EUDAMED user guide

Legacy Devices

Production v 2.14
2024

Table of Contents

1. Introduction 1

2. Identification details 2
   2.1. Generation of identification details for a Legacy Device when a UDI-DI already exists 2
   2.2. Generation of identification details for a Legacy Device when a UDI-DI does not exist 2

3. Registering Legacy Devices 4
   3.1. Step 1: EUDAMED DI identification information 4
   3.2. Step 2: Certificate information 6
   3.3. Step 3: Device identification information 7
   3.4. Step 4: Device characteristics 8
   3.5. Step 5: Device information 10

4. Management of Regulation Devices and Legacy Devices ... 15

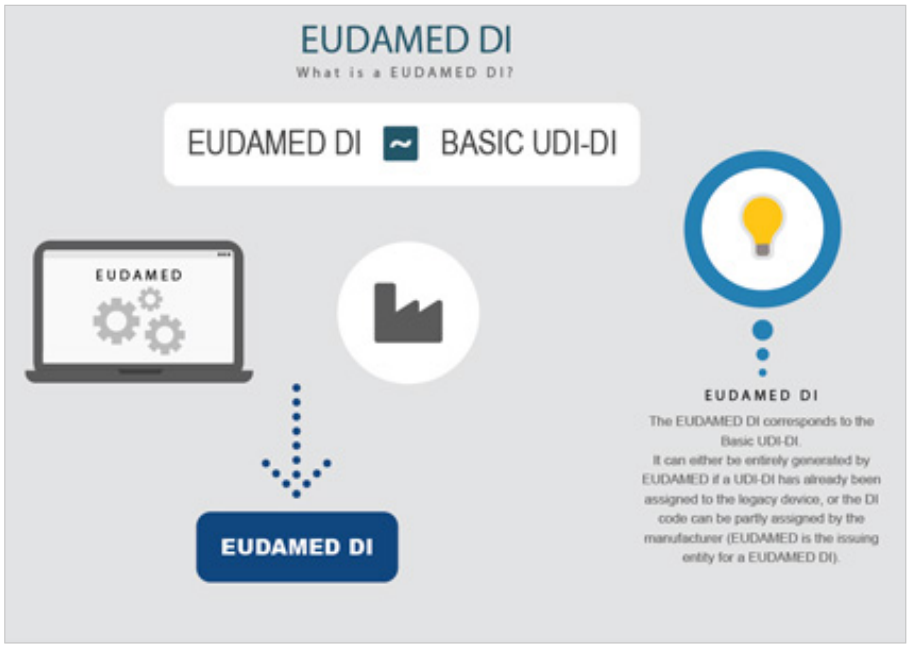
5. Linking the Regulation Devices to Legacy Devices 16

6. Annex – Legacy Device certificate types 17

1 Introduction

This document contains the details of how Legacy Devices are identified in EUDAMED and how you can register a Legacy Device in EUDAMED.[1]

INFOGRAPHIC: Identifiers of a legacy device



[1]For a wider understanding on how to use the platform, including FAQs and process infographics, visit the EUDAMED Information Centre. For information specific to UDI, visit the UDI Helpdesk.

2 Identification details

To keep the same standard structure and identification elements for all Devices registered in EUDAMED, an identification element EUDAMED DI (the equivalent of the Basic UDI-DI) will be required, and a EUDAMED ID (in case no UDI-DI has been assigned) will be generated from the EUDAMED DI.

2.1 Generation of identification details for a Legacy Device when a UDI-DI already exists

In case the manufacturer has already a UDI-DI assigned to a Legacy Device, they will be able to use it as a device identifier for the Legacy Device. In this case, the EUDAMED DI is automatically generated from the UDI-DI value.

The Legacy Device will therefore have the following identification elements: a EUDAMED DI (equivalent of the Basic UDI-DI and generated based on the UDI-DI) and a UDI-DI (provided by the manufacturer).

In order to generate the EUDAMED DI identification element from the UDI-DI provided, EUDAMED will use a standard format, placing the characters "**B-**" in front of the UDI-DI.

UDI-DI: **M991CVS12130NES2**

Generated EUDAMED DI: **B-M991CVS12130NES2**

2.2 Generation of identification details for a Legacy Device when a UDI-DI does not exist

In case the manufacturer does not have a UDI-DI assigned for a Legacy Device, the manufacturer will have to assign a EUDAMED DI and EUDAMED ID.

The EUDAMED DI will have a strict format, starting with 'B-' as a prefix and continuing with a set of characters. For further information on the EUDAMED DI format please consult the Format of the EUDAMED DI identification number document.

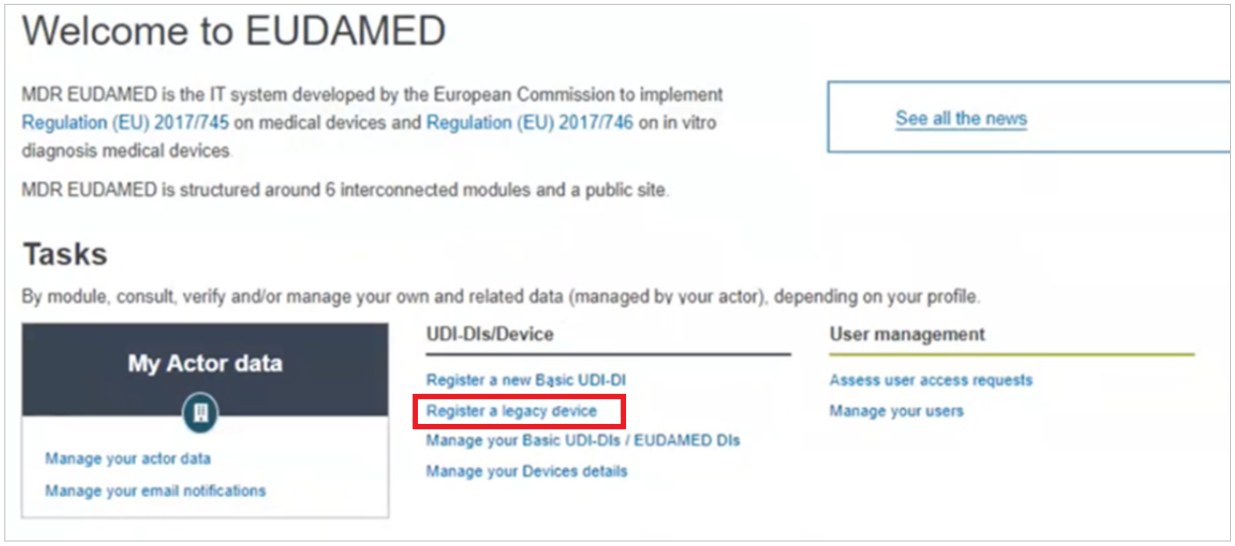
The EUDAMED ID will have the same format and value as EUDAMED DI except the first prefix character. It will start with 'D' instead of 'B'.

EUDAMED DI: **B-BEMF000000106CR023335WE**

EUDAMED ID: **D-BEMF000000106CR023335WE**

3 Registering Legacy Devices

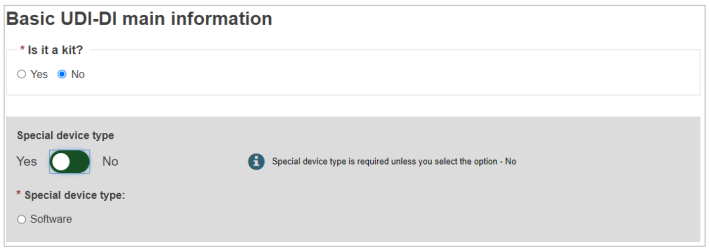
On the dashboard, click on *Register a Legacy device*:



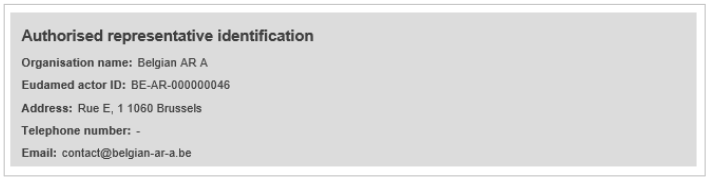
3.1 Step 1: EUDAMED DI identification information

1. Select the applicable legislation:

2. Select **Yes** or **No** to whether a UDI-DI is already assigned to the legacy device. If yes, enter the Issuing Entity and the UDI-DI code, and click **Generate**. EUDAMED will create a corresponding EUDAMED DI (the UDI-DI code with “B-“ as prefix).

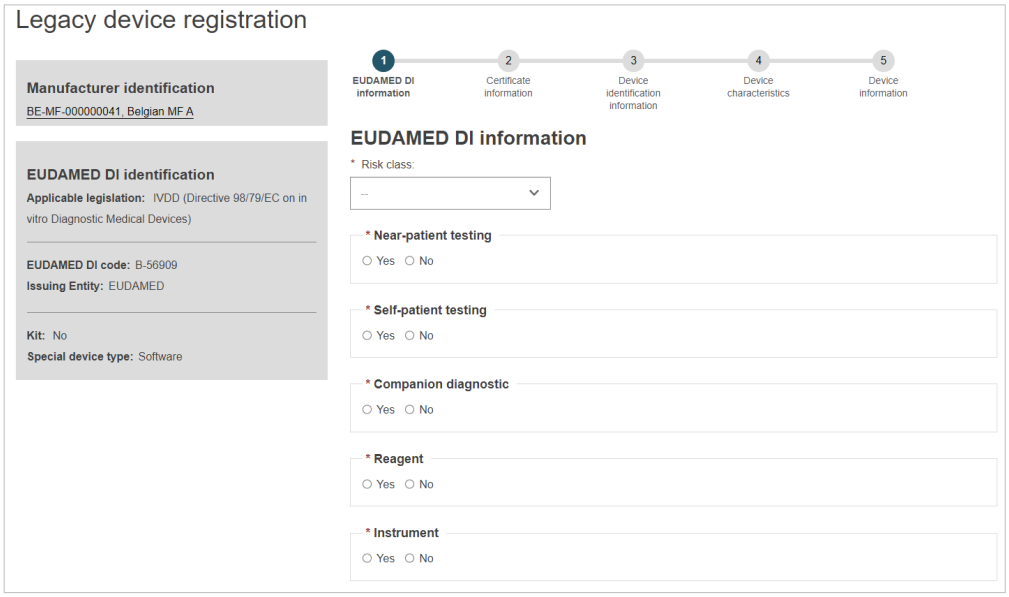


3. Non-EU manufacturers have to select the authorised representative (AR) for the current device from the options available.
If there is only one AR with an active Mandate with the manufacturer, it will be automatically retrieved:

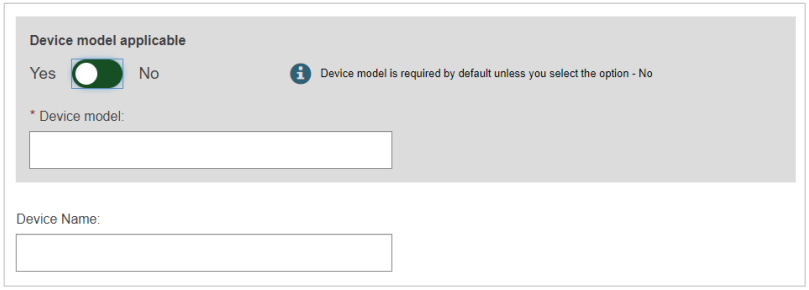


4. Click on **Save & Next** to save it as a draft and continue with the following steps:

5. On the left you will see a summary of the device characteristics.
Choose a *Risk class* from the list and select **Yes** or **No** for each of the options.



6. Select **Yes** or **No** if the device model is applicable and, if applicable, enter the Device model and enter a Device name if there is one, otherwise enter only a Device name:



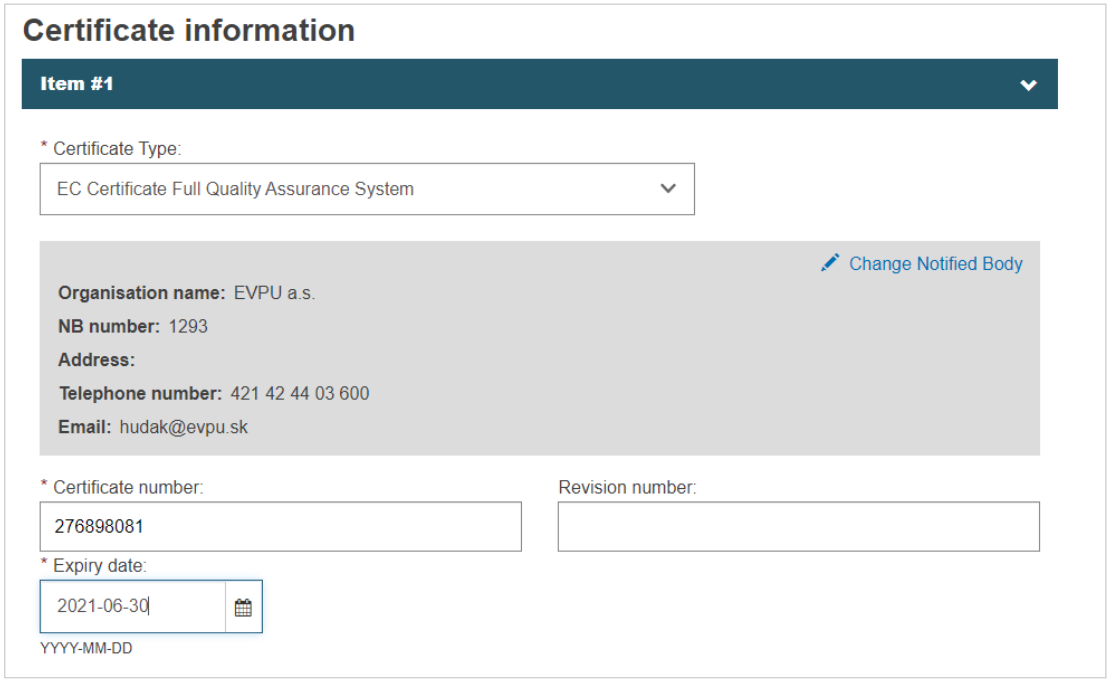
7. Click on **Save** to save your draft and complete it later, or **Save & Next** to save it as a draft and continue with the following steps:

3.2 Step 2: Certificate information

Select a certificate type, enter the NB number or name and click **Find**. Enter the *Certificate number* and *Expiry date*. If applicable, enter a *Revision number*.

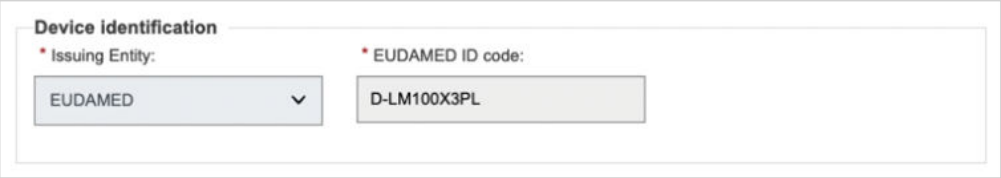
NOTE

Annex - Legacy Device Certificate Types [17] lists the certificate types for Legacy Devices.

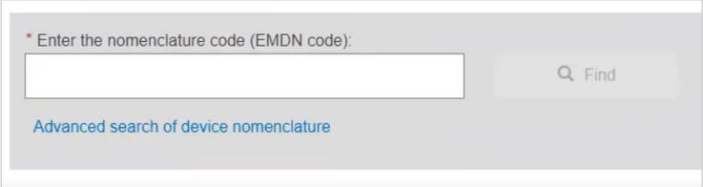


3.3 Step 3: Device identification information

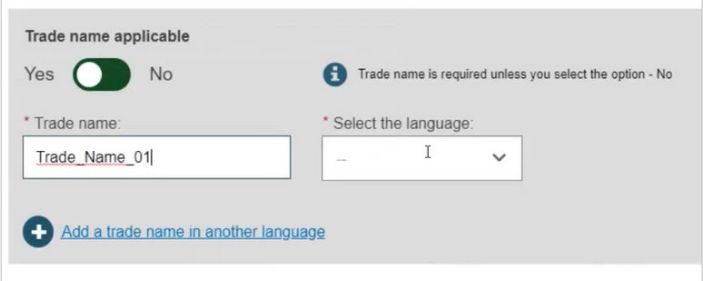
EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED **ID** generated based on the provided/generated EUDAMED **DI**. EUDAMED ID has the same code as the EUDAMED DI, except that it is with a "**D-**" prefix instead of the "**B-**" prefix):



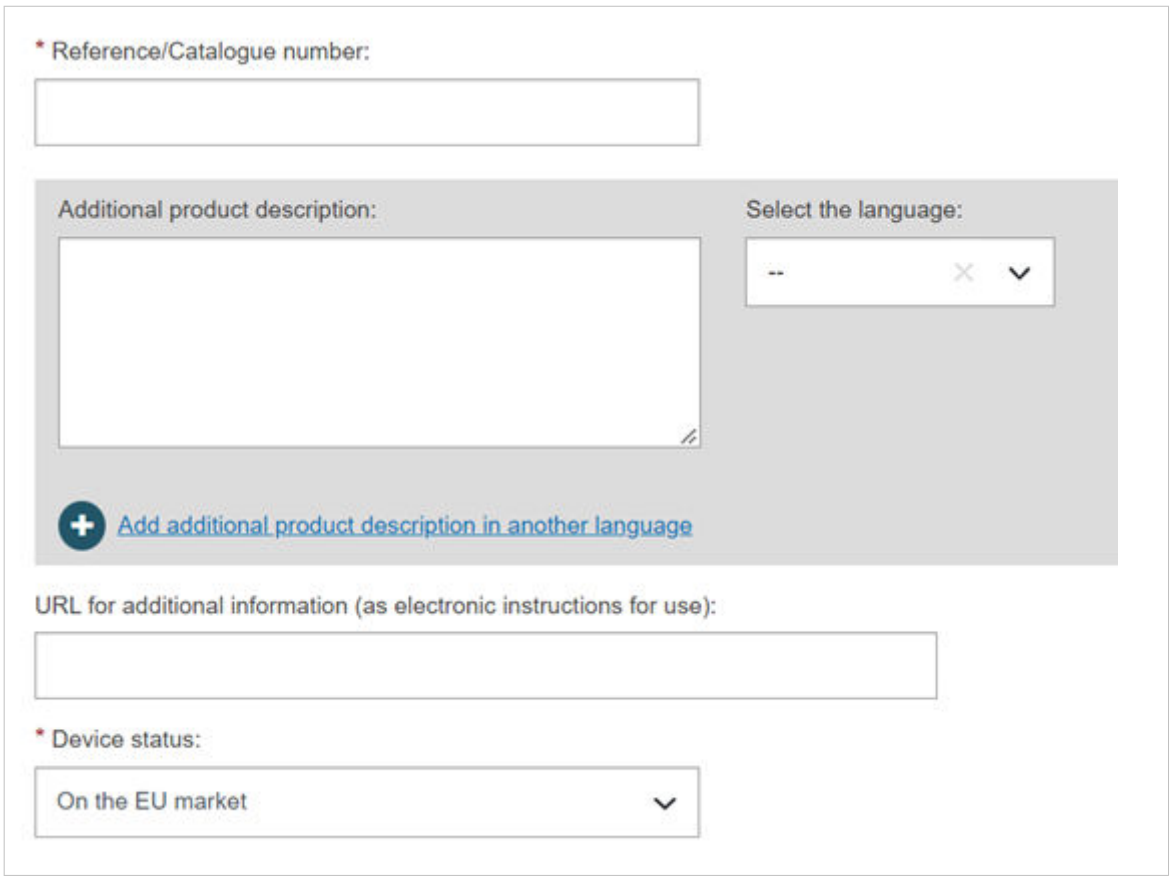
1. Enter the EMDN code. Click on **Find** and select the correct one:



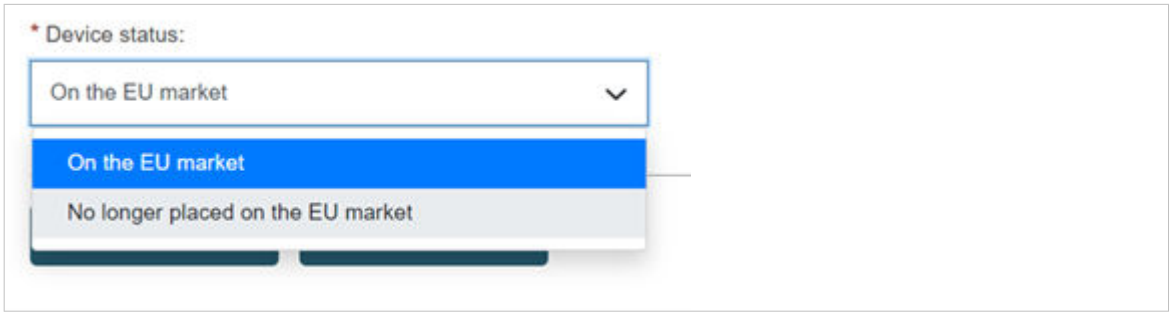
2. If applicable, enter the trade name and select the language, otherwise select **No**:



3. Enter a reference/catalogue number and any additional information you might have:

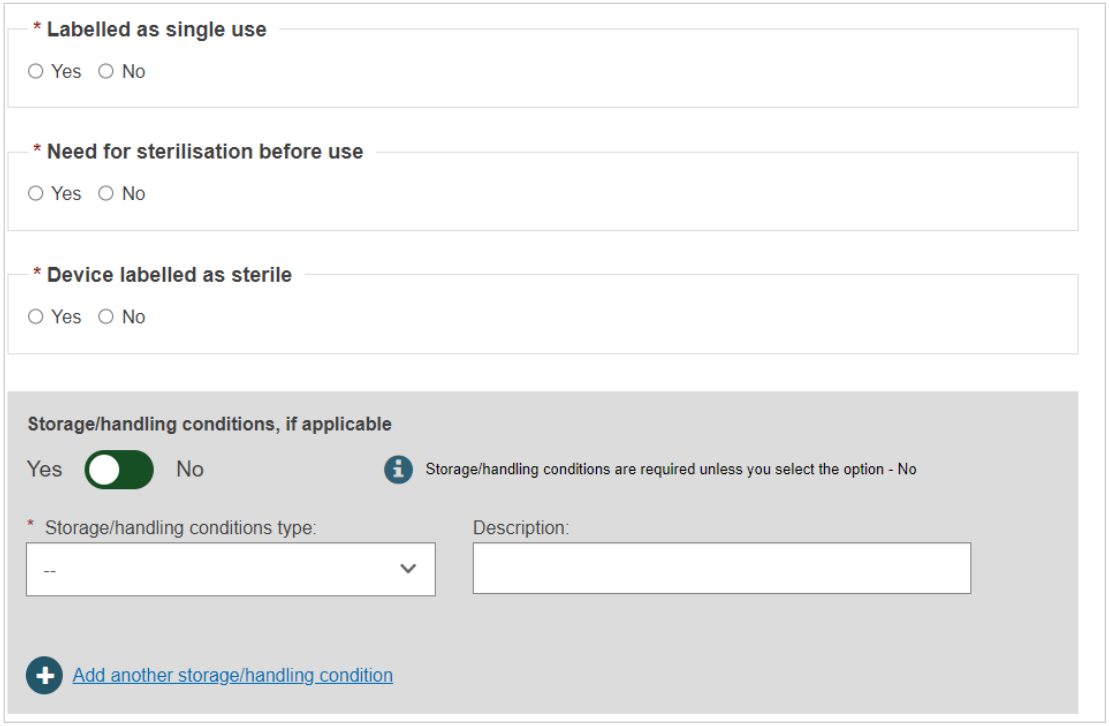


4. You can choose the market status of the Device:

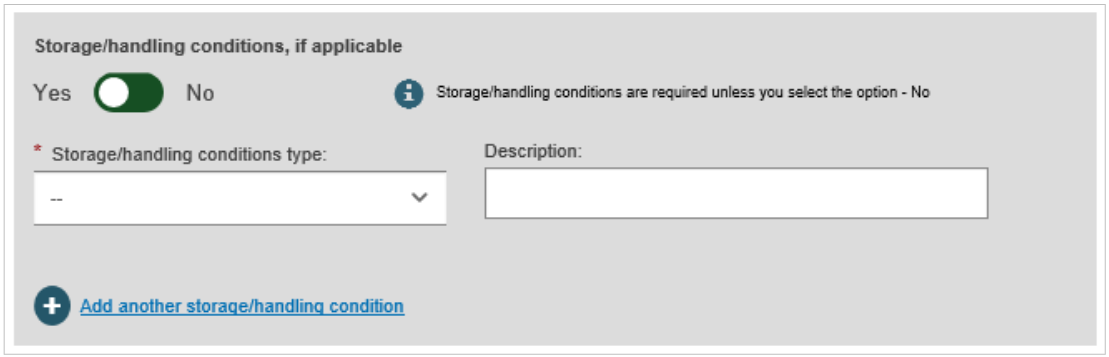


3.4 Step 4: Device characteristics

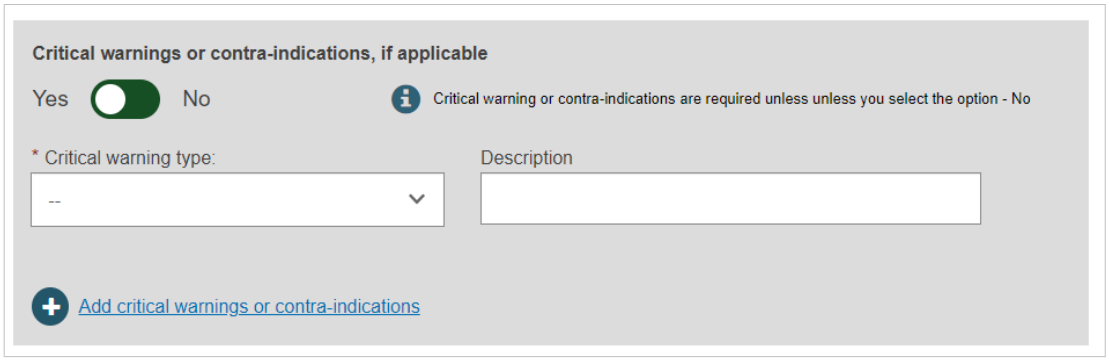
1. Select **Yes** or **No** for the first three options, then select **Yes** or **No** whether if Storage/ handling conditions are applicable:



2. If applicable, provide the correct values by selecting from the options provided and enter a description:

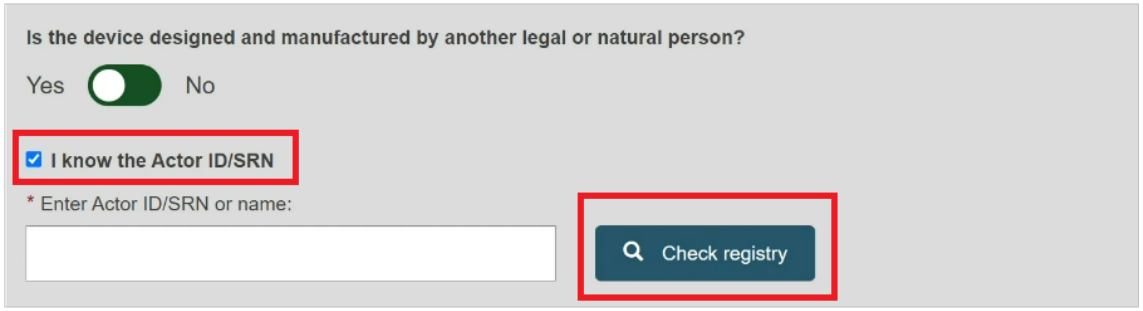


3. Select **Yes** or **No** for Critical warnings or contra-indications and if *Yes*, enter the type and description. After completing, click on **Save** or **Save & Next**:



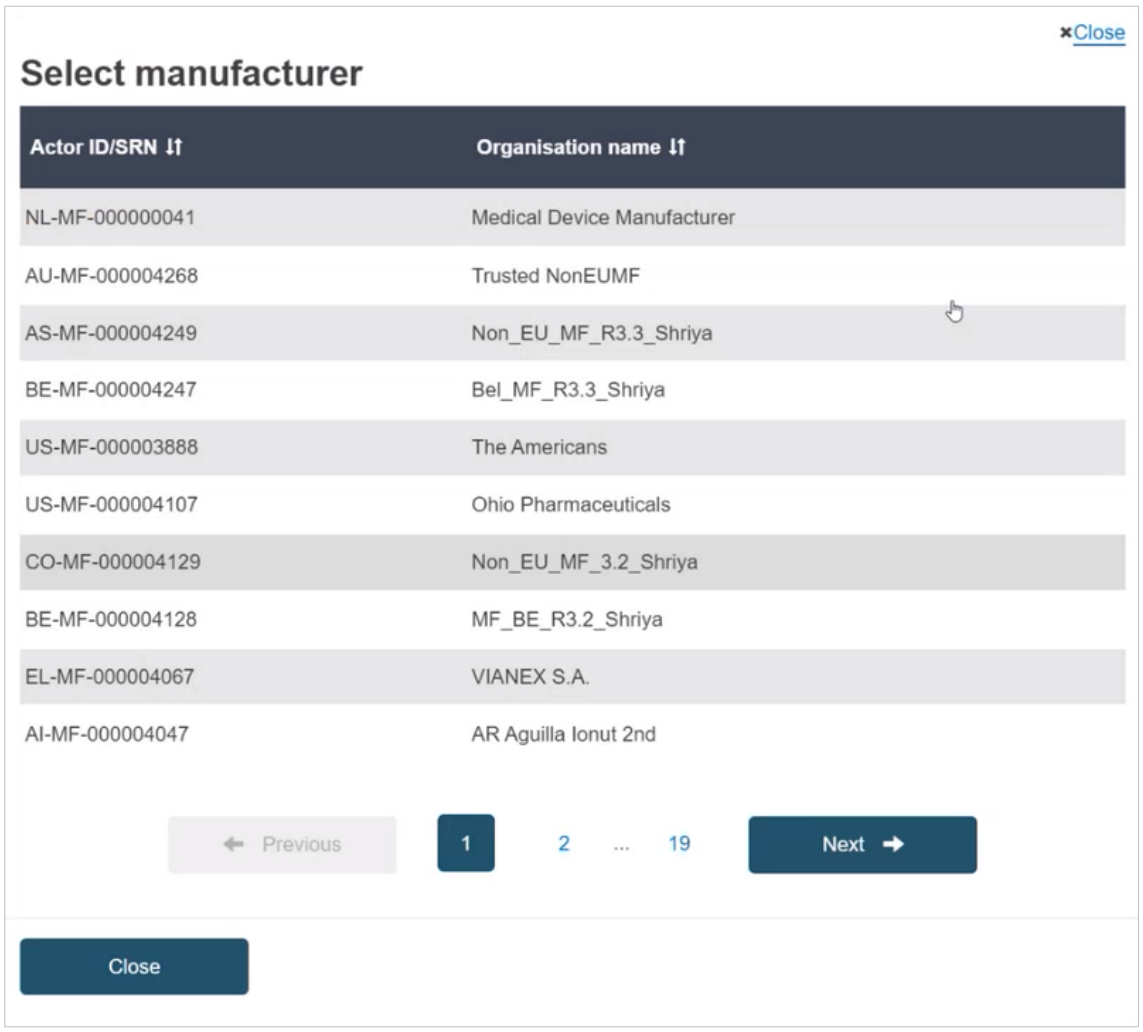
3.5 Step 5: Device information

1. Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person.
   If *Yes*, there are two different ways to find the *Product original manufacturer* of the device:
   - Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRN or name of the *Product original manufacturer* of the device and click **Check registry**:



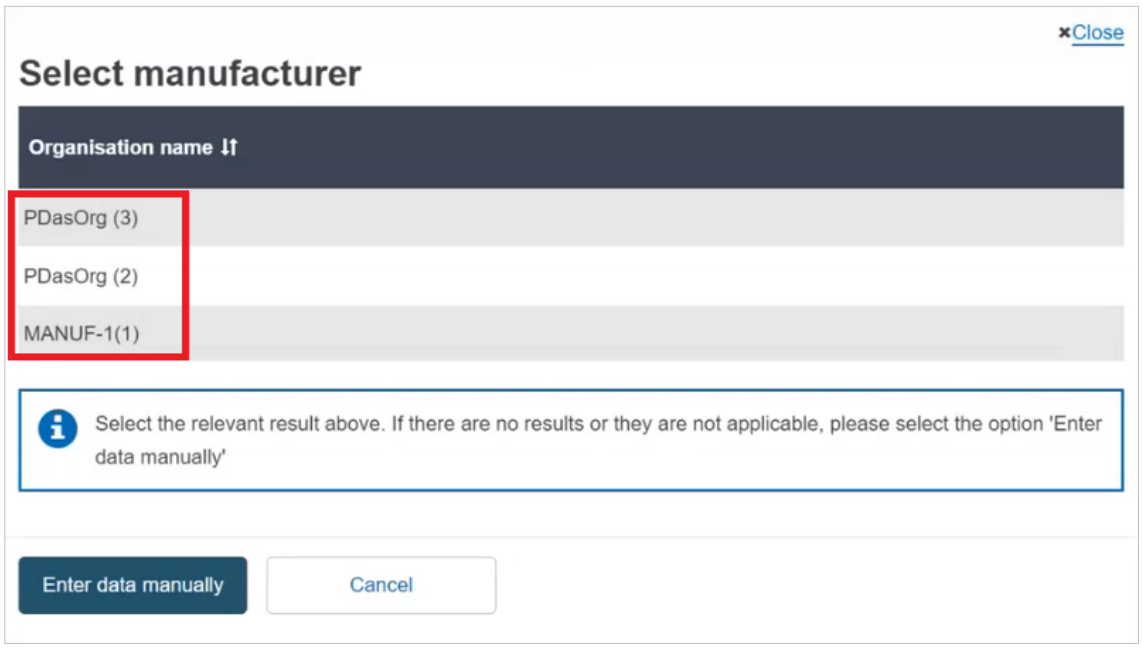
NOTE
Please ensure to check the box *I know the Actor ID/SRN* in order to search for an existing registered Manufacturer Actor either by SRN or by name.

Select the Actor from the list:

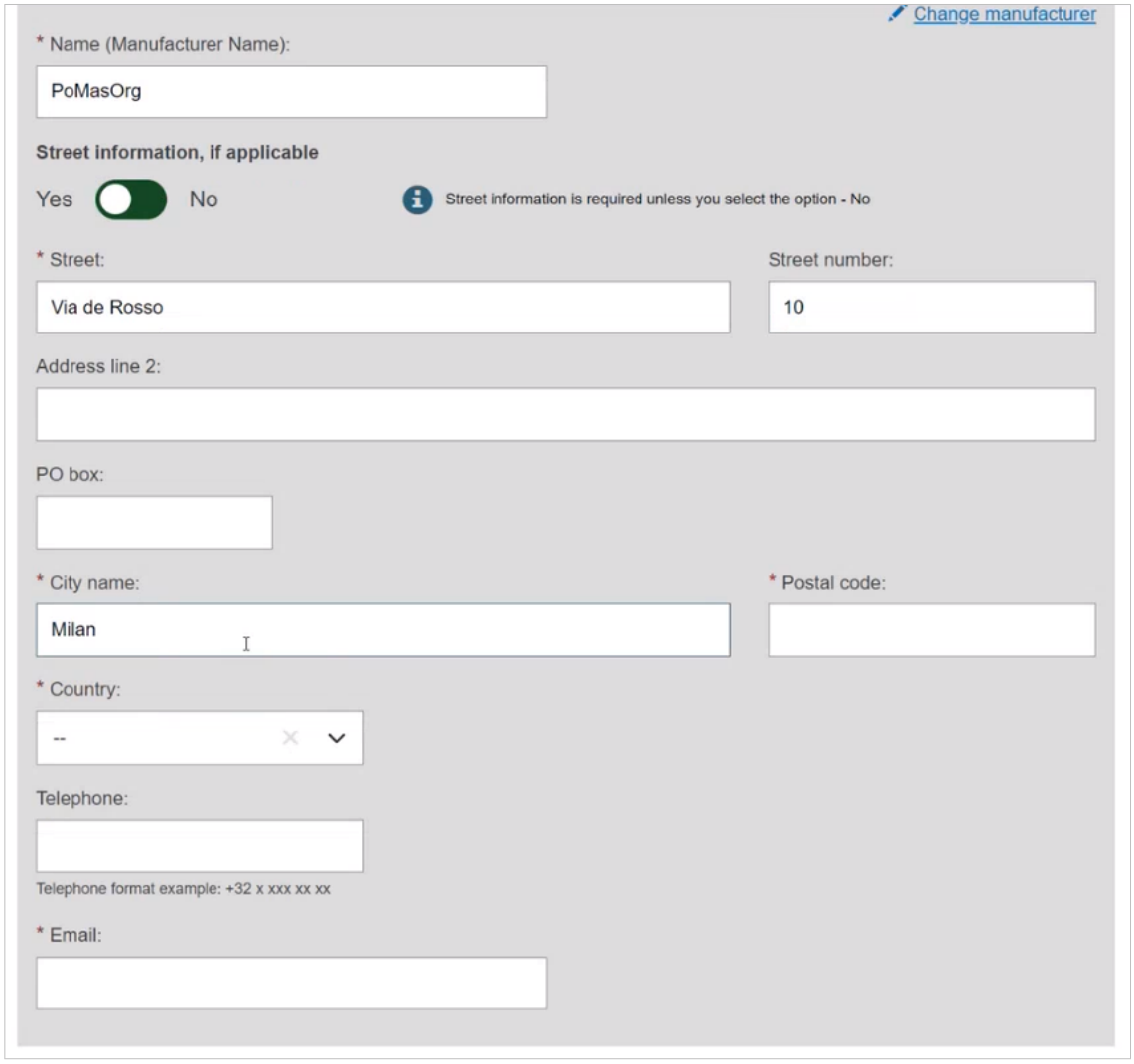


- Enter the name of the *Product original manufacturer organisation name* and click on **Check registry**:

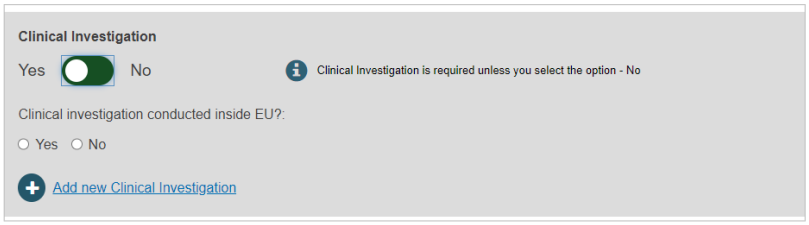
Select the Organisation name from the list:



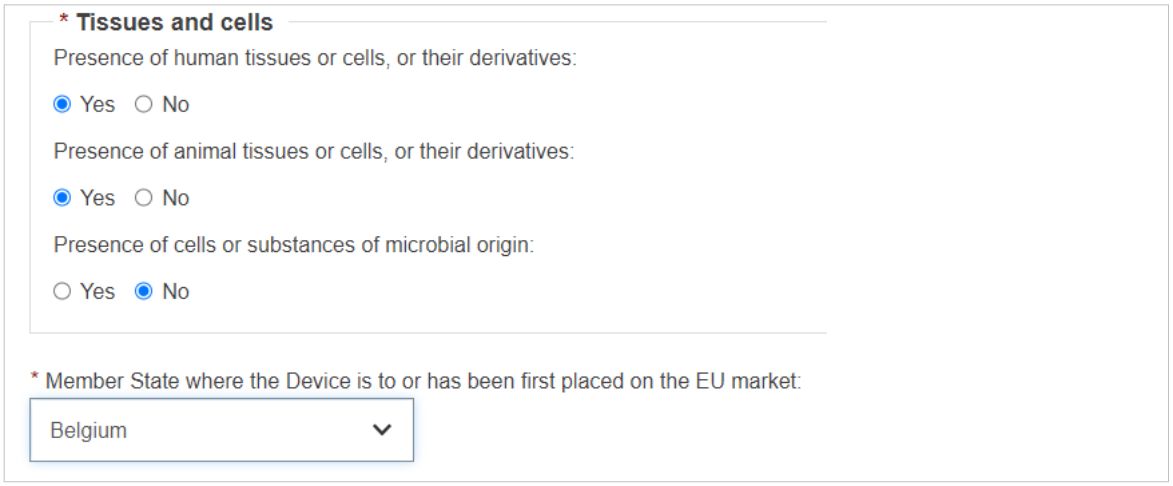
If the Organisation name is not in the list, click on **Enter data manually** and fill in the required fields with the details on the *Product original manufacturer* of the device:



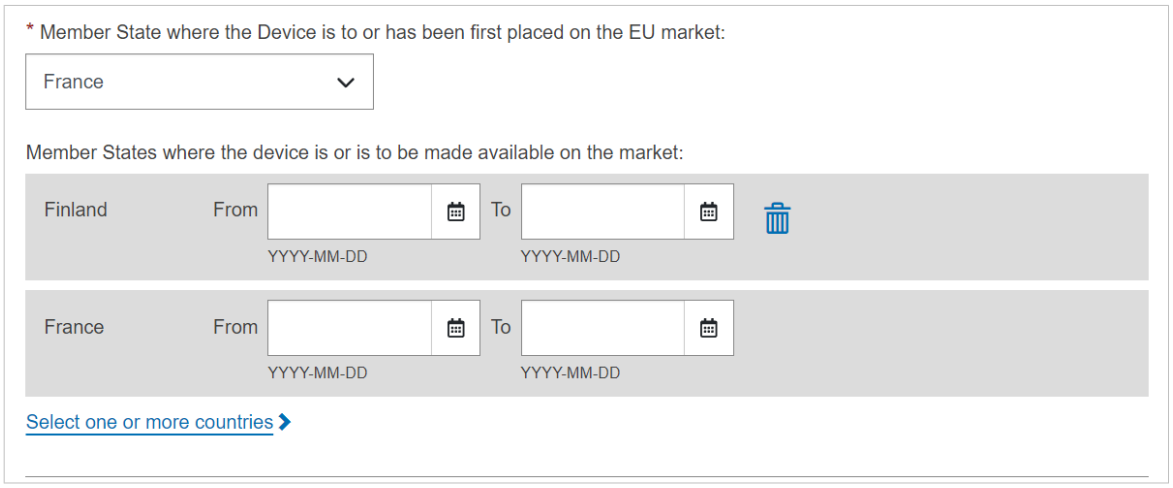
2. Select **Yes** or **No** to provide the Clinical Investigation reference(s):



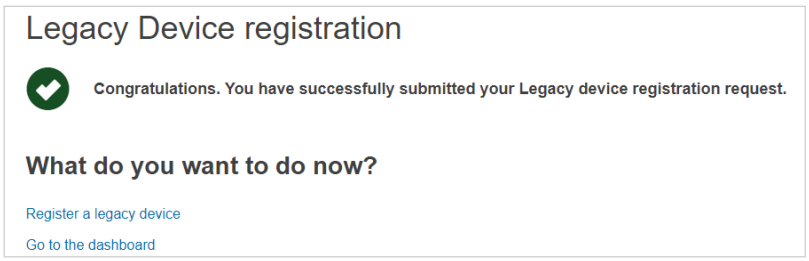
3. Select **Yes** or **No** for the three following options on Tissues and cells:



4. Select a Member State from the drop-down list where the device has been placed on the EU market, and click on **Submit** to submit it directly or **Preview** to view before submitting:



5. A pop-up window will appear asking you to confirm your submission. Once you confirm, you will be brought to a new window confirming the submission of your Legacy device:


Legacy Device registration
Congratulations. You have successfully submitted your Legacy device registration request.
What do you want to do now?
Register a legacy device
Go to the dashboard

4 Management of Regulation Devices and Legacy Devices

For further information on how to manage Regulation and Legacy Devices please consult the following chapters of the dedicated UDI Devices user guide:

- Manage your device Basic UDI-DI/EUDAMED DI details
- Manage your device UDI-DI/EUDAMED ID details
- Search & View Devices, Systems and/or Procedure Packs

5 Linking the Regulation Devices to Legacy Devices

EUDAMED will allow linking a Regulation Device with the correspondent Legacy Device and it will perform this linking automatically when both have the same UDI-DI. The link will be made at the level of the UDI-DI.

NOTE
See Sections *Link a registered Regulation Device to a registered Legacy Device* and *Delete the link between a Regulation Device and a Legacy Device* of the UDI Devices user guide.

6 Annex – Legacy Device certificate types

The Annex presents the certificate types that can be used when registering a Legacy Device.

Certificate types depend on the applicable legislation of the Device.

Applicable Legislation	Certificate Type
MDD	Directive 93/42/EEC Annex II excluding section 4
	Directive 93/42/EEC Annex II section 4
	Directive 93/42/EEC Annex III
	Directive 93/42/EEC Annex IV
	Directive 93/42/EEC Annex V
	Directive 93/42/EEC Annex VI
AIMDD	Directive 90/385/EEC Annex 2 excluding section 4
	Directive 90/385/EEC Annex 2 section 4
	Directive 90/385/EEC Annex 3
	Directive 90/385/EEC Annex 4
	Directive 90/385/EEC Annex 5
IVDD	Directive 98/79/EC Annex III section 6
	Directive 98/79/EC Annex IV excl. section 4 and 6
	Directive 98/79/EC Annex IV section 4
	Directive 98/79/EC Annex IV section 6
	Directive 98/79/EC Annex V
	Directive 98/79/EC Annex VI
	Directive 98/79/EC Annex VII excluding section 5
	Directive 98/79/EC Annex VII section 5


European
Commission