EUDAMED user guide

UDI Devices

Production v 2.11
June 2023

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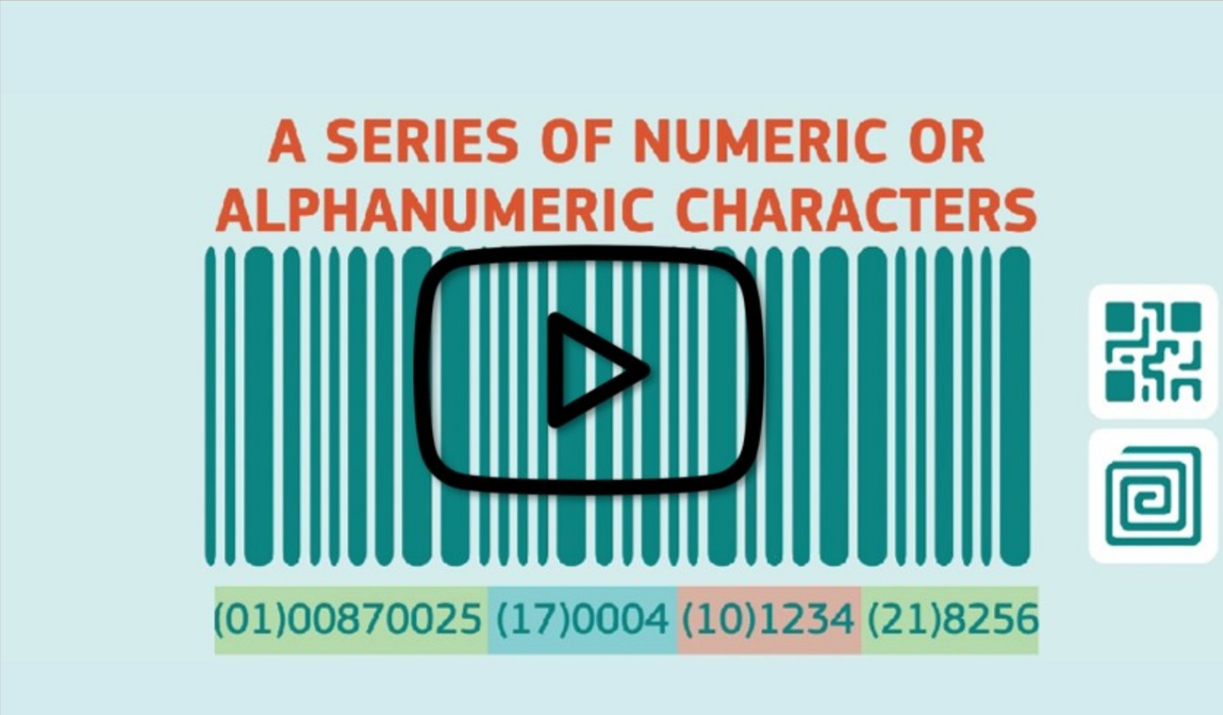
1 Introduction

Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnosis medical devices introduce an EU identification system for medical devices based on a Unique Device Identifier (UDI).

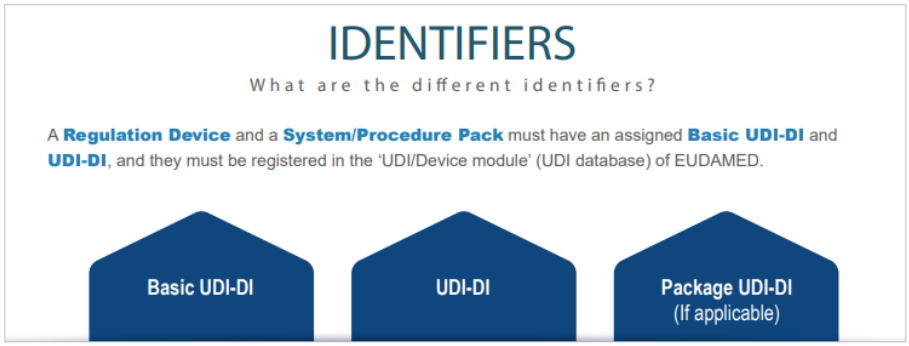
The UDI-DI/Device module of EUDAMED is used for the manufacturers to provide their UDIs/Devices information and to make it available to everyone.[1]

VIDEO: What is a UDI?



[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.

INFOGRAPHIC: What are device identifiers?



2 Getting started

What I need to access EUDAMED:

1. EU Login (ECAS) account

To use EUDAMED, you must have an EU Login account associated with your professional email address and the manufacturer for which you want to act on behalf must be registered as an actor in EUDAMED.

2. User profile registration in EUDAMED

For information on how to gain access to EUDAMED, please consult the user guide for Economic Operators (EO) available for download on the EUDAMED landing page.

NOTE
EUDAMED is also available in a Playground environment, intended to enable you to experiment with the application. All the information in this environment is dummy (including the Actor ID/SRN) and will never be moved to the Production environment. Access to the Playground requires a separate registration.

Every user in EUDAMED is granted by default the profile *Viewer* for the UDI/Device module, and can search and view registered devices. However, to enter UDI/Device data in EUDAMED, you must request access for the UDI/Device module with a higher profile[2] as either:

- A *Proposer* – this profile allows you to create and delete draft records related to your manufacturer, or
- A *Confirmer* – this profile includes the Proposer rights and additionally, allows you to submit and discard records.

[2]See the Economic Operators user guide, *Section 1.2.3*, for more information on user rights and profiles.

IMPORTANT

A Local Actor Administrator (LAA)/Local User Administrator (LUA) of your manufacturer must approve your user access request for your profile(s) to be granted.

Before you start entering details of a UDI/device in EUDAMED, please make sure that you have all requested information at hand, including firstly the Basic UDI-DI and UDI-DI codes. Fields marked with a red asterisk are mandatory.

3 Registering Regulation Devices

VIDEO: Registering Regulation Devices

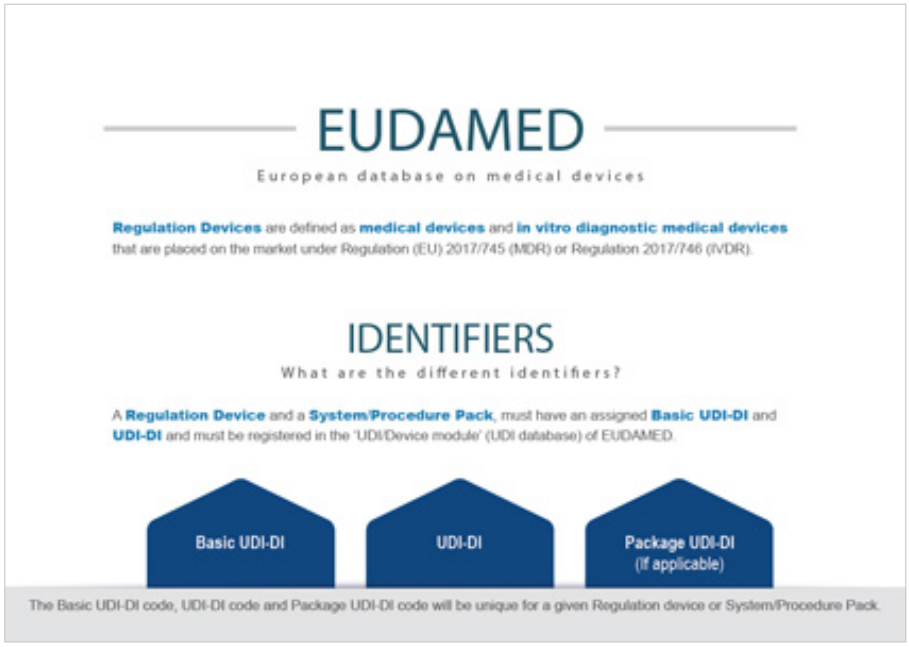
Each Regulation Device must have a unique Basic UDI-DI and a unique UDI-DI assigned to it. Both are always required – you cannot register a Basic UDI without a UDI-DI.

You will be asked to enter EUDAMED via your EU Login account.

INFOGRAPHIC: Registration process for Regulation devices

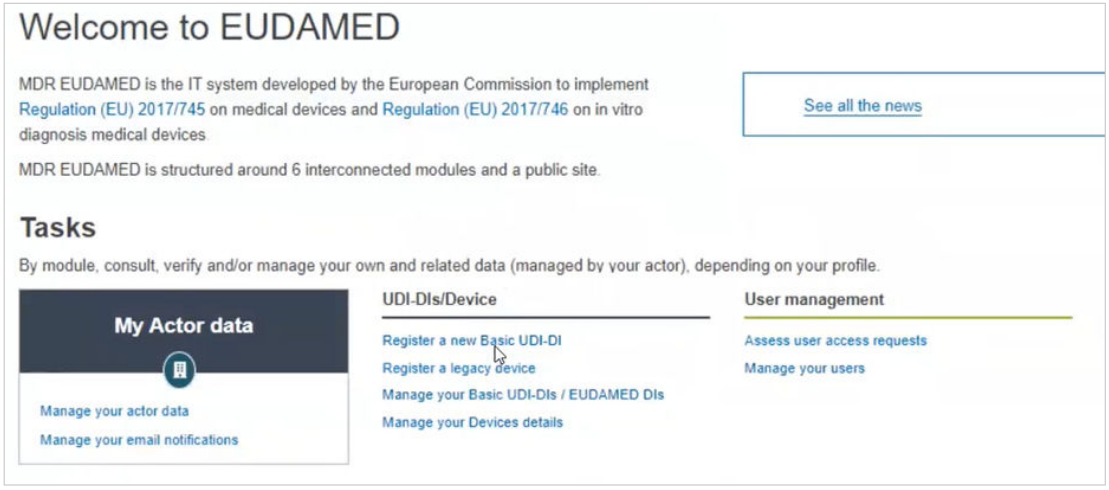
3.1 Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device

INFORGRAPHIC: UDI identifier



3.1.1 Step 1: Basic UDI-DI identification information

1. Click on **Register a new Basic UDI-DI**:

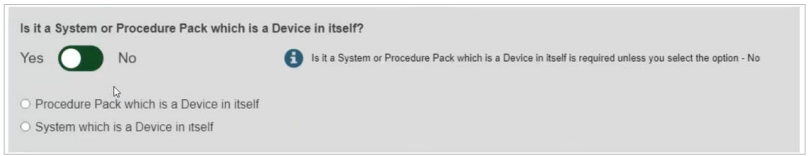


2. On the next page, enter the Basic UDI-DI information. Select the applicable regulation.

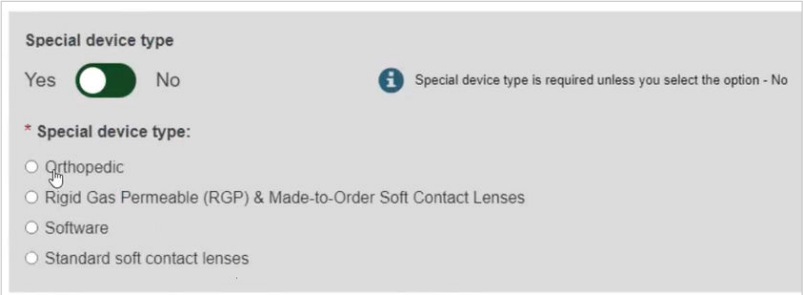
> **NOTE**
> In this guide demonstration, the selection is MDR (Regulation (EU) 2017/745). Based on the regulation you choose, the characteristics of the Device to be entered will vary.

Depending on the regulation that you have selected an additional question appears at the bottom of the page:

Regulation	Additional question
MDR	*Is it a System or Procedure Pack which is a Device in itself?* + additional sub-questions about the device type, depending on whether your answer is *Yes* or *No* to this first question
IVDR	*Is it a kit?* + additional sub-question about the device type, if you answer *No* to this first question



If you select **No**, please choose the right information under the appearing section *Special Device type* (for IVDR, if you select **No** for *Is it a Kit?*, the only option for Special device type if applicable is *Software*[3]):



NOTE
As of now it is not possible to register devices with the following Special Device types:

- Standard soft contact lenses
- Rigid Gas Permeable (RGP) Contact Lenses
- Made-to-order soft contact lenses
- Spectacle frames
- Spectacle lenses
- Ready-made reading spectacles

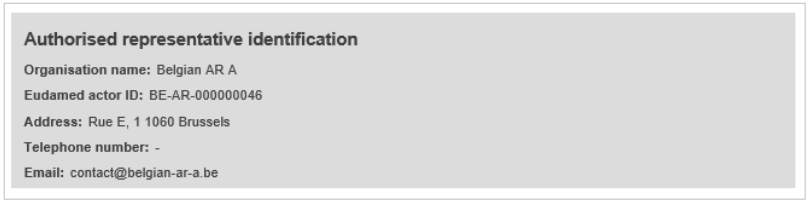
3. Fill in the Basic UDI-DI identification details and click on **Save & Next**:

IMPORTANT
EUDAMED will validate the Basic UDI-DI code based on the specific format for each Issuing Entity and will prevent you from going further if the code is not valid.

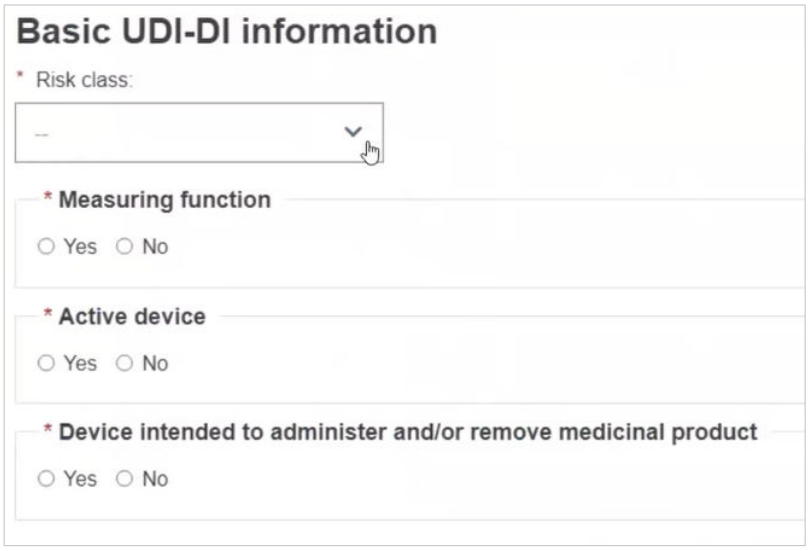
If the Basic UDI-DI code already exists in EUDAMED, the system will prevent you from saving, as a Basic UDI-DI must be unique.

4. Non-EU Manufacturers will have to select the authorised representative for the Basic UDI-DI amongst those with which they have an active mandate registered in EUDAMED.
If there is only one authorised representative with an active Mandate with the non-EU manufacturer, it will be automatically retrieved:

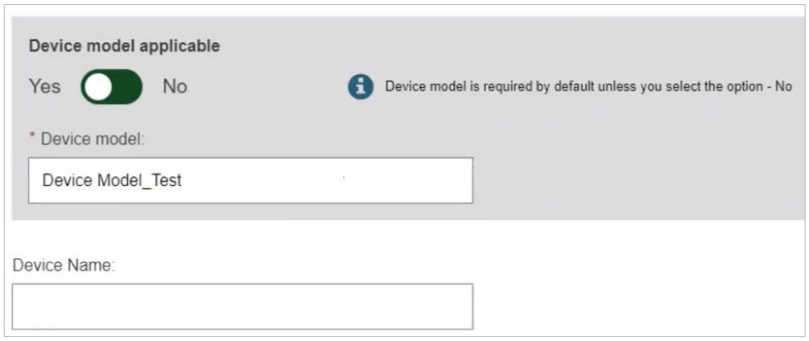
[3]For more information, visit the EUDAMED Information Centre, or the UDI Assignment to Medical Device Software webpage.



5. Choose a Risk Class and select **Yes** or **No** for each option that follows.



6. Select **Yes** or **No** if Device model is applicable. If the Device model is not applicable, the Device Name will be mandatory, otherwise, it is mandatory to enter the Device model and the Device name (at the Basic UDI-DI level) if there is one (note that the device trade name is part of the UDI-DI data):



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

3.1.2 Step 2: Certificate information (when applicable)

This section will become active depending on the information provided for Risk Class and additional properties in the Basic UDI-DI.

In the case of certificate information, at least the following should be provided:

- whether *EU type examination certificate* is applicable.
- the Notified Body (NB) responsible for the product certificate.
- if known, the certificate identification.

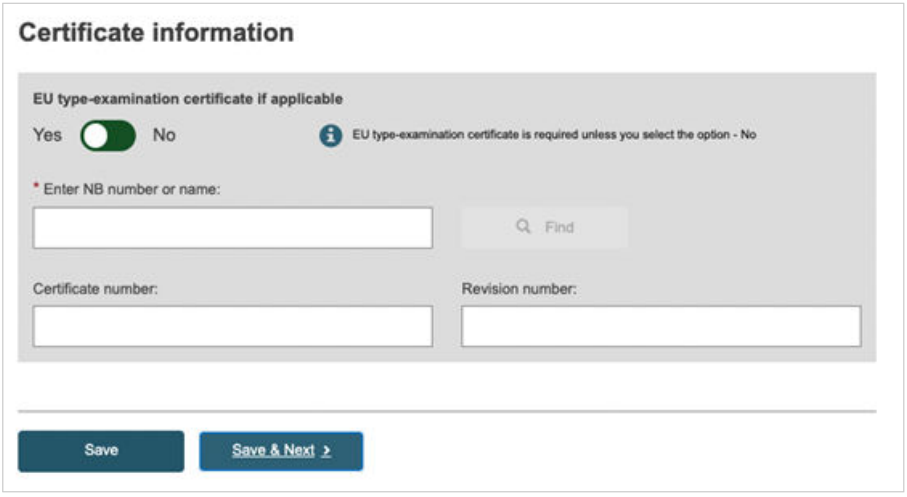
Additionally, more information on the certificate type could be required depending on the risk class and properties specified for the Basic UDI-DI. For the NB, enter some or all of the NB name or number, click **Find** and choose the correct Notified Body from the new window.

If known, enter the certificate number and revision number and click on **Save** or **Save & Next**.

NOTE

Certificate Information for a Basic UDI-DI registration is applicable only when its confirmation by the Notified Body from the certificate registration is required (as specified in Art 29(3) MDR/Art 26(2) IVDR).

In Annex 1 [88] – Device Certificate Information [88] you can find the different cases in which Certificate information is needed and the type of certificate. (In summary, it is applicable for MDR risk class III and IIb and IVDR risk class B with self-patient testing/ near-patient testing, risk class D and C).



3.1.3 Step 3: UDI-DI identification information

VIDEO: UDI carrier and display formats

1. Select the *Issuing Entity* from the drop-down list and enter the *UDI-DI code*.

> **IMPORTANT**
> The UDI-DI code you enter must be unique. If it already exists in EUDAMED, you will not be able to Save.
>
> **Exception**: the same UDI-DI can be used for a Legacy Device and its Regulation Device equivalent.

If the same UDI-DI code was already provided for a Legacy Device (i.e. Applicable Legislation MDD, AIMDD or IVDD), you will be prompted that a link will be created between the two devices (the Regulation and the Legacy Device) on the condition there is no conflict between some of the Basic UDI-DI properties and the related legacy device EUDAMED DI properties. In case of conflict, the system will prevent you from using the same UDI-DI.

NOTE

In the case of a GS1 Issuing Entity, the UDI-DI code you enter must be a 14-digit code including the check digit that will be used by EUDAMED to validate the UDI-DI code. If your GS1 UDI-DI (GTIN code) is less than 14 digits (check digit included), when populating EUDAMED field, please add leading zero(s) until you reach 14 digits.

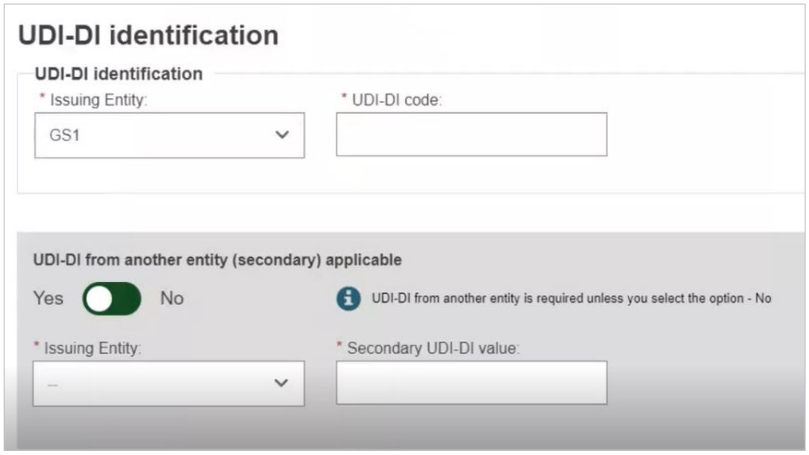
For example:

000000nnnnnnnn (GTIN-8)

00nnnnnnnnnnn (GTIN-12)

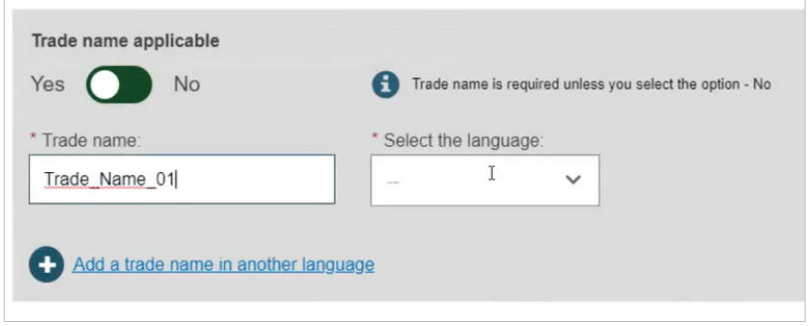
0nnnnnnnnnnnn (GTIN-13)

2. If applicable, enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI:



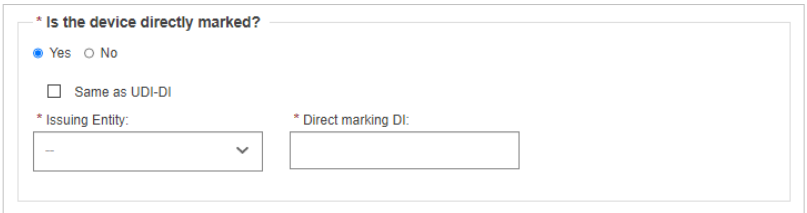
3. Enter the EMDN code and click on **Find**, and select the correct one from the list:

4. If applicable, enter the trade name (as specified on the device label) and select its related language (select **All languages** if not language dependent):



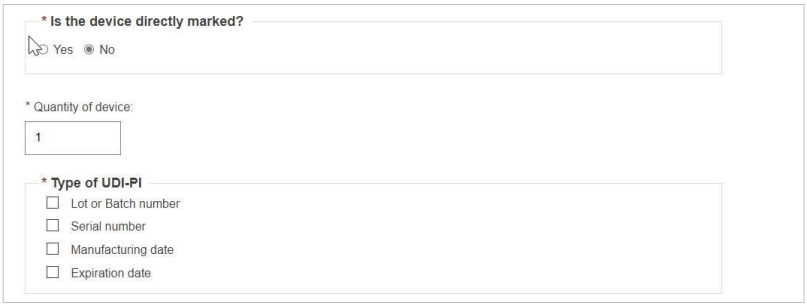
5. Enter the *Reference/Catalogue number*:

6. Specify whether the device is directly marked or not:
   - If the device is directly marked, you must either indicate it is the same as the UDI-DI or enter the UDI-DI and issuing entity of the Direct marking DI.

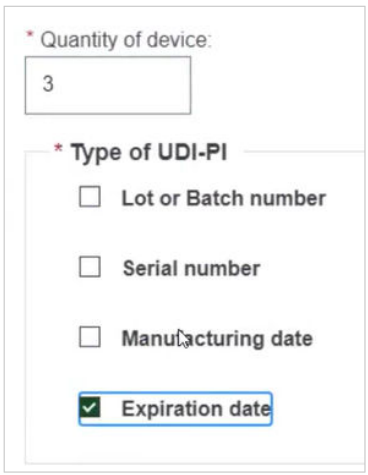


7. If the device is not directly marked and the base quantity of the device is **greater than one**, you may enter the Unit of Use DI and its issuing entity:
   - The same Unit of Use DI can be used for different UDI-DIs in case the same device has different root packaging (each one having a different UDI-DI).

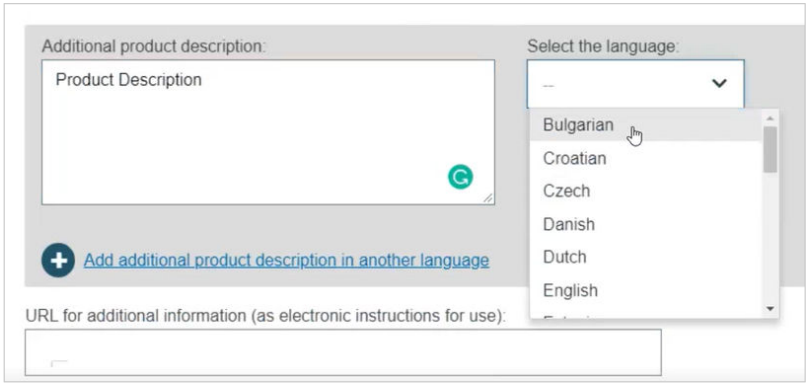
8. If the base quantity is **less than two**, then no unit of use Di is provided:



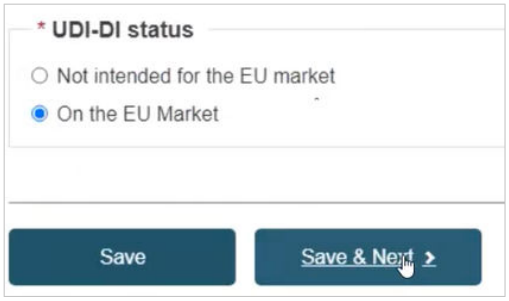
9. Select the *Type of UDI-PI*:



10. Enter any additional information you think important to specify about the device, select the language in which the additional information is provided and enter a URL (web address) if you have one for additional information online:



11. Specify the UDI-DI status in selecting whether it is *On the EU market* or *Not intended for the EU market* and click on **Save** or **Save & Next**:



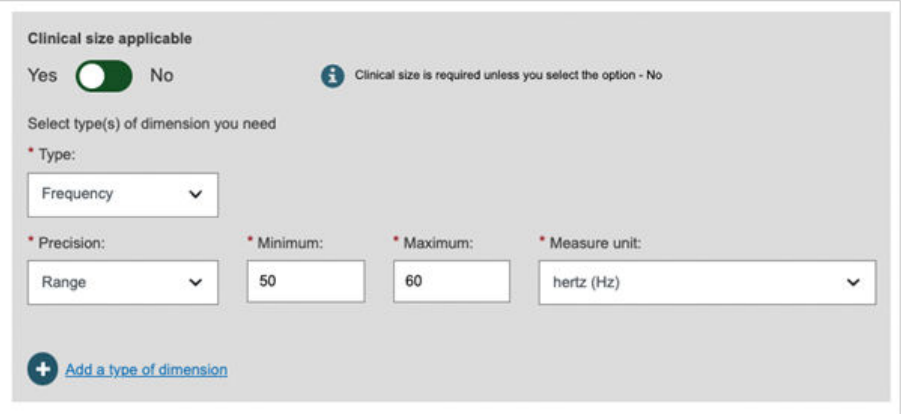
3.1.4 Step 4: UDI-DI characteristics

1. If applicable, specify clinical size for the UDI-DI and choose the dimension and the precision values in the drop-down lists below:

NOTE

When the selected Clinical size type has the option *Other*, users will be required to enter the Description of the Clinical size type and the language in which the description is given. The same applies for Measure unit.

In case both the Clinical size and Measure unit have the option *Other*, the description for the two fields needs to be given in the same languages.

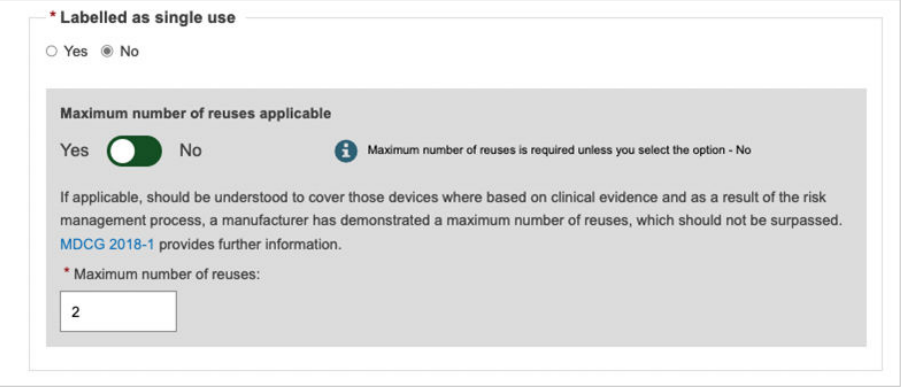


You shall provide one of the following precision type:

- Range – requires minimum and maximum values and the measure unit
- Text – requires free text entry
- Value – requires the size and the measuring unit

You may add several clinical sizes by adding different types of dimension, but only one dimension for a given type.

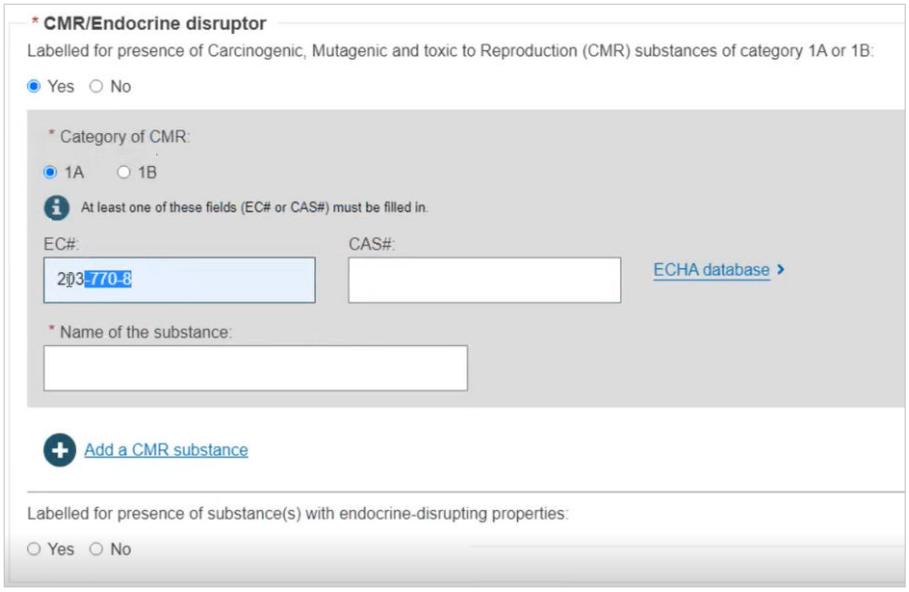
2. Specify if the device is labelled as single use.
   When device is not labelled as single use you will be asked to provide the number of reuses if applicable:
   - If the *Maximum number of reuses* is not applicable, then the device is considered as a non-Single Use Device and the device does not have a maximum number of reuses (infinite number of reuses)
   - If value provided is >=1, the device is considered as a non-Single use Device having a limited number of reuses (the value provided)



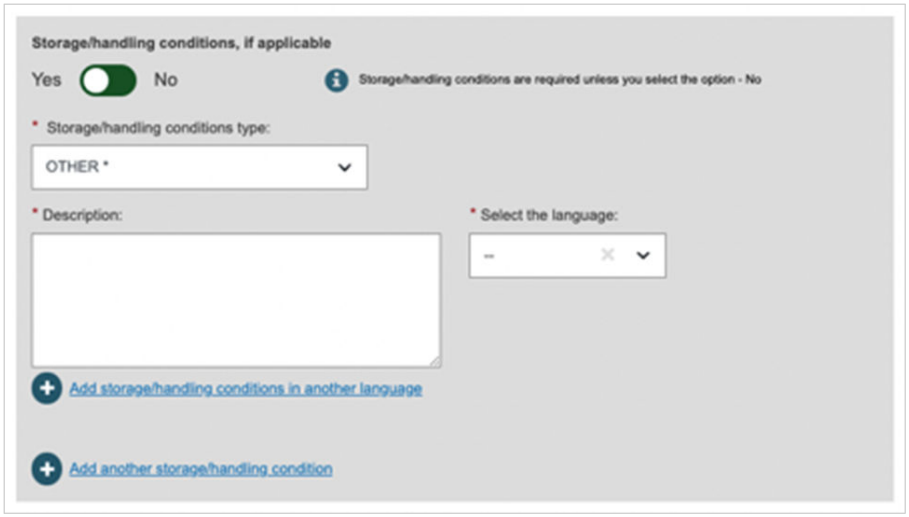
3. Select **Yes** or **No** for each of the options below:

Containing latex is only for MDR, not applicable for IVDR.

4. For MDR, if applicable, enter the CMR and/or Endocrine disruptor substances. When specifying CMR and/or Endocrine substances you have the option to provide the EC# or CAS#. If you do provide them, only the *Name of substance* is required (i.e. the language is no longer required):

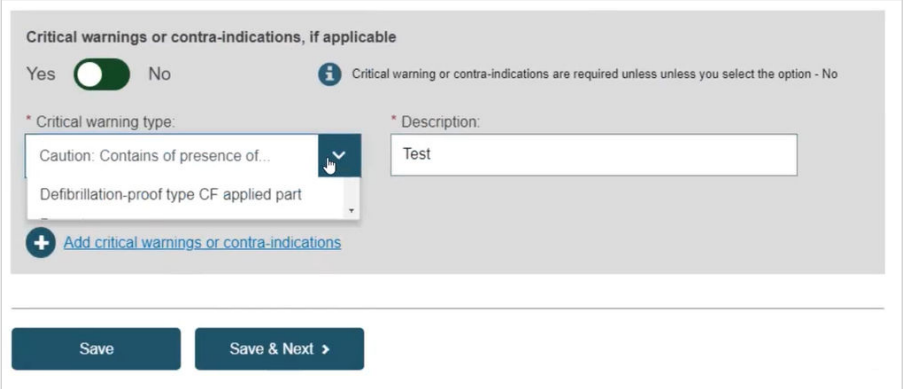


5. If applicable, the Storage/handling conditions; choose the correct information from the list and provide a description where relevant:



NOTE
When the selected Storage/handling conditions type has the option *Other*, users will be required to enter the Description of the *Storage/handling condition type* and the language in which the description is given.

6. Do the same for Critical warnings or contra-indications, and click **Save** or **Save & Next**:

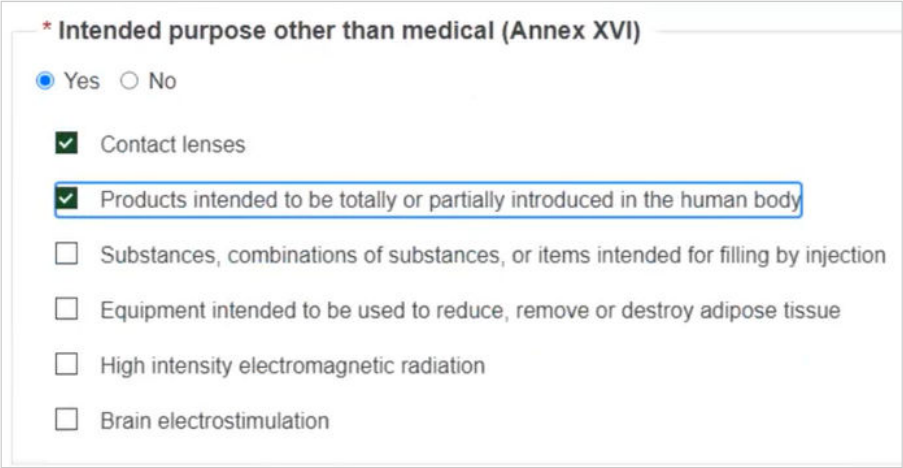


NOTE
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the language in which the description is given.

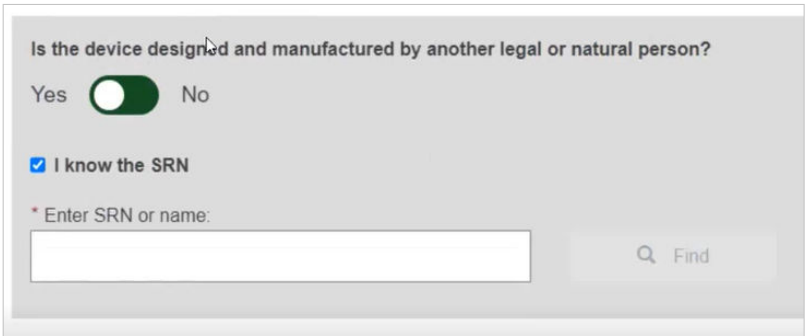
3.1.5 Step 5: Device information

1. For MDR, specify whether it is a reprocessed single use device and whether it has an Intended purpose other than medical (Annex XVI):

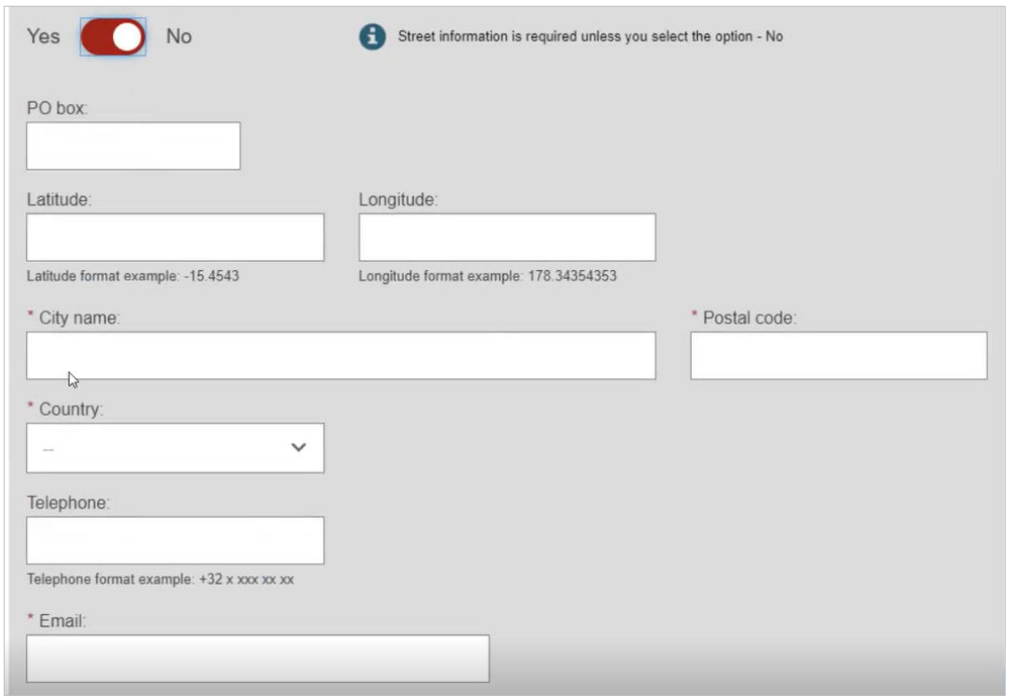
2. If you select *Yes* for the Intended purpose other than medical (Annex XVI), possible options will appear. Select the relevant purpose(s):



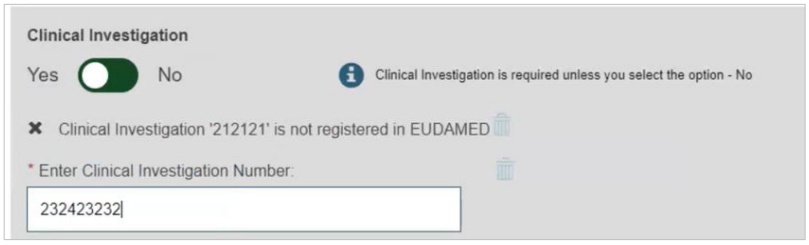
3. Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person.
   If *Yes*, enter the Actor ID/SRN or name of the other legal or natural person that designed and manufactured the device. Click **Find** to see the search outcome. If registered as manufacturer in EUDAMED, the system will provide a list of matching records from which you can select one, and the system will retrieve the information:



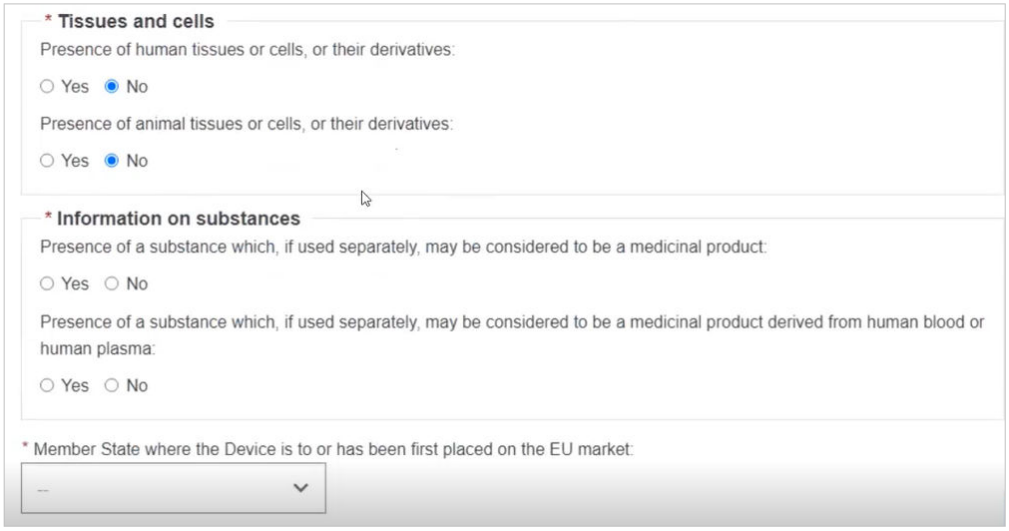
4. If you cannot find the other legal or natural person that designed and manufactured the device because they are not registered as a manufacturer in EUDAMED, uncheck the box *I know the SRN* and complete the required fields with the details on the other legal or natural person that designed and manufactured the device:



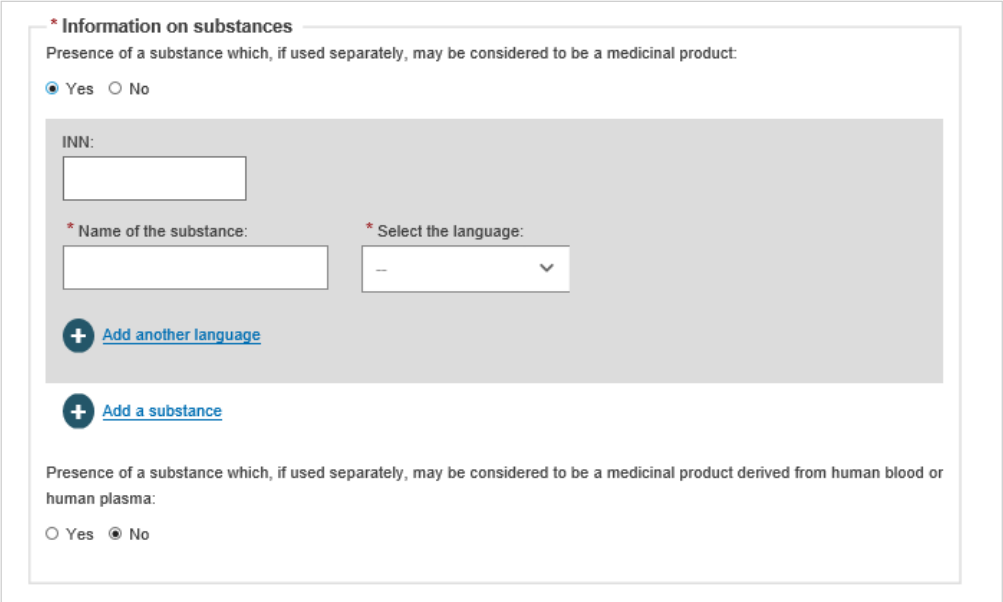
5. Select **Yes** or **No** to provide the Clinical Investigation reference for the current UDI-DI:



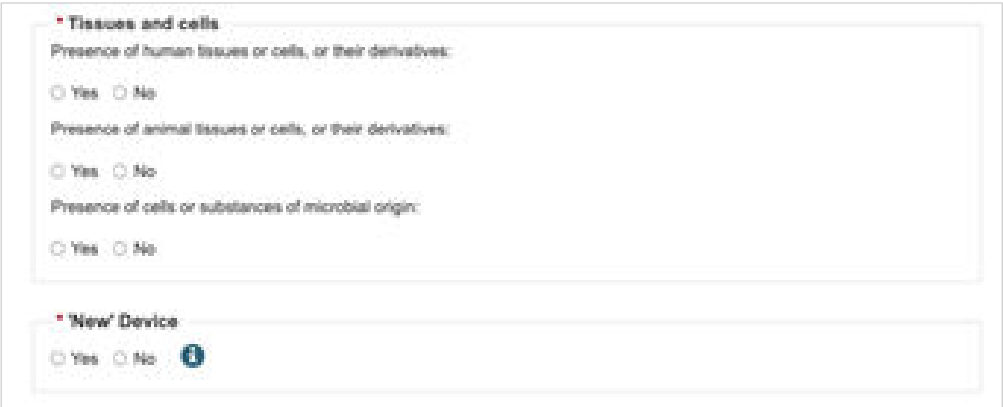
6. When registering under MDR, select **Yes** or **No** to complete information on tissues and cells, and information on substances:



If you answer *Yes* to Information on substances, enter the details:



For IVDR, select **Yes** or **No** to complete information on tissues and cells, in addition you shall specify if the device is new:

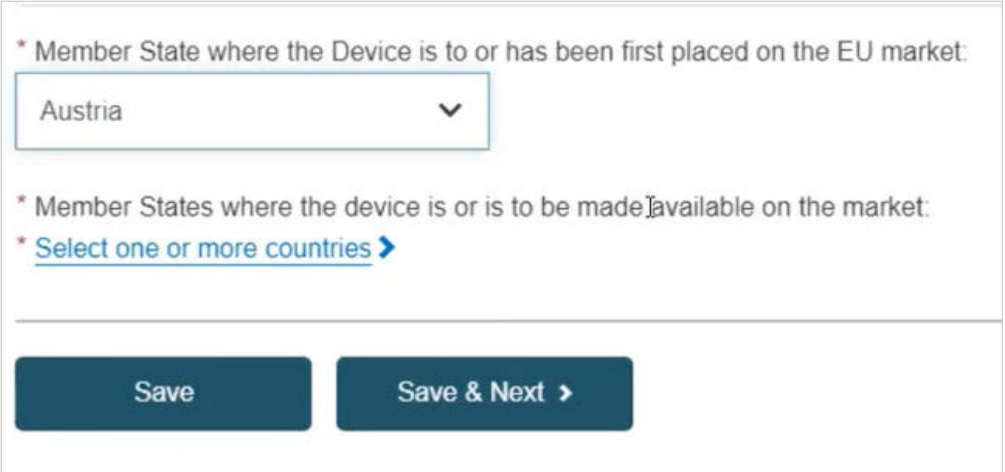


NOTE

A device shall be considered *new* if:

- There has been no such device continuously available on the Union market during the previous three (3) years for the relevant analyte or other parameter.
- The procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three (3) years.

7. Choose a Country in the drop-down list where the device is or has been first placed on the EU market, and click **Save** or **Save & Next**:

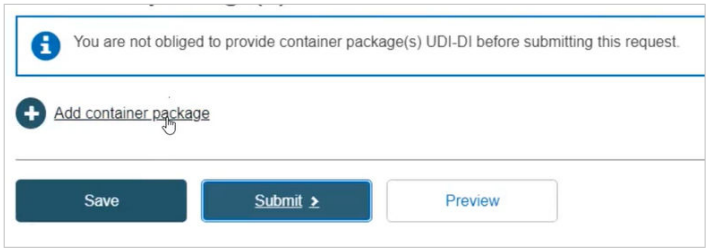


NOTE
The countries where the device is or is to be made available on the market are mandatory, to be provided when the device's status is 'On the EU market' and device's risk class is **not risk class I (MDR) and not risk class A (IVDR)**.

3.1.6 Step 6: Container package details

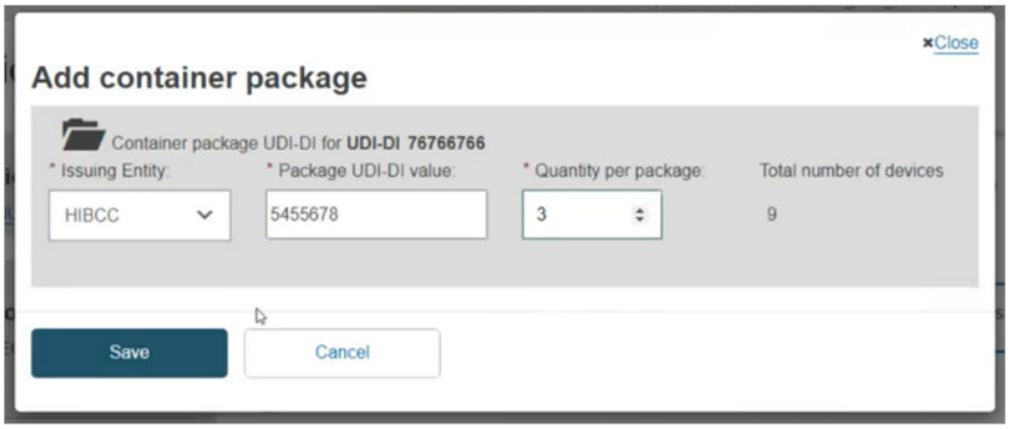
VIDEO: UDI carrier placing

1. Click on **Add container package** when there is a higher packaging level for the root UDI-DI:

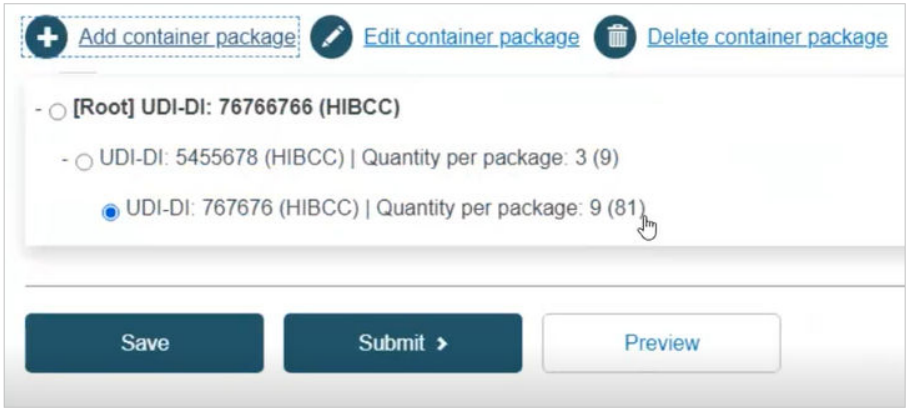


Each package level requires a unique UDI-DI assignment. You begin by registering the container package associated with the root UDI-DI (also known as the primary UDI-DI). You have the option to add multiple levels and container packages. Input the *Issuing Entity*, UDI-DI code for the package, and *Quantity per package*, then click **Save**:

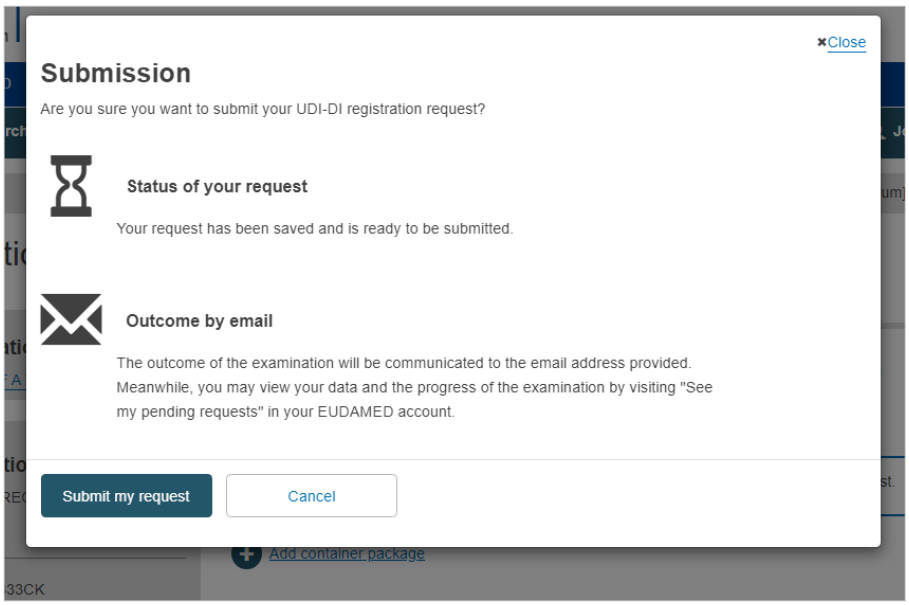
NOTE
If the UDI-DI already exists in EUDAMED, the system will prevent you from saving.



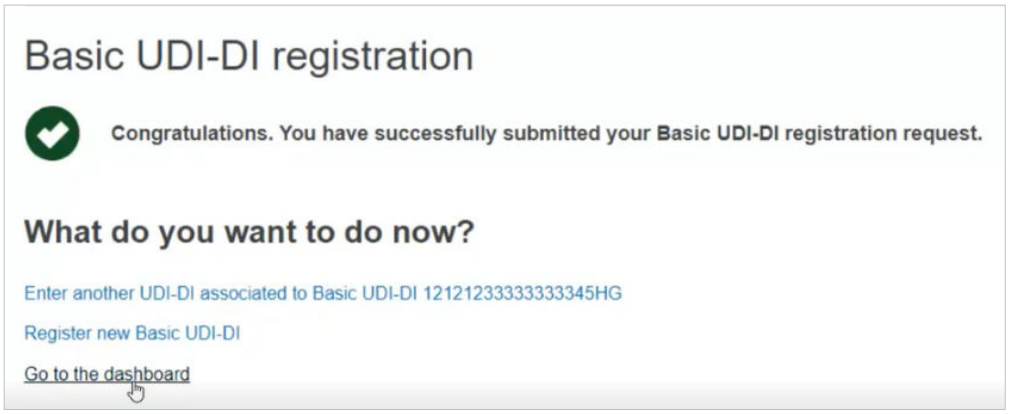
2. Select the generated information and click on **Submit**:



3. A pop-up window will appear asking you to confirm your submission:



4. You will be redirected to a new page saying you successfully submitted your registration:



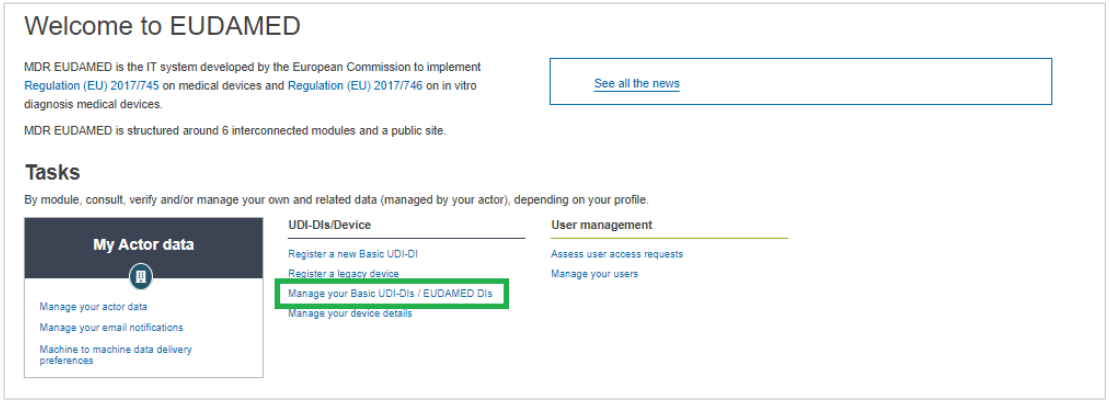
IMPORTANT

After submitting the Device, the state of the Device (Basic UDI-DI and UDI-DI) will be:

- **Registered**, if the Basic UDI-DI data does not require a confirmation from the Notified Body (Basic UDI-DI and UDI-DI are publicly available in the EUDAMED public website);
- **Submitted**, if the Basic UDI- DI data requires a confirmation from the Notified Body (Basic UDI-DI and UDI-DI are not publicly available and will only get the Registered state and become publicly available after Notified Body confirmation).

3.2 Registration of a UDI-DI for an existing Basic UDI-DI of a Regulation Device

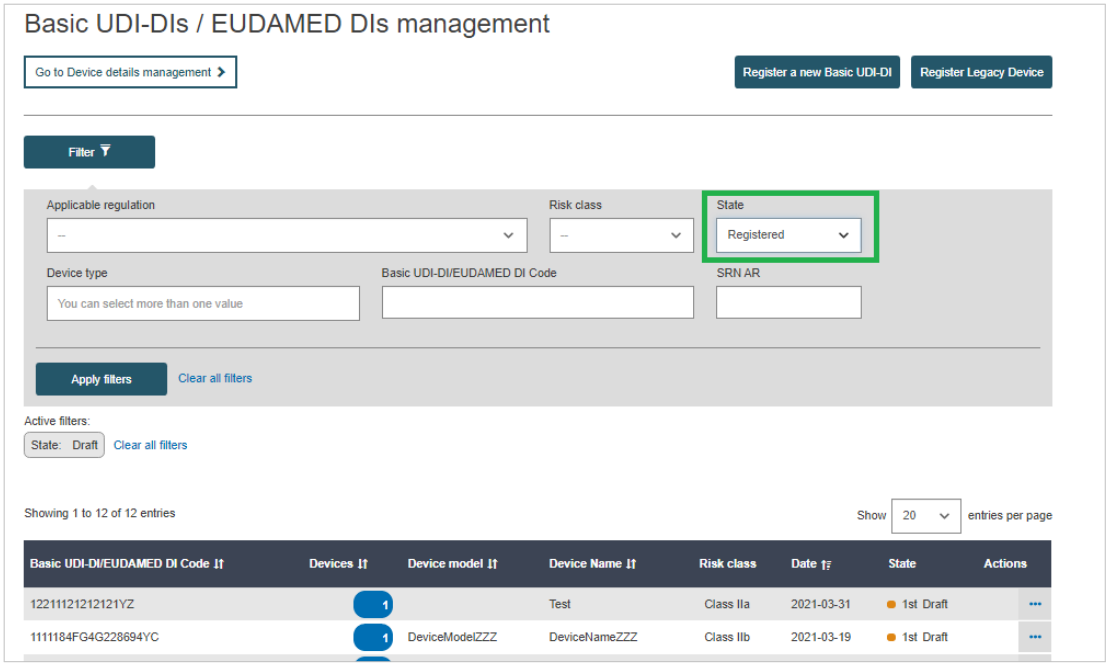
1. On the EUDAMED Dashboard, select **Manage your Basic UDI-DIs/ EUDAMED DIs**:



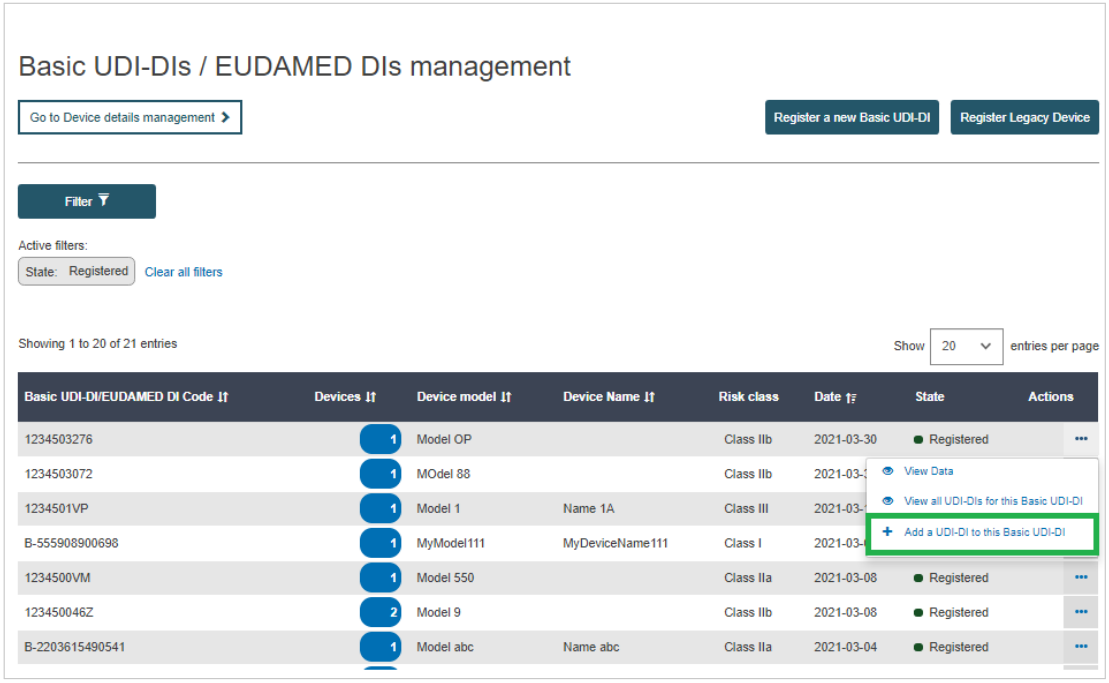
2. Filter the Basic UDI-DIs/ EUDAMED DIs in state *Submitted* or *Registered*:

> **IMPORTANT**
> Additional UDI-DIs for a Basic UDI-DI can be added only for Regulation Devices (not for Legacy Devices).

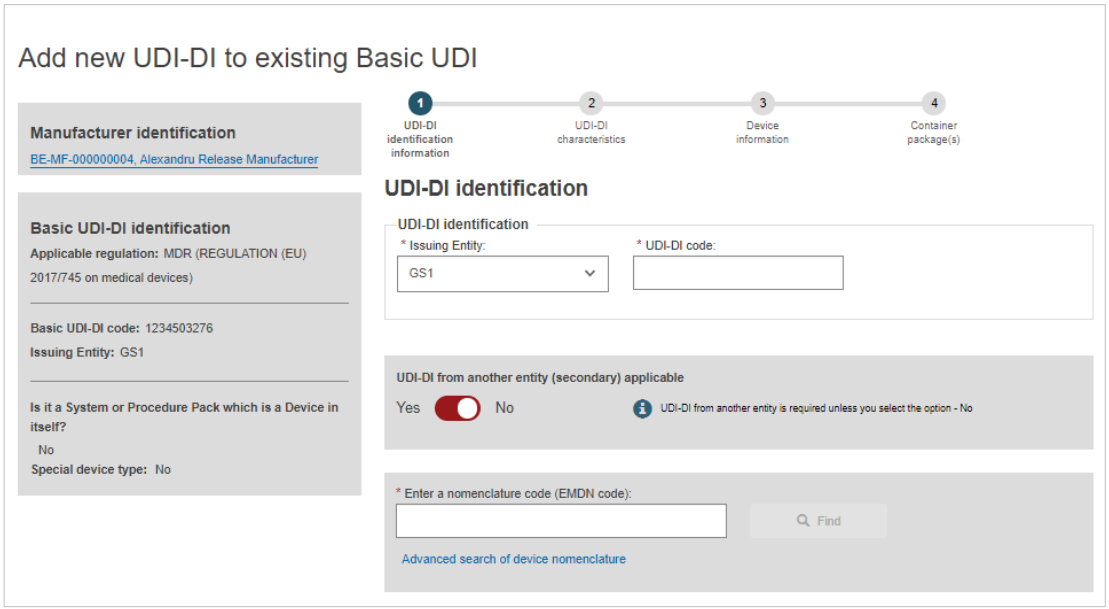
New UDI-DIs can be added only to Basic UDI-DIs that are in state *Registered* or *Submitted*:



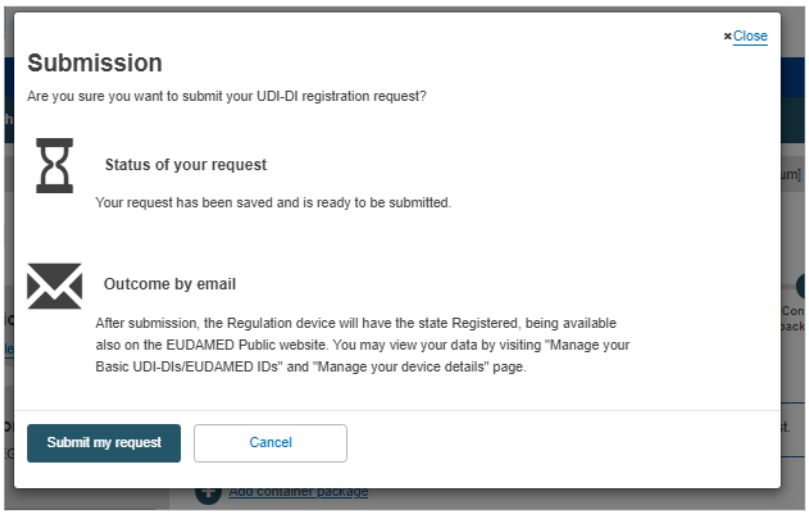
3. From the results, find the Basic UDI-DI for which you would like to add a new UDI-DI. Click on the three dots on the right and click on **Add a new UDI-DI to this Basic UDI-DI**:



4. Complete the series of steps required for the registration of a UDI-DI for an existing Basic UDI-DI (*Step 3:* UDI-DI identification information [11], *Step 4:* UDI-DI Characteristics [14], *Step 5:* Device information [17], *Step 6:* Container Package Details [21]):



5. When you have completed all steps, click on **Submit my request** to submit the new UDI-DI:

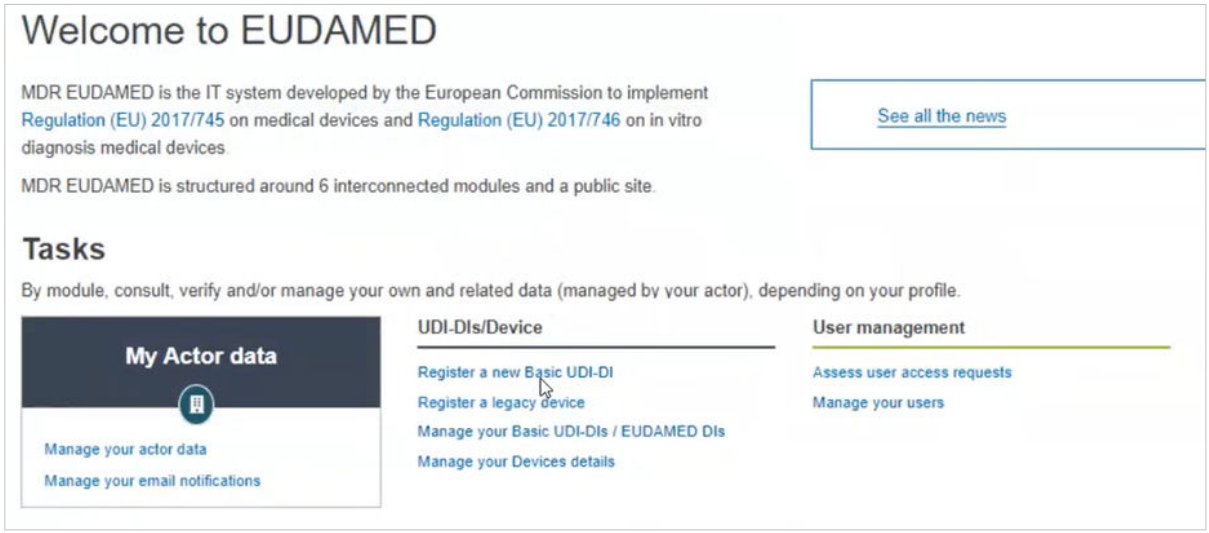


IMPORTANT
After Submitting the UDI-DI, the state of the UDI-DI will be:

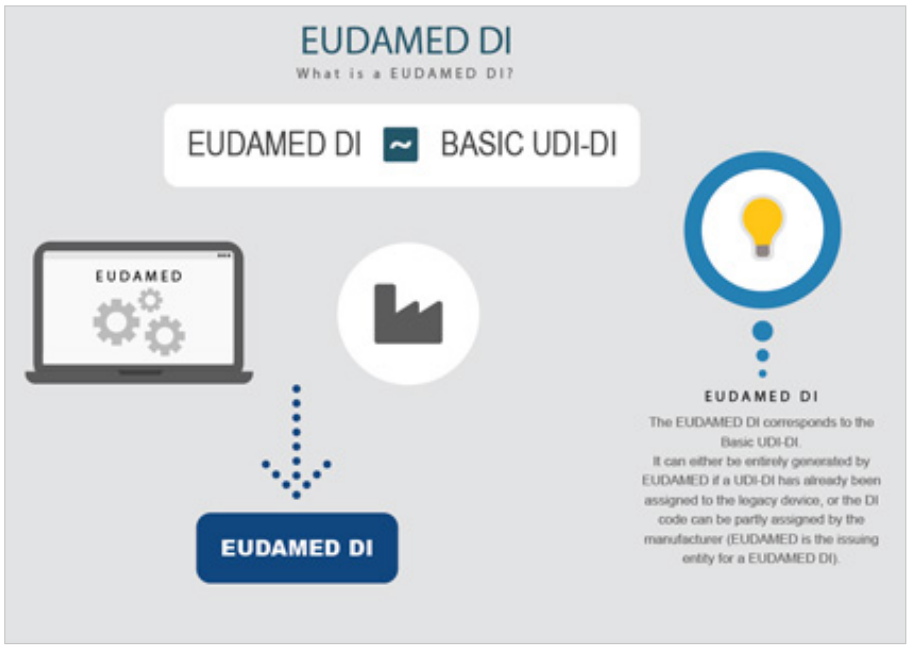
- **Registered** if the Basic UDI-DI has the state *Registered*;
- **Submitted** if the Basic UDI-DI has the state *Submitted*.

4 Registering Legacy Devices

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



INFOGRAPHIC: Identifiers of a legacy device



4.1 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).

NOTE

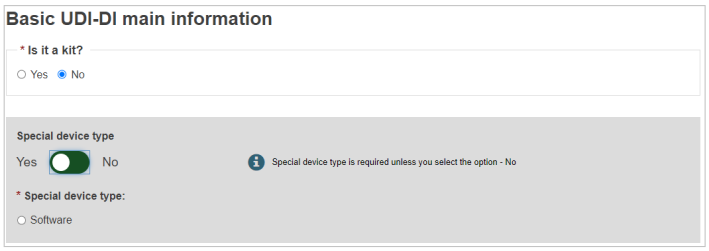
In the case of a GS1 Issuing Entity, the UDI-DI code you enter must be a 14-digit code including the check digit that will be used by EUDAMED to validate the UDI-DI code. If your GS1 UDI-DI (GTIN code) is less than 14 digits (check digit included), when populating EUDAMED field, please add leading zero(s) until you reach 14 digits.

For example:

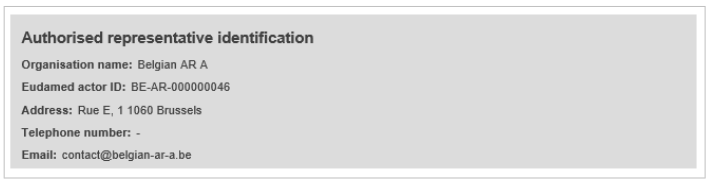
- **000000nnnnnnnn (GTIN-8)**
- **00nnnnnnnnnnn (GTIN-12)**
- **0nnnnnnnnnnnn (GTIN-13)**

If the legacy device has no UDI-DI assigned to it, the EUDAMED DI must be provided. The EUDAMED DI can be either assigned by the manufacturer respecting the check digits rules or will be generated by EUDAMED during the registration process from the manufacturer’s device identification by adding to it the “B-“ prefix and the two characters check digits at the end.

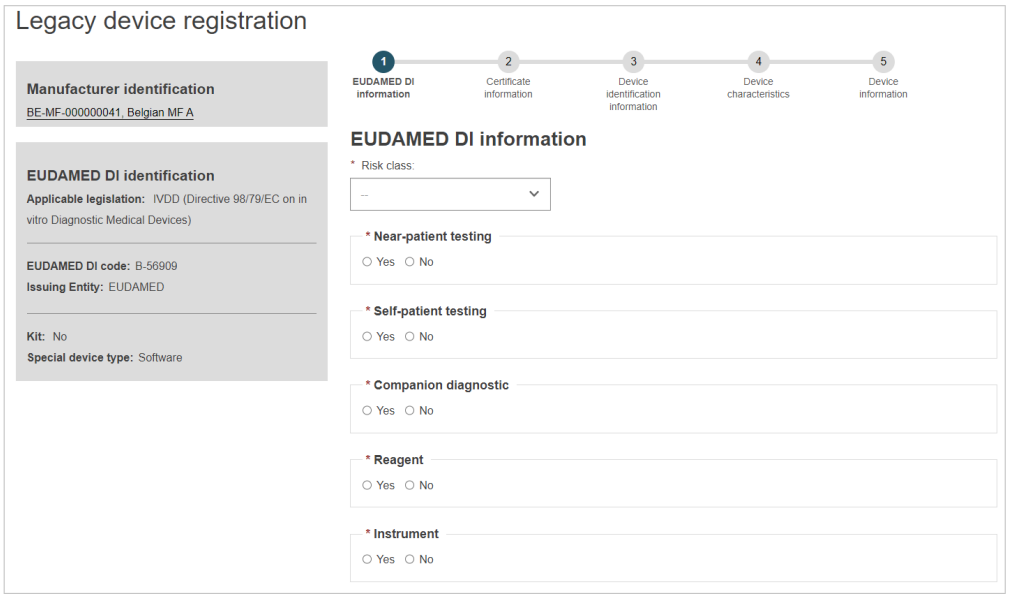
3. Non-EU manufacturers have to select the authorised representative (AR) for the current device from the options available.



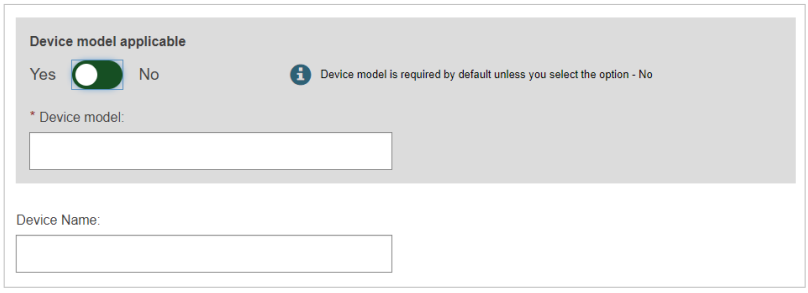
If there is only one AR with an active Mandate with the manufacturer, it will be automatically retrieved:



4. 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.



5. 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:



6. 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:

4.2 Step 2: Certificate information

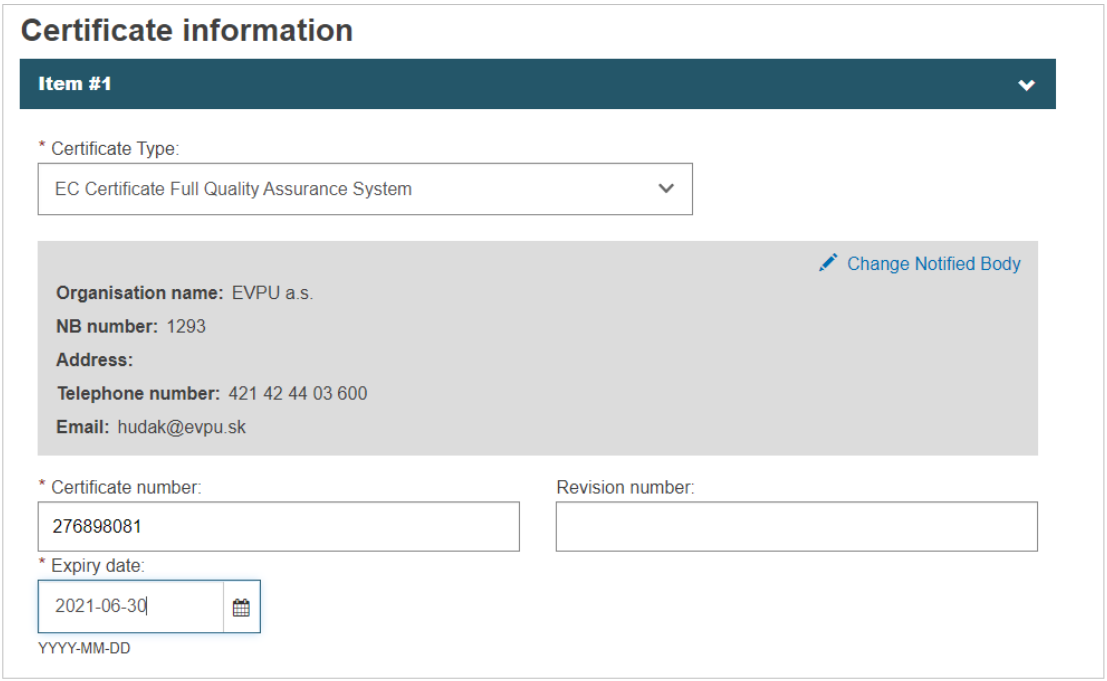
Select a certificate type, enter an NB number and click “**Find**”. Enter the certificate number and expiry date. If available, enter a revision number.

NOTE

Information on active certificates must be provided for Legacy Devices. Legacy devices could have no certificate information only in case a certificate would be required only under MDR/IVDR (like for class I reusable surgical instruments).

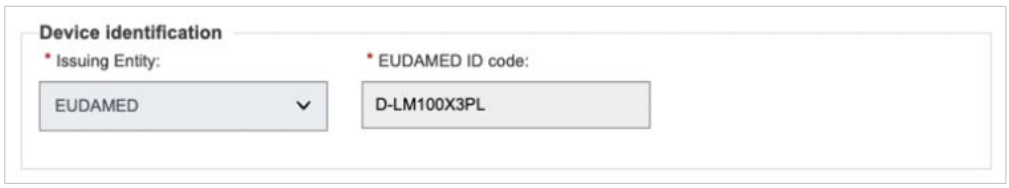
In *Annex 2 [89]* to this document you may find the certificate types that can be provided for the Legacy Devices specific for each applicable legislation of the Device.

Several identification details for several certificates can be entered:

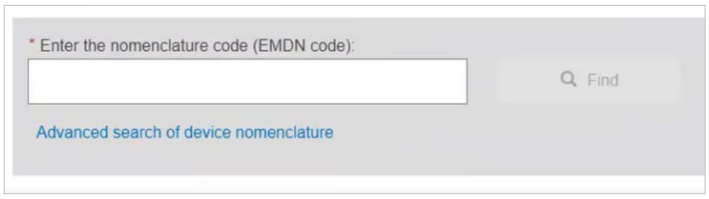


4.3 Step 3: Device identification information

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):

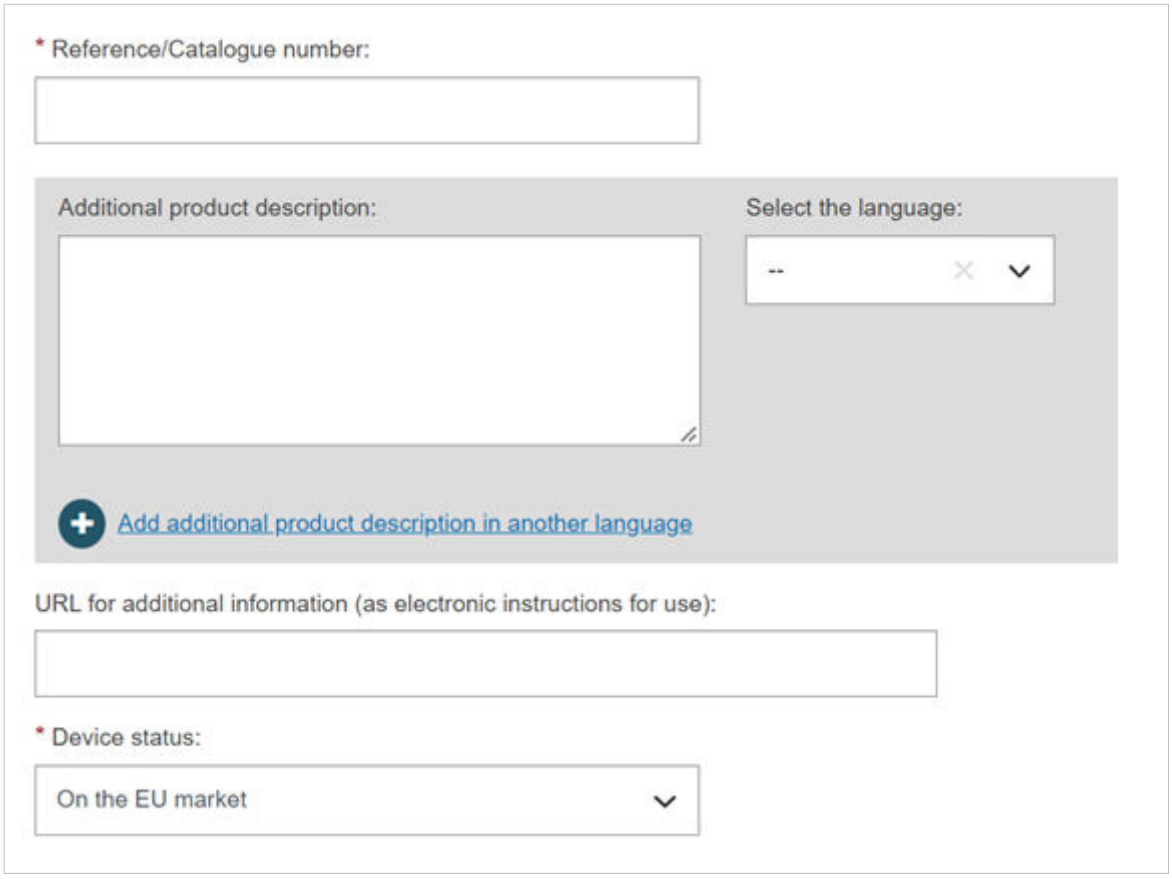


1. Enter the EMDN code. Click on **Find** and select the correct one:

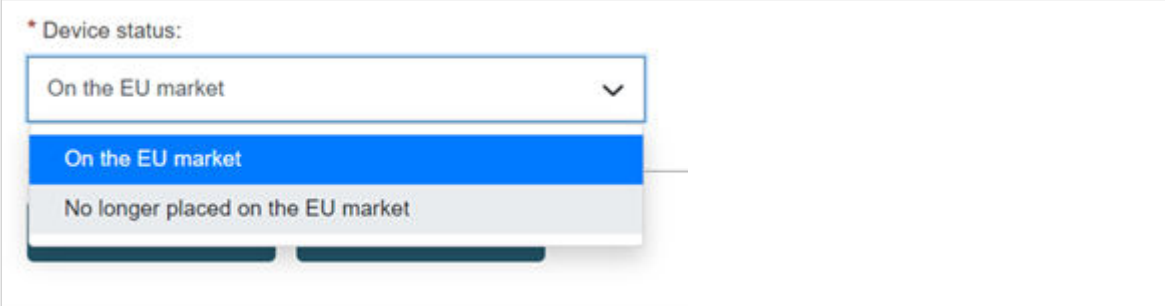


2. If applicable, enter the trade name and select the language, otherwise select **No**:

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

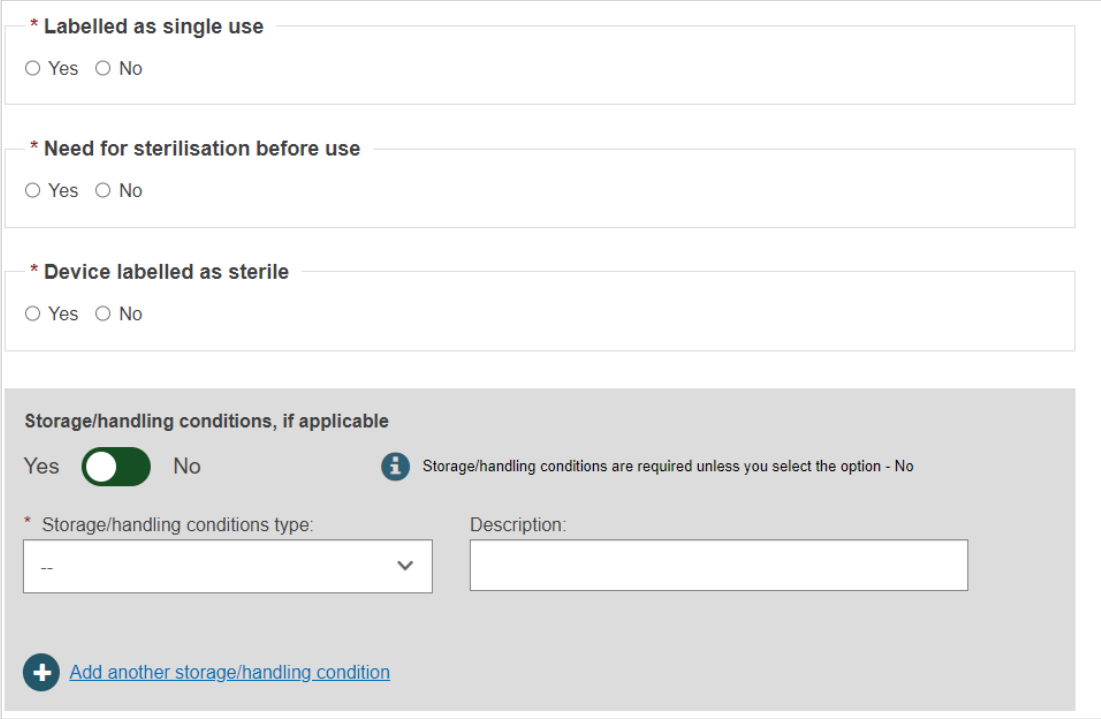


4. You can choose the market status of the Device:

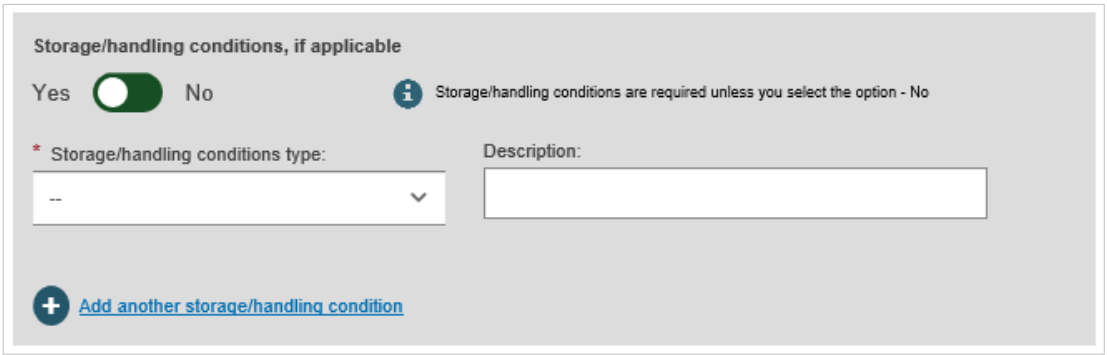


4.4 Step 4: Device characteristics

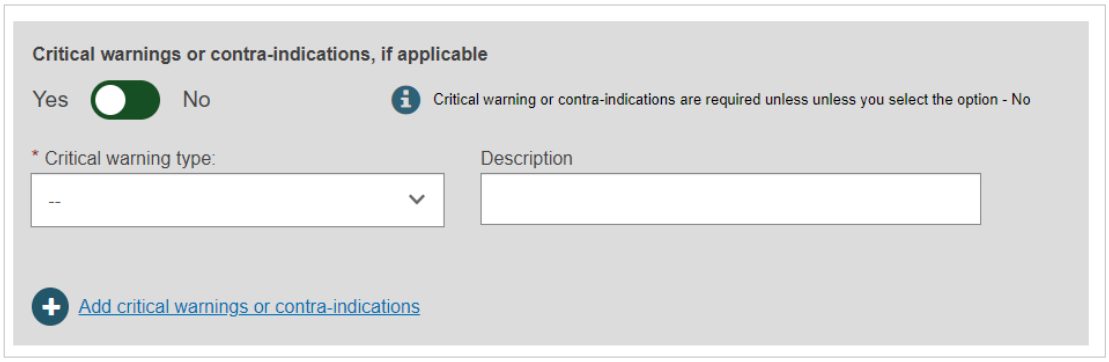
1. Select **Yes** or **No** for the first three options, then select **Yes** or **No** whether if Storage/ handling conditions are applicable:



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

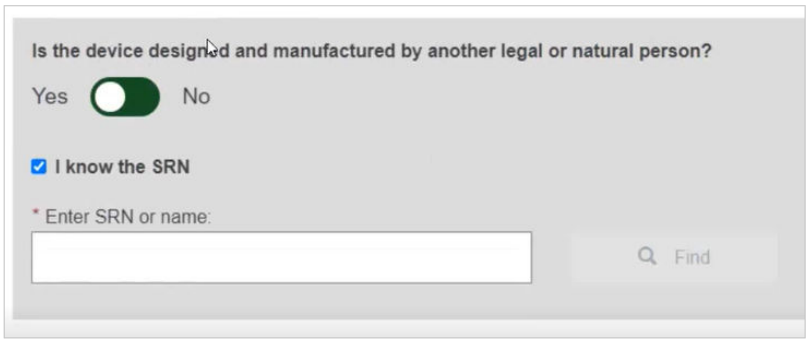


3. Select **Yes** or **No** for Critical warnings or contra-indications and if *Yes*, enter the type and description. After completing, click on **Save** or **Save & Next**:

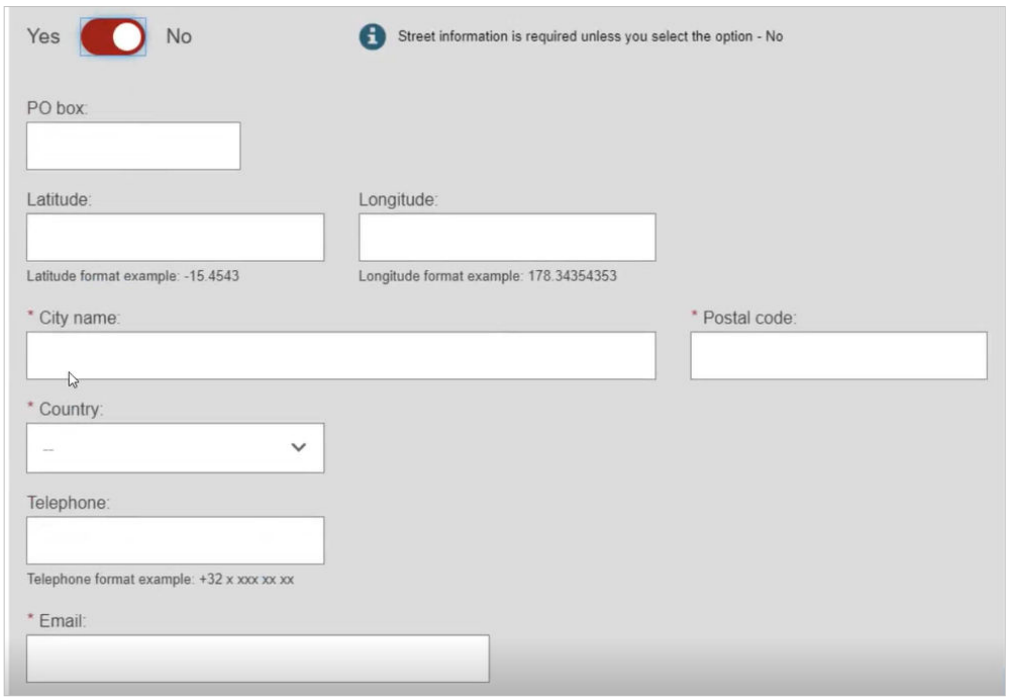


4.5 Step 5: Device information

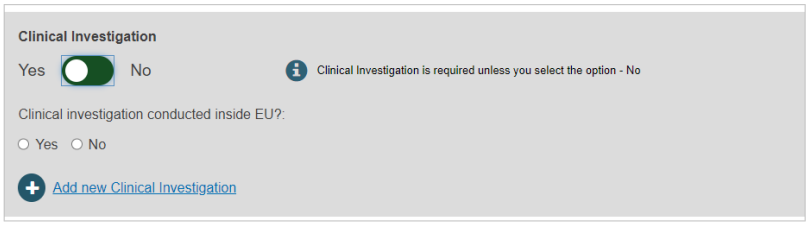
1. Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person, and enter the SRN number if you know it:



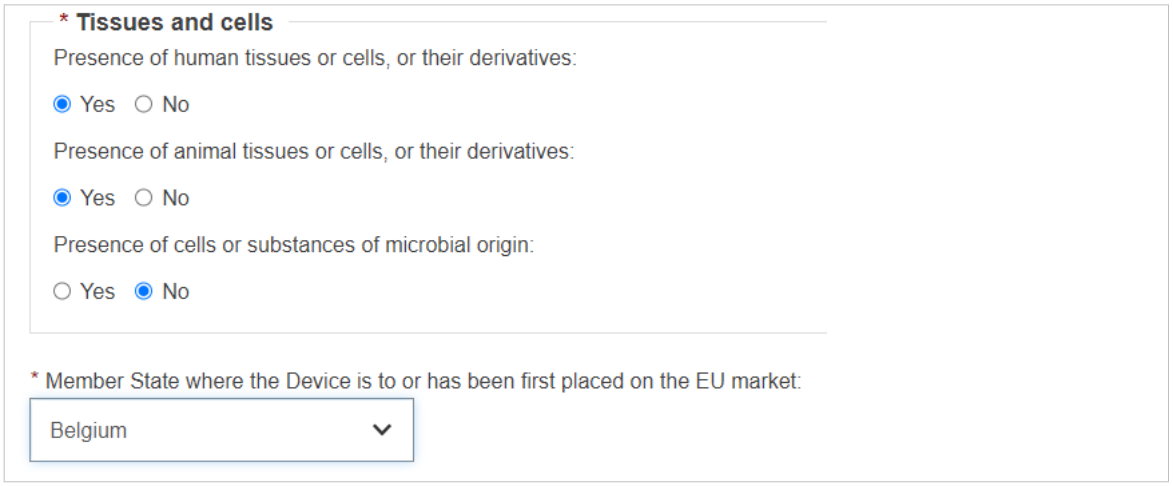
If you do not know the ActorID/SRN, uncheck the box and complete the required fields:



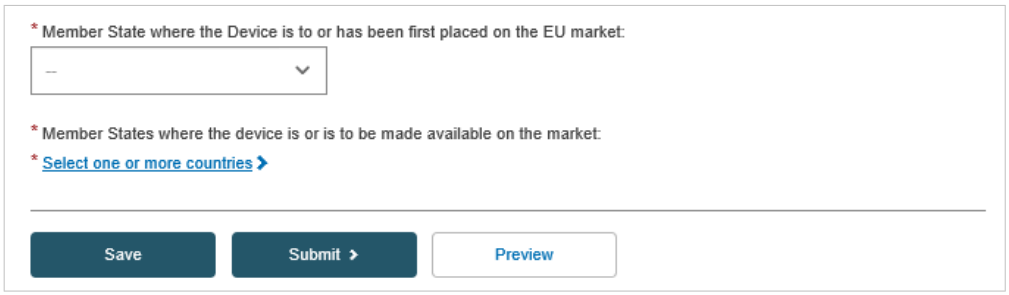
2. Select **Yes** or **No** to provide the Clinical Investigation reference:



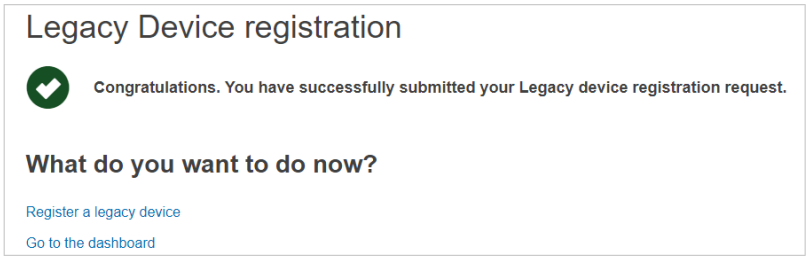
3. Select **Yes** or **No** for the three following options on Tissues and cells:



4. Select a Country 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:



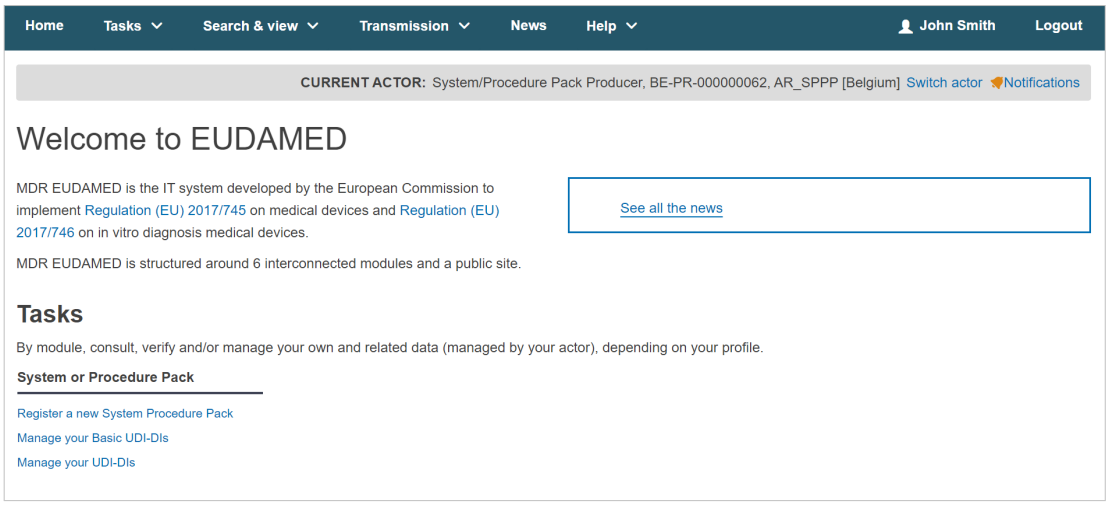
5 Registering System or Procedure Packs (SPP)

5.1 Registration of a Basic UDI-DI together with a UDI-DI for a System or Procedure Pack

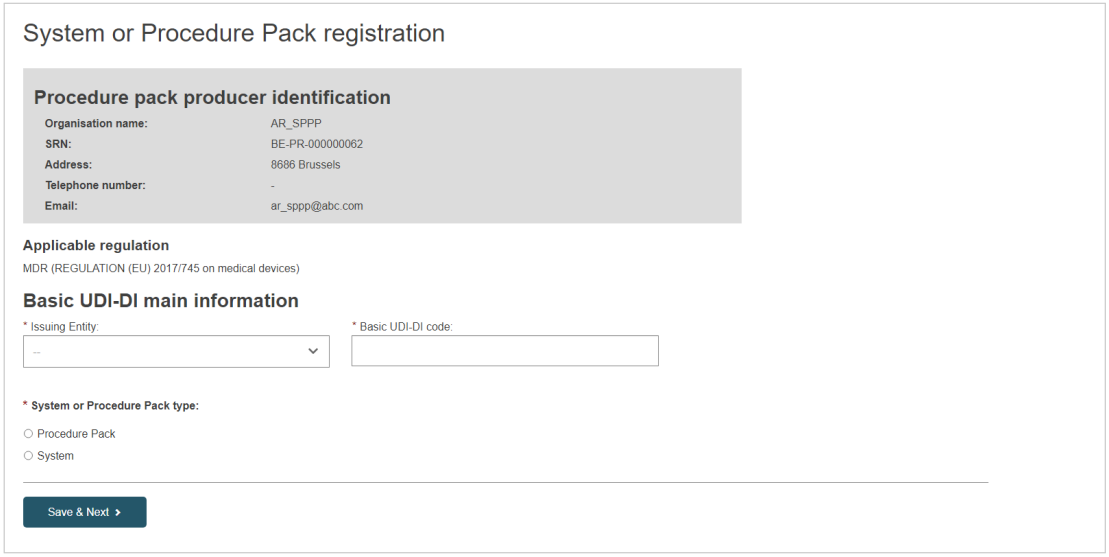
Registering System or Procedure Packs is only possible for users belonging to an actor that is a System and Procedure Pack producer.

5.1.1 Step 1: Basic UDI-DI main information

1. On the EUDAMED dashboard, click on **Register a New System Procedure Pack**:



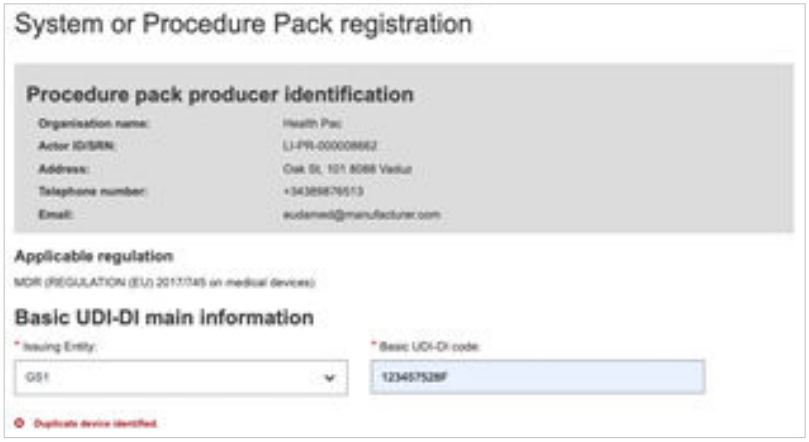
2. On the next page, specify the Issuing entity and the Basic UDI-DI code:



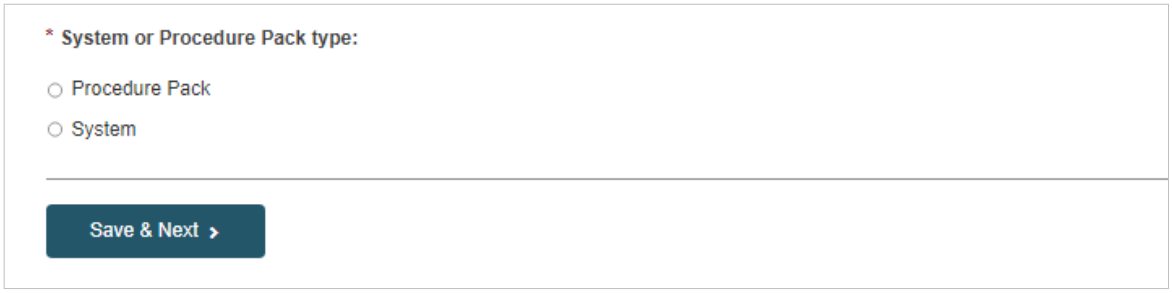
NOTE
Only the applicable legislation MDR (REGULATION (EU) 2017/745 on medical devices) is possible for system and procedure packs (selected by default).

IMPORTANT
EUDAMED will validate the Basic UDI-DI code you insert based on the specific format provided by each Issuing Entity. Please ensure that you enter the correct code with the check digits.

If the *Basic UDI-DI code* already exists in EUDAMED, the system will prevent you from saving – a Basic UDI-DI must be unique:

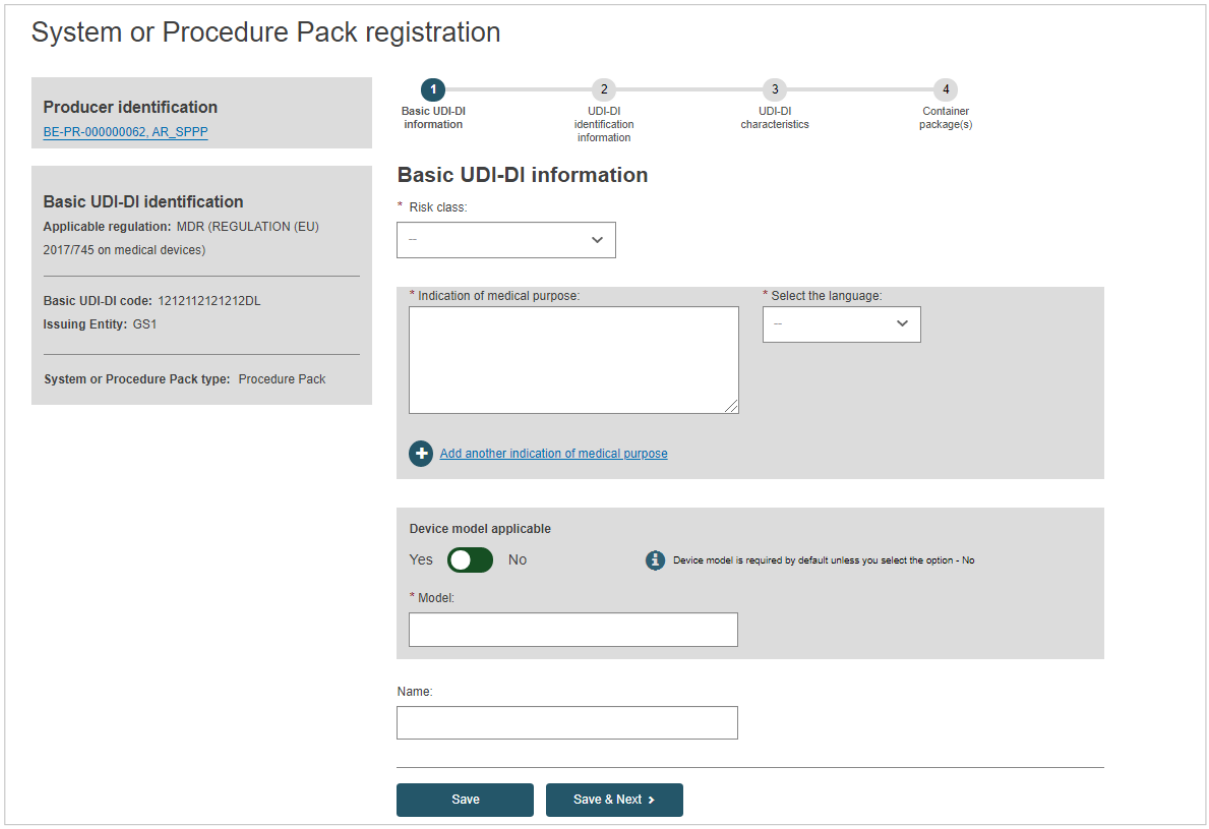


3. Choose if you are registering a system or procedure pack and click on **Save & Next** to save your registration as a draft and move on to the next steps:

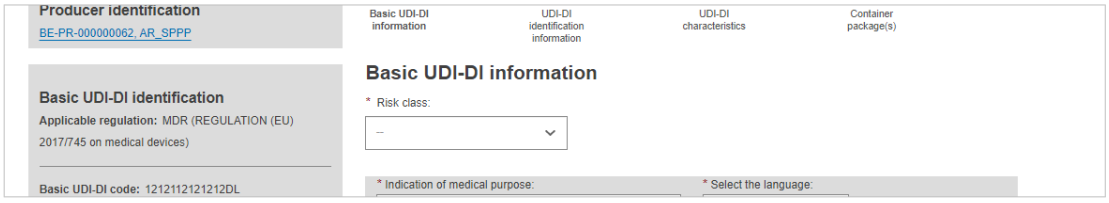


5.1.2 Step 2: Basic UDI-DI information

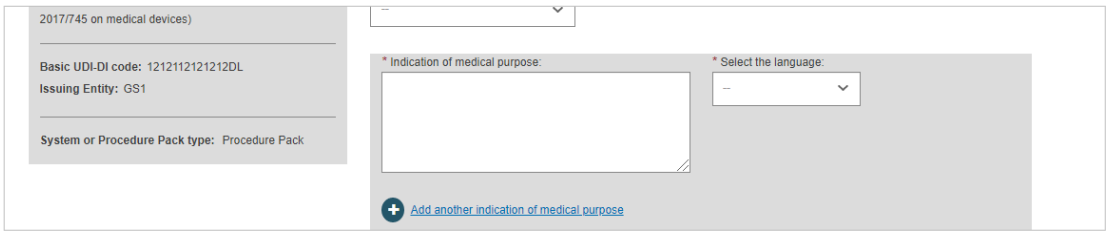
On the next page, enter the Basic UDI-DI information:



1. Choose a *'Risk Class'* from the drop-down list (the risk class must be the highest risk class of devices that are parts of the system or procedure pack):

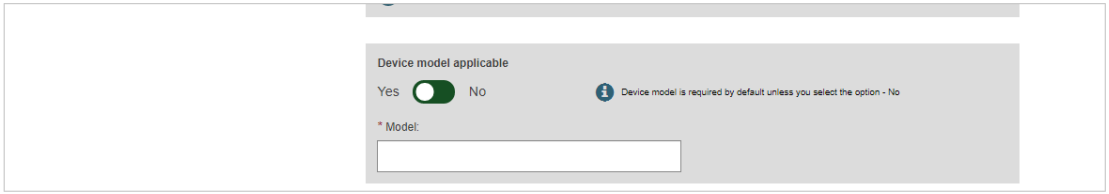


2. Fill in the indication of medical purpose and select the related language from the drop-down list.

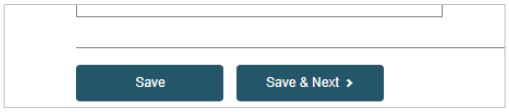


If you add the indication in several languages, click on “Add another indication of medical purpose” and select its language.

Select “**Yes**” or “**No**” if Device model is applicable and, if applicable, enter the Device model and a device name if there is one. Otherwise, enter only a Device name):



3. Click on “**Save**” to save your registration as a draft and come back to it later, or click on “**Save & Next**” to save it as a draft and continue to the next steps:



5.1.3 Step 3: UDI-DI identification information

1. Select the *Issuing Entity* from the drop-down list and enter the UDI-DI code:

IMPORTANT

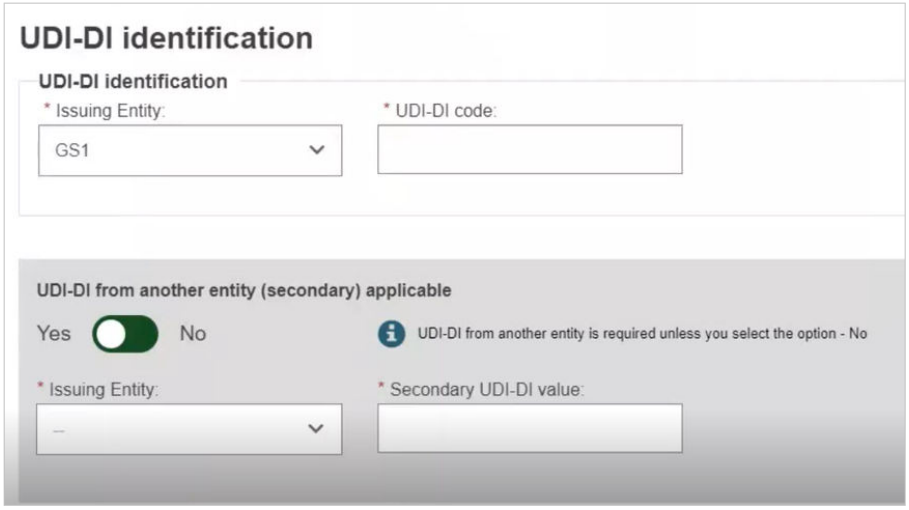
The UDI-DI code you enter must be unique. If it already exists in EUDAMED, you will not be able to Save.

NOTE
In the case of a GS1 Issuing Entity, the UDI-DI code you enter must be a 14-digit code including the check digit that will be used by EUDAMED to validate the UDI-DI code. If your GS1 UDI-DI (GTIN code) is less than 14 digits (check digit included), when populating EUDAMED field, please add leading zero(s) until you reach 14 digits.

For example:

- **000000nnnnnnnn (GTIN-8)**
- **00nnnnnnnnnnn (GTIN-12)**
- **0nnnnnnnnnnnn (GTIN-13)**

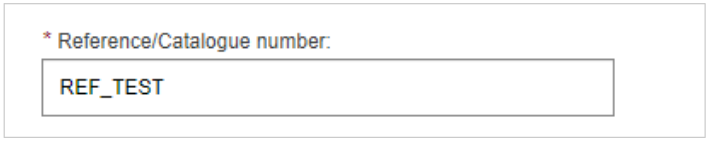
2. If applicable, enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI:



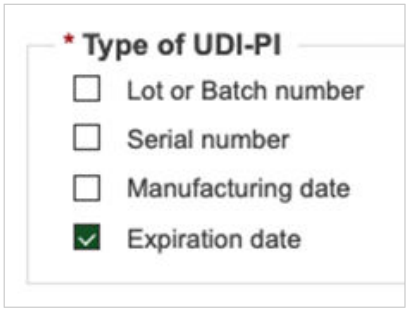
3. Enter the EMDN code and click on **Find**, and select the correct one from the list:

4. If applicable, enter the trade name enter the trade name (as specified on the device label) and select its related language (select **All languages** if not language dependent):

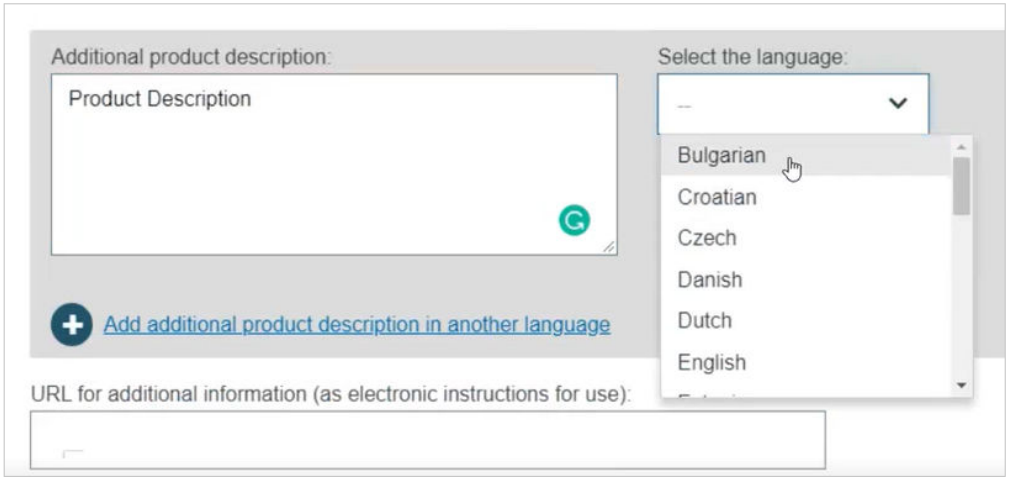
5. Enter the *Reference/Catalogue number*:



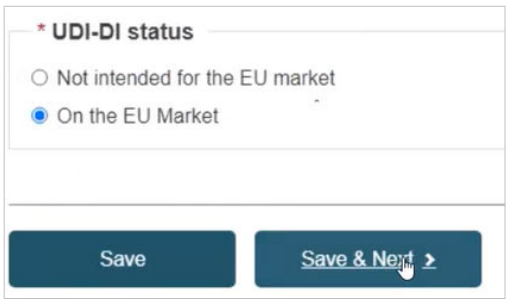
6. Select the *Type of UDI-PI*:



7. Enter any additional information you think important to specify about the System or Procedure Pack, select the language in which the additional information is provided and enter a URL (web address) if you have one for additional information online:

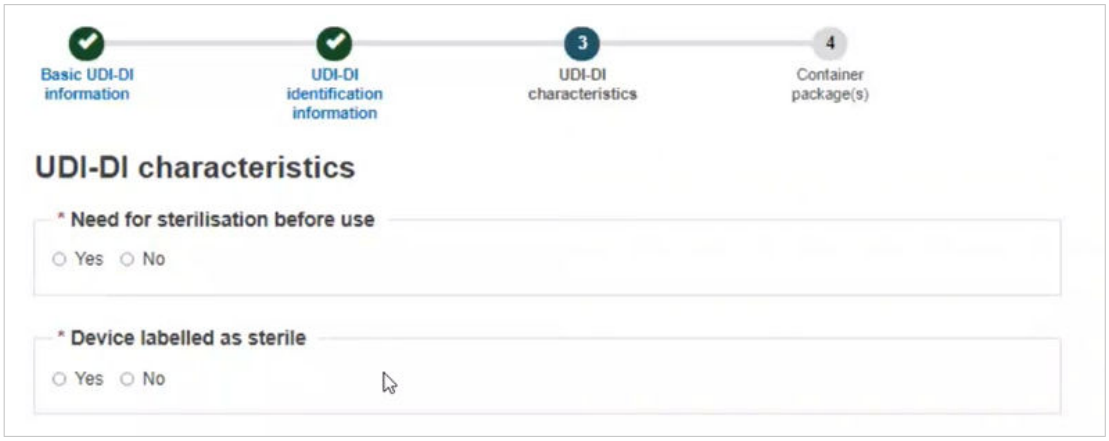


8. Specify the *UDI-DI status* in selecting whether it is **On the EU market** or **Not intended for the EU market** and click on **Save** or **Save & Next**:

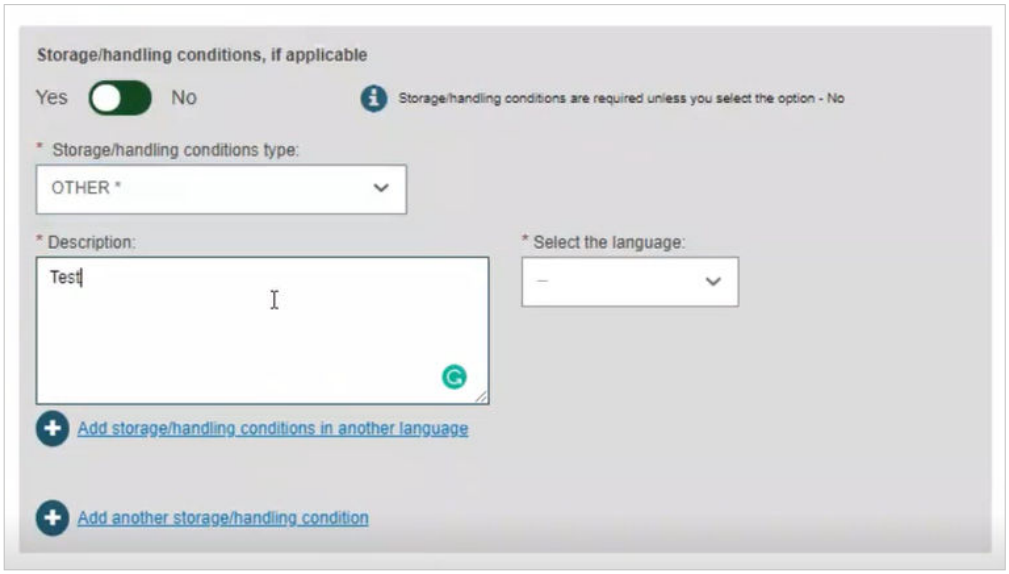


5.1.4 Step 4: UDI-DI characteristics

1. Select *Yes* or *No* for each option regarding sterilisation:

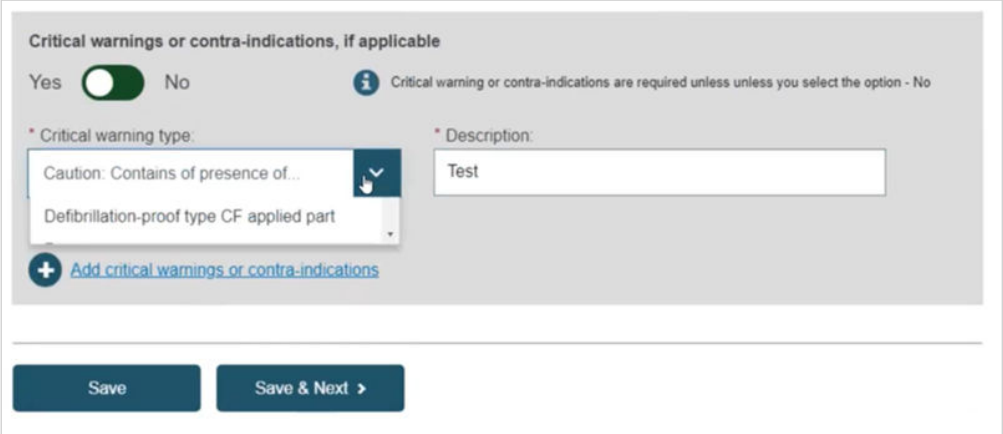


2. If Storage/handling conditions are applicable, slide the toggle to **Yes**. Choose the correct information from the list and provide a description where relevant:



NOTE
When the selected Storage/handling conditions type has the option *Other*, users will be required to enter the Description of the Storage/handling condition type and the language in which the description is given.

3. Do the same for Critical warnings or contra-indications, and click **Save** or **Save & Next**:

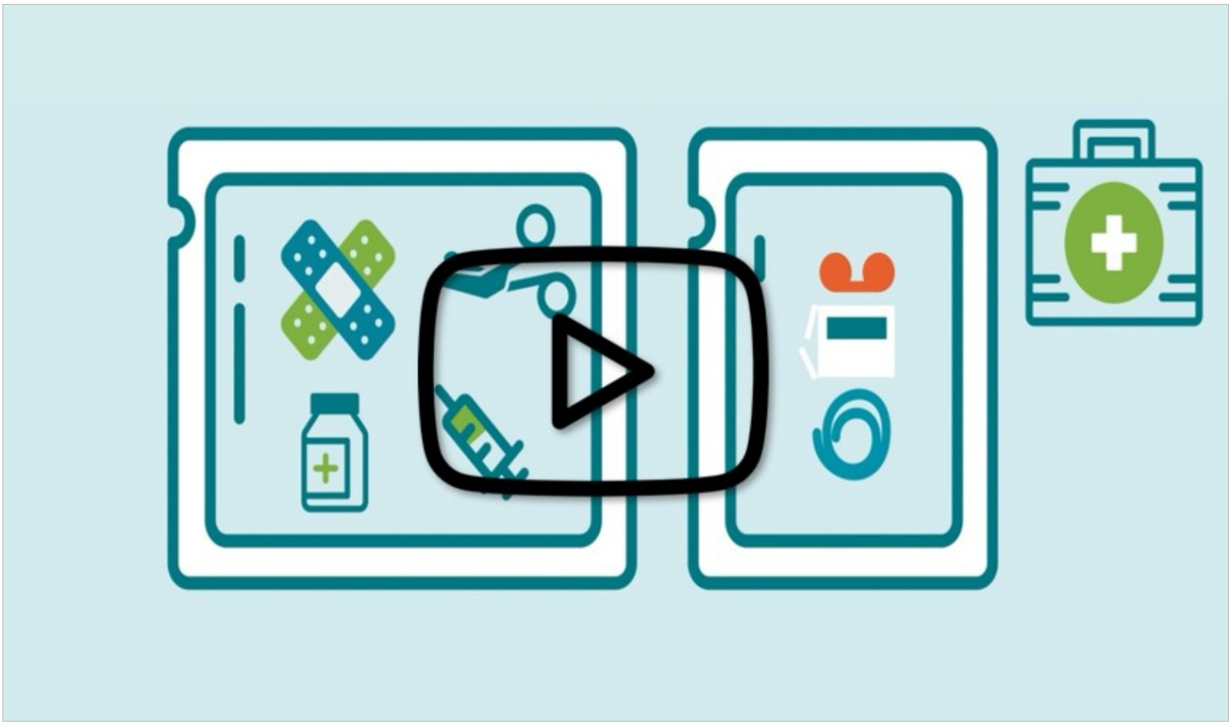


NOTE
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the language in which the description is given.

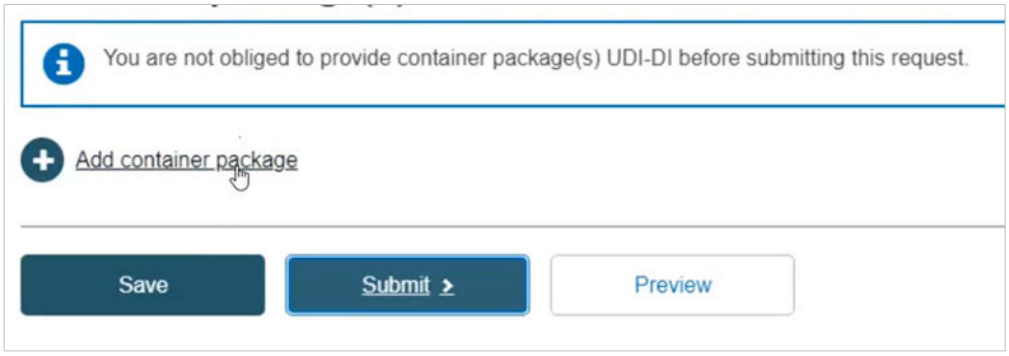
4. Click on **Save** to save draft and finish later or **Save & Next** to move directly to the next step of the process:

5.1.5 Step 5: Container package details

VIDEO: UDI and Systems and Procedure Packs

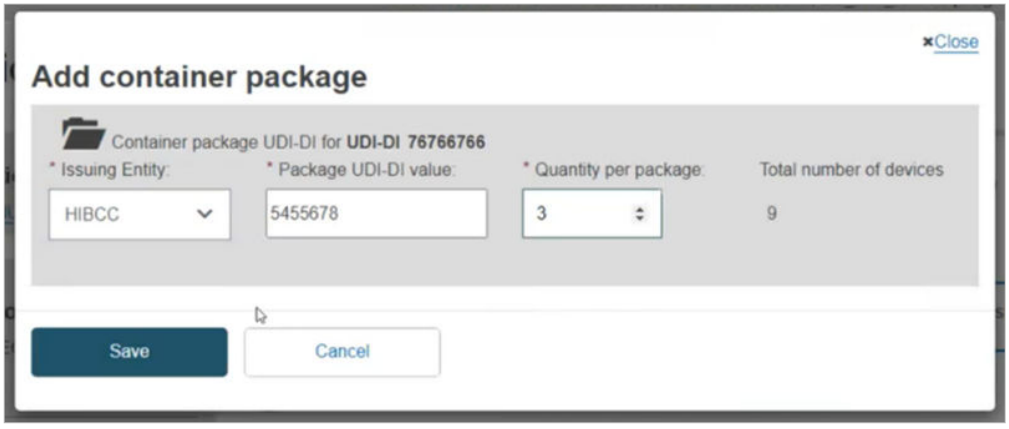


1. Click on **Add container package** when there is a higher packaging level for the root UDI-DI:

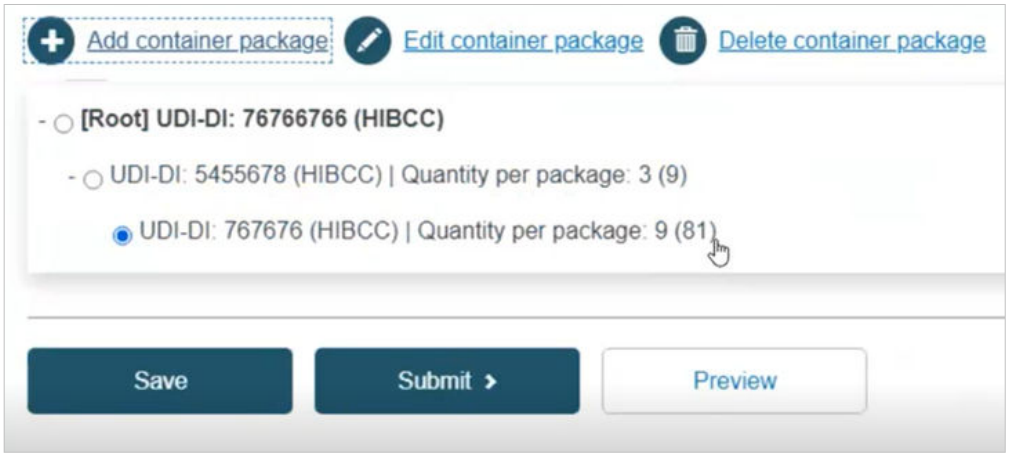


A unique UDI-DI must be assigned to each package level. You add a higher container package to the root UDI-DI if there is no container package UDI-DI yet, or to the selected UDI-DI (you can add as many levels and as many container packages per level as you have). Add the *Issuing Entity*, *Package UDI-DI code* and the *Quantity per package*, and click on **Save**:

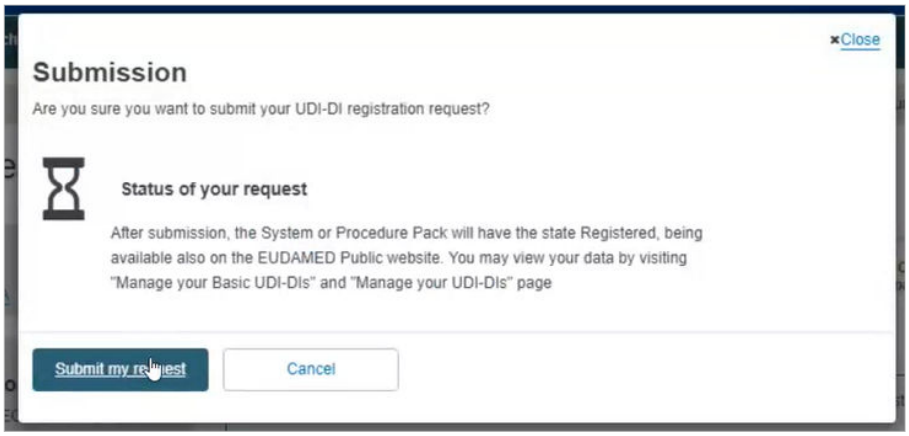
NOTE
If the UDI-DI already exists in EUDAMED, the system will prevent you from saving.



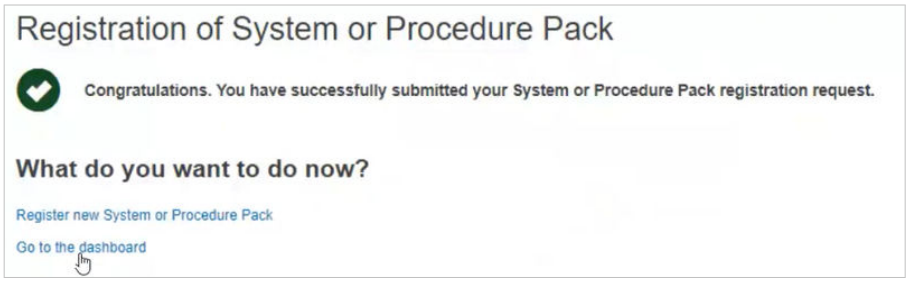
2. Select the generated information and click on **Submit**:



3. As a final step, a pop-up window will appear, asking you to confirm that you are ready to submit your registration request. If so, click on **Submit my Request**:

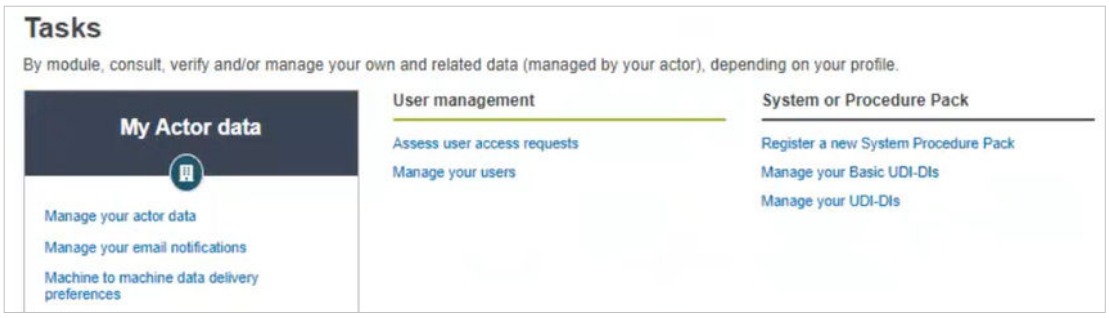


Upon submission, you will see a message that you have successfully submitted a SPP registration request:

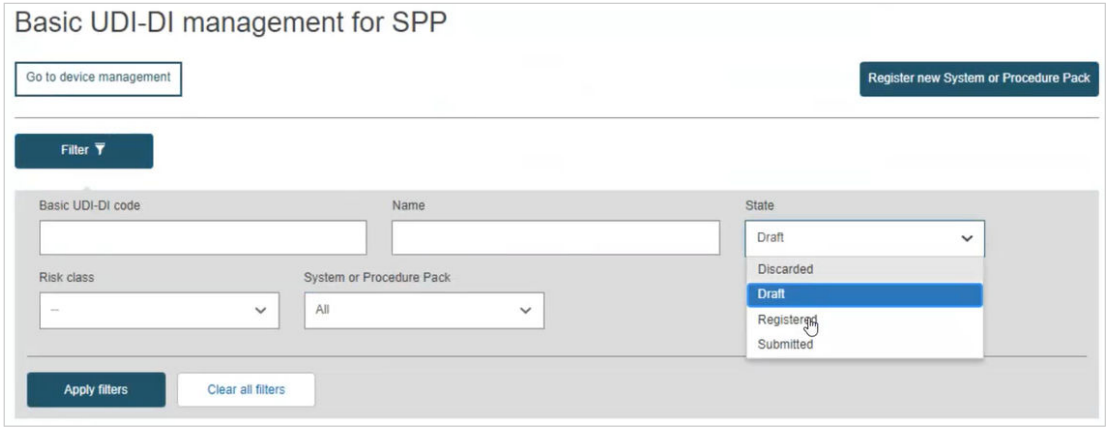


5.2 Registration of a UDI-DI for an existing Basic UDI-DI of a System or Procedure Pack

1. On the Dashboard, select **Manage your Basic UDI-DIs**:

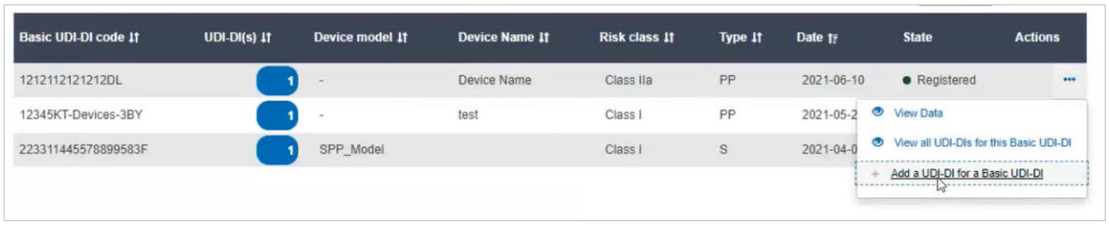


2. Filter the Basic UDI-DIs with the state *Registered*:
To do that click on the button **Filter**, then select *Registered* in the *State* box and then click on the button **Apply filter**:



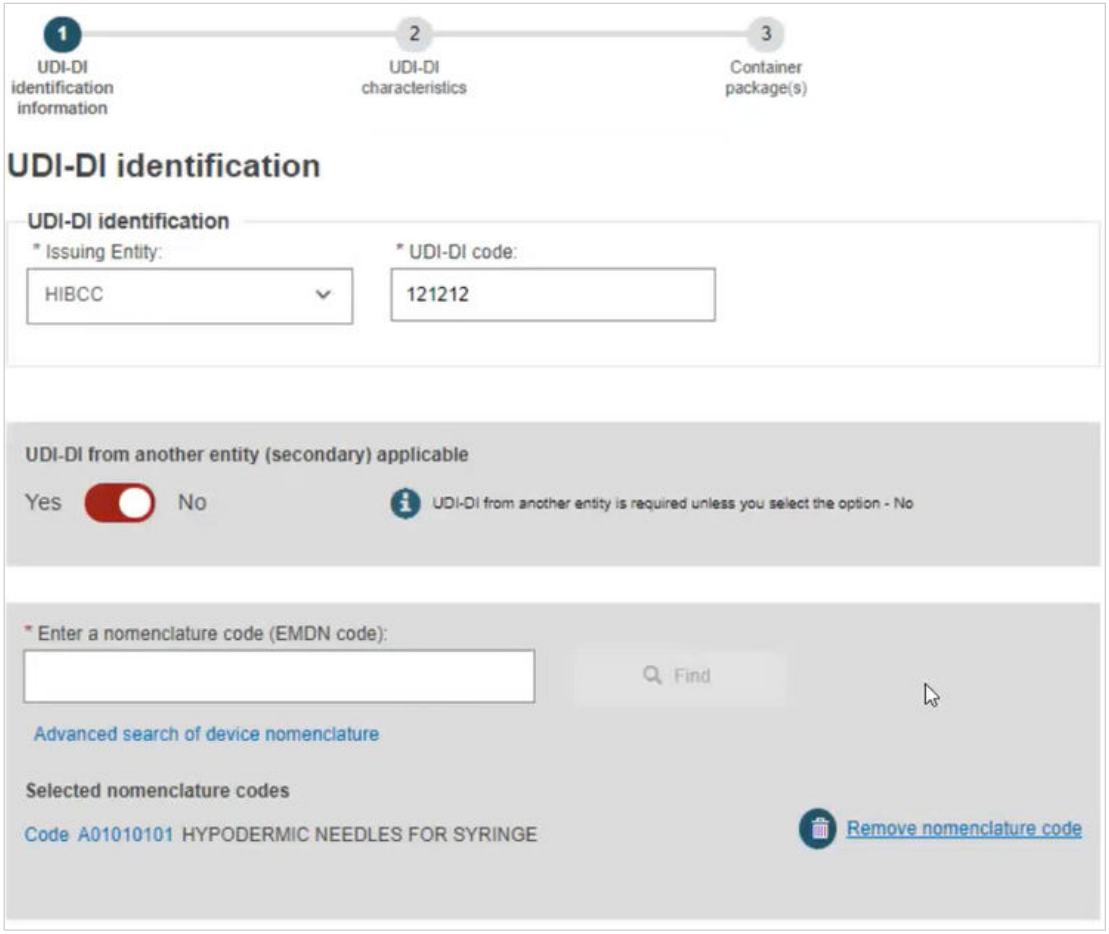
New UDI-DIs can be added only for Basic UDI-DIs in state *Registered* or *Submitted*.

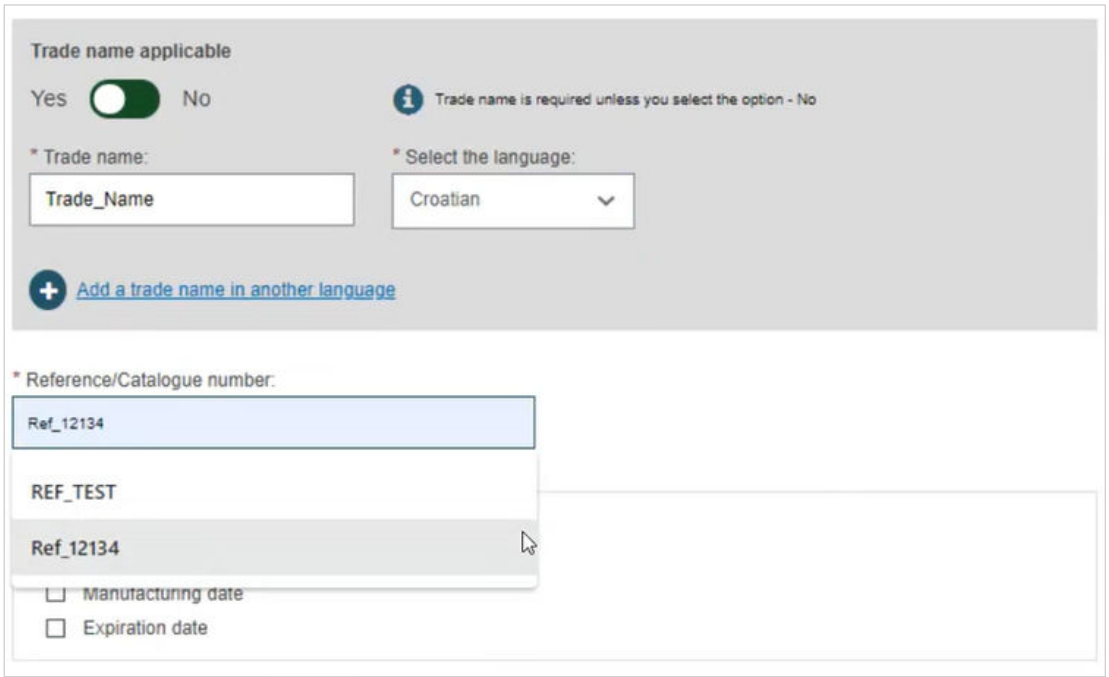
3. Identify the Basic UDI-DI for which you would like to add a new UDI-DI and click on the ellipsis symbol to add it:



5.2.1 Step 1: UDI-DI identification information

1. Complete all the necessary information in the *UDI-DI identification* information tab:

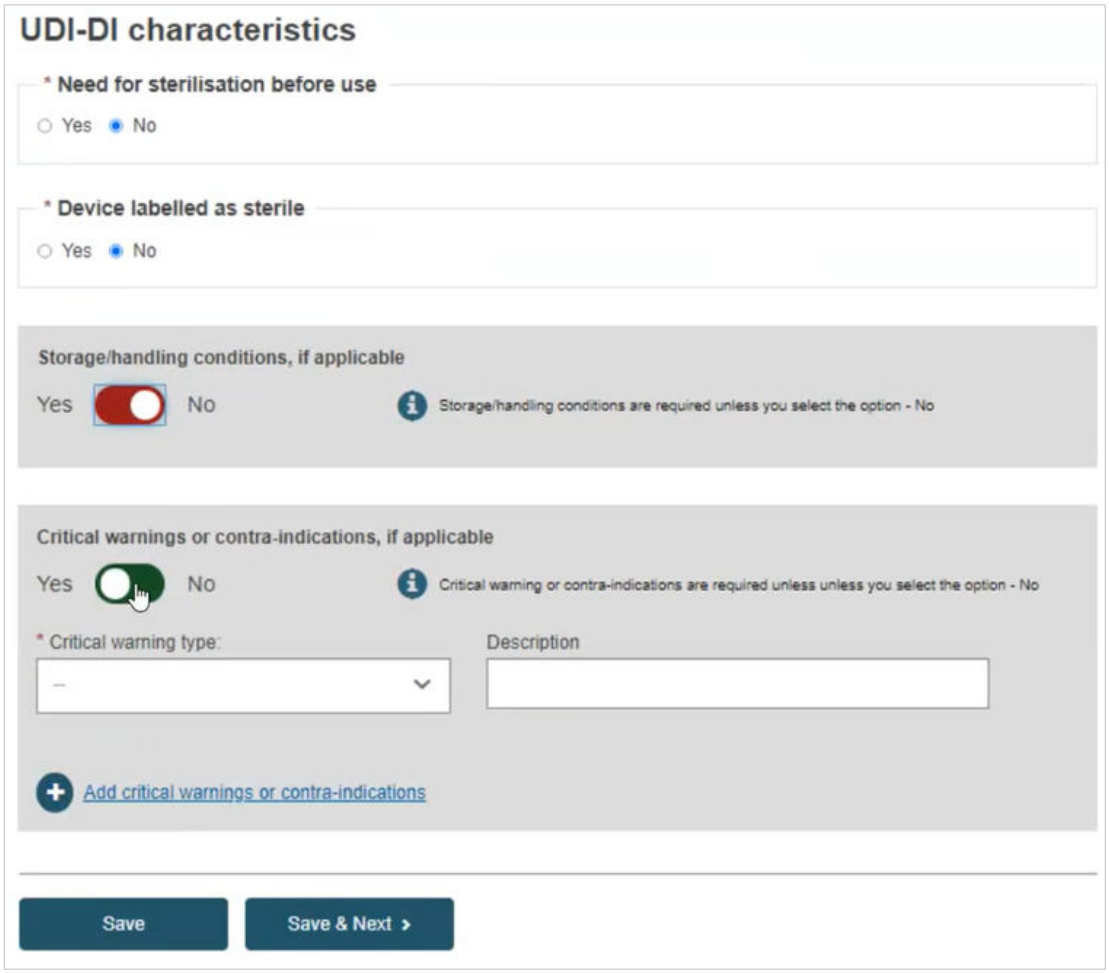




2. Click on **Save & Next** to move to the next step:

5.2.2 Step 2: UDI-DI characteristics

1. Fill in the fields for the *UDI-DI Characteristics* tab:



2. Click on **Save & Next** to move directly to the next step (or click on **Save** to save your draft for later).

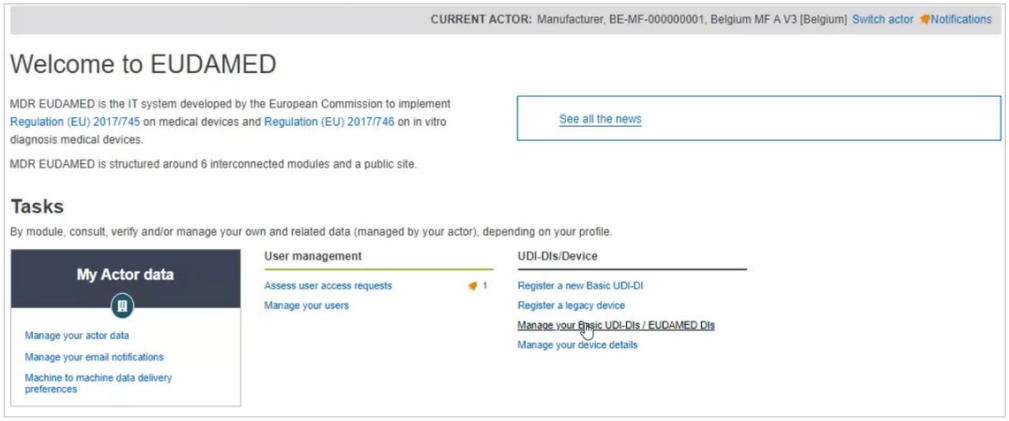
5.2.3 Step 3: Container package details

To complete this step, please consult *Section 5.1.5 [42] Container Package Details [42]* of this guide.

6 Manage your own device information

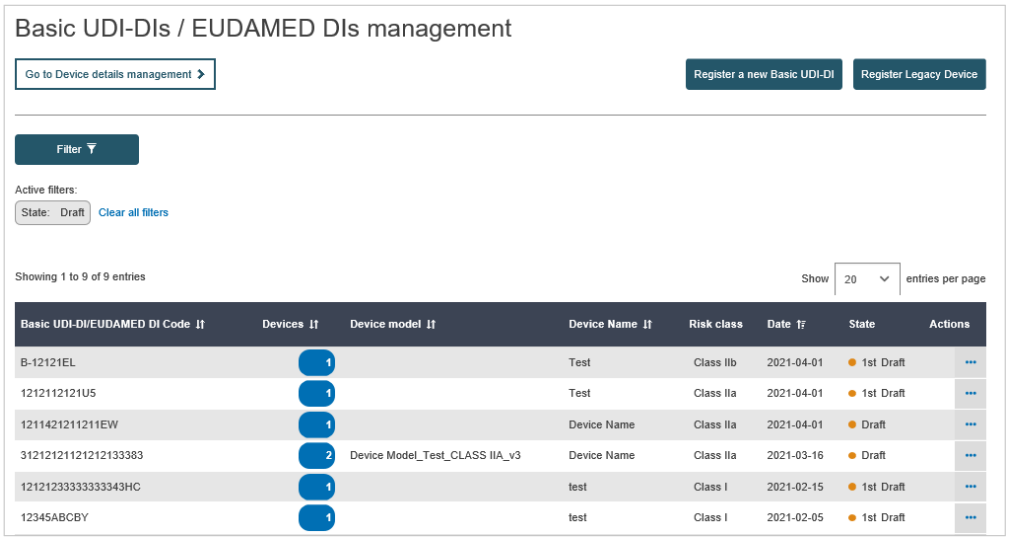
6.1 Manage your device Basic UDI-DI/ EUDAMED DI details

1. On the dashboard, click on **Manage your Basic UDIs/EUDAMED DIs**:

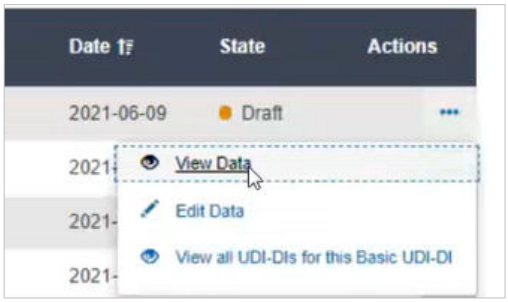


2. You will see a list with all of the Basic UDI-DIs /EUDAMED DIs registered to the current actor:

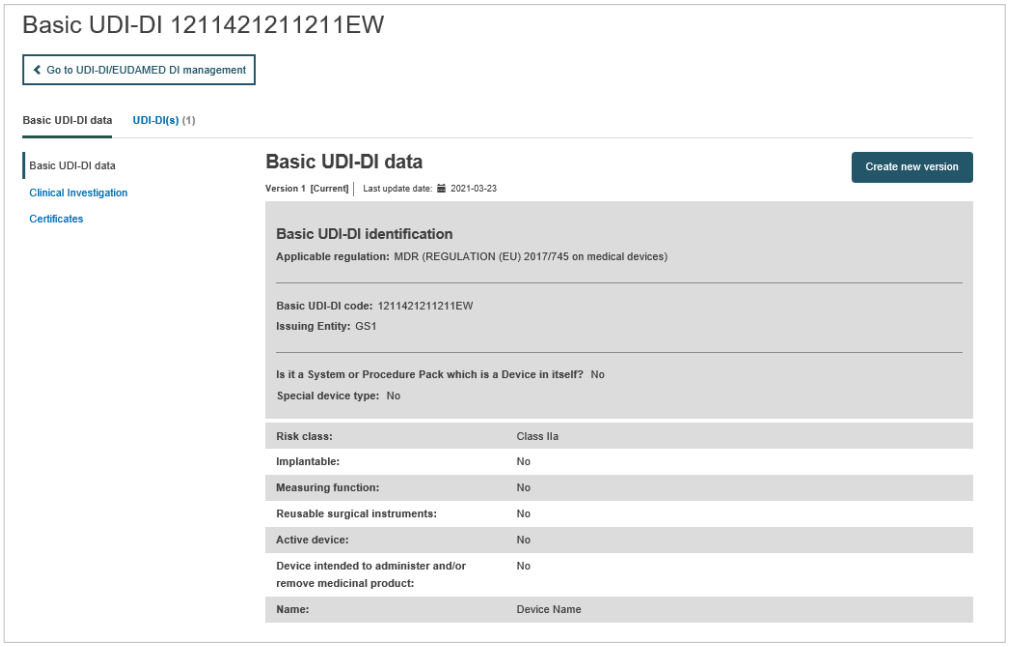
> **NOTE**
> By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in *draft* state. To retrieve Basic UDI-DIs/EUDAMED DIs in other states, use the filters.



3. Click on the three dots on the right of the desired entry and then click on **View Data** from the list:



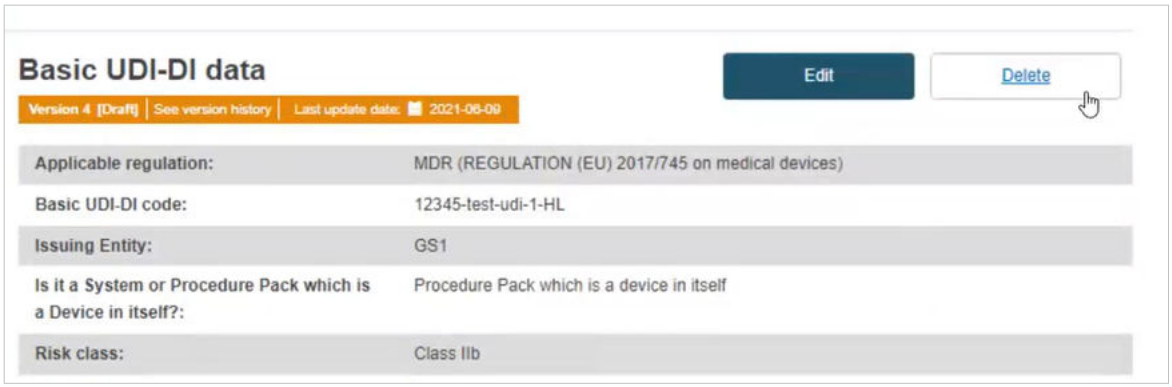
4. You will see a summary of the details concerning your Basic UDI-DI/EUDAMED DI:



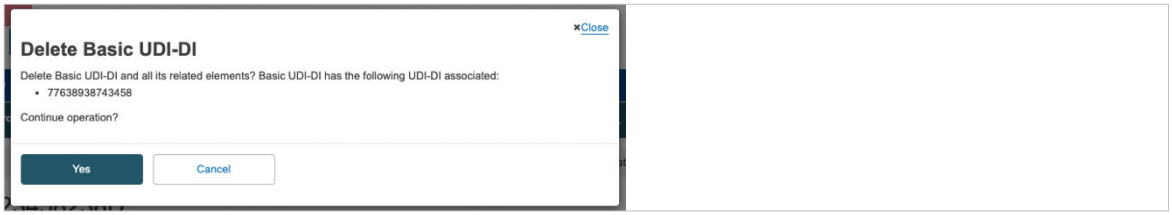
6.1.1 Delete a draft Basic UDI-DI/EUDAMED DI

After following steps 1, 2 and 3 from *Manage your device Basic UDI-DI/EUDAMED DI details* [48] to view a Draft Basic UDI-DI/EUDAMED DI in state *1st draft*, you have the option to delete this draft.

1. When you are inside the *View details* page of the desired 1st draft, click on **Delete**:

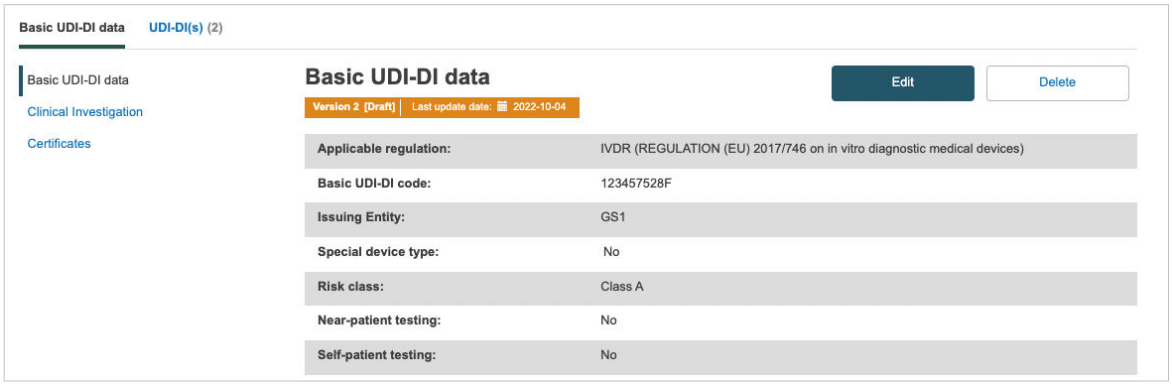


A pop-up will ask you to confirm the *delete* action:



The system also warns about deletion of the UDIs under the *1st draft* device.

2. To delete a draft version of a device open the *View details* page of the device. The system will display the existing draft version. Click on **Delete**:

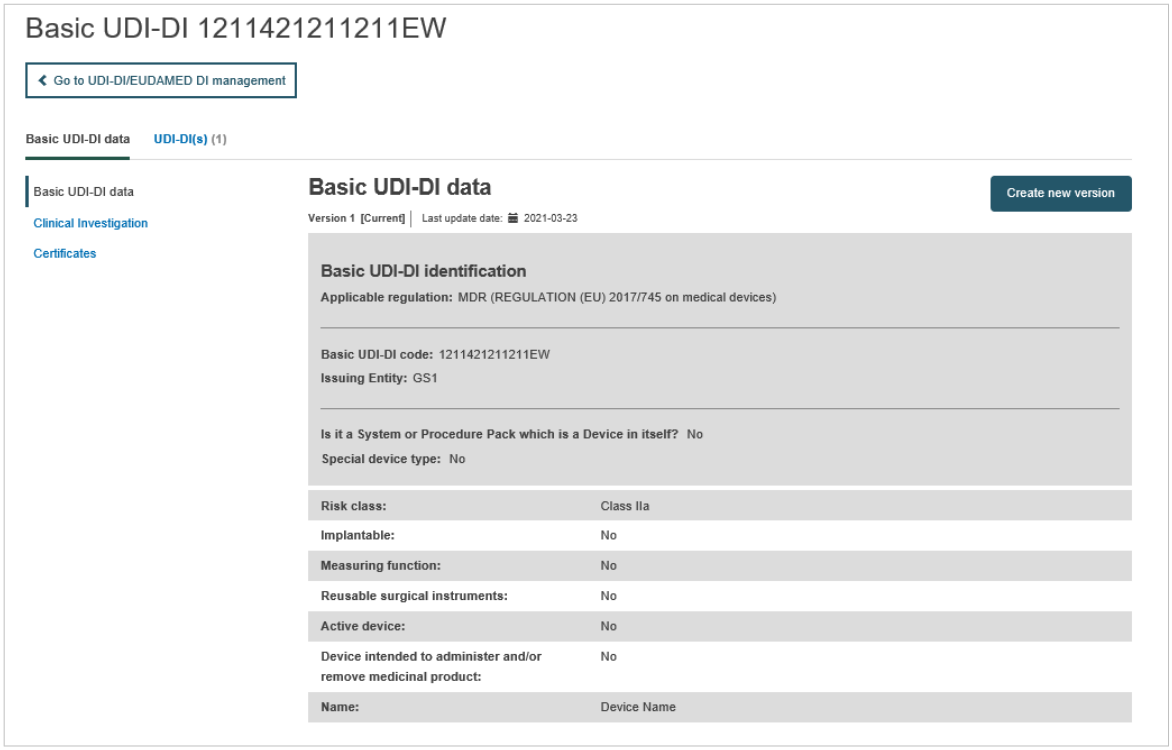


A pop-up will ask you to confirm the *delete* action:

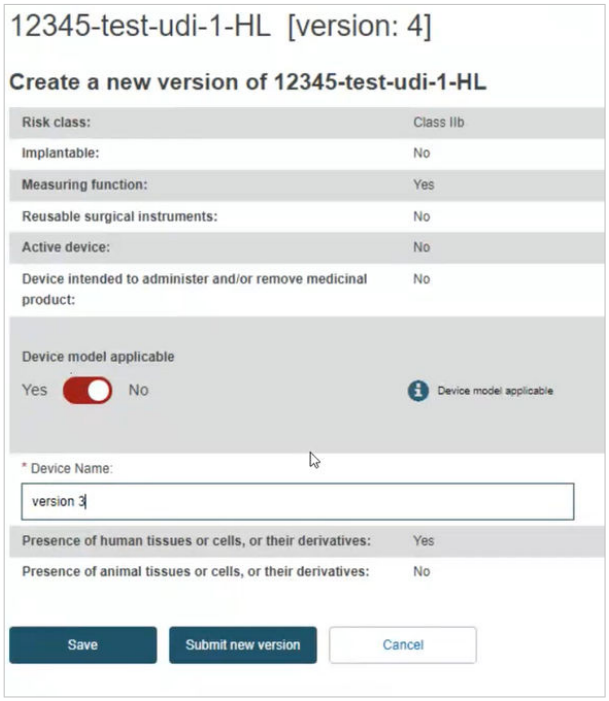
6.1.2 Update (create new version) for Basic UDI-DI/ EUDAMED DI

Follow the steps in section *Manage your device Basic UDI-DI/EUDAMED DI details* [48] to view a Basic UDI-DI/EUDAMED DI.

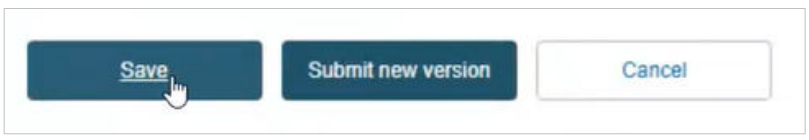
1. Once inside the details page for the desired Basic UDI-DI, click on **Create new version** on the top right corner:



2. Update the desired details:



3. To complete the action:
   a. Click on **Save** to save to your registration as a draft and continue at a later point.



   b. Click on **Submit new version**, if you are certain about the update and wish to submit it.

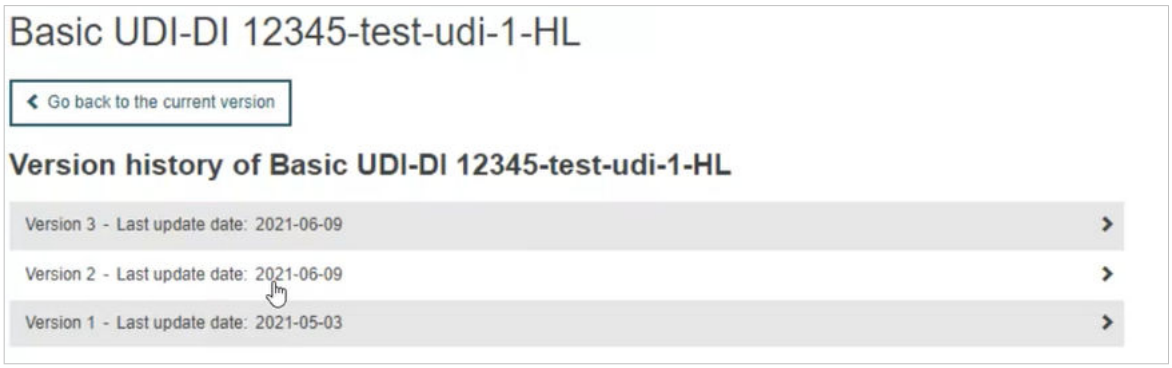
Alternatively, click on **Cancel** to cancel the update.

6.1.3 View historical versions for Basic UDI-DI/ EUDAMED DI

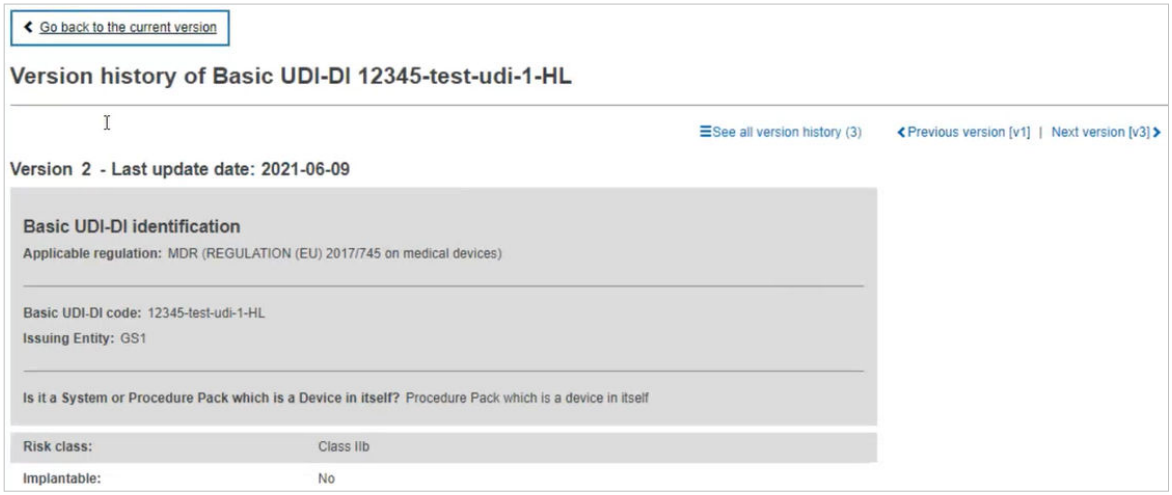
Follow the steps in section *Manage your device Basic UDI-DI/EUDAMED DI details* [48] to view a Basic UDI-DI/EUDAMED DI.

1. Once inside the details of the selected Basic UDI-DI, click on **See version history**:

2. View the list of versions for the desired Basic UDI-DI and click on the version you wish to view:

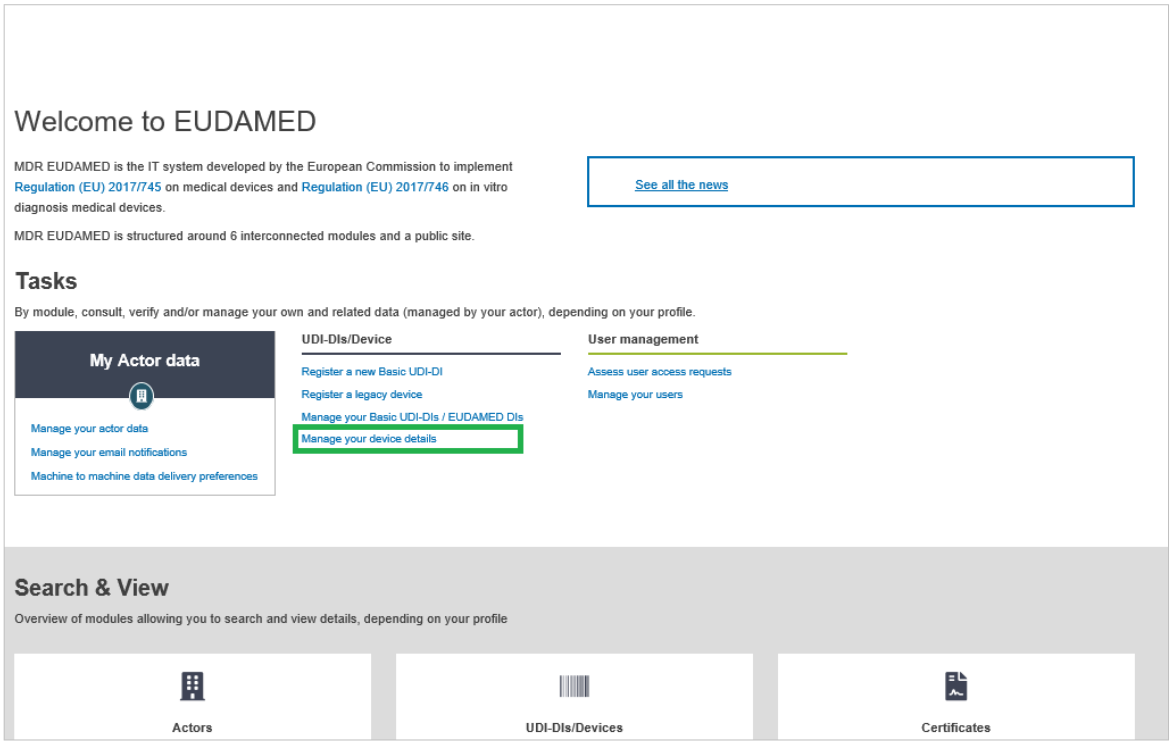


3. Inside a version, you can browse through the different versions by clicking on the arrows on the top right corner:



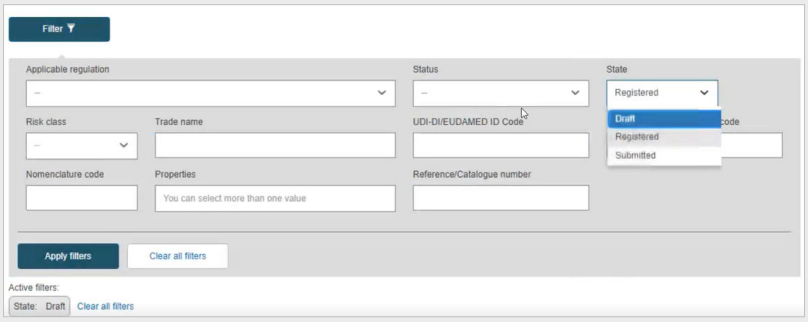
6.2 Manage your device UDI-DI/EUDAMED ID details

1. On the dashboard of EUDAMED, click on **Manage your Device details**:

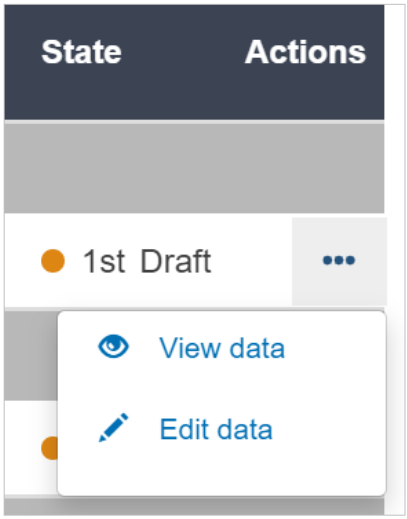


2. You will see a list:

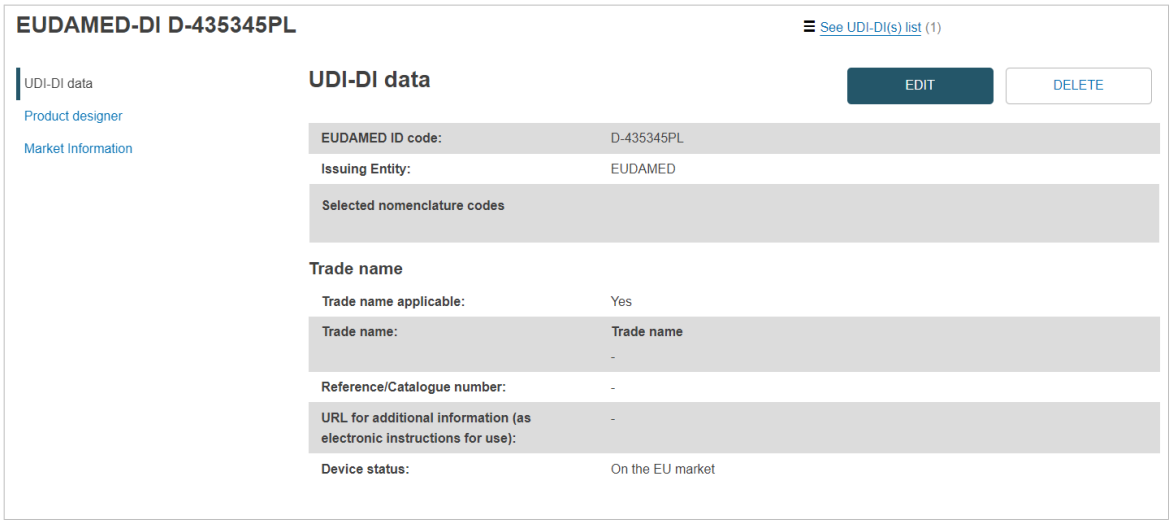
NOTE
By default, the system lists the devices in *draft* state. To retrieve other states use the filters:



3. Click on the three dots symbol on the right of the desired entry and then click on **View data**:



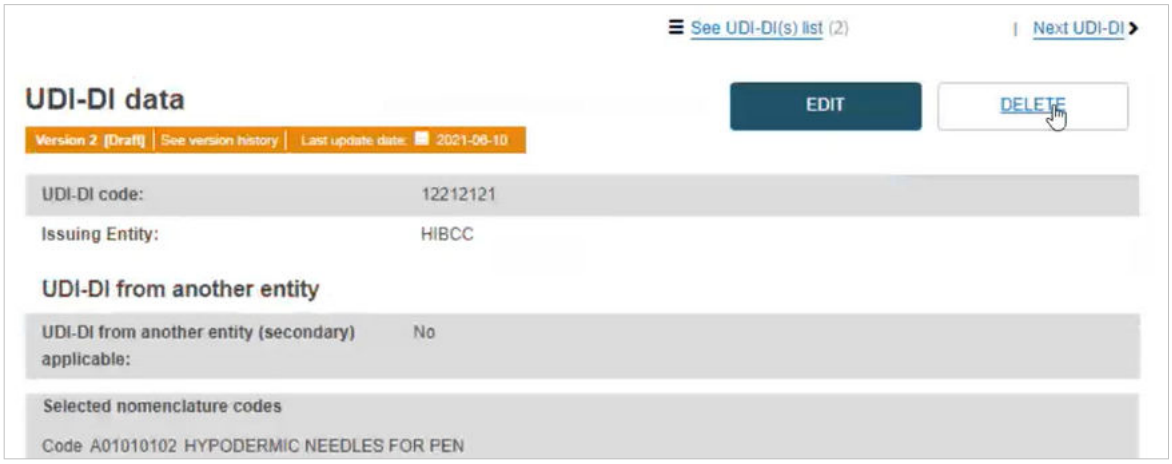
4. You will see a summary of the details of your device:



6.2.1 Delete a draft UDI-DI/EUDAMED ID

Follow the steps in *Manage your device UDI-DI/EUDAMED ID details* [53] to view a draft UDI-DI.

1. Once inside the desired Draft UDI-DI, click on **Delete**:



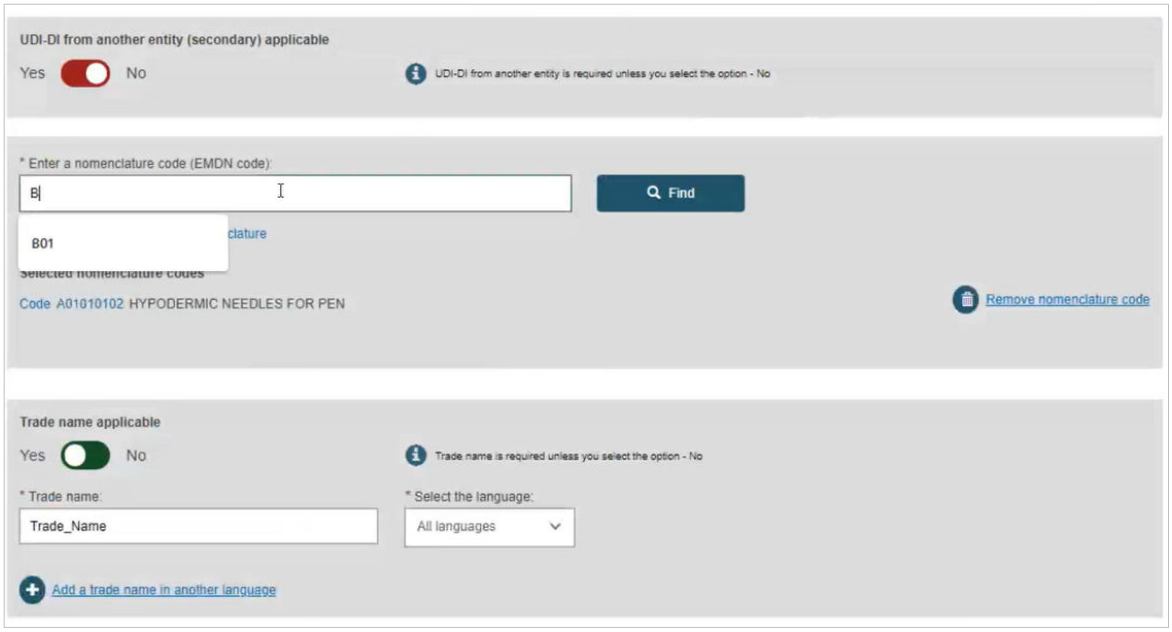
2. A pop-up message will ask you to confirm the *delete* action:

6.2.2 Update (create a new version) for UDI-DI/ EUDAMED ID

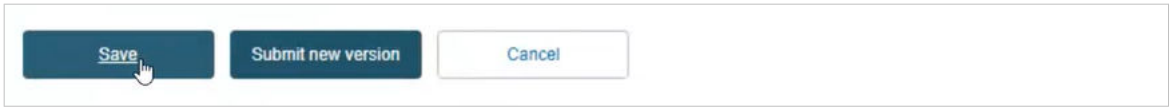
VIDEO: UDI assignment and updates

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [53] to view a UDI-DI/EUDAMED ID.

1. Once inside the details of the selected UDI-DI, click on **Create new version** and proceed to update:



2. To finish the action you have two options:
   a. **Save** to save the updated details without submitting the new version.
   b. **Submit new version**, if you wish to finalise the update.

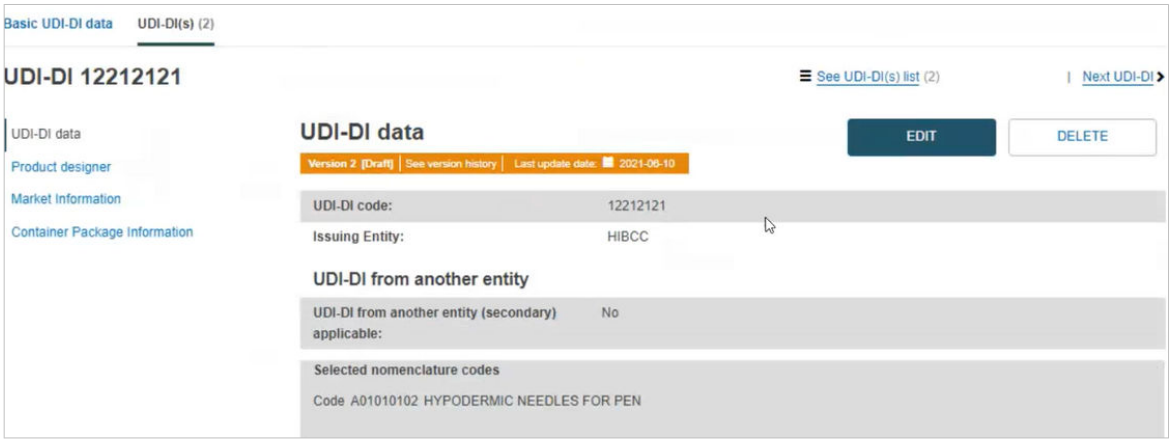


6.2.3 Update (create new version) for Product Designer

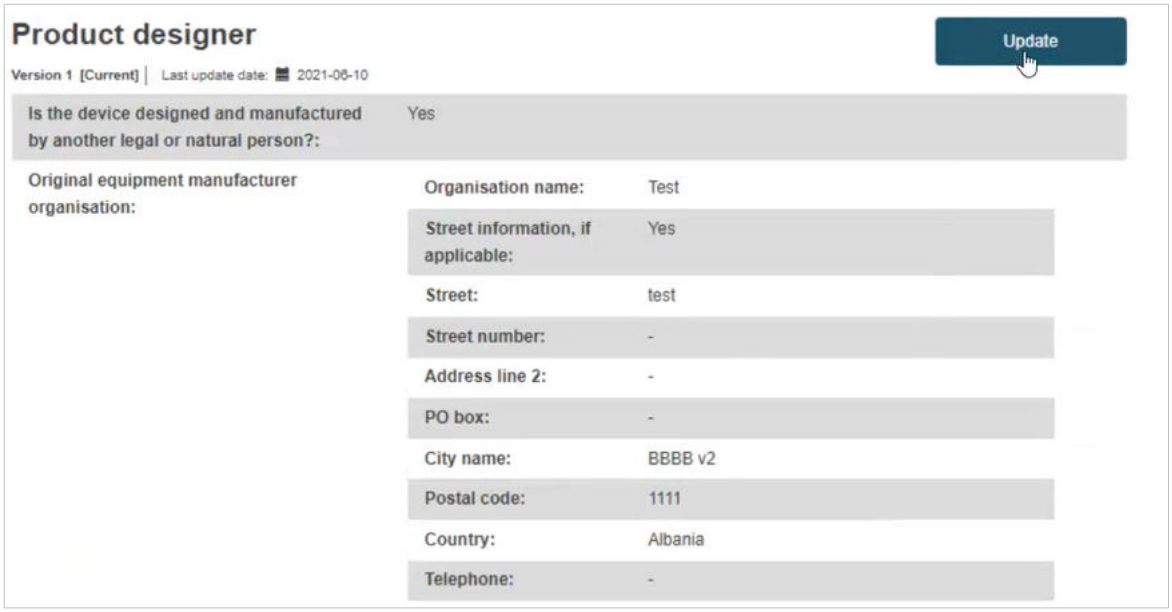
The *Product Designer* information can be updated independently of the other data in a device UDI-DI record.

1. Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [53] to view a UDI-DI/EUDAMED ID.

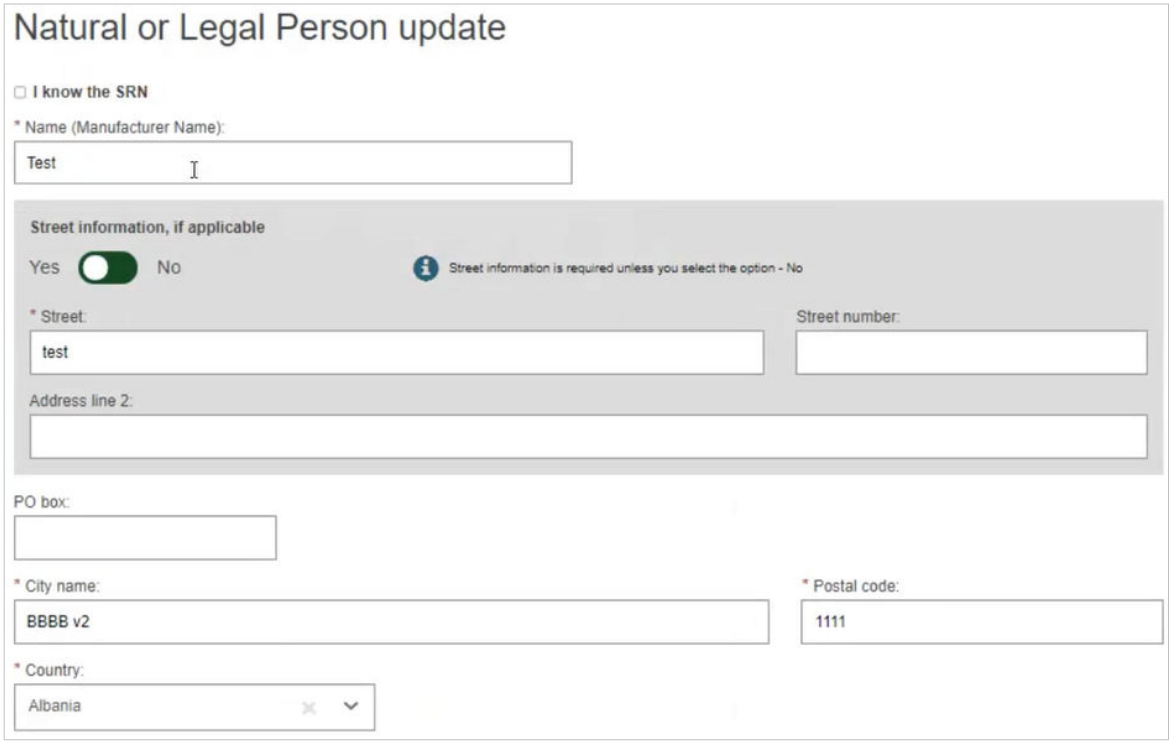
2. Once inside the details of the selected UDI-DI, click on **Product Designer** from the list on the left (or scroll down to the *Product Designer* section):



3. Click on **Update**:



4. Update the information under *Product Designer*:



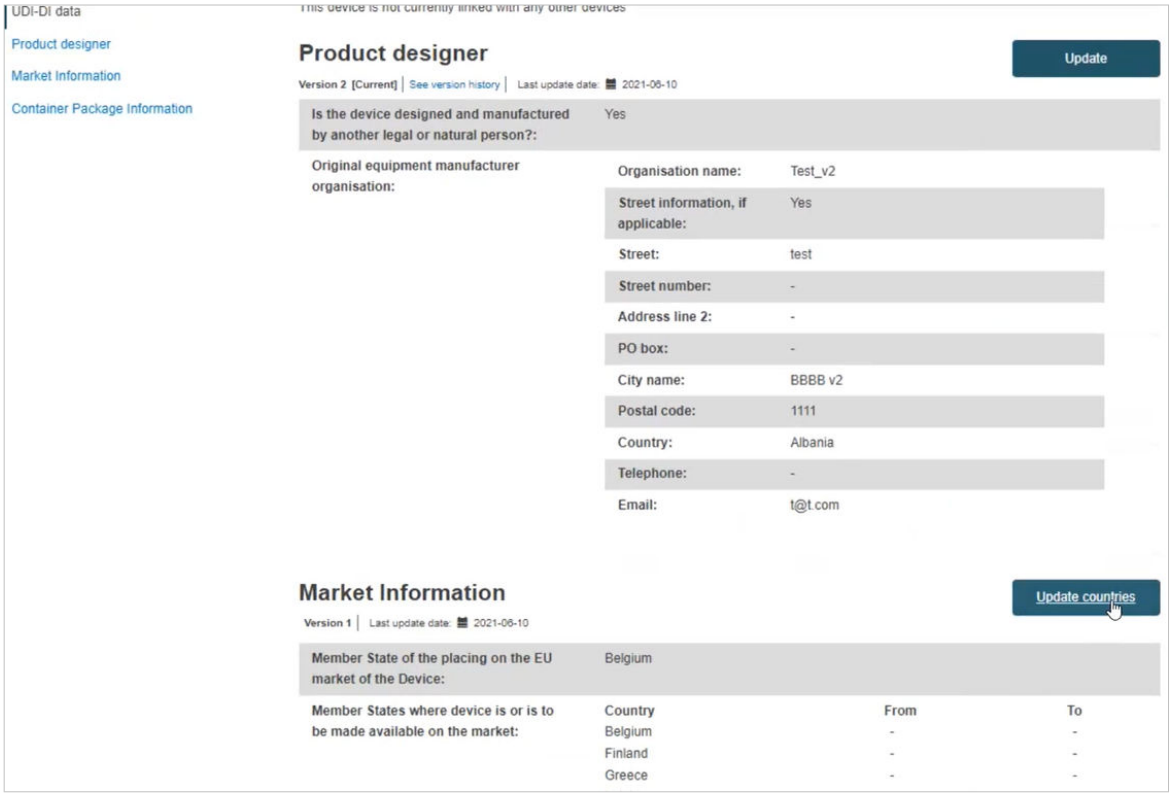
5. Click on **Submit** at the bottom of the screen to finalise the update.
   You will be able to see the new version created for the *Product Designer* information.

6.2.4 Update (create new version) for Market Information

The Market Information can be updated independently of the other data in a device UDI-DI record.

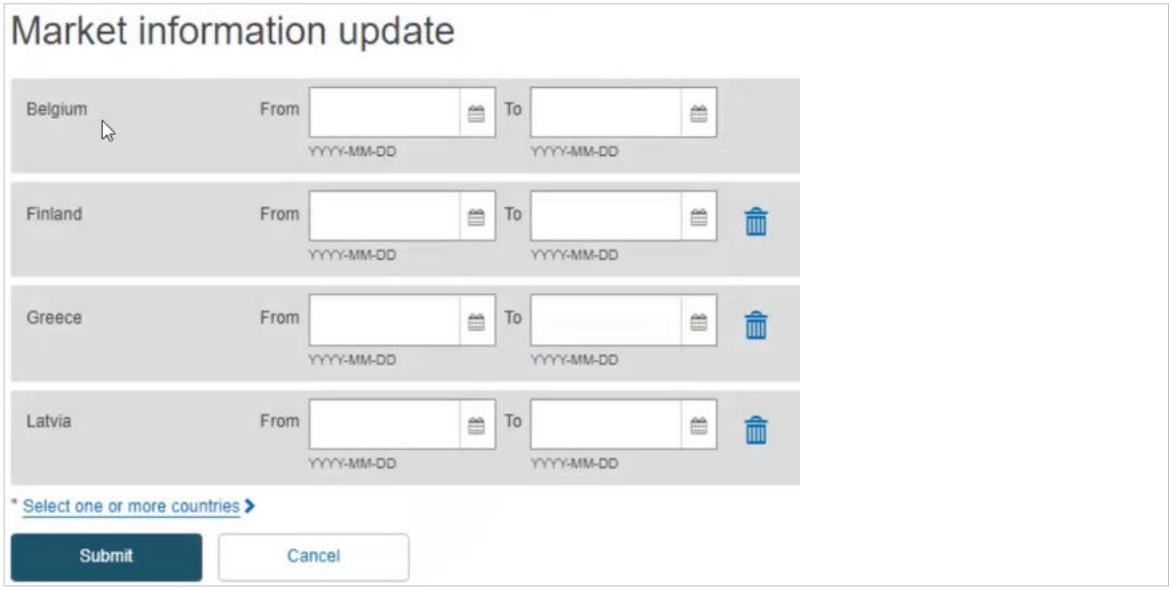
1. Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [53] to view a UDI-DI/EUDAMED ID.

2. Once inside the details of the selected UDI-DI, click on **Market Information** from the list on the left (or scroll down to the *Market Information* section):



3. Click on **Update countries**.

4. Update the relevant fields under *Market Information*:



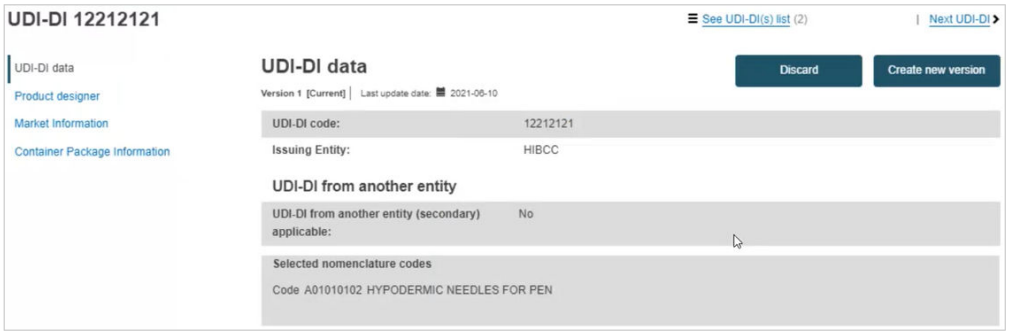
5. Click on **Submit** to finalise the update. You will be able to see the updated version of Market Information:

6.2.5 Update (create new version) for Container Packages

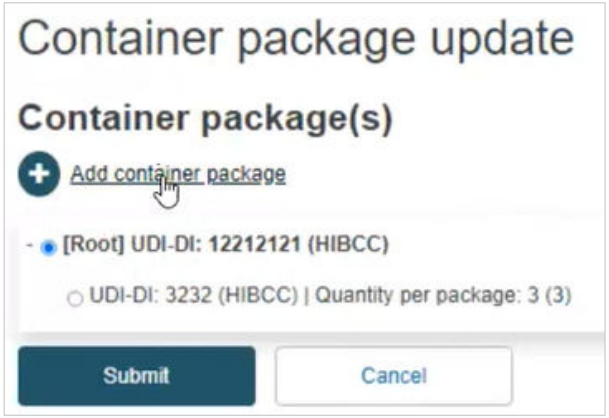
The Container Packages information can be updated independently of the other data in a device UDI-DI record.

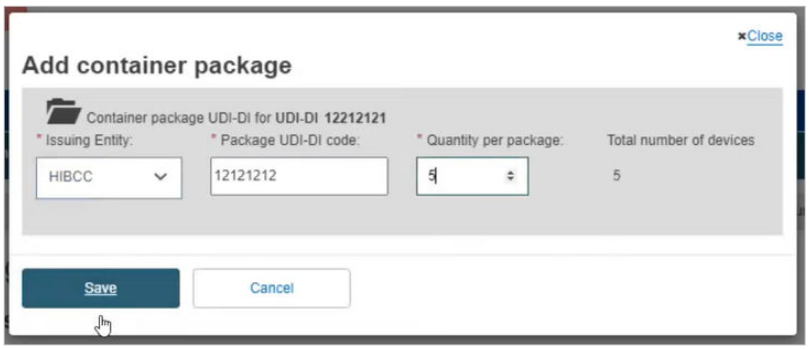
1. Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [53] to view a UDI-DI/EUDAMED ID.

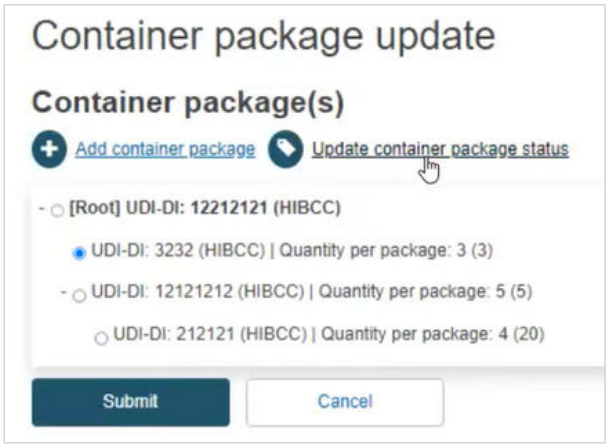
2. Once inside the details of the selected UDI-DI, click on **Container Package information** from the list on the left (or scroll down to the relevant section):

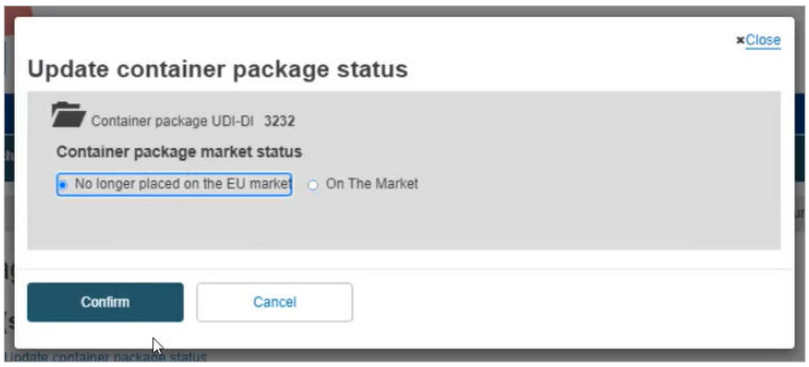


3. Click on **Create new version** in the *Container Package* section and proceed to update:

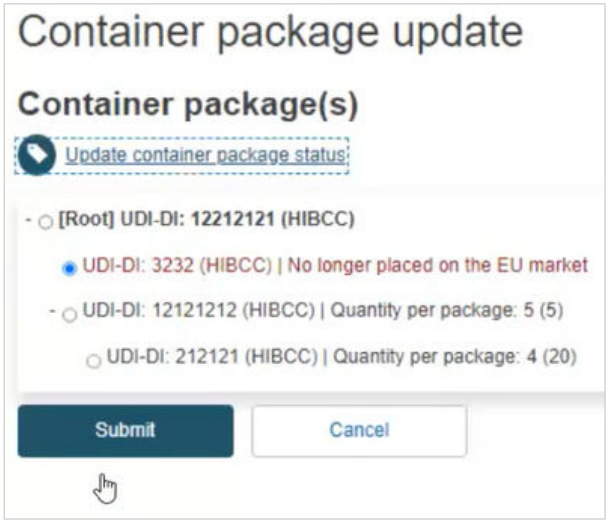








4. Click on **Submit** to finalise the container package update:



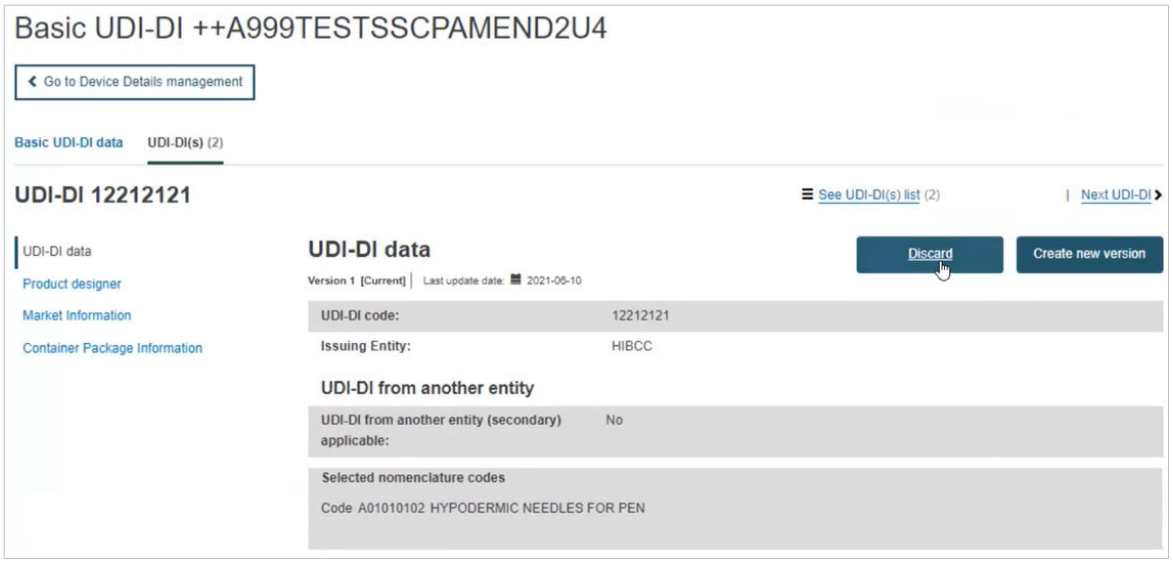
6.2.6 Discard registered UDI-DIs/EUDAMED IDs (and their Basic UDI-DI/EUDAMED DI)

IMPORTANT
The *discard* operation acts as a final deactivation. A device in state *discarded* is therefore not listed and cannot be viewed in the public site of EUDAMED. However, it can be viewed by the MF (owner of the discarded device), CA and NB actors.

You may wish to discard a registered UDI-DI in case you discover errors that cannot be corrected.

1. Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [53] to view a registered UDI-DI/EUDAMED ID.

2. Once inside the details page of the selected UDI-DI, click on **Discard** on the top right corner:



3. Confirm whether your wish to discard the registered UDI-DI:

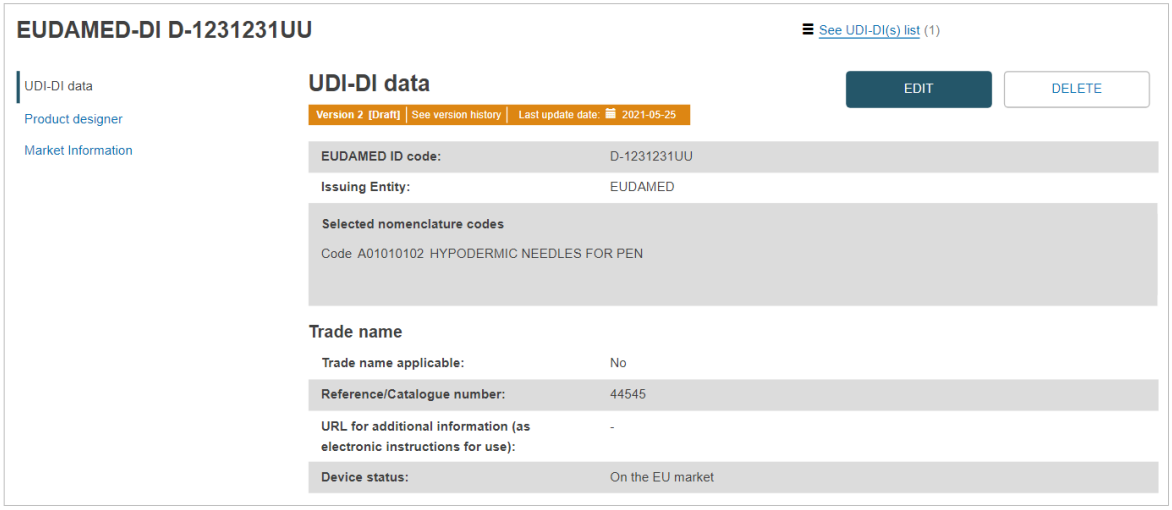
The UDI-DI will be discarded and will no longer be visible on the public EUDAMED website.

CAUTION
If the UDI-DI is the only one remaining in this Basic UDI-DI category, performing the *discard* action will also discard the Basic UDI-DI. The system will alert you accordingly:

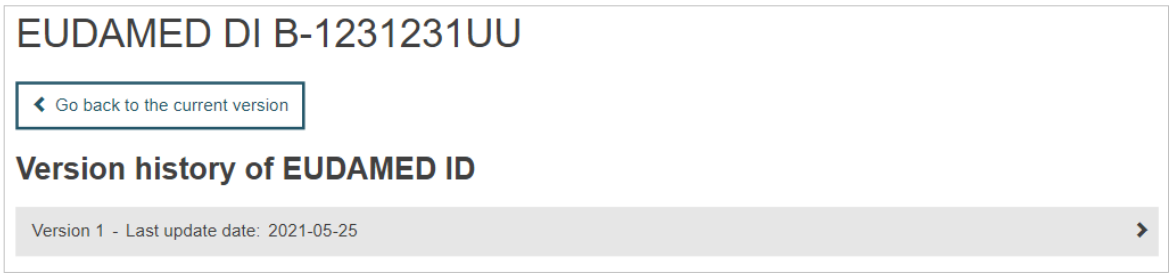
6.2.7 View historical versions of UDI-DI/EUDAMED ID and associated entities

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details [53]* to view a UDI-DI/EUDAMED ID.

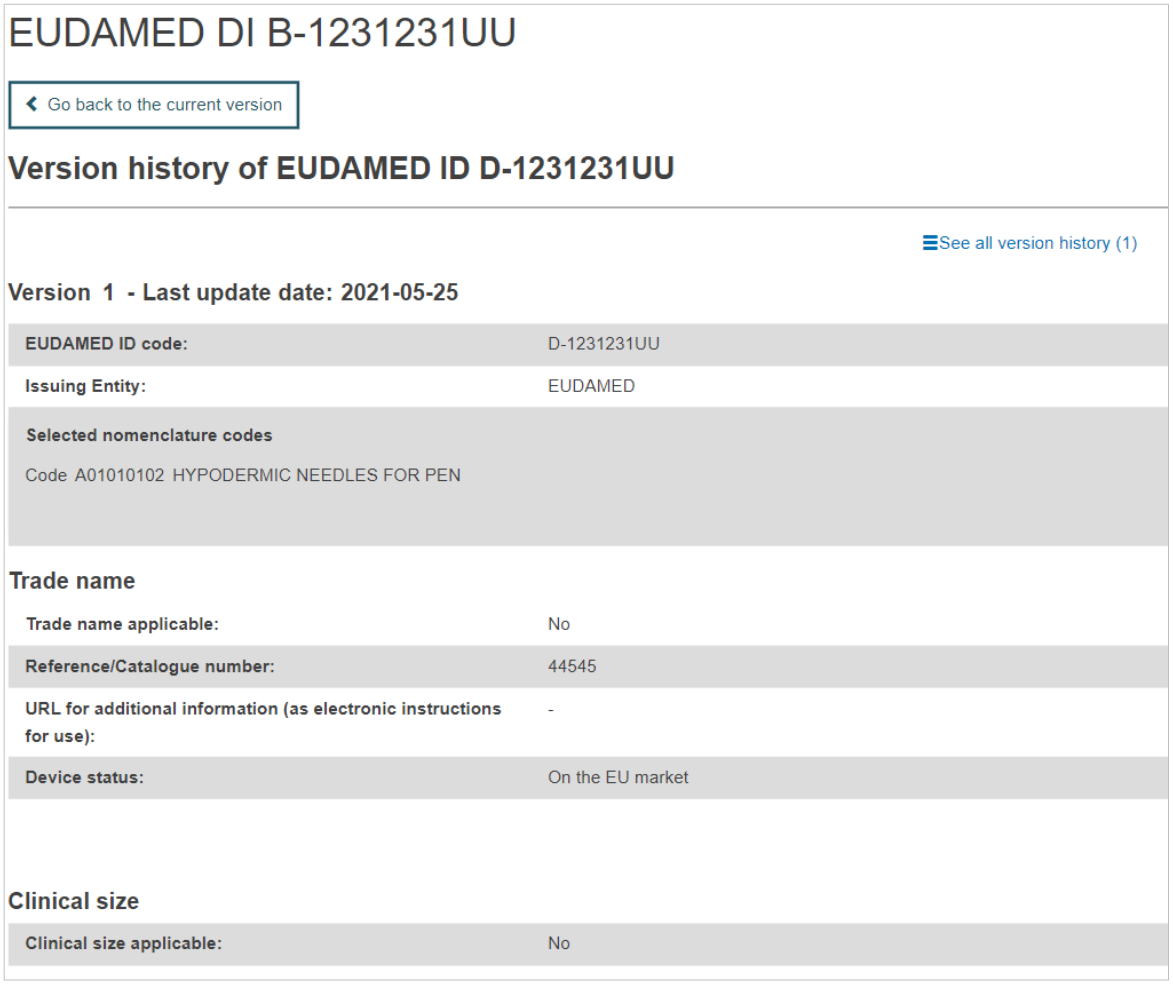
1. Once inside the details page of the selected UDI-DI, click on **See version history** on the top of the table:



You will see a list of all versions:



2. Click on the version you wish to view to access its details:

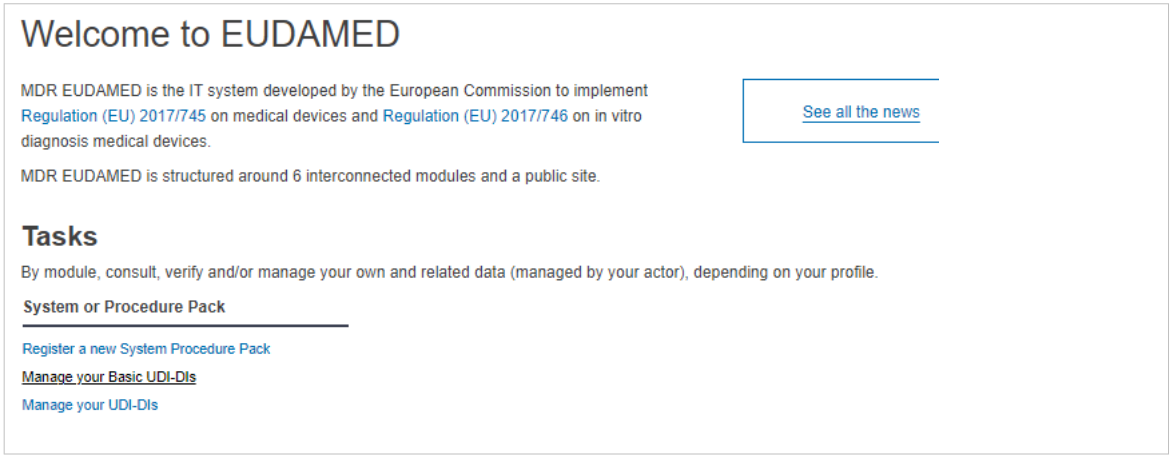


3. You can return to the version history list, by clicking on **See all version history** on the top right corner.

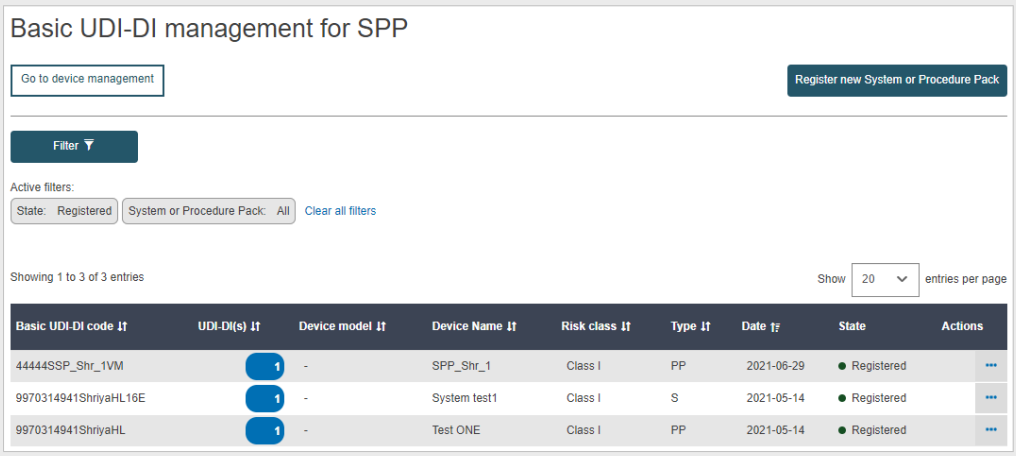
7 Manage your own System or Procedure Pack (SPP) information

7.1 Manage your SPP Basic UDI-DI details

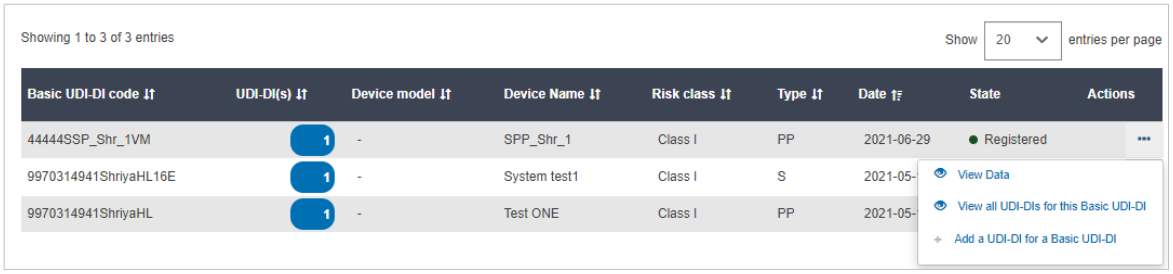
1. On the EUDAMED dashboard, click on **Manage your Basic UDI-DIs** to see a list of all your Basic UDI-DIs:



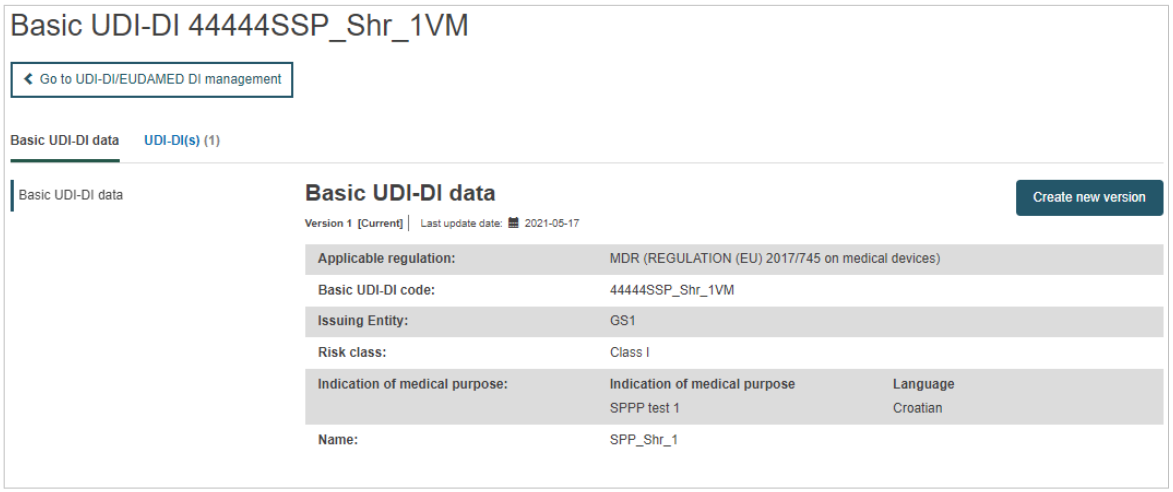
NOTE
By default, the system displays the System or Procedure Packs in state *draft*. To see other states, use the filters.



2. Click on the three dots of the selected entry and then click on **View data** from the menu:

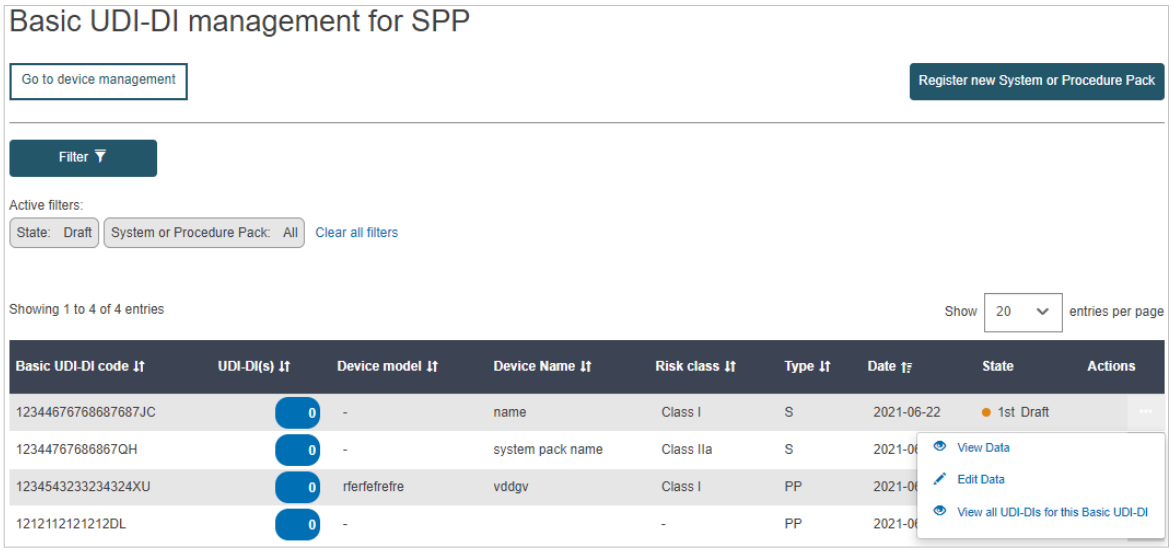


3. You will see a summary of the details concerning your system or procedure pack:

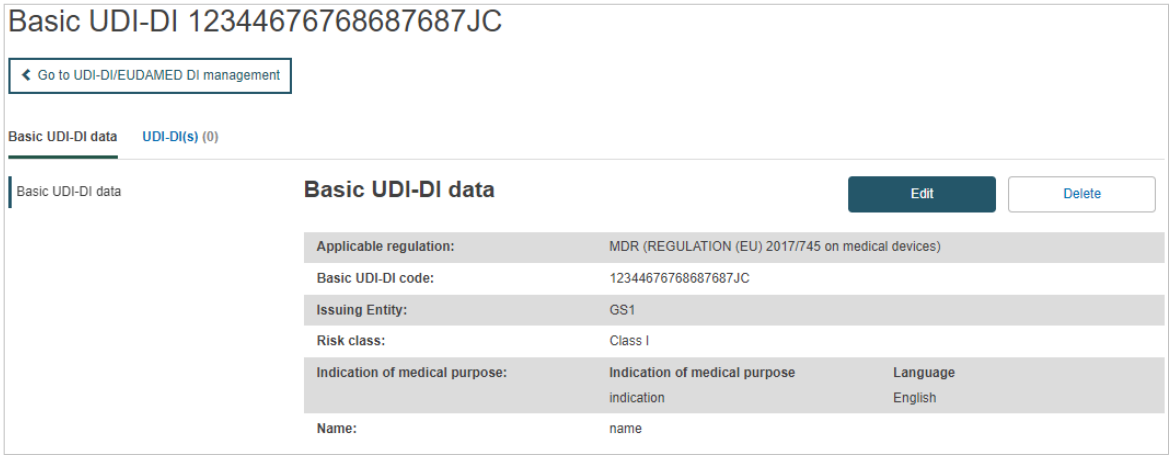


7.1.1 Delete a draft Basic UDI-DI

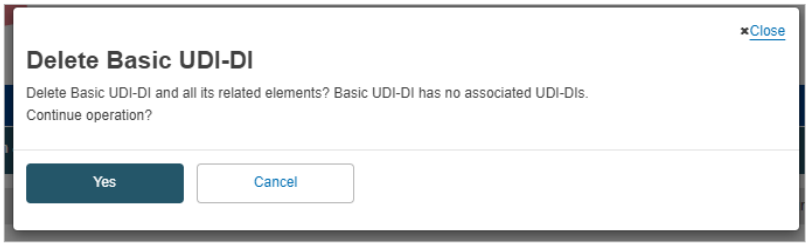
1. Follow the steps in section *Manage your SPP Basic UDI-DI details* [65] to view a Draft Basic UDI-DI:



2. Once inside the draft, click on **Delete**:

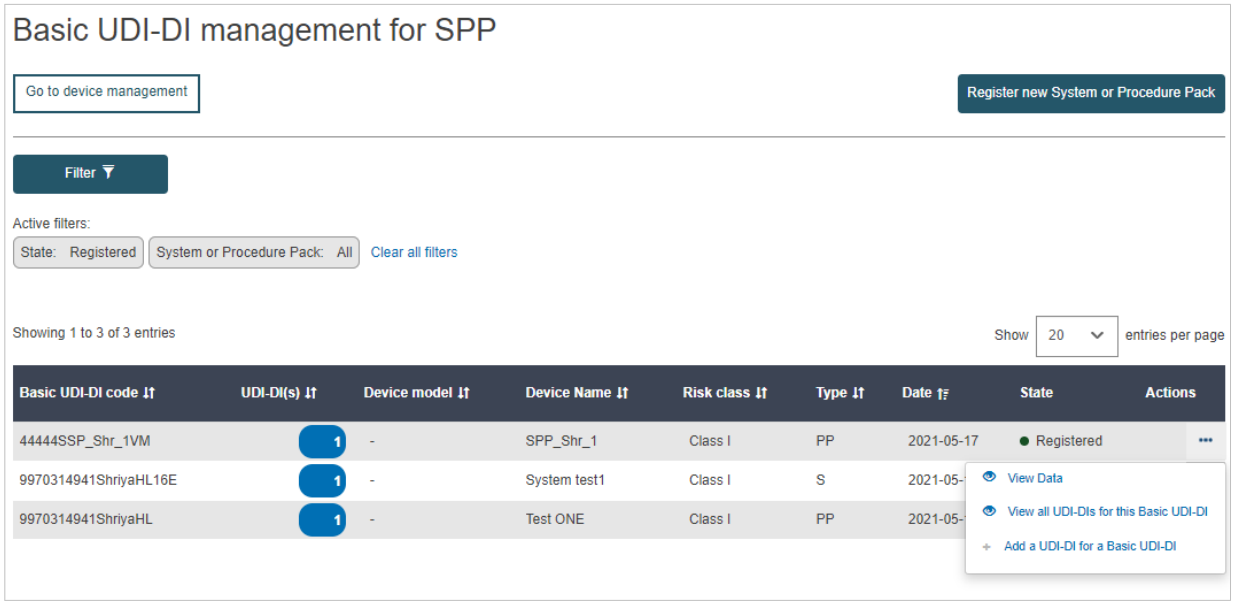


3. A pop-up message will ask you to confirm the *delete* action:

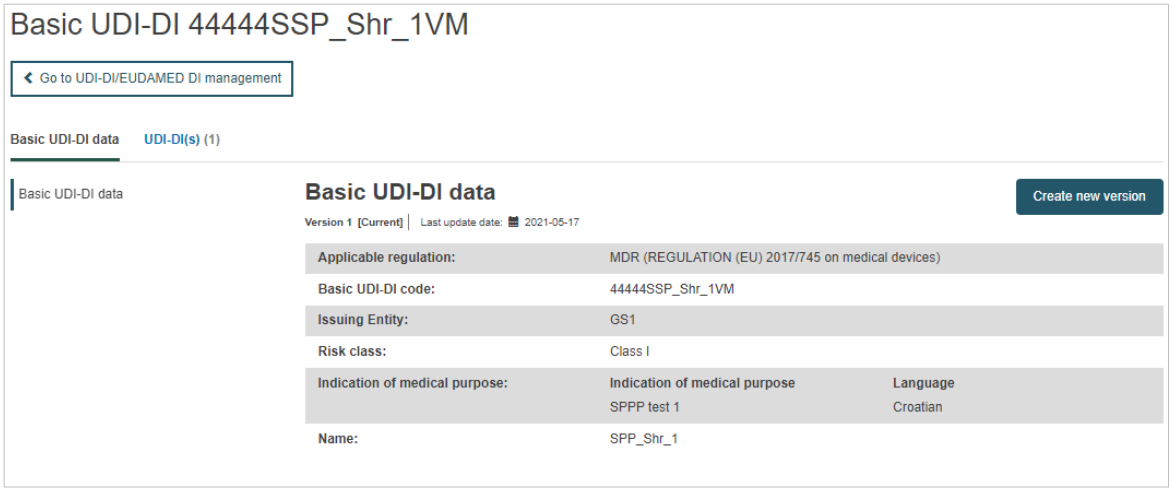


7.1.2 Update (create new version) for Basic UDI-DI

Follow the steps in section *Manage your SPP Basic UDI-DI details* [65] to view a Basic UDI-DI:



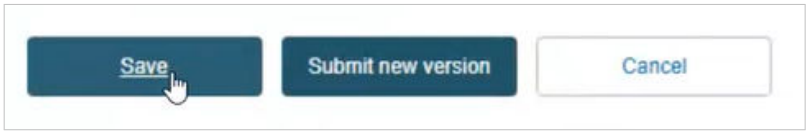
1. Once inside the details page of the relevant Basic UDI-DI, click on **Create new version**:



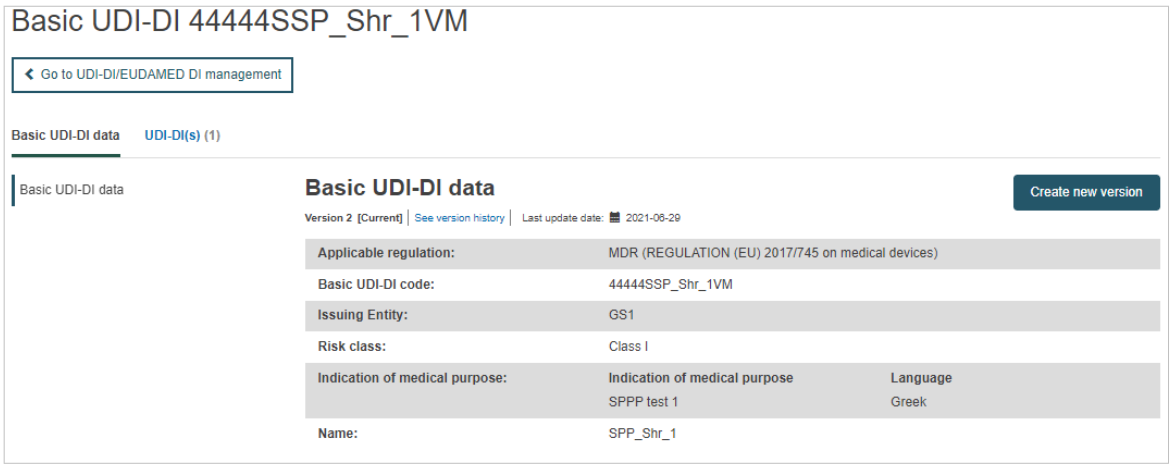
2. Update the desired details.

NOTE
Only some details can be updated depending on the actor's specifics:

3. To finish the action you have two options:
   a. Click on **Save** to save the updated details without submitting the new version.
   b. Click on **Submit new version** if you wish to submit it.
   Alternatively, you can click on **Cancel** to cancel the update.



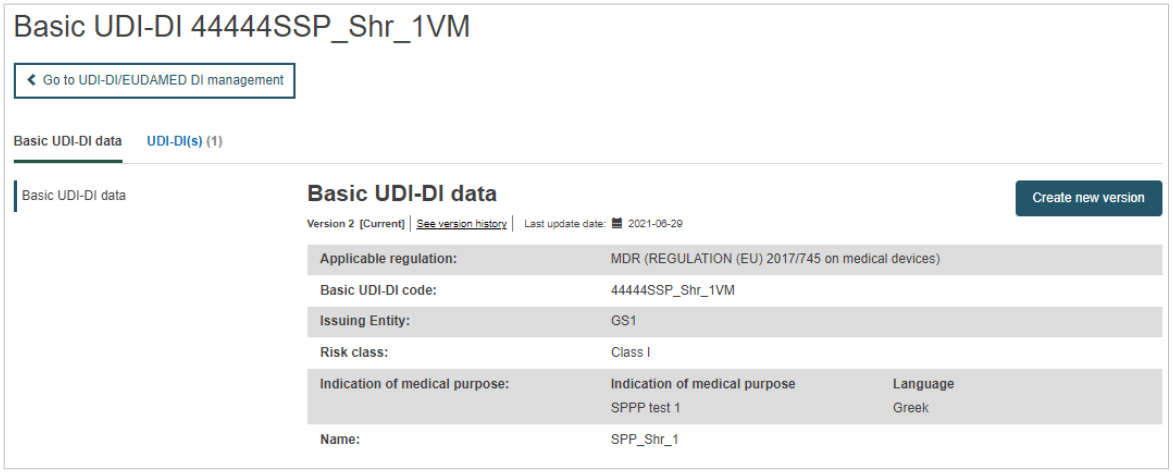
4. After you have submitted the new version, you can see the update under the Basic UDI-DI details:

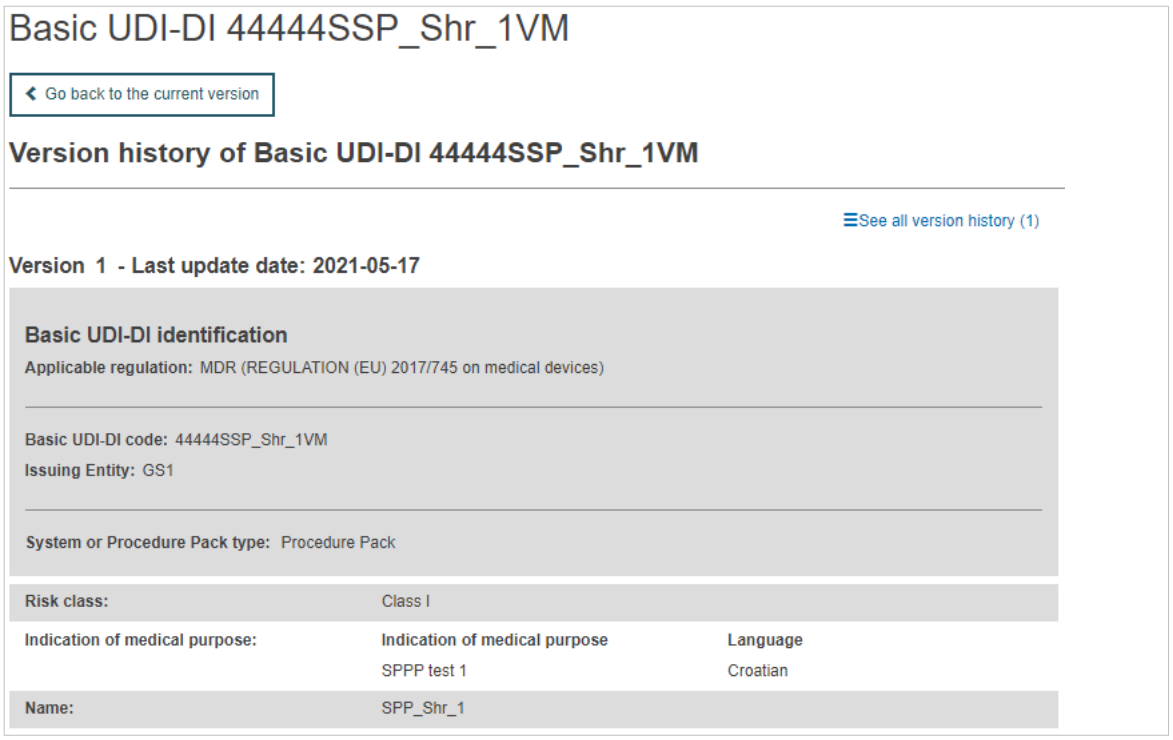


7.1.3 View historical version for Basic UDI-DI

1. Follow the steps in section *Manage your SPP Basic UDI-DI details* [65] to view a Basic UDI-DI.

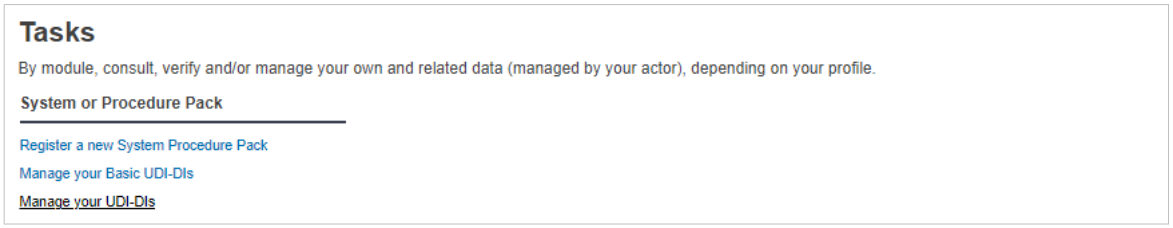
2. Once inside the details page for the selected Basic UDI-DI, click on **See version history** at the top of the table:



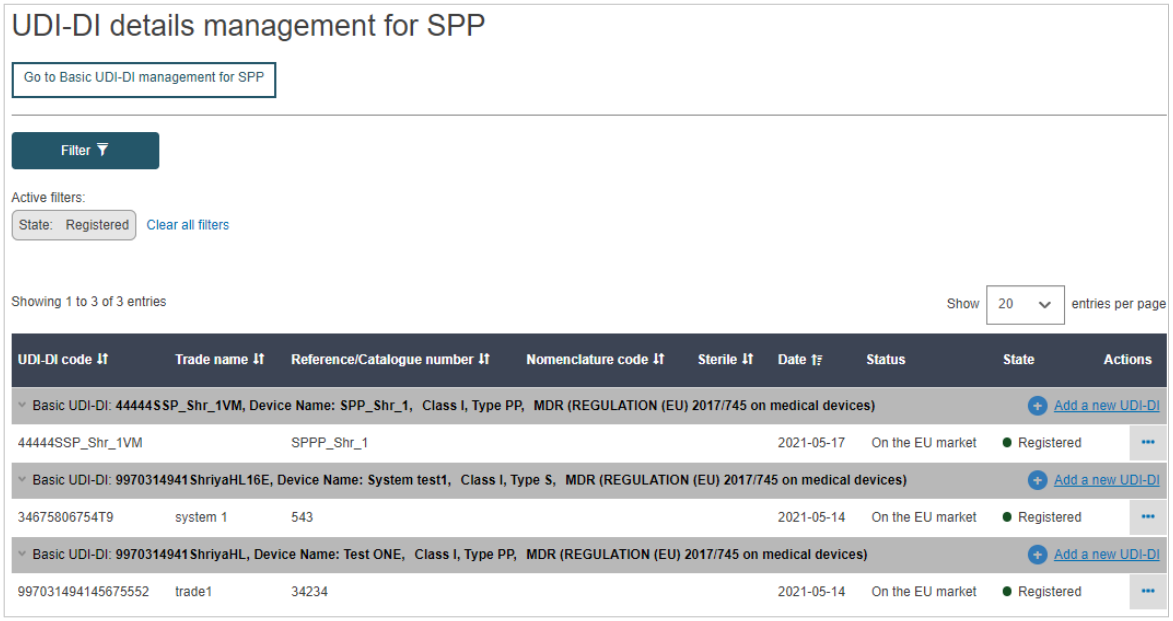


7.2 Manage your SPP UDI-DI details

1. On the EUDAMED dashboard, click on **Manage your UDI-DIs** to see the list:

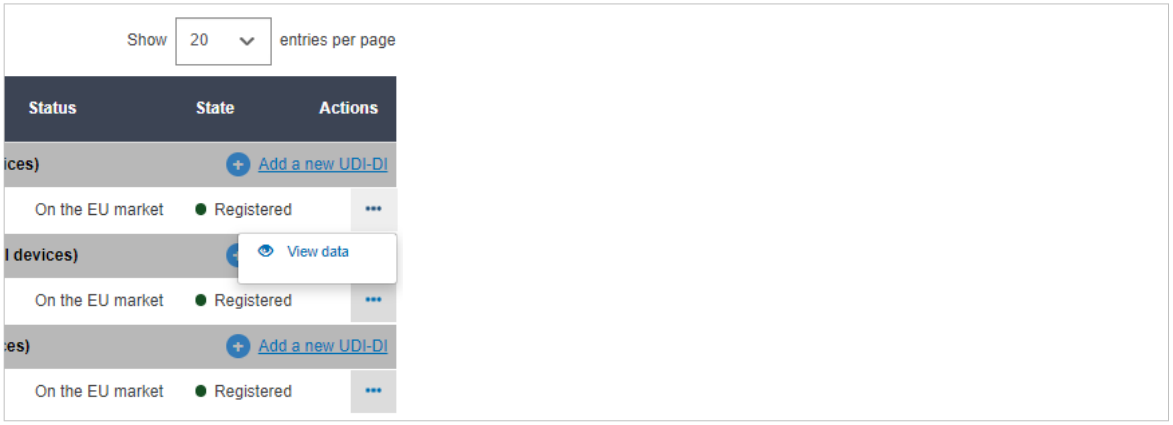


2. In order to find the desired UDI-DI, click on the **Filter** button and choose the right parameters:

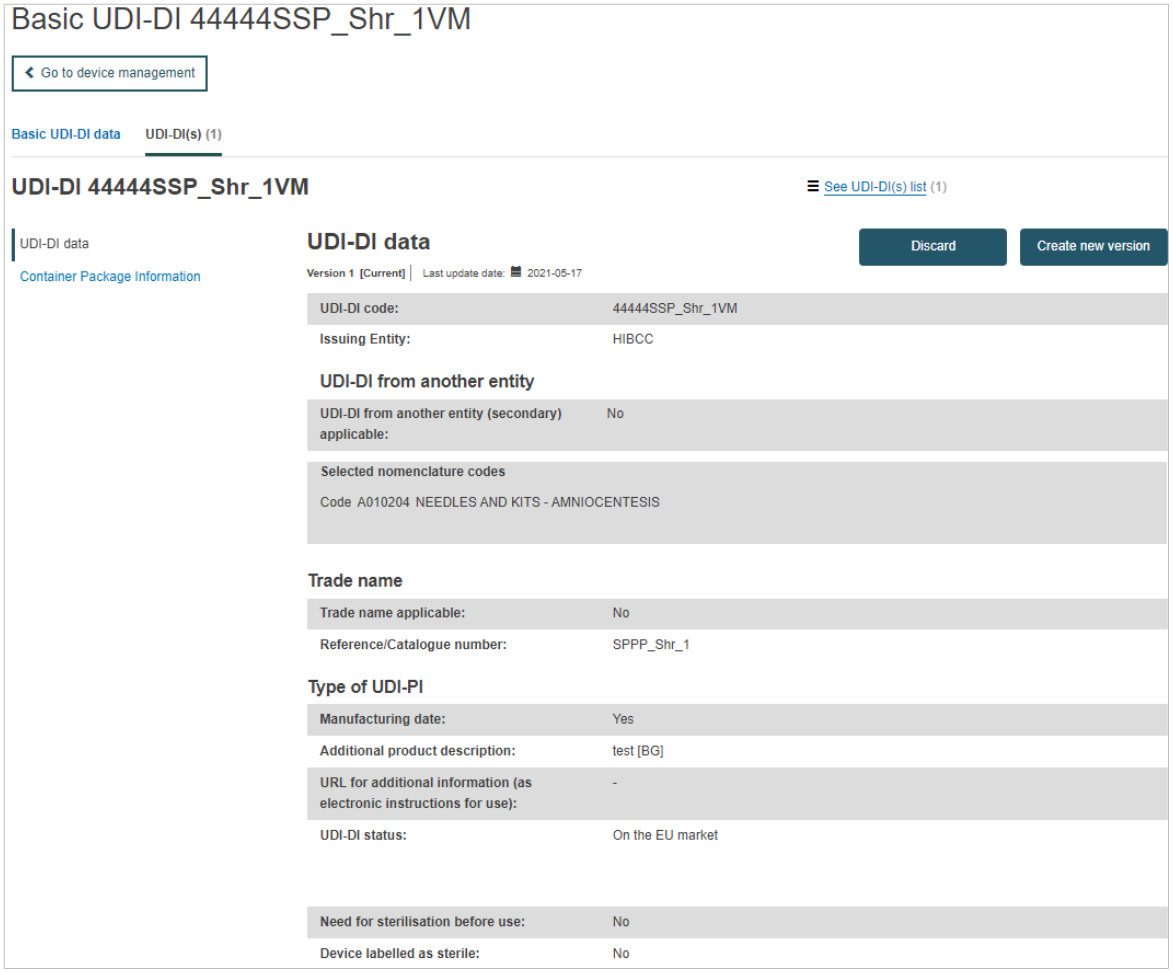


NOTE
By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in *draft* state. To retrieve other states, use the filters.

3. Click on the three dots of the desired entry and then click on **View data** from the menu:



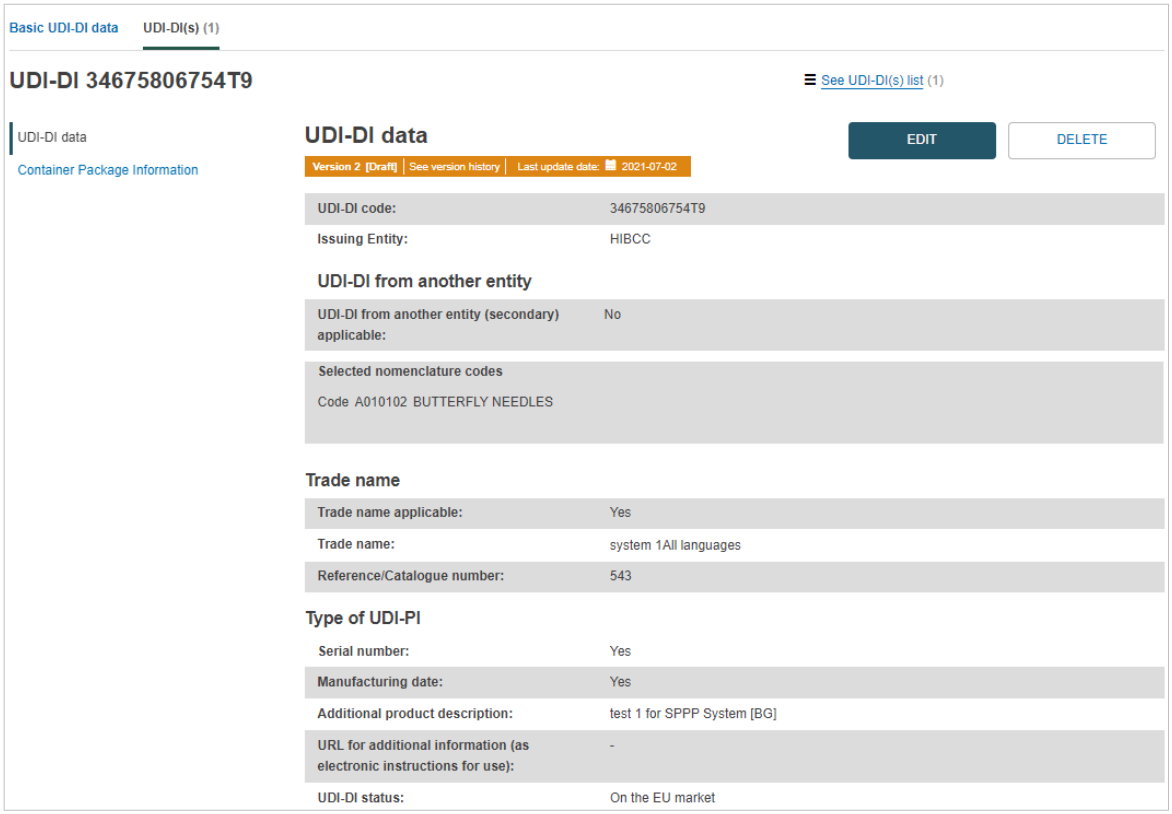
4. You will see a summary of the details concerning your chosen SPP UDI-DI:



7.2.1 Delete a draft UDI-DI

1. Follow the steps in section Manage your SPP UDI-DI details [70] to view a Draft UDI-DI.

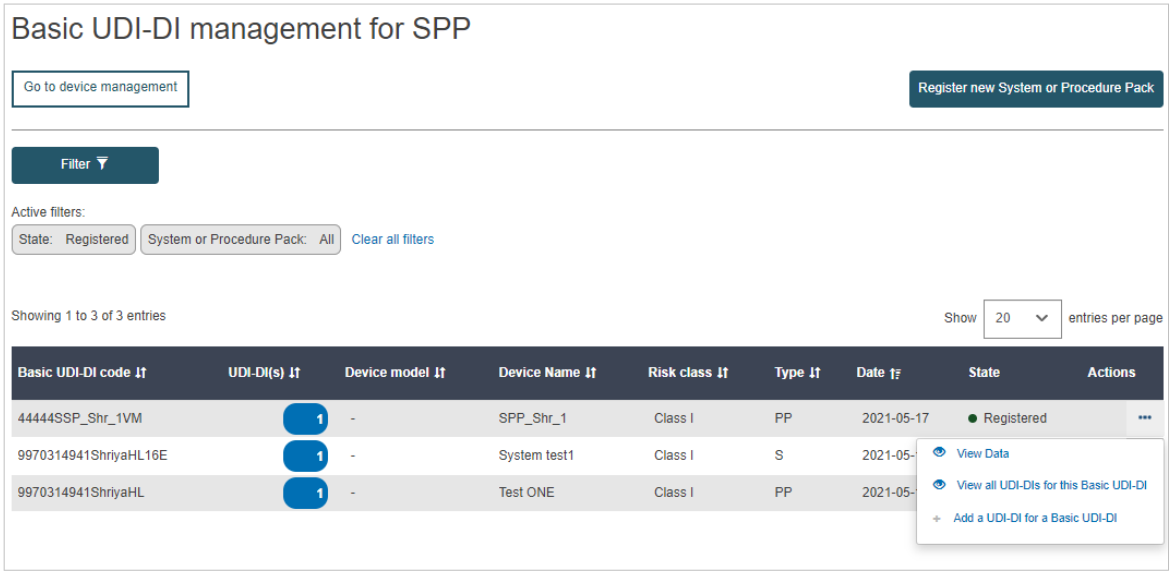
2. Once inside the draft, click on **Delete**:



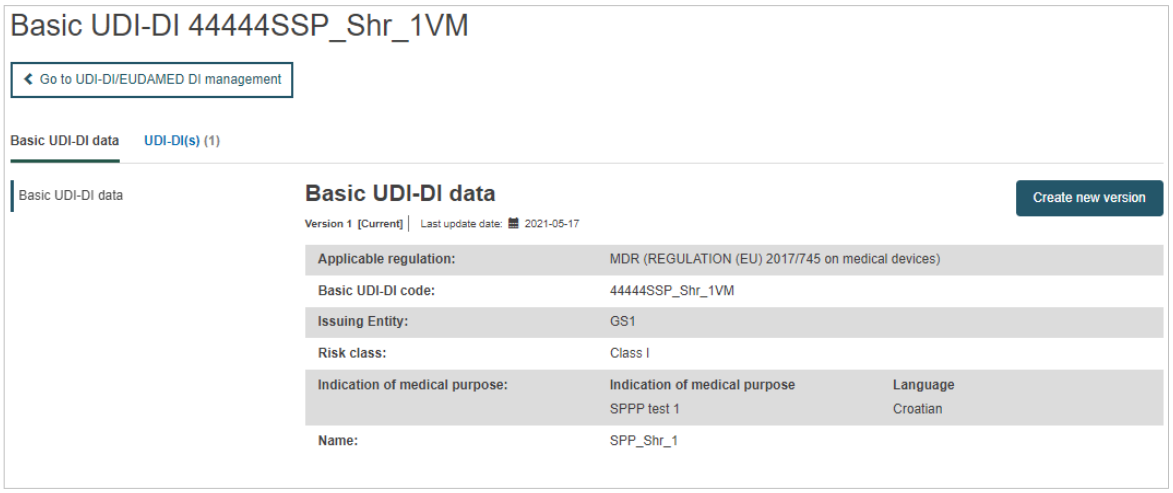
3. A pop-up message will ask you to confirm the action:

7.2.2 Update (create new version) for UDI-DI

1. Follow the steps in Manage your SPP UDI-DI details [70] to view a UDI-DI.



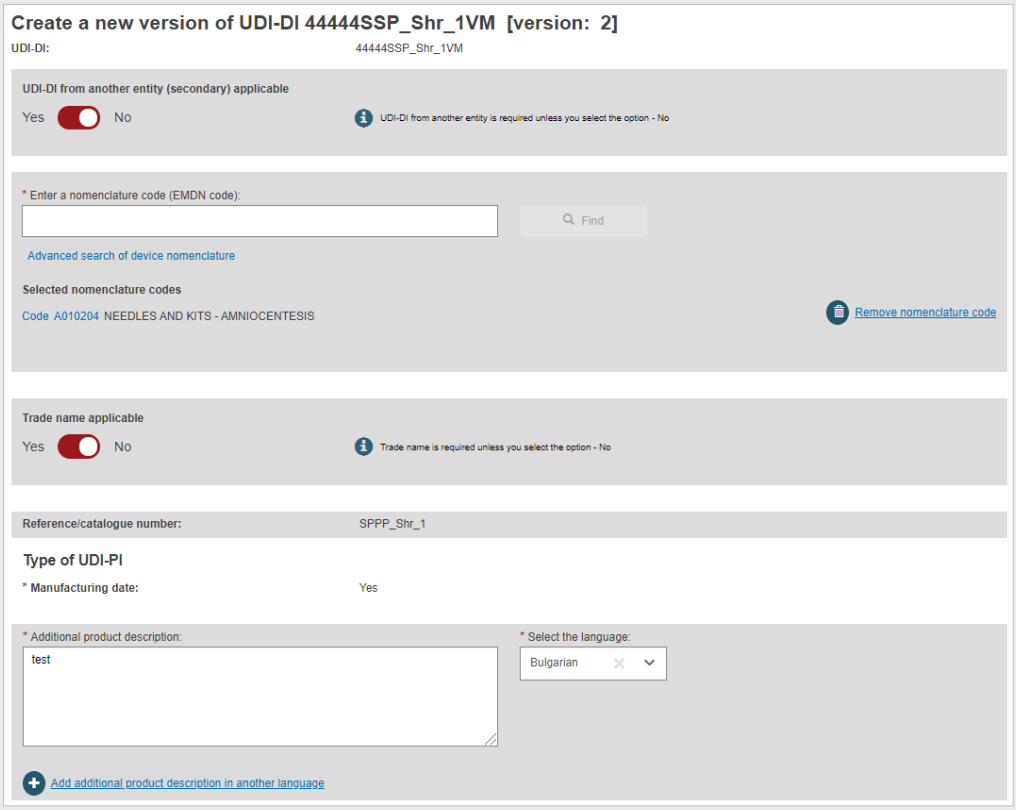
2. Once inside the details of the chosen UDI-DI, click on **Create new version** on the top right corner:



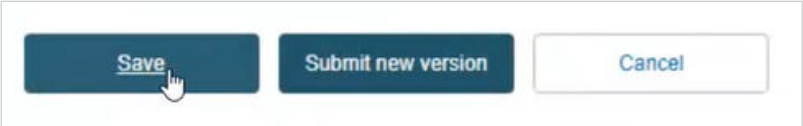
3. Update the necessary details.

NOTE

Only some details can be updated depending on the actor's specifics:



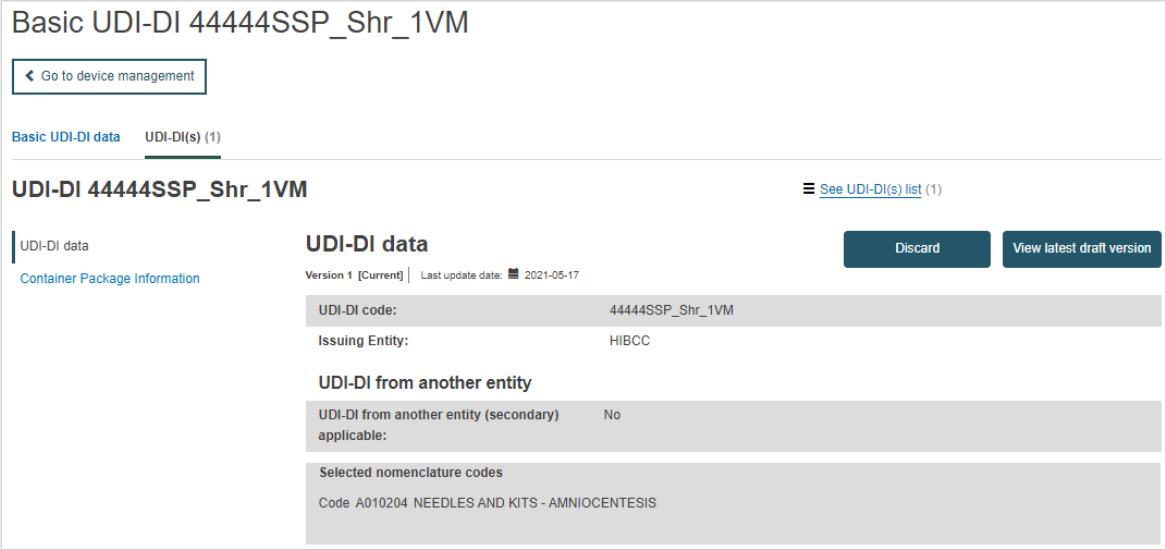
4. To finish the action you have two options:
   a. Click on **Save** to save the updated details without submitting the new version.
   b. Click on **Submit new version**, if you wish to submit it.
   Otherwise, you can press **Cancel** to cancel the update.



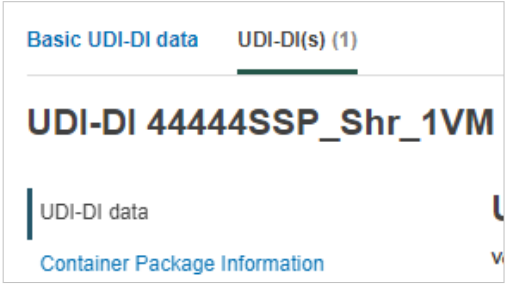
7.2.3 Update (create new version) for Container Packages

The Container Packages information can be updated independently of the other data in a System Procedure Pack (SPP) UDI-DI.

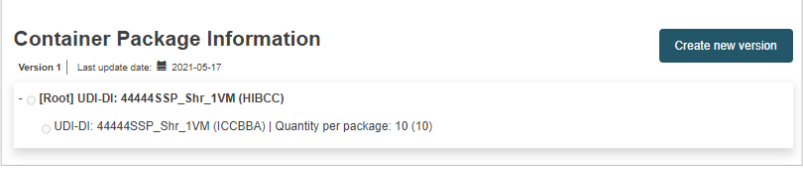
1. Follow the steps in section Manage your SPP UDI-DI details [70] to view a specific UDI-DI:



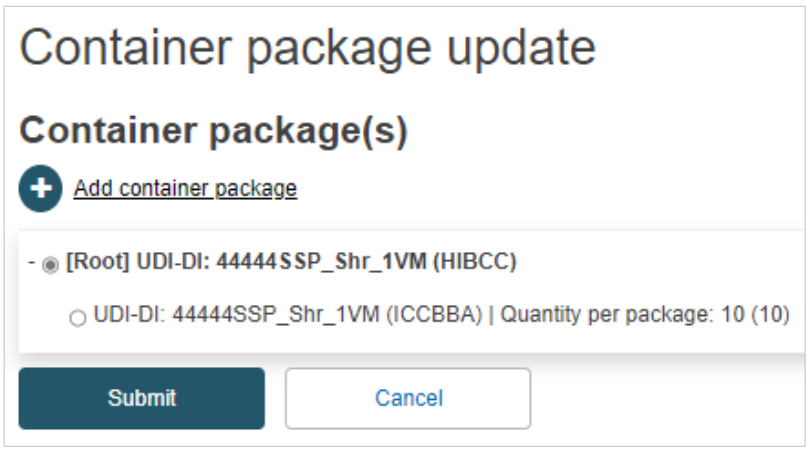
2. Click on **Container Package information** from the list on the left (or scroll down to the relevant section):



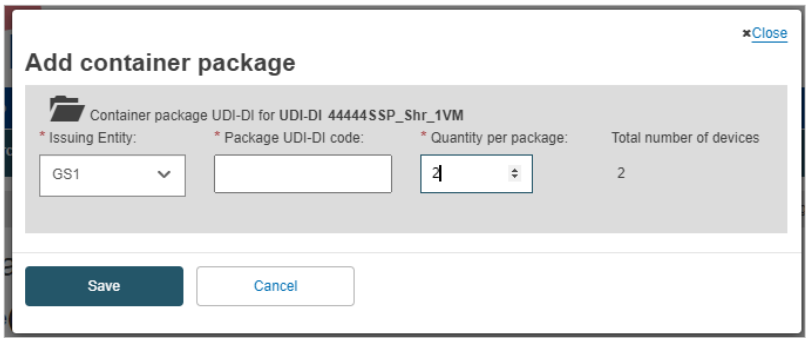
3. Click on **Create new version** in the *Container Package* section:



4. Click on **Add container package** to add new information about the packaging format of the SPP:

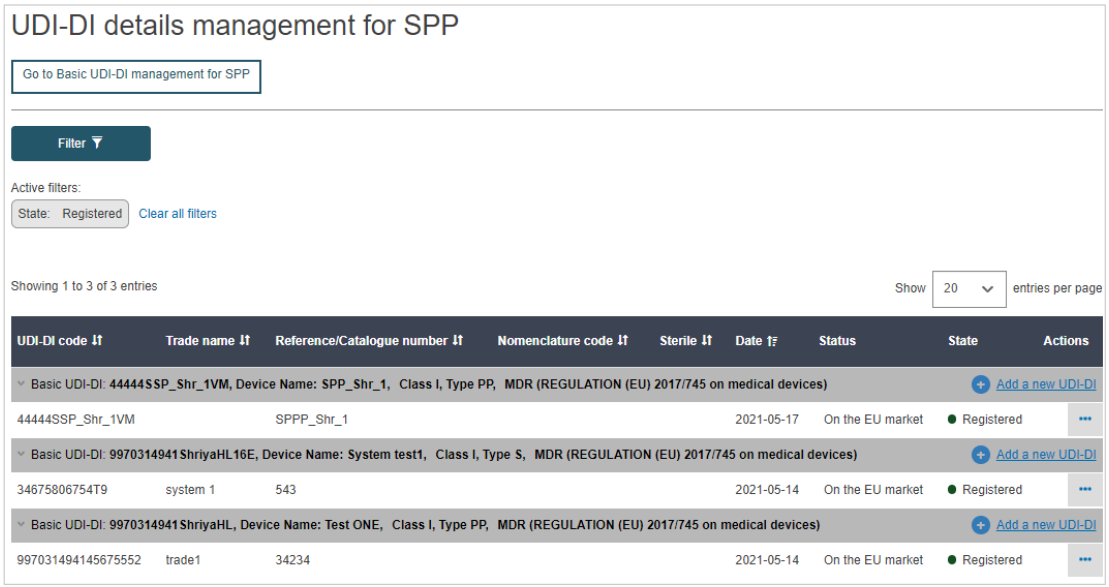


5. Insert the package details in the pop-up window and click on **Save**:

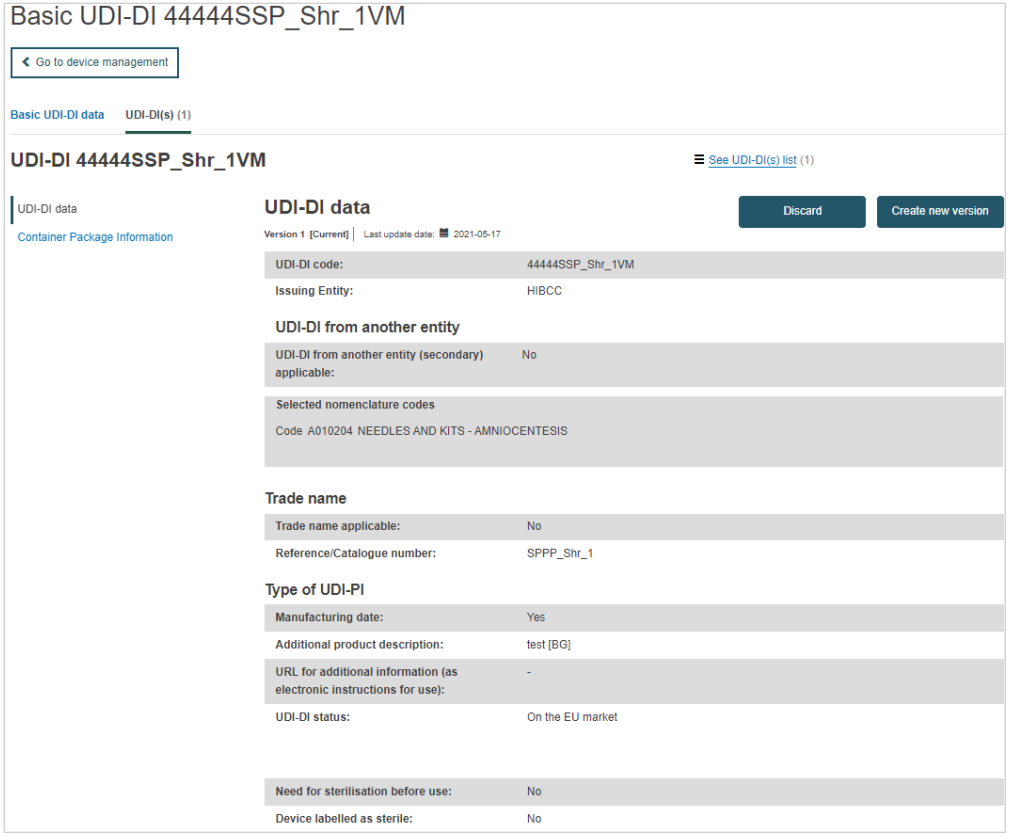


7.2.4 Discard SPP registered UDI-DIs

1. Follow the steps in section Manage your SPP UDI-DI details [70] to view a chosen Registered UDI-DI:



2. Once inside the details page of the chosen UDI-DI, click on **Discard** on the top right corner:

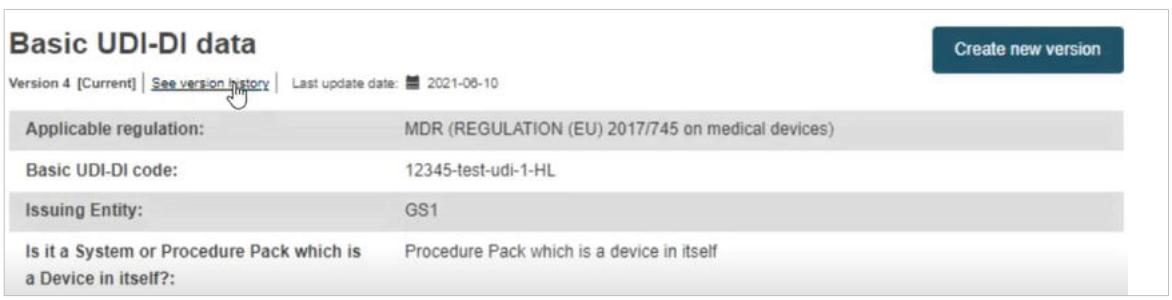


3. The system will ask you to confirm if you wish to discard the record:

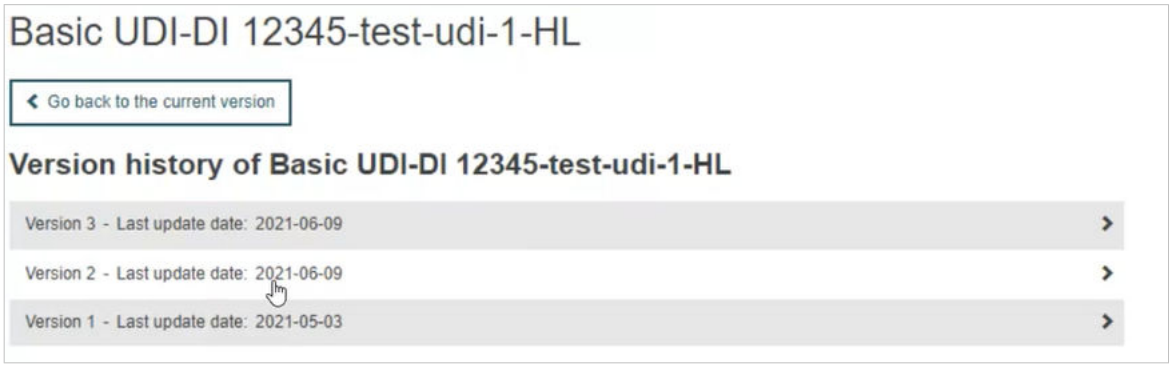
7.2.5 View SPP historical versions for UDI-DI and associated entities

1. Follow the steps in section *Manage your SPP UDI-DI details* [70] to view a UDI-DI for the SPP.

2. Once inside the details of the chosen UDI-DI, click on **See version history** on the top of the table:



3. You will see a list of all old versions:



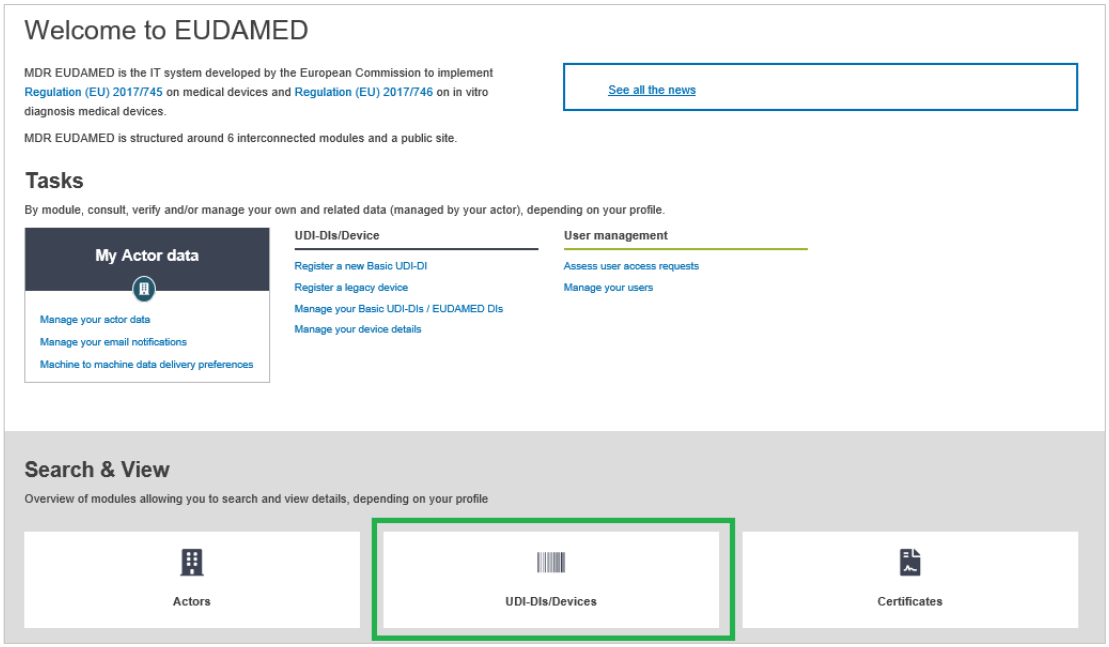
4. Click on the version you wish to view to access its detailed summary:

You can return to the version history list by clicking on **See all version history** on the top right corner.

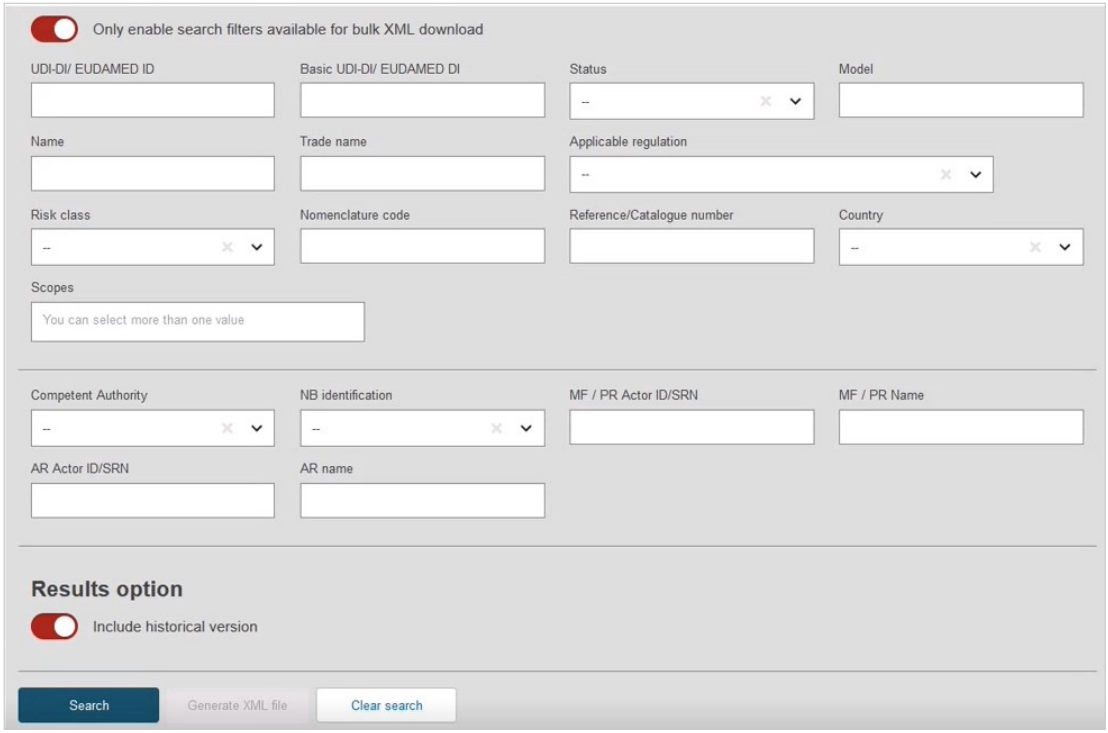
8 Search & View Devices, Systems and/or Procedure Packs

1. On the header menu, click on **Search & View**, then **UDI-DIs/Devices**:

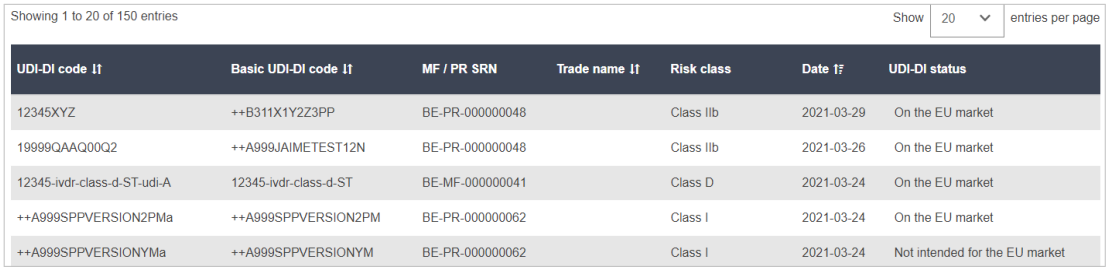
Alternatively, use the option available in the dashboard called *Search & View*:



2. You can use the filters to search for *Devices*, *Systems* and/or *Procedure Packs (SPP) registered* in EUDAMED, or, in the case of Competent Authorities and Notified Bodies, those *submitted* or *discarded*:

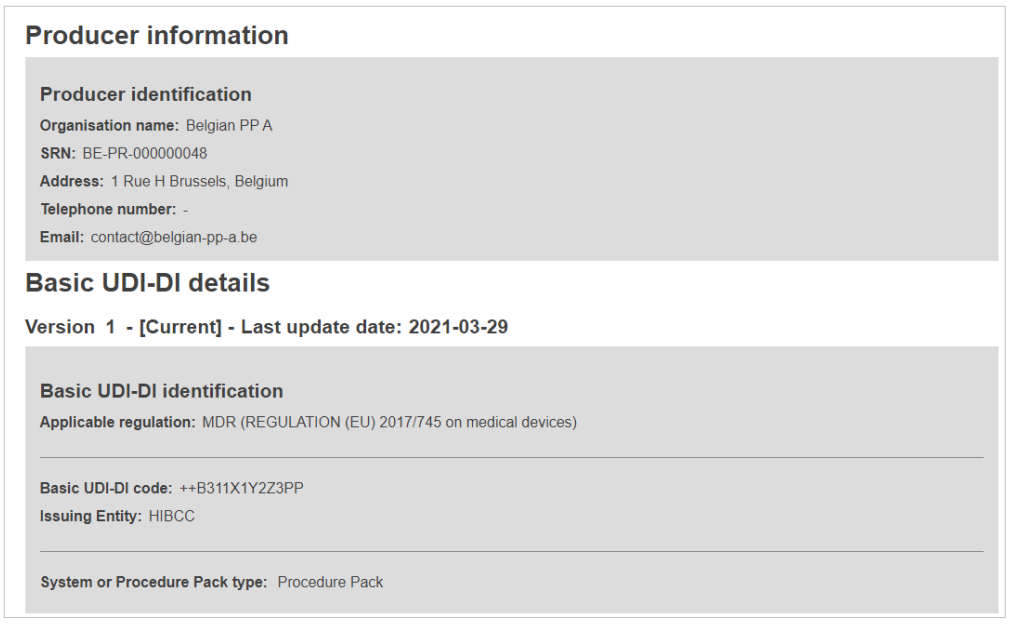


3. Once you have entered your search filters, click on **Search** (the record will have to match all the filters). A list of Devices (UDI-DIs/EUDAMED IDs) and/or Systems or Procedure Packs will appear if any are found (otherwise *No data available* will be displayed):



UDI-DI code	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
12345XYZ	++B311X1Y2Z3PP	BE-PR-000000048		Class IIb	2021-03-29	On the EU market
19999QAAQ00Q2	++A999JAIMETEST12N	BE-PR-000000048		Class IIb	2021-03-26	On the EU market
12345-ivdr-class-d-ST-udi-A	12345-ivdr-class-d-ST	BE-MF-000000041		Class D	2021-03-24	On the EU market
++A999SPPVERSION2PMa	++A999SPPVERSION2PM	BE-PR-000000062		Class I	2021-03-24	On the EU market
++A999SPPVERSIONYMa	++A999SPPVERSIONYM	BE-PR-000000062		Class I	2021-03-24	Not intended for the EU market

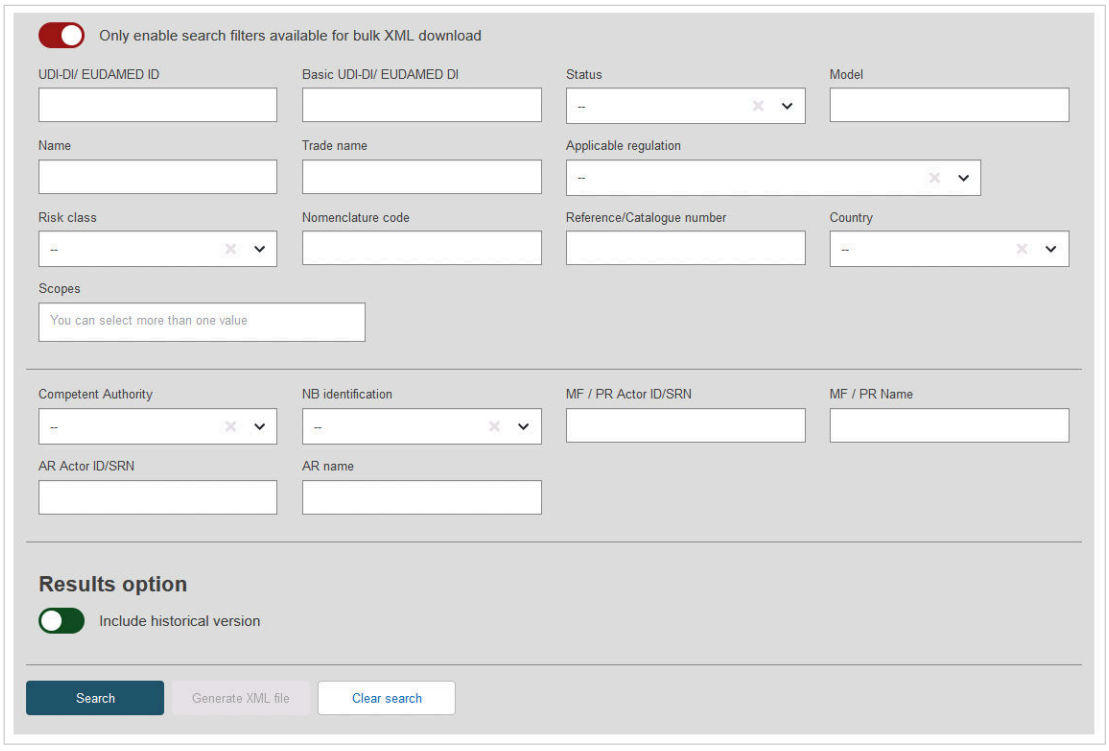
4. Click on the UDI-DI/EUDAMED ID row of your choice to see the details:



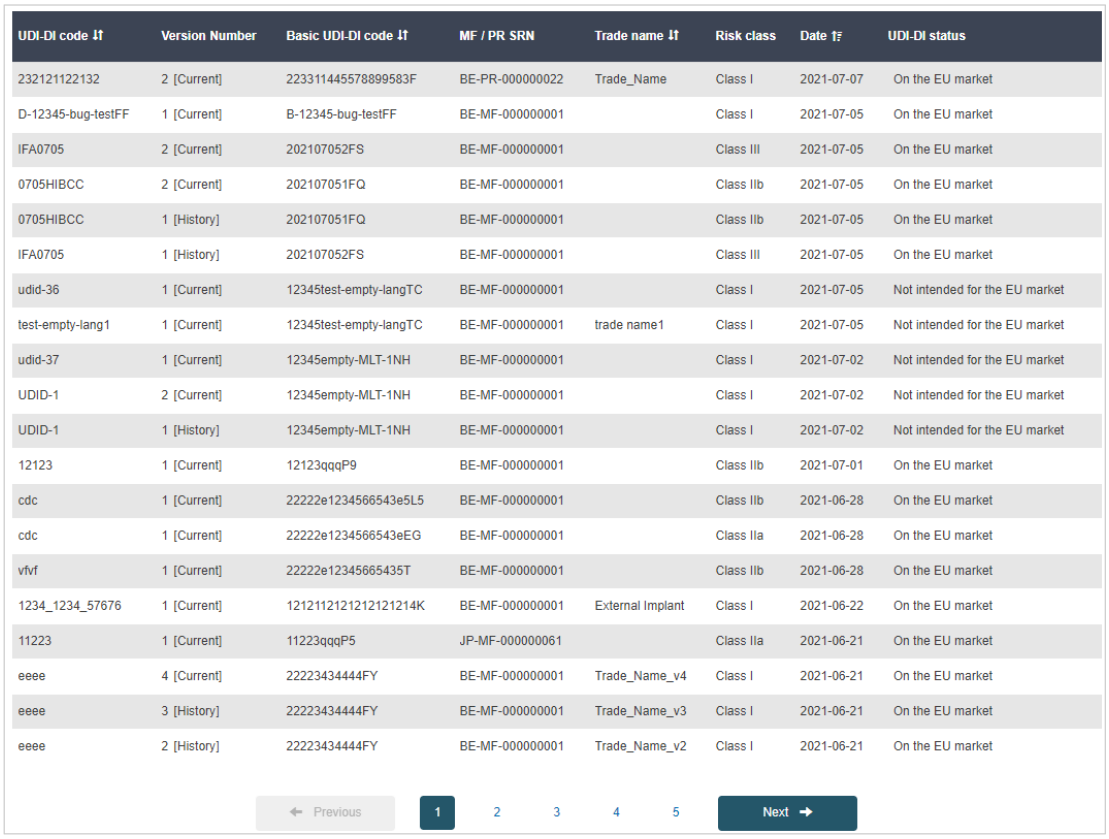
8.1 Search & View historical versions of Devices, Systems and Procedure Packs

1. Follow the steps in Search & View Devices, Systems and/or Procedure Packs [79] to search and view a device or system or procedure pack.

2. Inside the search page, select the filters for your search, activate the option to include historical versions (toggle just above the **Search** button) and click on **Search**:



3. The list generated below will include the desired current UDI-DI as well as its versions. Click on the version you wish to view:

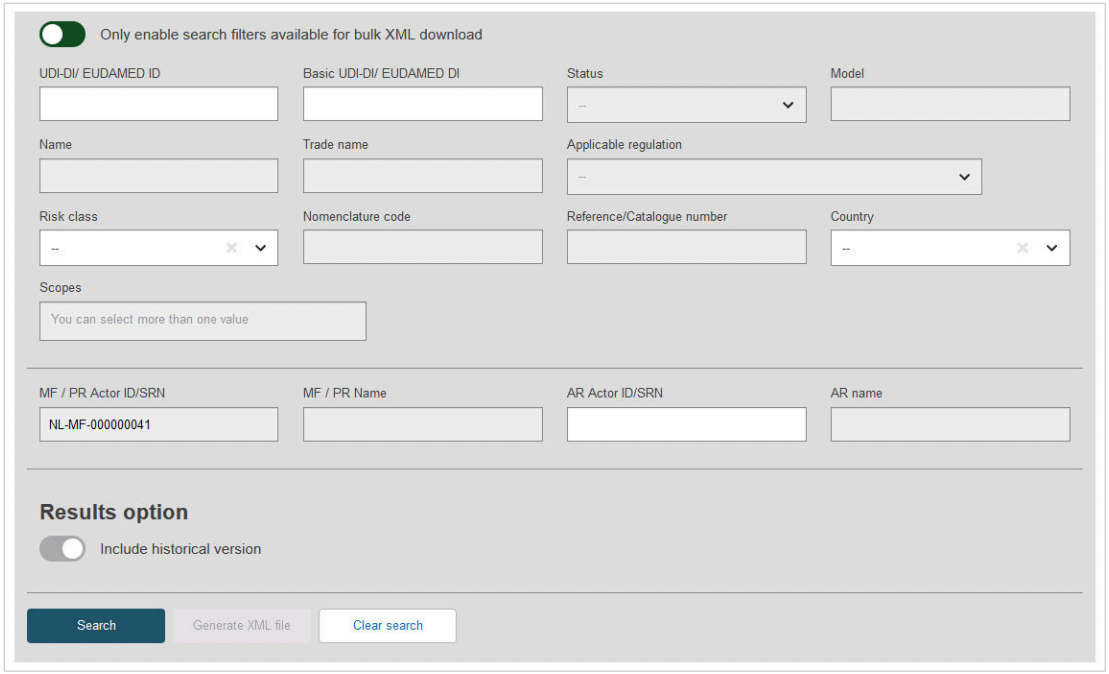


UDI-DI code	Version Number	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
232121122132	2 [Current]	2233114455788995 83F	BE-PR-000000022	Trade_Name	Class I	2021-07-07	On the EU market
D-12345-bug-testFF	1 [Current]	B-12345-bug-testFF	BE-MF-000000001		Class I	2021-07-05	On the EU market
IFA0705	2 [Current]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
0705HIBCC	2 [Current]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
0705HIBCC	1 [History]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
IFA0705	1 [History]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
udid-36	1 [Current]	12345test-empty-langTC	BE-MF-000000001		Class I	2021-07-05	Not intended for the EU market
test-empty-lang1	1 [Current]	12345test-empty-langTC	BE-MF-000000001	trade name1	Class I	2021-07-05	Not intended for the EU market
udid-37	1 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	2 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	1 [History]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
12123	1 [Current]	12123qqqP9	BE-MF-000000001		Class IIb	2021-07-01	On the EU market
cdc	1 [Current]	22222e1234566543e5L5	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
cdc	1 [Current]	22222e1234566543eEG	BE-MF-000000001		Class IIa	2021-06-28	On the EU market
vfvf	1 [Current]	22222e12345665435T	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
1234_1234_57676	1 [Current]	1212112121212121214K	BE-MF-000000001	External Implant	Class I	2021-06-22	On the EU market
11223	1 [Current]	11223qqqP5	JP-MF-000000061		Class IIa	2021-06-21	On the EU market
eeee	4 [Current]	22223434444FY	BE-MF-000000001	Trade_Name_v4	Class I	2021-06-21	On the EU market
eeee	3 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v3	Class I	2021-06-21	On the EU market
eeee	2 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v2	Class I	2021-06-21	On the EU market

8.2 Download Devices or Systems or Procedure Packs data in a structured format (XML)

NOTE
You can only manually bulk download in XML your own device or system/procedure pack data if you are a manufacturer or a system/procedure pack producer.

1. Follow the steps in Search & View Devices, Systems and/or Procedure Packs [79] to search and view a device or a system or procedure pack. On the search page, activate the top filter (**Only enable search filters available for bulk XML download**) so that you can only enter search criteria that can be used for search results that can be downloaded in an XML format, and enter your search criteria.
Enter the search criteria of your choice, and click on **Search**:

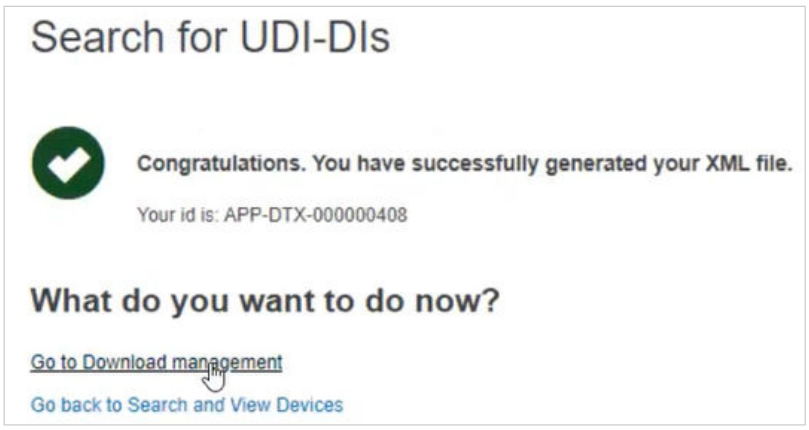


2. Click on **Generate XML file**:

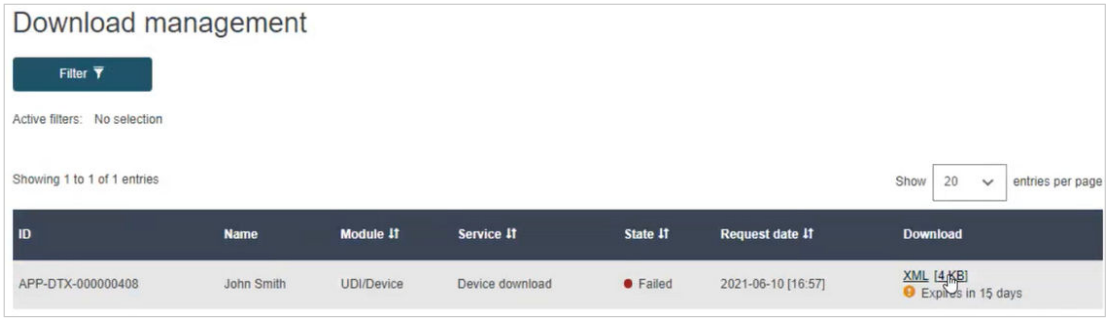
> **NOTE**
> Only what is shown on the result list will be included in the generated file and not all the results of your search (in case there are more pages of results).

3. A pop-up window will ask you to confirm your action:

4. The system will inform you that the action has been successful. Click on **Go to Download Management** under the question *What do you want to do now?*:



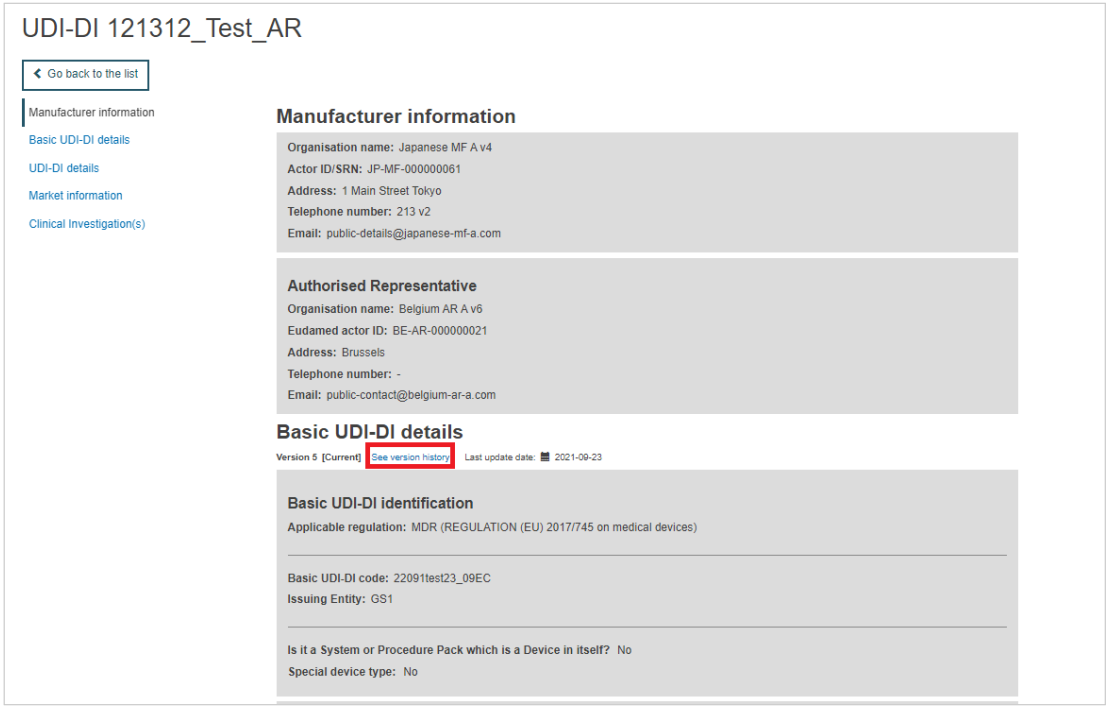
5. You can download the generated XML file by clicking on it under the **Download** column:

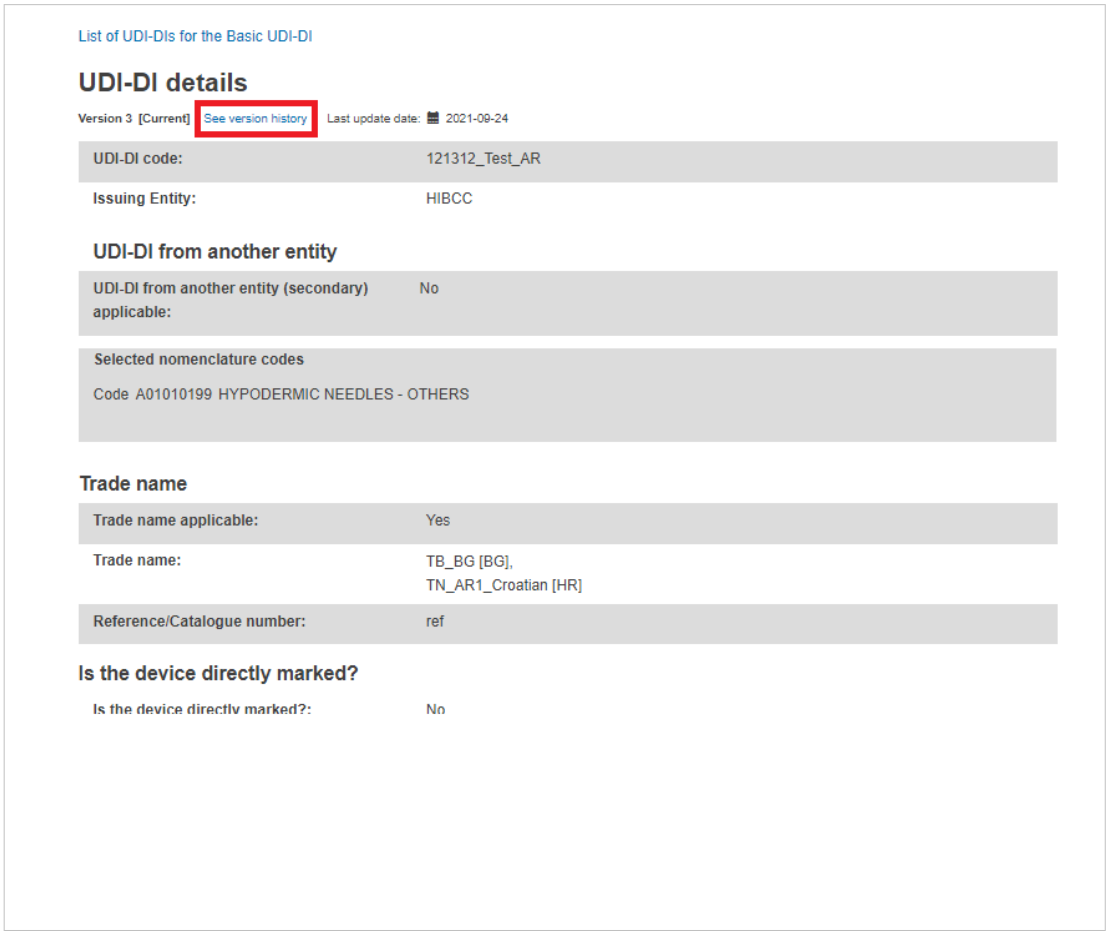


8.3 View historical versions for Basic UDI-DI/EUDAMED DI, UDI-DI/EUDAMED ID and associated entities

1. Follow the steps in Search & View historical versions of Devices, System and/or Procedure Packs [81] to view the details of a Device or System or Procedure Pack.

2. Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product Designer or Container Package) and click on **See version history**:


UDI-DI 121312_Test_AR
Go back to the list
Manufacturer information
Basic UDI-DI details
UDI-DI details
Market information
Clinical Investigation(s)
Manufacturer information
Organisation name: Japanese MF A v4
Actor ID/SRN: JP-MF-000000061
Address: 1 Main Street Tokyo
Telephone number: 213 v2
Email: public-details@japanese-mf-a.com
Authorised Representative
Organisation name: Belgium AR A v6
Eudamed actor ID: BE-AR-000000021
Address: Brussels
Telephone number: -
Email: public-contact@belgium-ar-a.com
Basic UDI-DI details
Version 5 [Current] See version history Last update date: 2021-09-23
Basic UDI-DI identification
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Basic UDI-DI code: 22091test23_09EC
Issuing Entity: GS1
Is it a System or Procedure Pack which is a Device in itself? No
Special device type: No


List of UDI-DIs for the Basic UDI-DI
UDI-DI details
Version 3 [Current] See version history Last update date: 2021-09-24
UDI-DI code: 121312_Test_AR
Issuing Entity: HIBCC
UDI-DI from another entity
UDI-DI from another entity (secondary) applicable: No
Selected nomenclature codes
Code A01010199 HYPODERMIC NEEDLES - OTHERS
Trade name
Trade name applicable: Yes
Trade name: TB_BG [BG], TN_AR1_Croatian [HR]
Reference/Catalogue number: ref
Is the device directly marked?
Is the device directly marked?: No

Market information

Version 1 [Current] | Last update date: 2021-09-23

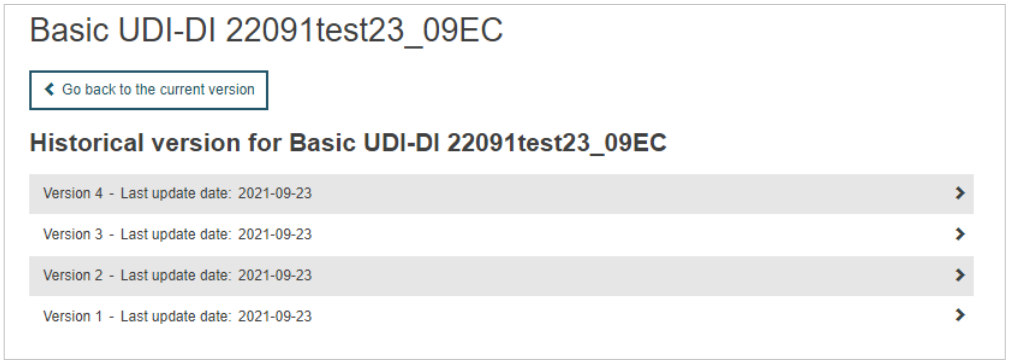
Member State of the placing on the EU market of the Device:	Belgium		
Member States where device is or is to be made available on the market:	Country	From	To
	Belgium	-	-
	Iceland	-	-
	Ireland	-	-
	Malta	-	-
	Netherlands	-	-

Clinical Investigation(s)

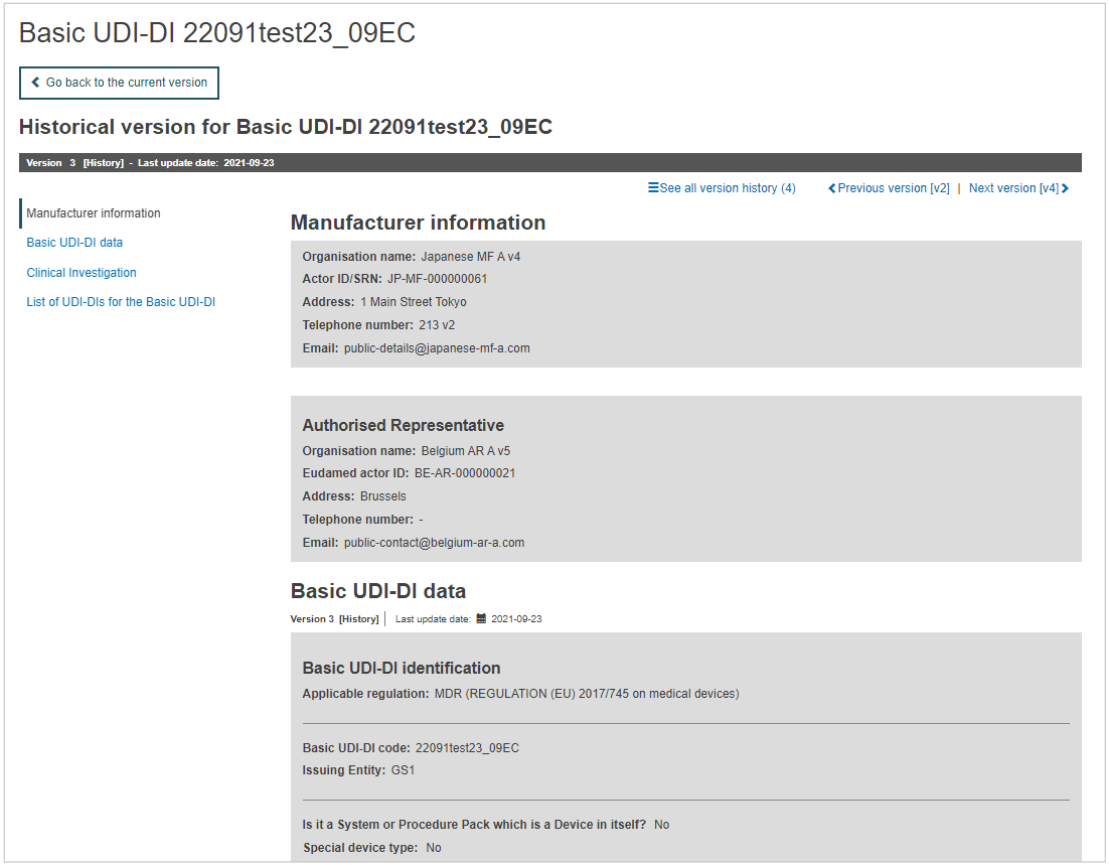
Clinical Investigation

Clinical Investigation, if applicable:	No

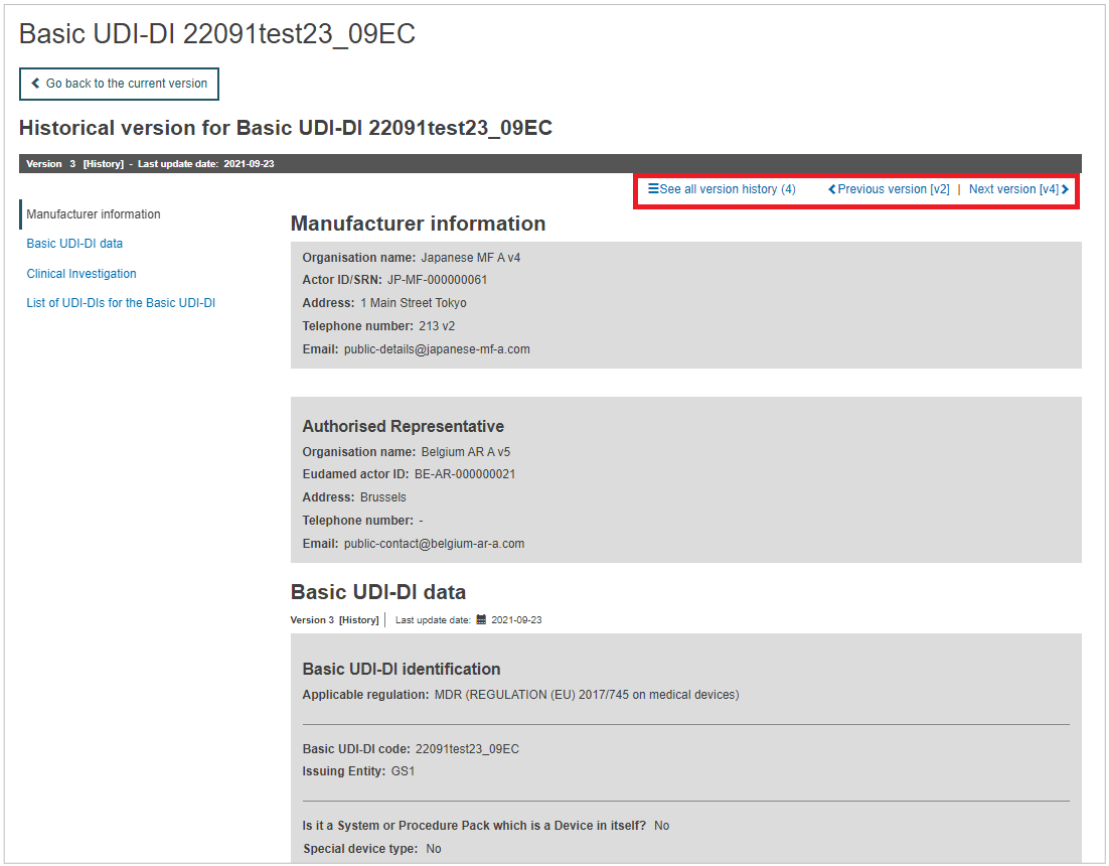
3. You will see, if any, a list of all old versions for the selected entity, e.g. version history of the Basic UDI-DI:



4. Click on the version you wish to view to access its details:



5. Inside a version, click on the links on the top right corner to browse through the different versions (*all versions*, *previous*, *next*):



9 Annex 1 – device certificate information

This Annex presents the cases in which the certificate information needs to be provided when registering a Regulation Device and the certificate type needed to be provided based on the properties of the device.

Applicable Legislation	Risk Class	Device Type (properties composing the Device)	Type Examination Certificate	Technical Documentation Certificate
MDR	IIb	Implantable = No	EU type-examination certificate (Annex X)	
MDR	IIb	Implantable=Yes, Suture/ Staples= Yes	EU type-examination certificate (Annex X)	
MDR	IIb	Implantable=Yes, Suture/ Staples= No	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided *EU technical documentation assessment certificate (Annex IX Chapter II)*
MDR	III	Any	Either TE or TD required to be provided *EU type-examination certificate (Annex X)*	Either TE or TD required to be provided *EU technical documentation assessment certificate (Annex IX Chapter II)*
IVDR	B	Self-patient testing= Yes or Near Patient Testing = Yes		*EU technical documentation assessment certificate (Annex IX Chapter II)*
IVDR	C	Self-patient testing= No, Near Patient Testing = No	*EU type-examination certificate (Annex X)*	
IVDR	C	Self-patient testing= Yes or Near Patient Testing = Yes	Either TE or TD required to be provided *EU type-examination certificate (Annex X)*	Either TE or TD required to be provided *EU technical documentation assessment certificate (Annex IX Chapter II)*
IVDR	D	Any	Either TE or TD required to be provided *EU type-examination certificate (Annex X)*	Either TE or TD required to be provided *EU technical documentation assessment certificate (Annex IX Chapter II)*

Colour-code description.

= Certificate is required to be provided if the Device is covered by a Certificate of this type

= Certificate is required to be provided in this case. In case there is an option to provide either a Type Examination or Technical Documentation – one of them is required to be provided (the Certificate type covering the Device)

10 Annex 2 – 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