



EUDAMED user guide

Registration of Old/custom-made devices in the Vigilance module

Playground v 3.27.2
2026

ground

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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 dossiers.



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.

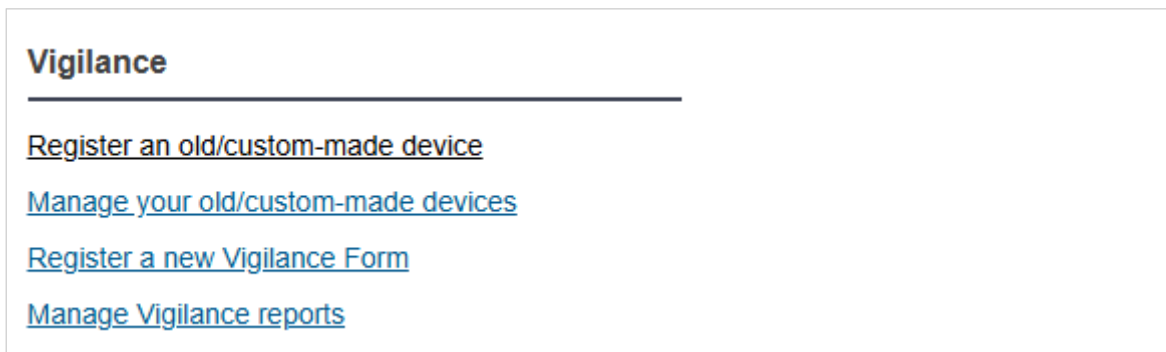
Custom-made Device: Any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use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

Playground

2 Register 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*:



Vigilance

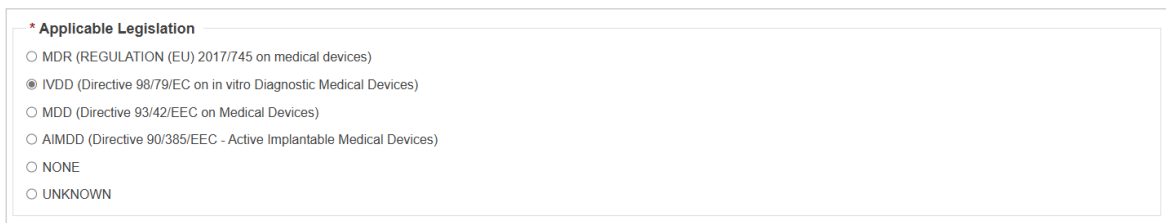
[Register an old/custom-made device](#)

[Manage your old/custom-made devices](#)

[Register a new Vigilance Form](#)

[Manage Vigilance reports](#)

2. Select the applicable legislation:



*** Applicable Legislation**

MDR (REGULATION (EU) 2017/745 on medical devices)

IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)

MDD (Directive 93/42/EEC on Medical Devices)

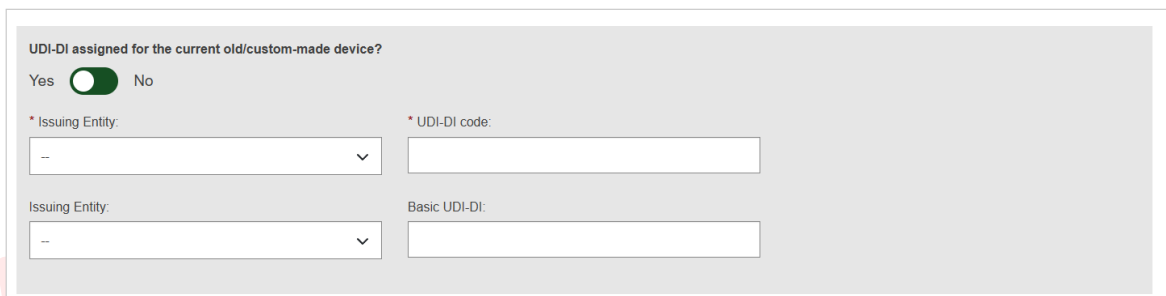
AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

NONE

UNKNOWN

3. **UDI-DI or Device identifier assignment**

If a UDI-DI has been 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 has not been assigned, toggle the button to *No* and enter the *Device code*.

Click **Generate** to generate the *Device identifier*.

UDI-DI assigned for the current old/custom-made device?

Yes No

* Issuing Entity: * Device code:

* Generate an old/custom-made device identifier based on your device code provided above:

4. Click **Save & Next** to continue:

* Generate an old/custom-made device identifier based on your device code provided above:

Generated Identifier

Device identifier: N-dev_ocm_ba1RL

Issuing Entity: EUDAMED



NOTE

In case of an OCM with a generated device identifier, its reference will always start with the prefix “N-”.

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 **Submit**:

3. Click **Confirm** in the pop-up window 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

Cancel

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 | | ✓ | | | | |
| Special device type | ✓ Mandatory if No is selected for the <i>Is it a System or Procedure Pack which is a Device in itself?</i> field | ✓ Mandatory if No is selected for the <i>Is it a kit</i> field | ✓ Mandatory if No is selected for the <i>Is it a System or Procedure Pack which is a Device in itself?</i> field | ✓ Mandatory if No is selected for the <i>Is it a System or Procedure Pack which is a Device in itself?</i> 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 <i>No longer placed on the EU market</i> and non-editable if No is selected for the <i>Device is custom-made</i> field | ✓ Set to <i>No longer placed on the EU market</i> and non-editable if No is selected for the <i>Device is custom-made</i> field | ✓ Set to <i>No longer placed on the EU market</i> and non-editable if No is selected for the <i>Device is custom-made</i> field | ✓ | ✓ |
| Device labelled as sterile | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Presence of human tissues or cells, or their derivatives | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Intended purpose other than medical (Annex XVI) | ✓ | | | | | |

| Legislation/ Fields | MDR | IVDD | MDD | AIMDD | NONE | UNKNOWN |
|---|-----|------|-----|-------|------|---------|
| 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 is no longer 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

* Device is custom-made

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.

Playground

3 Manage your old/custom-made devices

1. Click on *Manage your old/custom-made devices*:

Vigilance

[Register an old/custom-made device](#)

[Manage your old/custom-made devices](#)

[Register a new Vigilance Form](#)

[Manage Vigilance reports](#)

2. On the *Old/custom-made devices management* page, select your search criteria and click on **Apply filters** to view the results:

Old/custom-made devices management

Filter
Register an old/custom-made device

Applicable legislation
--

Status
--

Risk class
--

UDI-DI/Device identifier

Basic UDI-DI

Device Model

Device Name

Trade name

Reference/Catalogue number

Device is custom-made

State

Apply filters
Clear all filters

Active filters:

State:
[Clear search](#)



NOTE

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

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Applicable legislation: -- × ▼ Status: -- × ▼ Risk class: -- × ▼

UDI-DI/Device identifier: Basic UDI-DI: Device Model:

Device Name: Trade name: Reference/Catalogue number:

Device is custom-made

State: Registered ▼

Apply filters Clear all filters

Active filters: State: Draft [Clear search](#)

2. On the list of old/custom-made devices displayed, click on *View data* under the three dots of the relevant entry:

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Active filters: State: Registered [Clear search](#)

Showing 1 to 20 of 26 entries Show entries per page

| UDI-DI/Device identifier <small>††</small> | Device Name <small>††</small> | Risk class | Applicable legislation | Trade name <small>††</small> | Date <small>††</small> | 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 | Registered | View data |
| 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. In the summary of your old/custom-made device details, click on **Create new version**:

Playground

Old/custom-made device N-5454_baDX

[Go back to the list](#)

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-00004867 |
| Manufacturer name: | Martin-Moreau & Fils. |
| Manufacturer address: | StreetNum--\ <>?é,â/è-i-ò.ù-â_ê+i@ôïü#ç/ë/ï"ü"--EndStreetNum AddressActor--\ <>?é,â/è-i-ò.ù-â_ê+i@ôïü#ç/ë/ï"ü"--EndAddress POBox--\ <>?é,â/è-i-ò.ù-â_ê+i@ôïü#ç/ë/ï"ü"--EndPOBox PostCode--\ <>?é,â/è-i-ò.ù-â_ê+i@ôïü#ç/ë/ï"ü"--EndPostCode City--\ <>?é,â/è-i-ò.ù-â_ê+i@ôïü#ç/ë/ï"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:

Playground

Old/custom-made device N-5454_baDX

Create a new version of old/custom-made device N-5454_baDX

Actor identification
[FR-MF-000004867, Martin-Moreau & Fils](#)

Old/custom-made device identification
 Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)

UDI-DI/Device 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:

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

Save **Submit new version >** Cancel

- In the pop-up window, click **Confirm** to create a new version of the old/custom-made device:

[✕Close](#)

Create new version

You are about to create a new 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 **Apply filters**:

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Applicable legislation: -- × ▼ Status: -- × ▼ Risk class: -- × ▼

UDI-DI/Device identifier: Basic UDI-DI: Device Model:

Device Name: Trade name: Reference/Catalogue number:

Device is custom-made

State: Registered ▼

Apply filters Clear all filters

Active filters: State: Draft [Clear search](#)

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

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Active filters: State: Registered [Clear search](#)

Showing 1 to 20 of 26 entries Show entries per page

| UDI-DI/Device identifier <small>††</small> | Device Name <small>††</small> | Risk class | Applicable legislation | Trade name <small>††</small> | Date <small>††</small> | 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 | Registered | View data |
| 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. Click *See version history*:

Old/custom-made device N-5454_baDX

[← Go 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,â/è-î-ò.ù-â_ê+i@ôlû#çlê/l'ü"--EndStreetNum AddressActor--\ <>?é,â/è-î-ò.ù-â_ê+i@ôlû#çlê/l'ü"--EndAddress POBox--\ <>?é,â/è-î-ò.ù-â_ê+i@ôlû#çlê/l'ü"--EndPOBox PostCode--\ <>?é,â/è-î-ò.ù-â_ê+i@ôlû#çlê/l'ü"--EndPostCode City--\ <>?é,â/è-î-ò.ù-â_ê+i@ôlû#çlê/l'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 |

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

Old/custom-made device N-5454_baDX

[← Go back to the current version](#)

Historical version(s) for old/custom-made device N-5454_baDX

Version 1 - Last update date: 2025-03-31 [>](#)

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

Playground

Old/custom-made device N-5454_baDX

[← Go back to the current version](#)

Historical version(s) for old/custom-made device N-5454_baDX


Version 1 [History] - Last update date: 2025-03-31

[See all version history \(1\)](#)

Old/custom-made device data

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,â/é-ï-ò.ù-â_ê+i@òlù#çlè/l'ü--EndStreetNum AddressActor-\\ <>?é,â/é-ï-ò.ù-â_ê+i@òlù#çlè/l'ü--End-Address POBox-\\ <>?é,â/é-ï-ò.ù-â_ê+i@òlù#çlè/l'ü--EndPOBox PostCode-\\ <>?é,â/é-ï-ò.ù-â_ê+i@òlù#çlè/l'ü--EndPostCode City-\\ <>?é,â/é-ï-ò.ù-â_ê+i@òlù#çlè/l'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 |

 **NOTE** You can navigate between 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 **Apply filters**:

Playground

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Applicable legislation: -- × ▼ Status: -- × ▼ Risk class: -- × ▼

UDI-DI/Device identifier: Basic UDI-DI: Device Model:

Device Name: Trade name: Reference/Catalogue number:

Device is custom-made

State: Registered ▼

Apply filters Clear all filters

Active filters: State: Draft [Clear search](#)

- On the old/custom-made devices list displayed, click **View data** under the three dots of the relevant entry:

Old/custom-made devices management

Filter ▼ Register an old/custom-made device

Active filters: State: Registered [Clear search](#)

Showing 1 to 20 of 26 entries Show entries per page

| 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 | Registered | View data |
| 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 | ... |

- Inside the summary of your old/custom-made device details, click **Discard**:

Playground

Old/custom-made device N-5454_baDX

[Go 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-00004867 |
| Manufacturer name: | Martin-Moreau & Fils. |
| Manufacturer address: | StreetNum--\ <>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç è/ï"ü"--EndStreetNum AddressActor--\ <>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç è/ï"ü"--EndAddress POBox--\ <>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç è/ï"ü"--EndPOBox PostCode--\ <>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç è/ï"ü"--EndPostCode City--\ <>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç è/ï"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 versions, all versions of that old/custom-made device will be discarded.

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

[*Close](#)

Discard old/custom-made device

Details of the old/custom-made device will be discarded (lost). The operation cannot be reverted. Do you want to finalise the operation?

Yes Cancel

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

Playground

Old/custom-made device N-5454_baDX

[Go back to the list](#)

This old/custom-made device has been discarded | Last update: 2025-03-31

Old/custom-made device data

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,â/è-ï-ò.ù-â_ê+i@ôlù#ç/è/ï"ü--EndStreetNum AddressActor--\ <>?é,â/è-ï-ò.ù-â_ê+i@ôlù#ç/è/ï"ü--End-Address POBox--\ <>?é,â/è-ï-ò.ù-â_ê+i@ôlù#ç/è/ï"ü--EndPOBox PostCode--\ <>?é,â/è-ï-ò.ù-â_ê+i@ôlù#ç/è/ï"ü--EndPostCode City--\ <>?é,â/è-ï-ò.ù-â_ê+i@ôlù#ç/è/ï"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 *Edit data* under the three dots:

Old/custom-made devices management

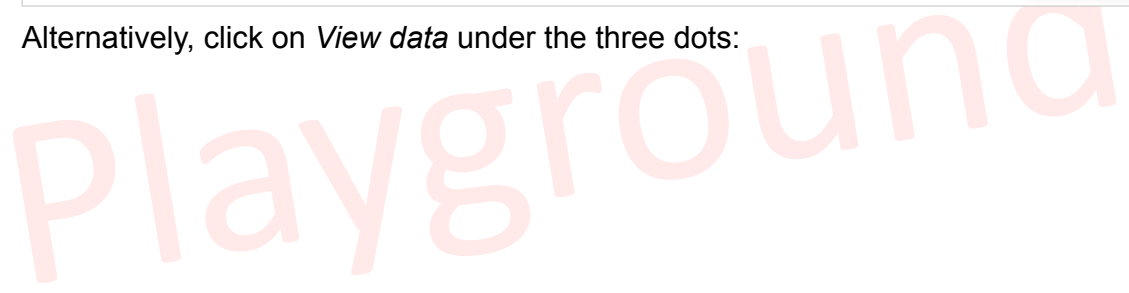
Filter Register an old/custom-made device

Active filters: State: Draft [Clear search](#)

Showing 1 to 2 of 2 entries Show 20 entries per page

| UDI-DI/Device identifier | 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 | | View data Edit data |

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



Old/custom-made devices management

Filter Register an old/custom-made device

Active filters: State: Draft [Clear search](#)

Showing 1 to 2 of 2 entries Show 20 entries per page

| UDI-DI/Device identifier It | Device Name It | Risk class | Applicable legislation | Trade name It | Date It | 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 | | View data Edit data |


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

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,â/è-i-ò.ù-â_ê+i@ôlû#ç)è/l"û"--EndStreetNum AddressActor--\ <>?é,â/è-i-ò.ù-â_ê+i@ôlû#ç)è/l"û"--End-Address POBox--\ <>?é,â/è-i-ò.ù-â_ê+i@ôlû#ç)è/l"û"--EndPOBox PostCode--\ <>?é,â/è-i-ò.ù-â_ê+i@ôlû#ç)è/l"û"--EndPostCode City--\ <>?é,â/è-i-ò.ù-â_ê+i@ôlû#ç)è/l"û"--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 relevant 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 relevant old/custom-made device and click **View data** under the three dots:

Old/custom-made devices management

Filter Register an old/custom-made device

Active filters: State: Draft [Clear search](#)

Showing 1 to 2 of 2 entries Show 20 entries per page

| UDI-DI/Device identifier | 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 | | View data Edit data |

2. On the *Old/custom-made device data* page, click **Delete**:

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/è-i-ò.ù-â_ê+i@ôlû#ç'è/l'ü--EndStreetNum AddressActor-\\/>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç'è/l'ü--End-Address POBox-\\/>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç'è/l'ü--EndPOBox PostCode-\\/>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç'è/l'ü--EndPostCode City-\\/>?é,à/è-i-ò.ù-â_ê+i@ôlû#ç'è/l'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: -

Playground



NOTE

An orange banner appears when viewing a draft version of the selected old/custom-made device:

Old/custom-made device 5747547475

[Go back to the list](#)

Old/custom-made device data Edit Delete

Version 2 [Draft] 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--\ <>?é.â/è-ï-ò.ù-â_ê+@0!0#ç!è/ï"Û--EndStreetNum AddressActor--\ <>?é.â/è-ï-ò.ù-â_ê+@0!0#ç!è/ï"Û--EndAddress POBox--\ <>?é.â/è-ï-ò.ù-â_ê+@0!0#ç!è/ï"Û--EndPOBox PostCode--\ <>?é.â/è-ï-ò.ù-â_ê+@0!0#ç!è/ï"Û--EndPostCode City--\ <>?é.â/è-ï-ò.ù-â_ê+@0!0#ç!è/ï"Û--EndCity |
| Basic UDI-DI code: | 43643752B |
| 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 finalise the deletion:

[*Close](#)

Delete old/custom-made device

Delete the Draft version of the old/custom-made device?

Yes Cancel

Playground

