✓	✓	✓
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	✓	✓
Device labelled as sterile	✓	✓	✓	✓	✓	✓
Presence of human tissues or cells, or their derivatives	✓	✓	✓	✓	✓	✓
Intended purpose other than medical (Annex XVI)	✓					
Presence of substance which, if used separately, may be considered to be a medical product	✓		✓	✓		
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	✓	✓	✓	✓	✓	✓

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.

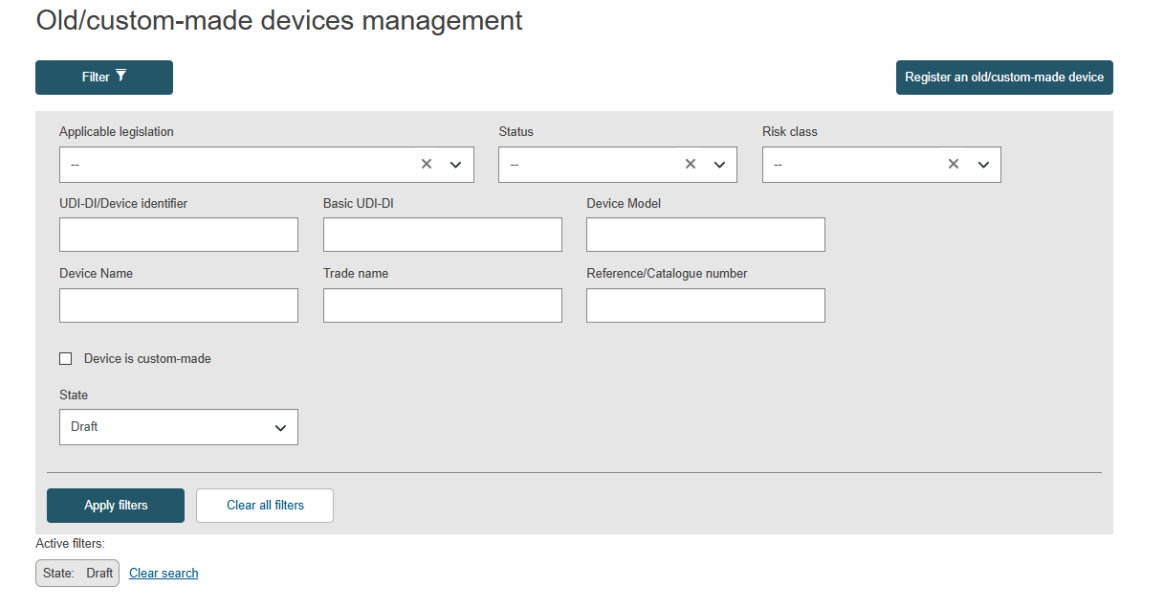
NOTE

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/custom-made 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:

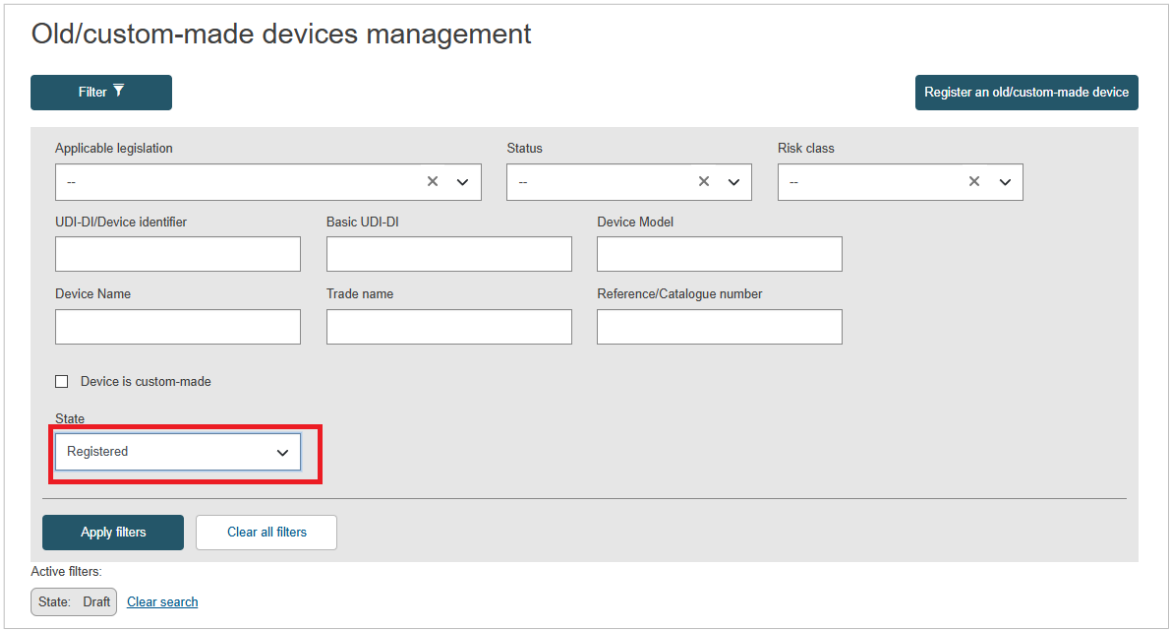


NOTE
By default, the system lists the old/custom-made devices in *draft* state. To retrieve other states use the filters.

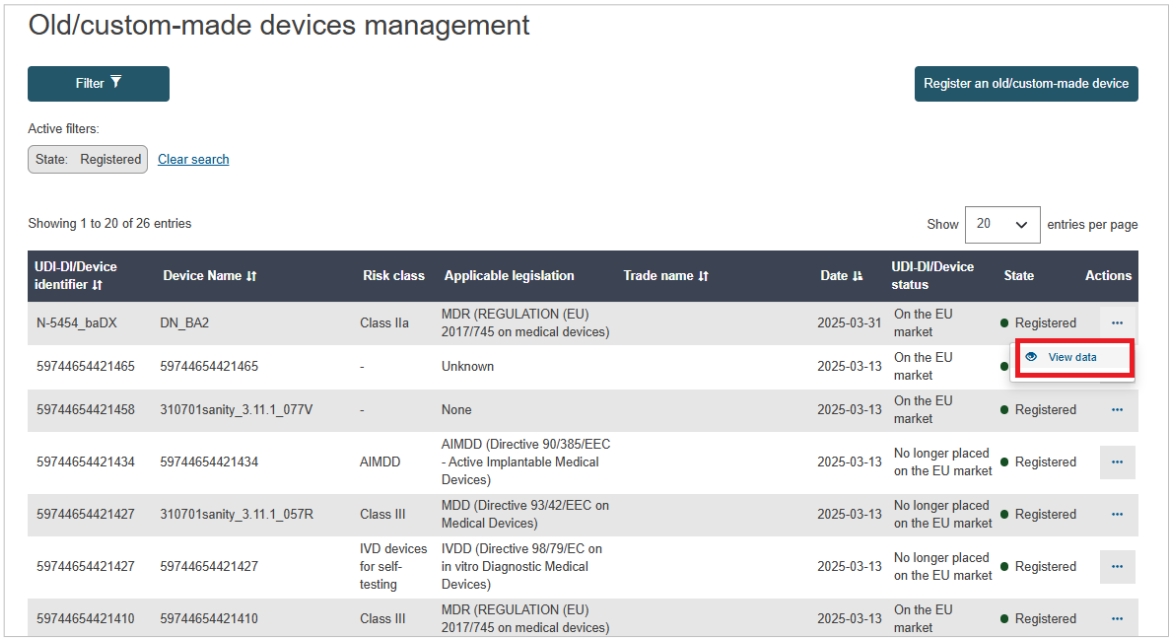
3.1 Create a new version of an old/ custom-made device

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:

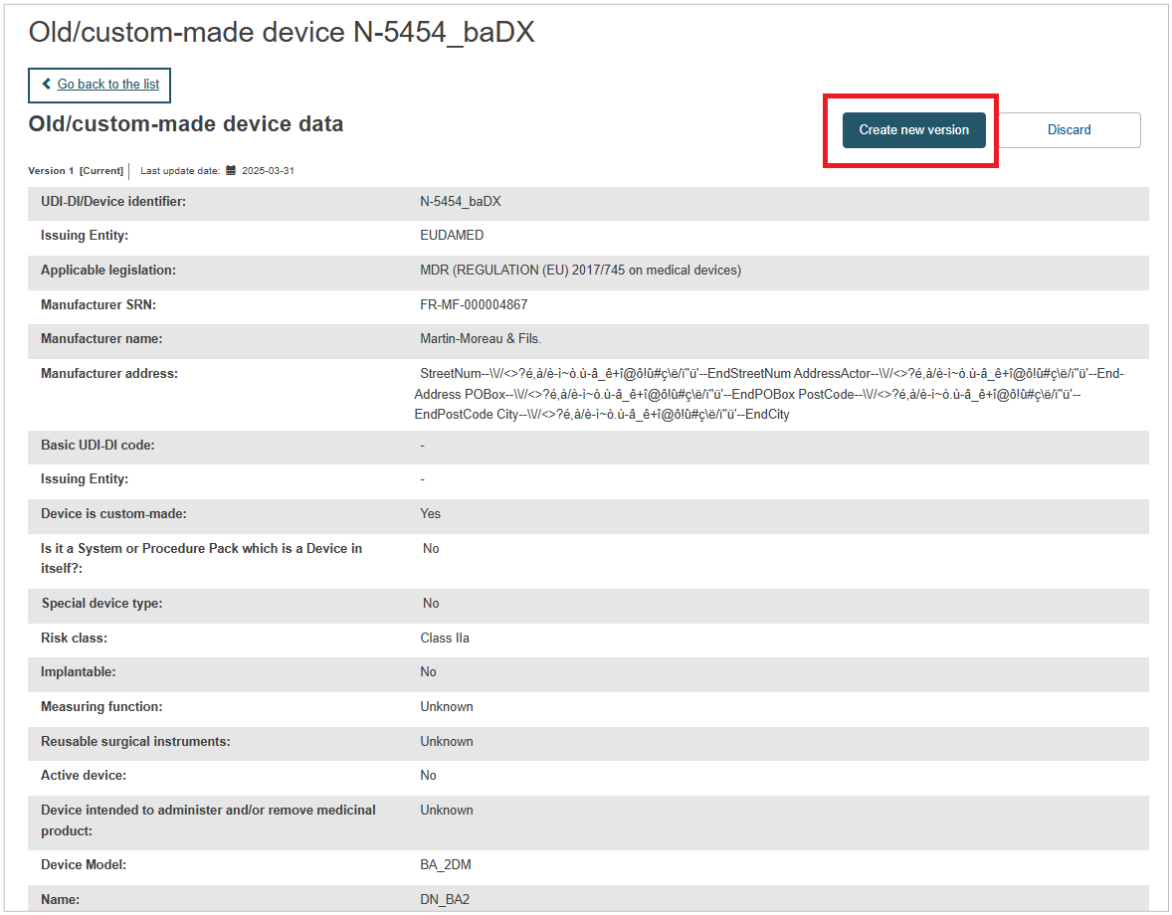


2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:

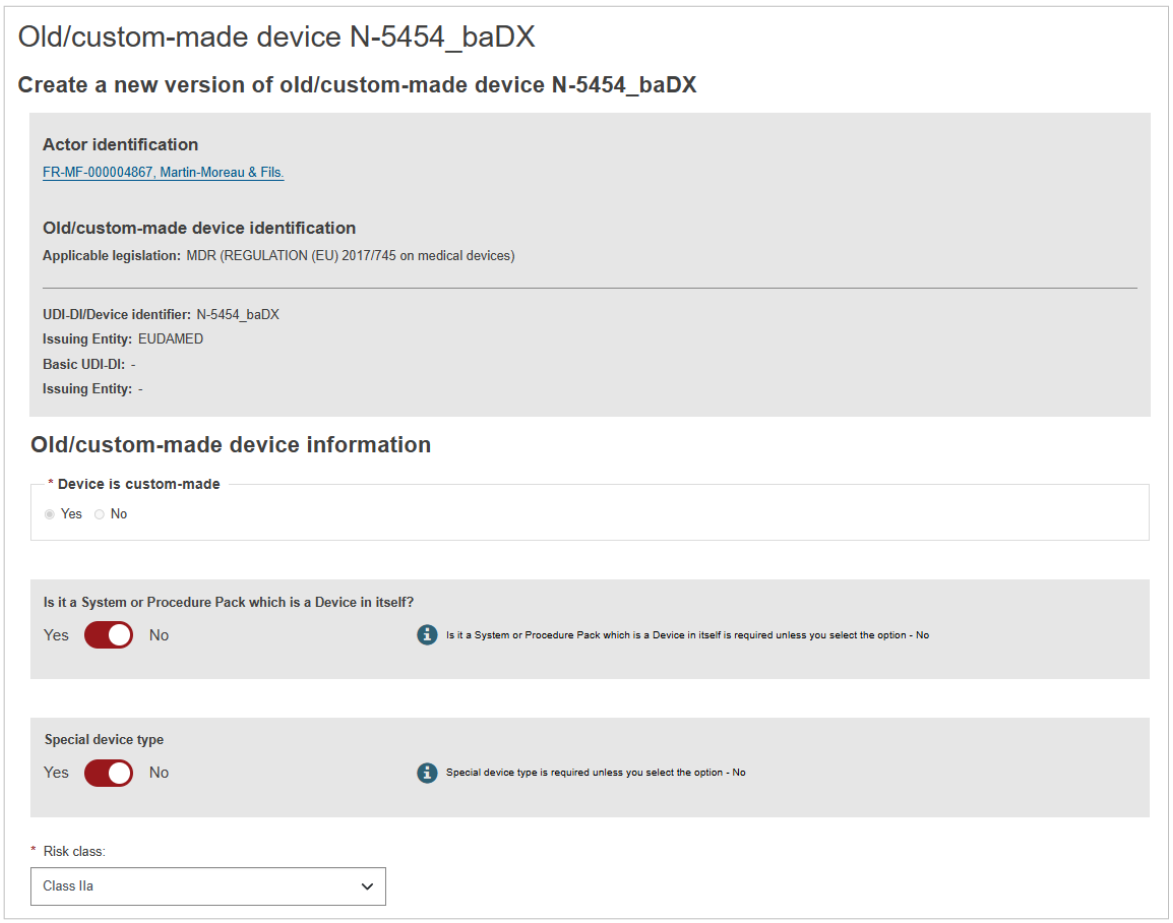


UDI-DI/Device identifier	Device Name	Risk class	Applicable legislation	Trade name	Date	UDI-DI/Device status	State	Actions
N-5454_baDX	DN_BA2	Class IIa	MDR (REGULATION (EU) 2017/745 on medical devices)		2025-03-31	On the EU market	Registered	...
59744654421465	59744654421465	-	Unknown		2025-03-13	On the EU market		
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:



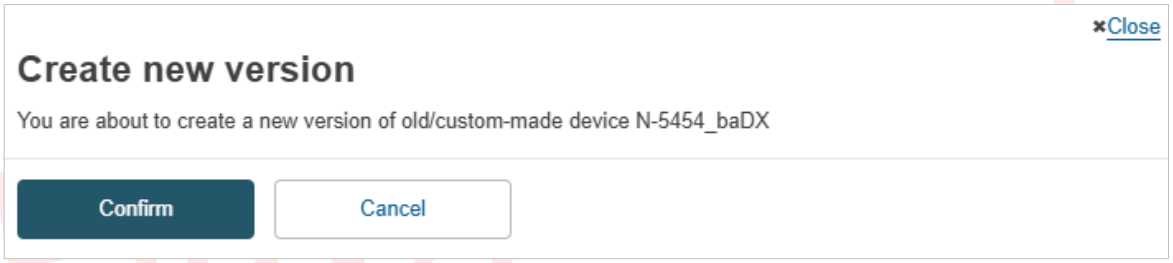
4. On the next screen, there are some fields that are not editable:



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:

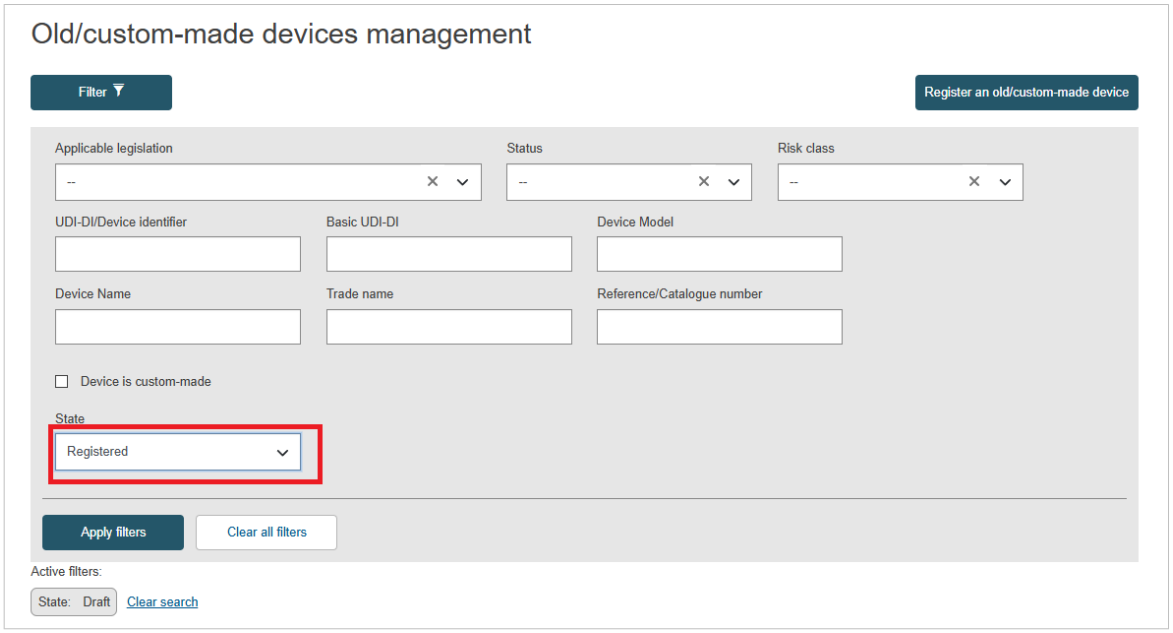
7. A pop-up window is displayed. Click **Confirm** to create a new version of the old/ custom-made device:



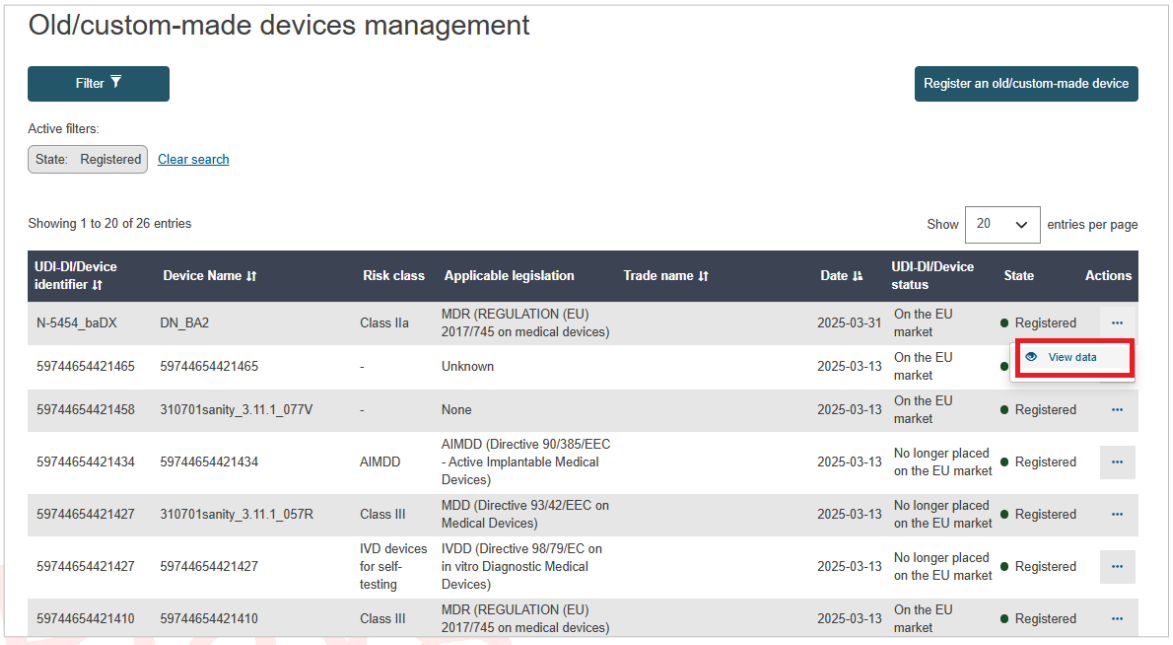
3.2 View historical versions of an old/ custom-made device

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:

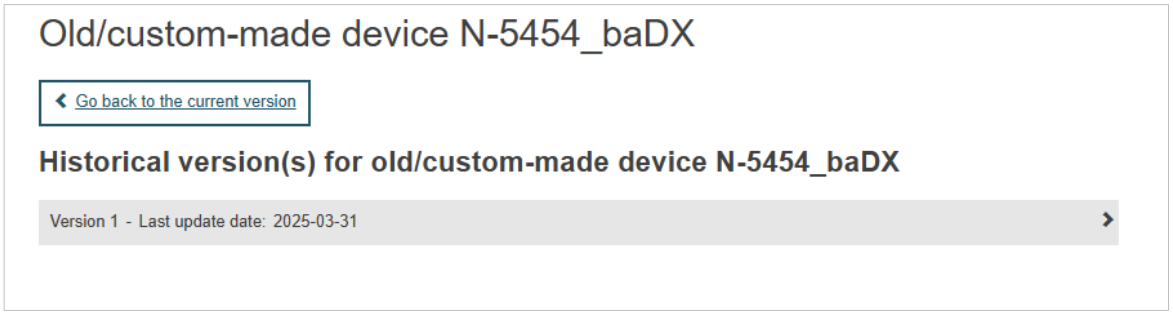


2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:

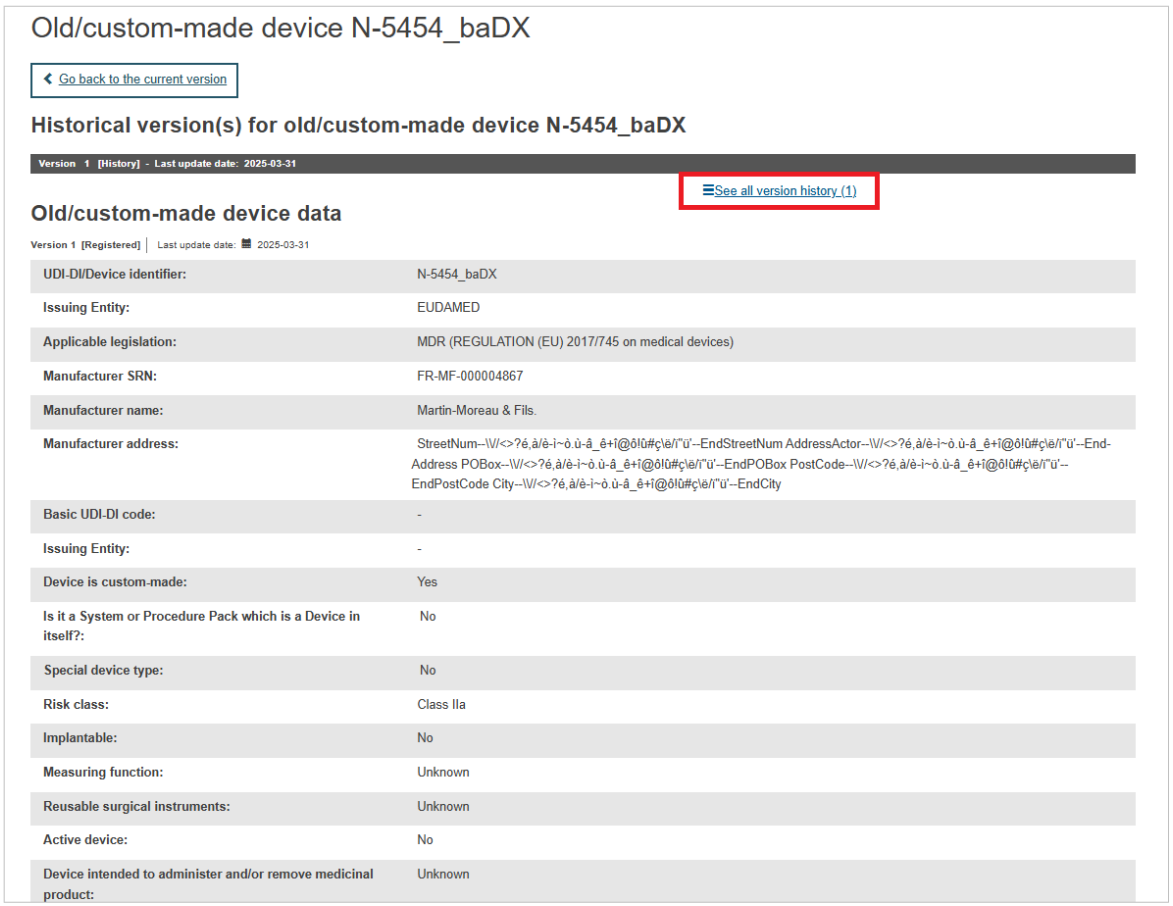


3. Click the *See version history* link:

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



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

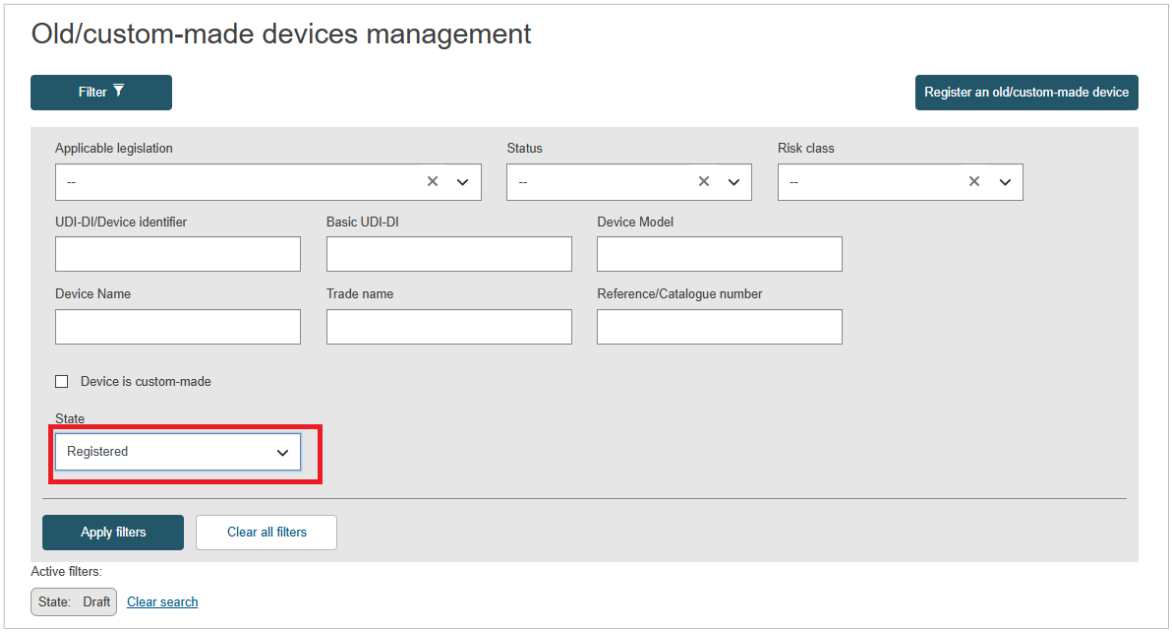


NOTE
You can navigate to the existing versions of the old/custom-made device by either clicking on the *See all version history* link or the *Next version* link at the top of the page.

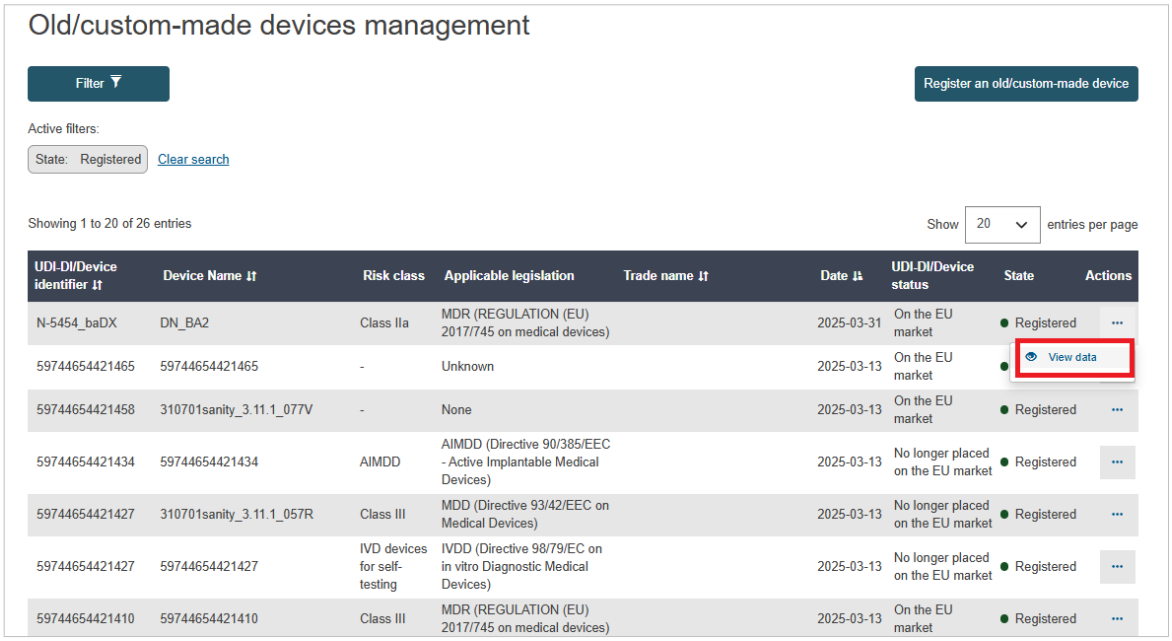
3.3 Discard a registered old/custom-made device

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:

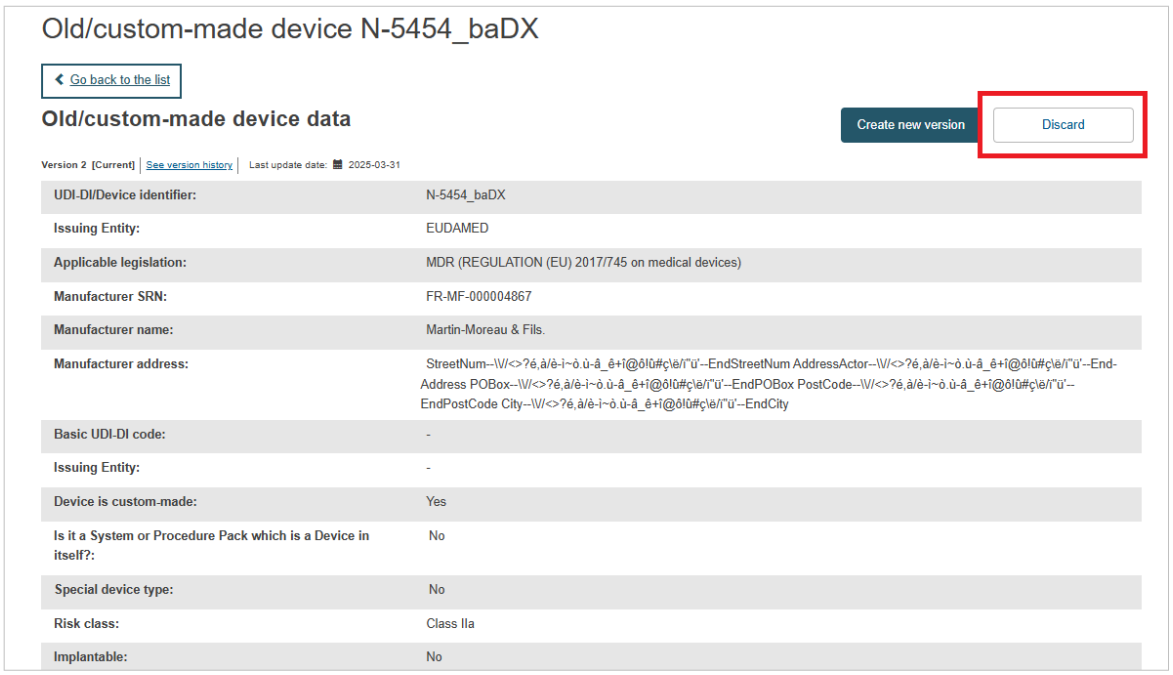


2. A list of old/custom-made devices will be displayed. Click on *View data* under the three dots of the desired entry:



UDI-DI/Device identifier	Device Name	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		
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	...

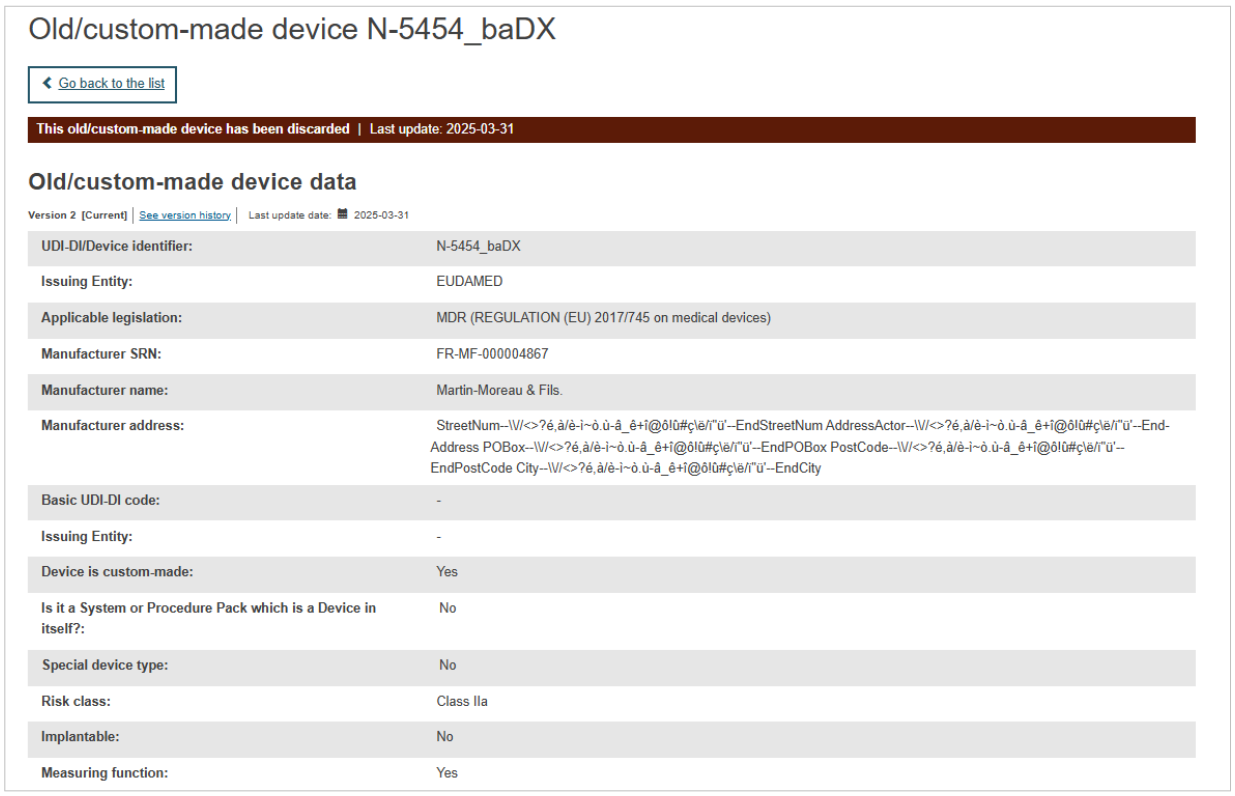
3. You will see a summary of your old/custom-made device details. Click on the **Discard** button:



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:

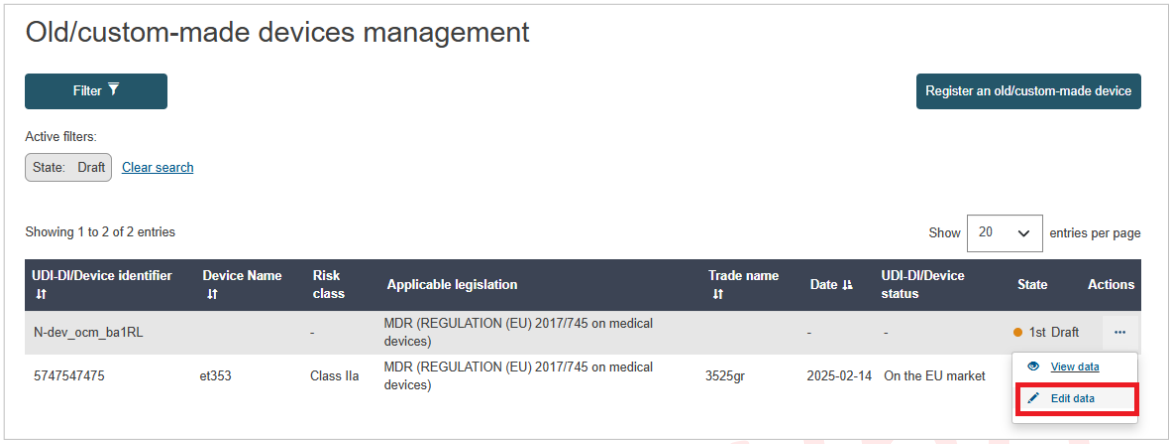
When the old/custom-made device is discarded, a red banner will appear at the top of the *Old/custom-made device data* page:



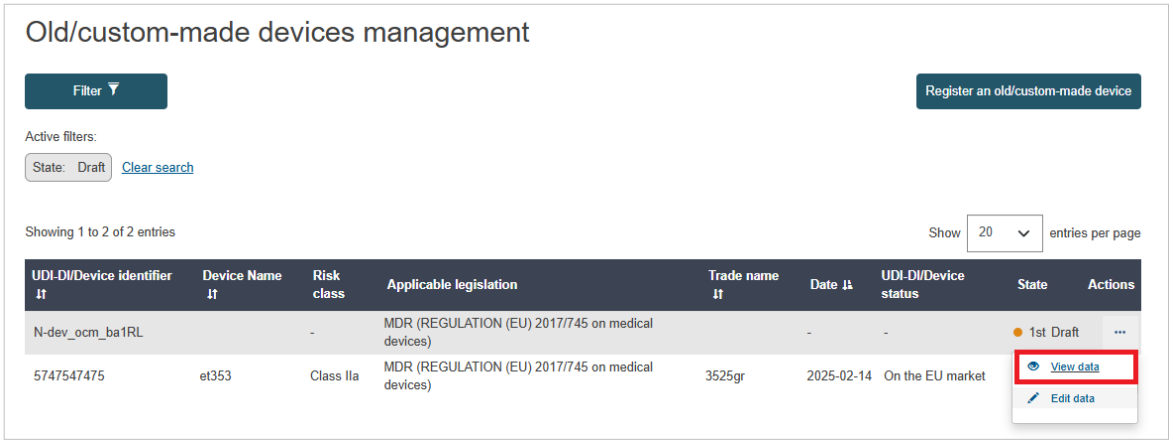
3.4 Edit a draft old/custom-made device

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

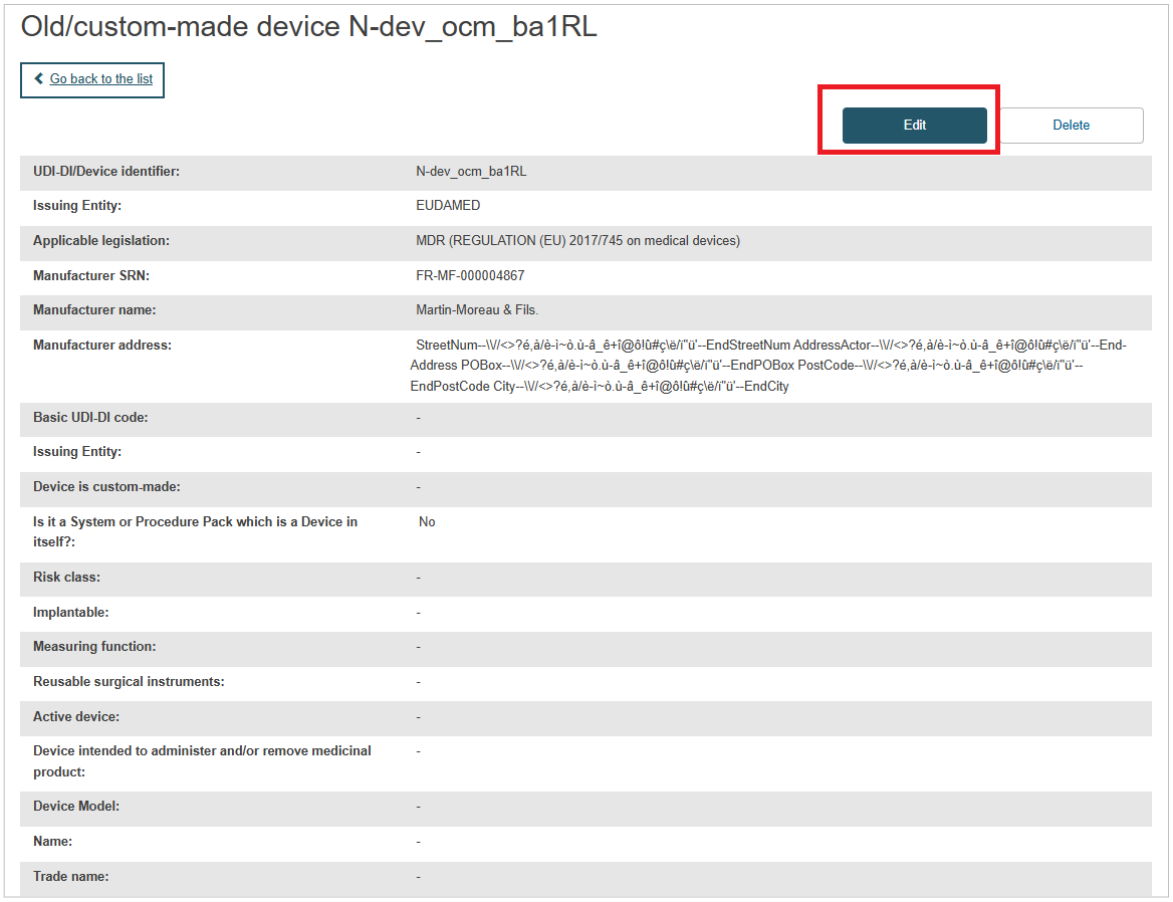
1. Select the desired old/custom-made device and click on *Edit data* under the three dots:



Alternatively, click on *View data* under the three dots:



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



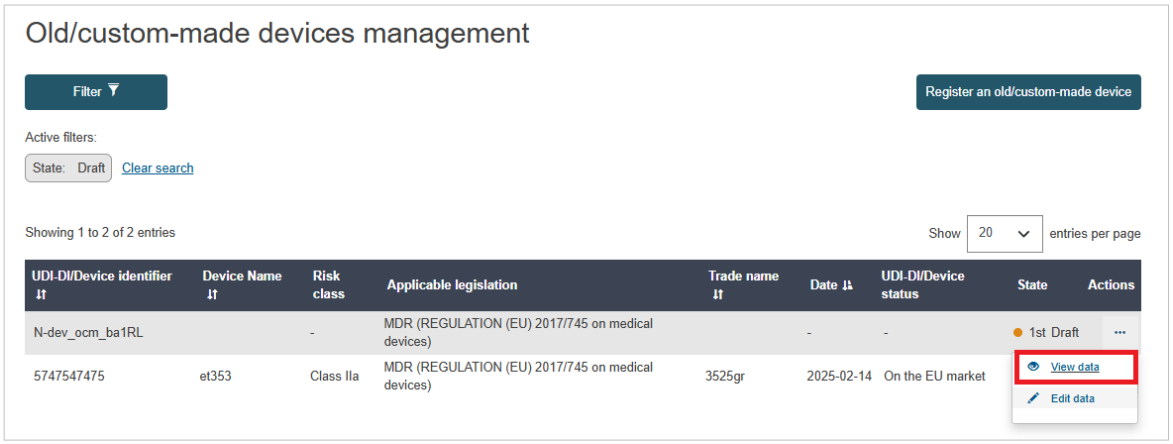
2. Update the desired fields.

> **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.

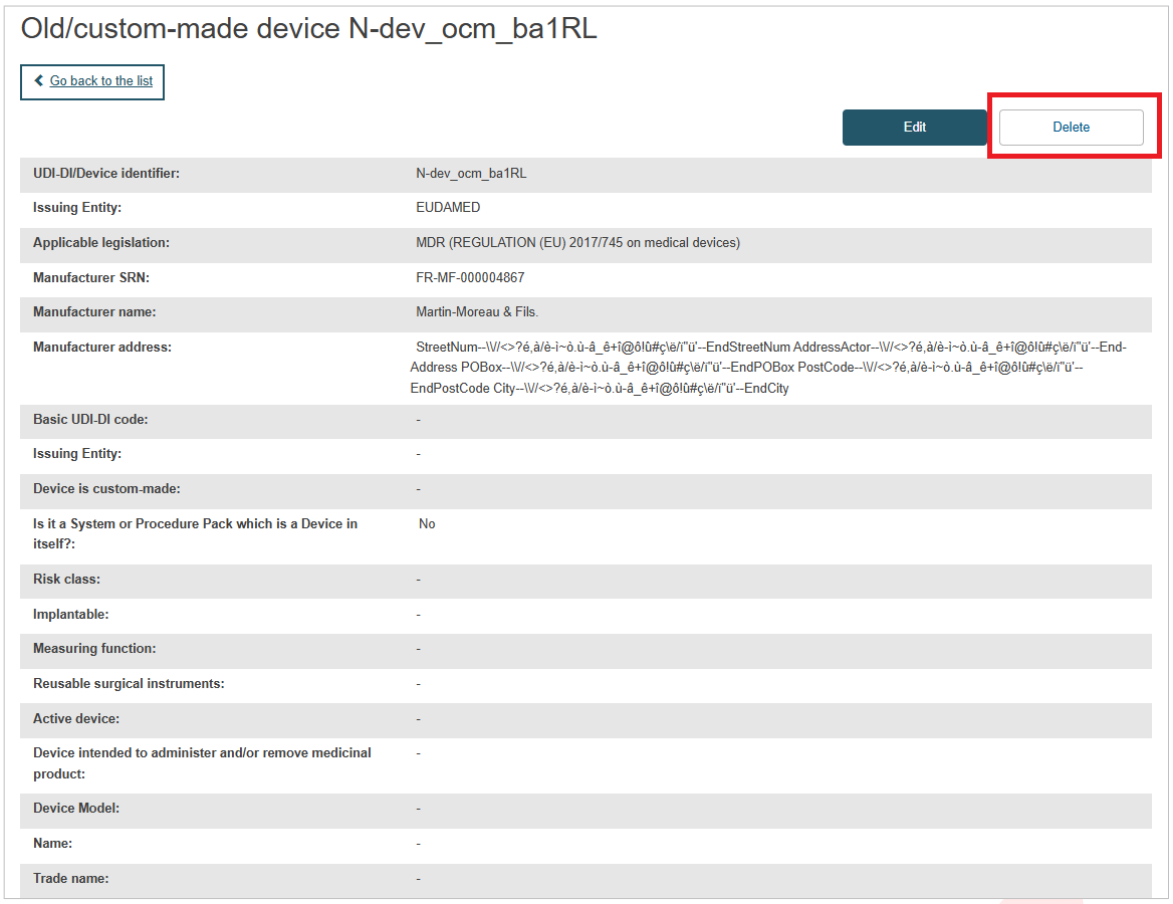
3.5 Delete a draft old/custom-made device

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

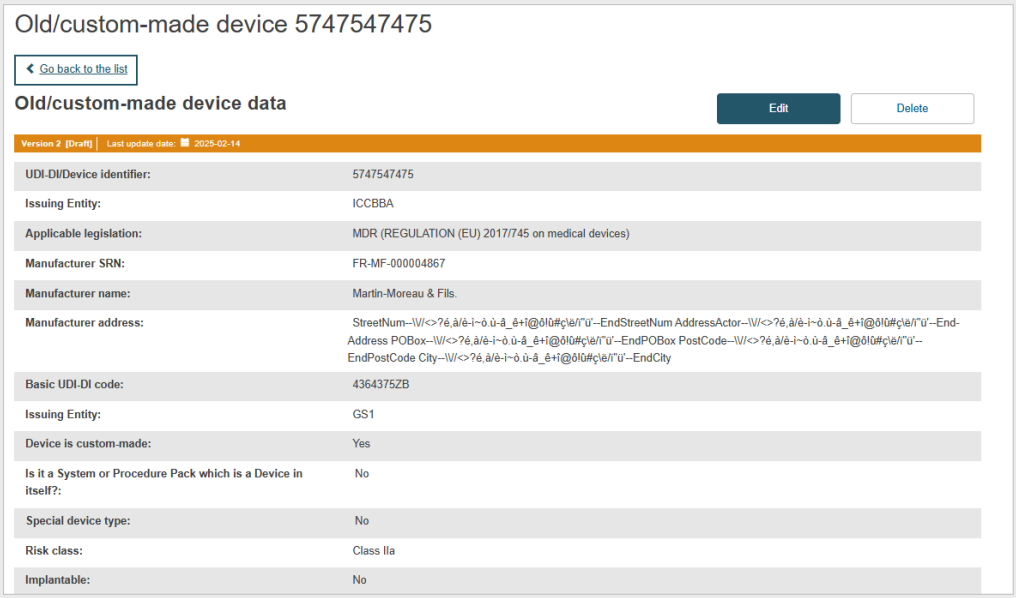
1. Select the desired old/custom-made device and click on *View data* under the three dots:



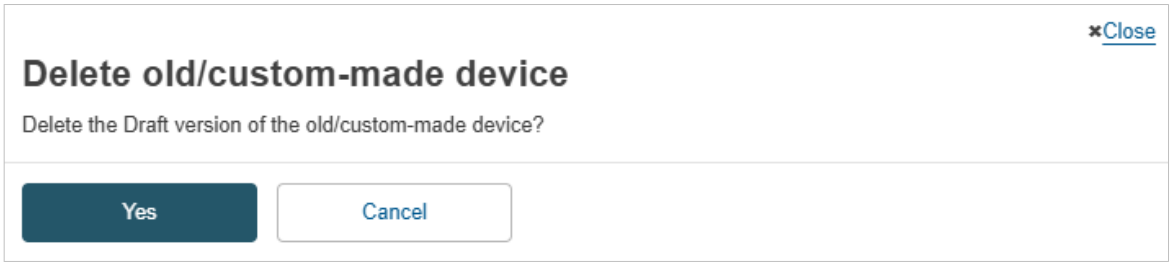
2. The *Old/custom-made device data* page is displayed. Click on the **Delete** button:



NOTE
A yellow banner appears when viewing a draft version of the selected old/custom-made device:



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

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