EUDAMED user guide

UDI Devices

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1 Introduction

Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic 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 ensure its availability to everyone. Moreover, it is used to manage the registration of devices and systems and procedure packs (SPPs) across the EU/EEA.

It falls within the responsibilities of manufacturers (MFs) of devices and system and procedure pack producers (SPPPs) to ensure product registration in the UDI/Device Module. Authorised Representatives and Importers cannot register devices or SPPs. The devices to be registered are defined by Article 2 in MDR and IVDR. UDI-DI/Device module of EUDAMED is used for the manufacturers to provide information on the devices and the corresponding UDIs and to make it available to everyone.



TIP
For a wider understanding on how to use the platform visit the EUDAMED Information Centre. For information specific to UDIUDI, visit the UDI Helpdesk.



NOTE
This user guide outlines the registration of medical devices, IVD medical devices, SPPs, the device data, including the corresponding Basic UDI-DI and UDI-DI.

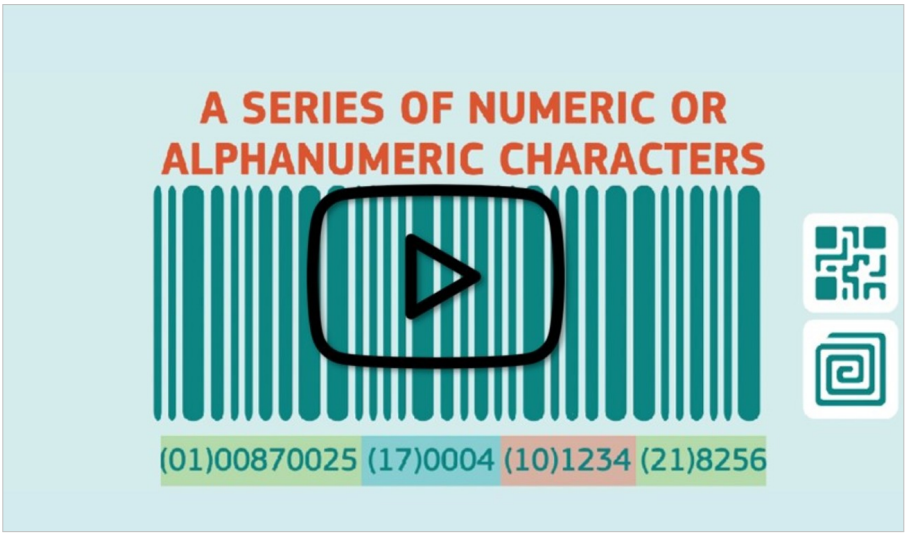
Economic Operators (EOs) must register their organisation in the Actor (ACT) module before they are given access to EUDAMED and become able to register their devices and SPPs in the UDI/Devices module. See the EOs User Guide. Devices and SPPs must be registered in the UDI/Devices module before they are placed on the union market (see Q&A on EUDAMED gradual roll out). Device registration does not involve any assessment, review or approval by a Competent Authority (CA). Some of the information in EUDAMED is publicly available for searching and viewing.

WARNING

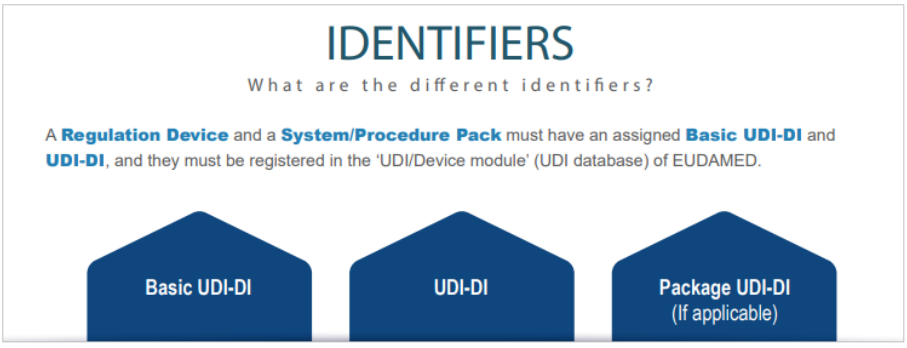
- The requirements for device registration differ, depending on when the device is placed on the market and depending on which legislation it is compliant with (“regulation devices”, "legacy devices", "old devices" – see Q&A on EUDAMED gradual roll out).
- In EUDAMED, device/SPP registration in the UDI/Devices module means registering a device/SPP at the level of the device identifier. Production identifiers are not required.
- EUDAMED does not contain all constraints defined in the MDR/IVDR, guidance and good practices, and therefore, it is not because something is possible in EUDAMED that it is necessarily allowed.

VIDEO: What is a UDI?

Please note that this video contains sound.



INFOGRAPHIC: Basic UDI-DI/UDI-ID concept



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 Economic Operators user guide.

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 data on the devices and their UDIs in EUDAMED, your profile for the UDI/Device module [1] must be either:

- A *Proposer* – this profile allows you to create and delete draft records related to your manufacturer, but not to submit a device, or
- A *Confirmer* – this profile includes the *Proposer* rights and additionally, allows you to submit and discard records. Moreover, it allows you to directly register a device.

NOTE
See the Economic Operators user guide, Section *Upgrading your user profile* for further information on how to upgrade your profile from *Viewer* to *Proposer* or *Confirmer*.

[1] See the Economic Operators user guide, Section *User rights and profiles*, 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 (If you don't have a second user with LAA/LUA profile, please refer to the Economic Operators user guide, Section *Requesting access as a second LAA user to an existing registered actor*).

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

Once you enter information into EUDAMED, it may not be possible to change it, if entered incorrectly. Certain fields are not editable after submission of the record.

NOTE

EUDAMED user interface is available in all EU languages and the information can be entered in any official language within the EU.

3 Register Regulation Devices

VIDEO: Registering Regulation Devices

Please note that this video does not contain sound.



NOTE

- Devices or SPPs to be placed on the market according to MDR/IVDR (“regulation devices”) must first be registered in the UDI/Devices module together with their UDI and other device data;
- 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-DI without a UDI-DI

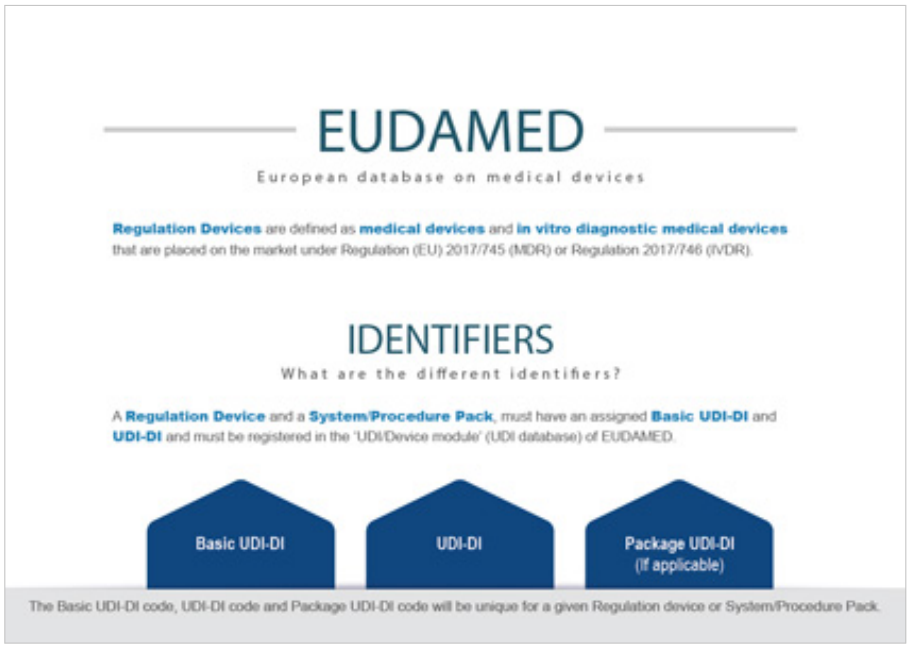
You will be asked to log into EUDAMED via your EU Login account. This will take you to the actor (manufacturer, system/procedure pack producer) to which you are connected through your user account. If you have user accounts for more than one actor, your options will be available on the screen. Choose the appropriate one by clicking on the actor name.

INFOGRAPHIC: UDI registration for regulation devices



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

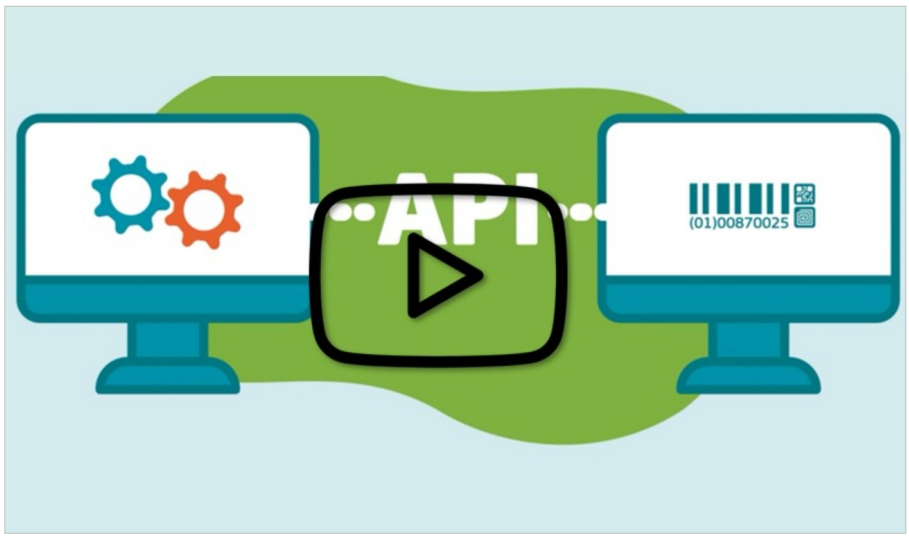
INFOGRAPHIC: Basic UDI-DI/UDI-ID concept



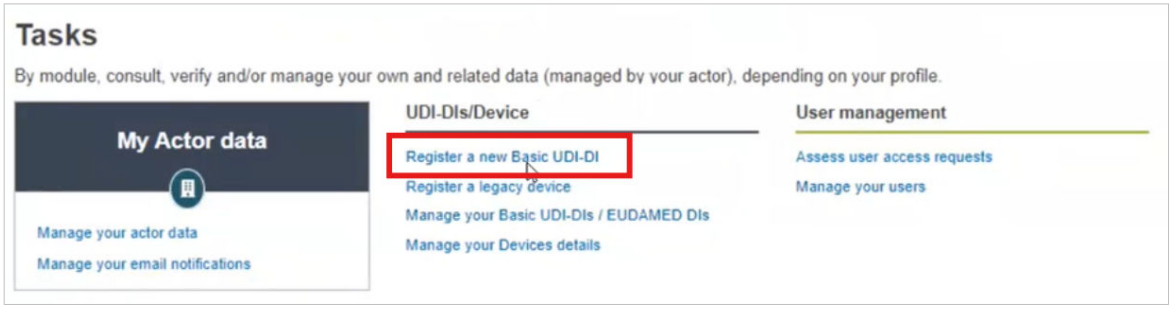
3.1.1 Step 1: Enter the device and its Basic UDI-DI information

VIDEO: UDI and medical software devices

Please note that this video contains sound.



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



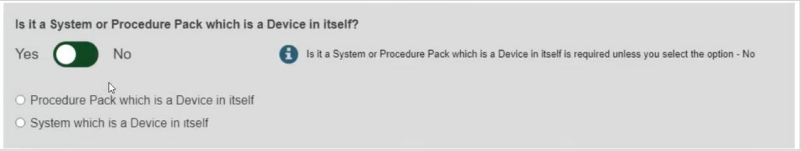
2. Enter the Basic UDI-DI information and select the applicable regulation for your device:

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

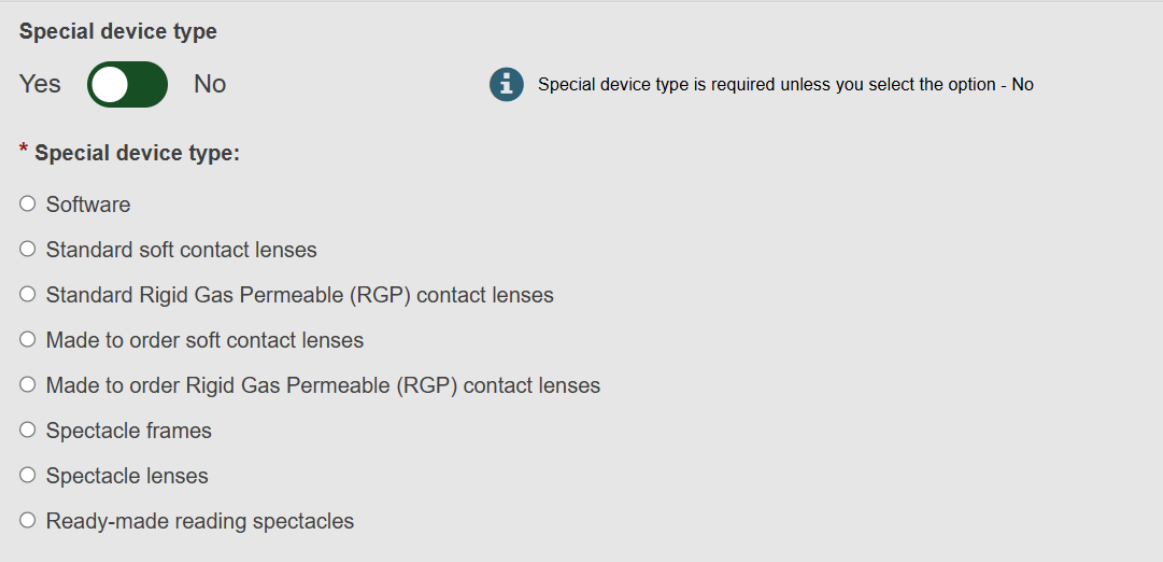


Depending on the regulation selected an additional question appears at the bottom of the page:

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*[2] (See video above):



NOTE

For certain MDR device types, the registration of a UDI-DI is not appropriate. If one of the following Special Device types is selected, the Master UDI-DI applies instead:

- Standard soft contact lenses
- Standard Rigid Gas Permeable (RGP) contact lenses
- Made to order soft contact lenses
- Made to order Rigid Gas Permeable (RGP) contact lenses.

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

NOTE
Currently, it is not possible to select certain devices. If one of the following Special Device types is selected, the system will block you from saving the registration:

- Spectacle frames;
- Spectacle lenses;
- Ready-made reading spectacles

It is not possible to register these devices through Machine-to-machine or Bulk uploads either.

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



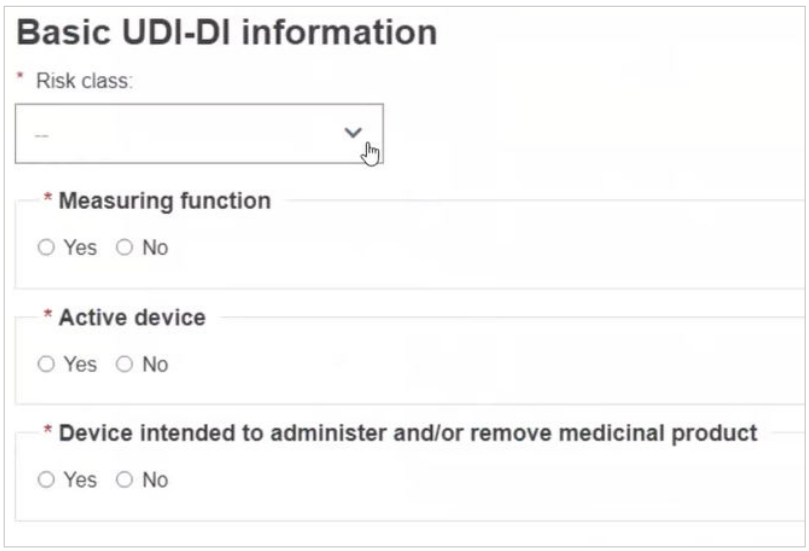
IMPORTANT
EUDAMED will validate the Basic UDI-DI code based on the specific format for each Issuing Entity and will prevent you from going further if the code is not valid. However, EUDAMED cannot verify that the code is correct beyond the format.

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. Once you save your changes, you will not be able to amend the information at a later stage.

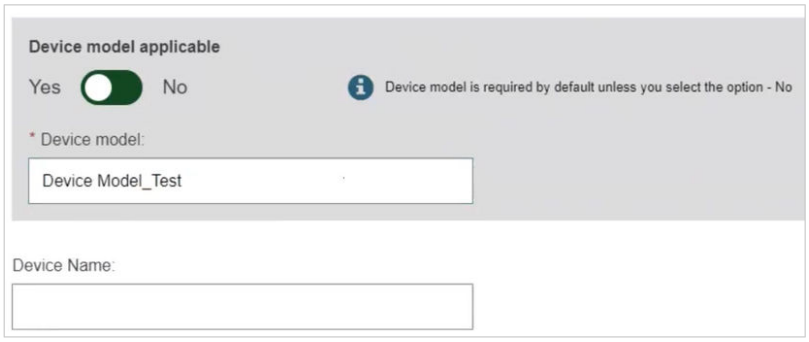
4. Non-EU manufacturers will have to select the Authorised Representative for the Basic UDI-DI amongst those with which they have an active mandate registered in EUDAMED.
If there is only one Authorised Representative with an active mandate with the non-EU Manufacturer, it will be automatically retrieved:



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



6. Select **Yes** or **No** if Device model is applicable. If you selected *No*, 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):



IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

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



3.1.2 Step 2: Enter certificate information (if applicable)

This section only becomes accessible depending on the Risk Class information provided and additional properties in the Basic UDI-DI and applies to certificates issued by the Notified Bodies (NBs).

NOTE

Certificate Information for registration of a device and its 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 – Device Certificate Information [108] you can find the different cases in which Certificate information is required and the type of certificate.

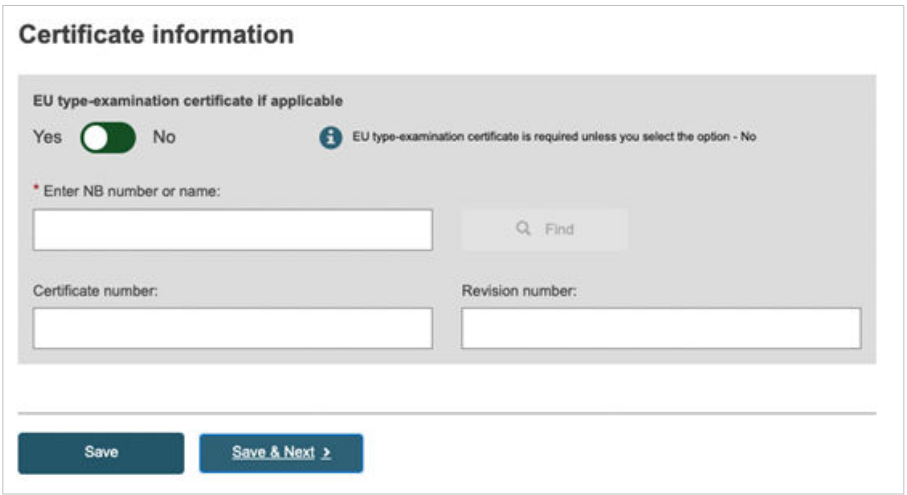
Depending on the risk class of the devices, SS(C)P provision may be applicable. Only manufacturer can register a new SS(C)P. During SS(C)P registration, the Manufacturer must provide the SS(C)P details, select the assigned Notified Body and the master document among the multiple SS(C)P documents in multiple languages that can be uploaded. The assigned Notified Body is notified of the SS(C)P registration.

For 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 NB from the new window. EUDAMED does not verify whether the NB is the right one for your device.

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



NOTE
Notifications to MFs and ARs

When a new Product Certificate has been registered in EUDAMED both the MF and, if applicable, the AR are notified.

3.1.3 Step 3: Enter UDI-DI identification information

VIDEO: UDI carrier and display formats

Please note that this video does not contain sound.



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 from the same manufacturer.

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 your chosen Issuing Entity is **GS1**, 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 shorter 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)

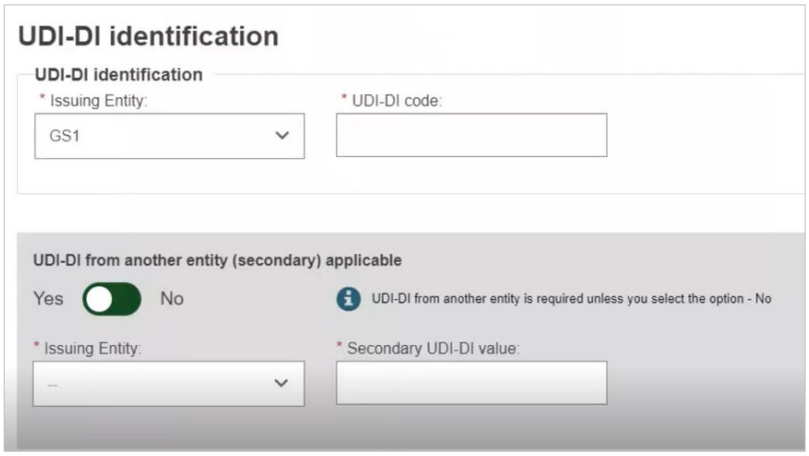
00nnnnnnnnnnn (GTIN-12)

0nnnnnnnnnnnn (GTIN-13)

NOTE
When registering a Master UDI-DI code, a specific format validation algorithm is applied when the issuing entity is GS1:

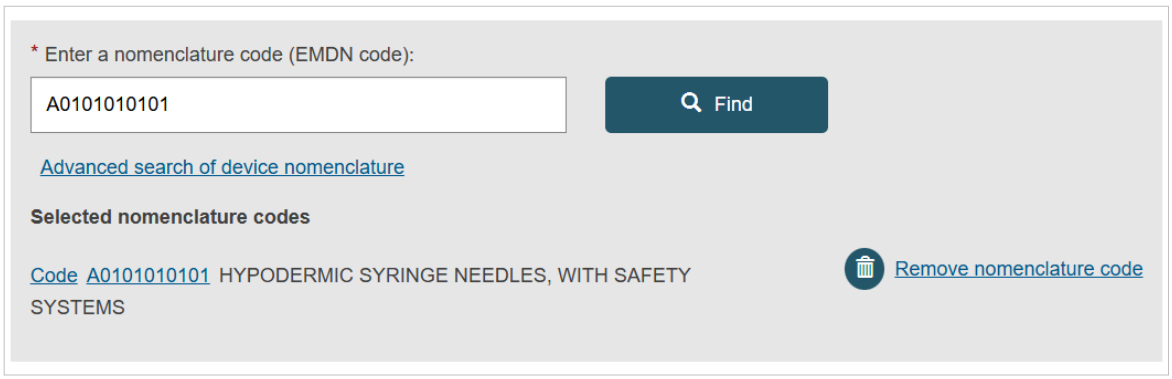
- For **Standard soft contact lenses** and **Standard Rigid Gas Permeable (RGP) contact lenses** the system applies the GMN format validation algorithm.
- For **Made-to-order soft contact lenses** and **Made-to-order Rigid Gas Permeable (RGP) contact lenses** the system applies the GTIN UDI-DI format validation algorithm.

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



NOTE
Secondary UDI-DI may exist due to the fact that the manufacturer changed issuing entity. The UDI-DI assigned to the device being registered from the previous issuing entity can be referenced in EUDAMED together with the new one.

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

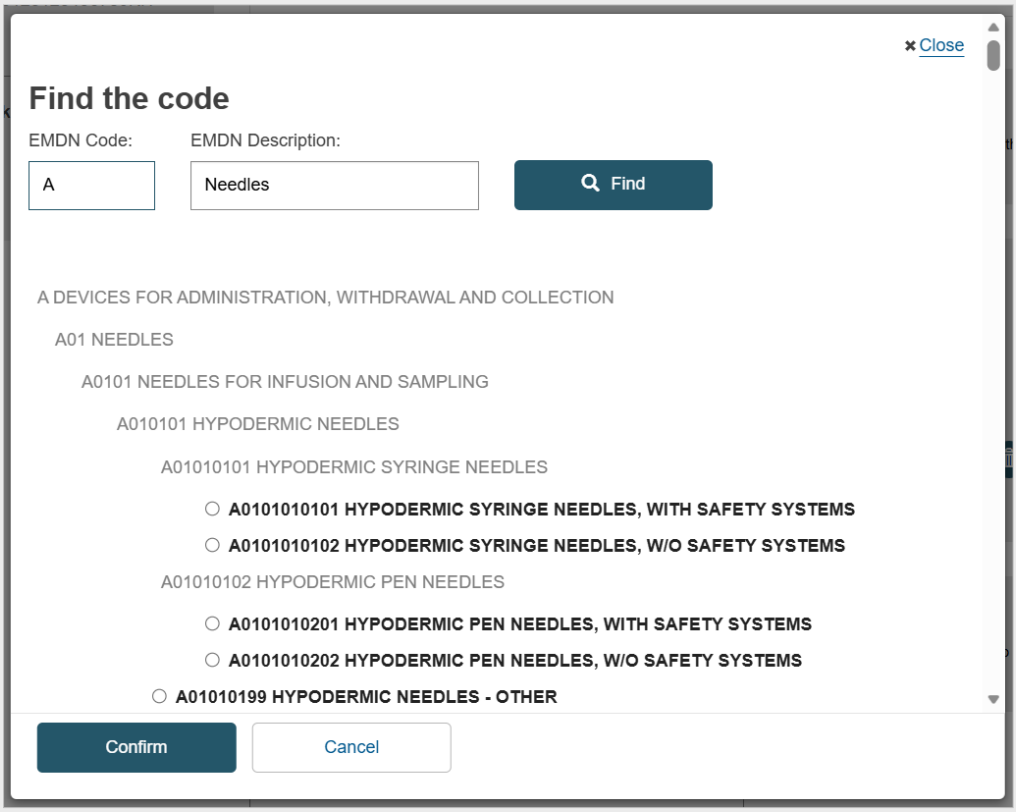


NOTE

MDR and IVDR require that an internationally recognised medical devices nomenclature is used when registering devices in EUDAMED. The nomenclature to be used according to MDR/IVDR is EMDN.

NOTE
Search for Nomenclature codes (EMDN)

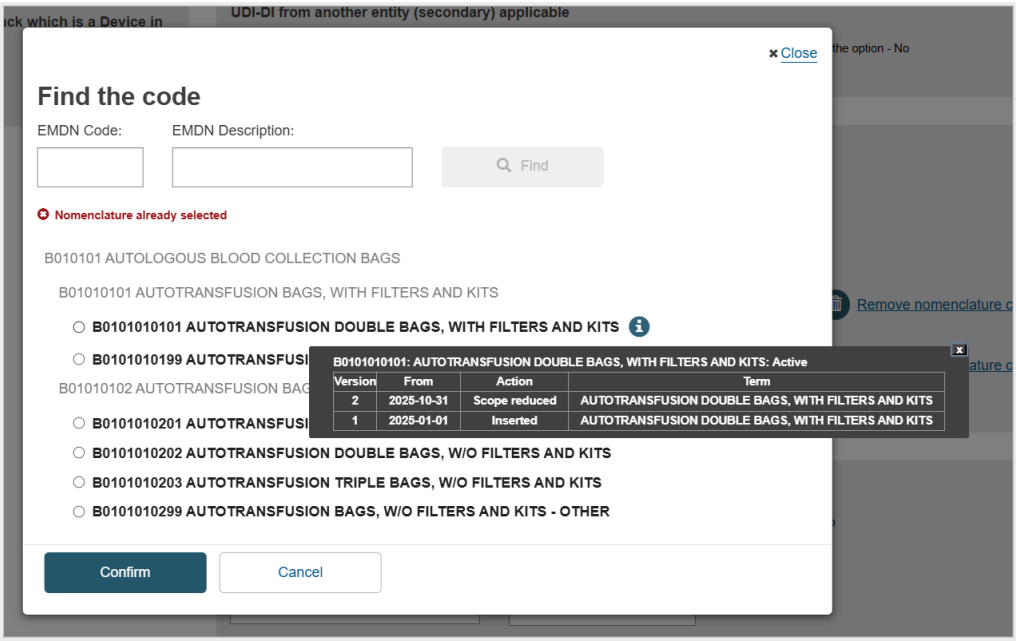
Click on **Advanced search of device nomenclature** to search by partial code name and view the list of codes alphabetically:



EMDN Code updates

EMDN codes may get updated and therefore have a version history, which is indicated by an *information* icon.

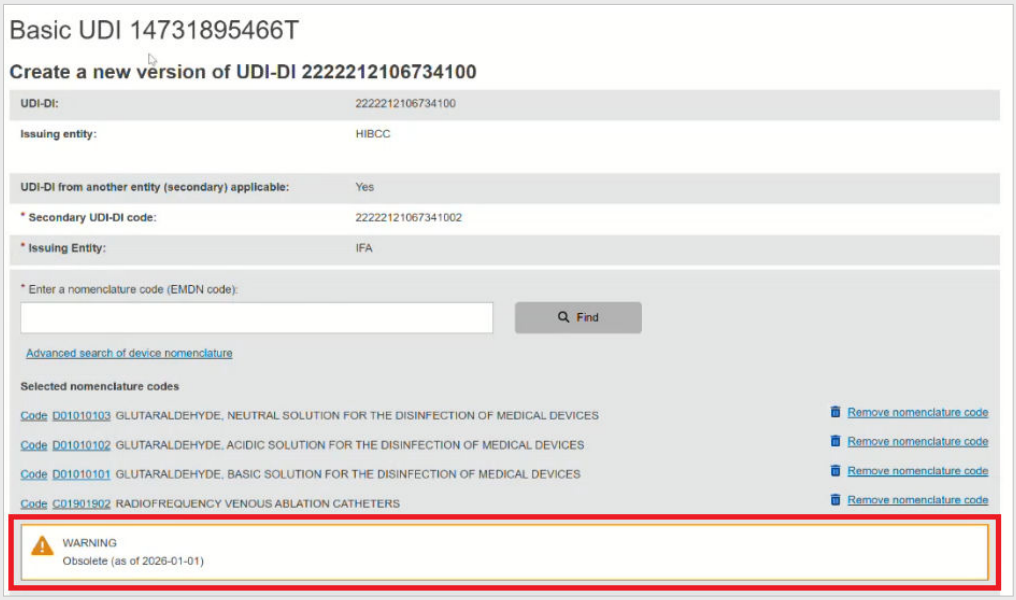
Click on the *information* icon to view details about a code's versions and status:



How does an EMDN code update affect my device?

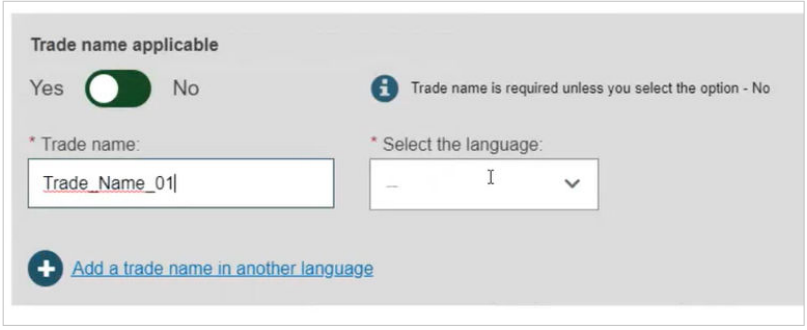
1. If an EMDN code becomes *scope-extended* or *corrected*, the device entry is not affected and no action is necessary.

2. If an EMDN code becomes *obsolete* (*inactive* status), *split* or *scope-reduced*, the system will issue a warning (*UDI details* section):

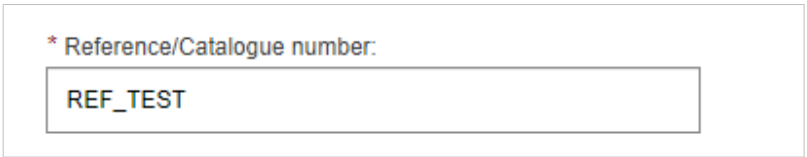


Depending on the specific case, the system may prompt the user to remove the obsolete EMDN code before creating a new device version with the correct EMDN code. In such cases, the user will receive EUDAMED and email notifications.

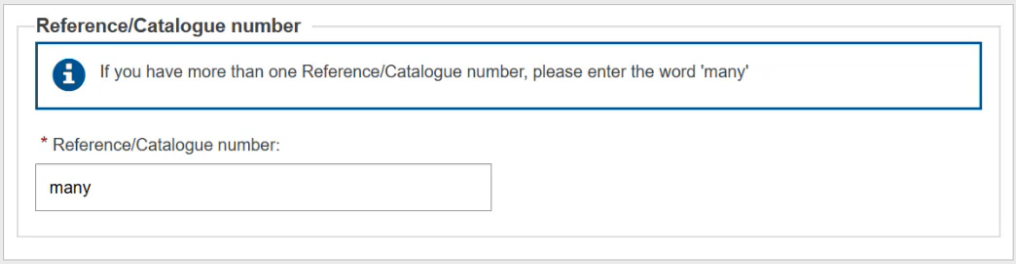
4. If applicable, enter the trade name (as specified on the device label) and select its related language (select **All languages** if not language-dependent):



5. Enter the *Reference/Catalogue number*:

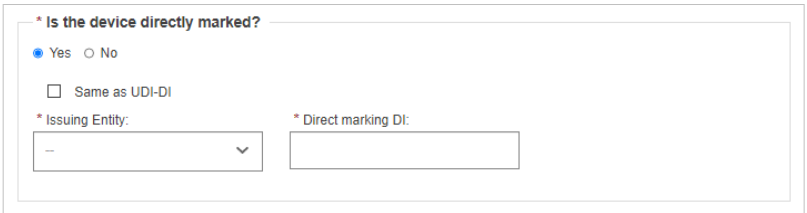


NOTE
For a Master UDI-DI, if there are multiple Reference/Catalogue numbers, you may enter "**many**" as the value:



IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

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.



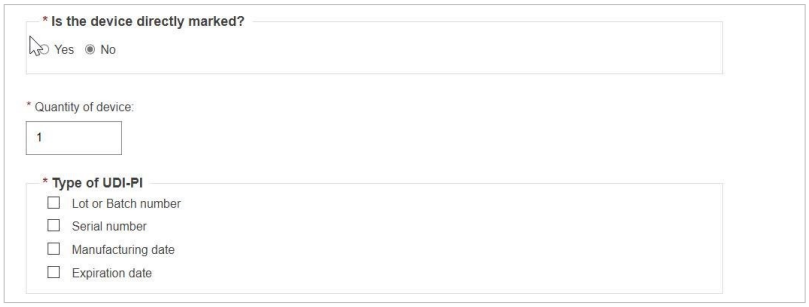
NOTE
Direct Marking UDI-DI is not applicable for a Master UDI-DI. The field is set to *No* and it is greyed out.

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 (UoU DI) can be used for different UDI-DIs in case several units of the same device have different root packaging (each one having a different UDI-DI).

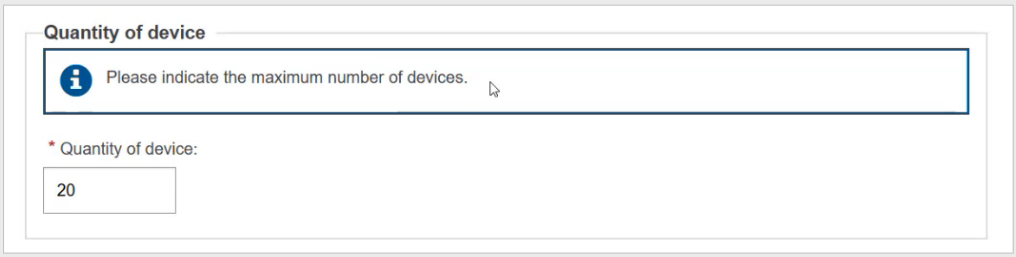


NOTE
The *Unit of Use DI* and its *Issuing Entity* fields are not applicable for a Master UDI-DI. They are set to *No* and they are greyed out.

8. If the base quantity is **less than two**, then no Unit of Use DI (UoU DI) is provided:

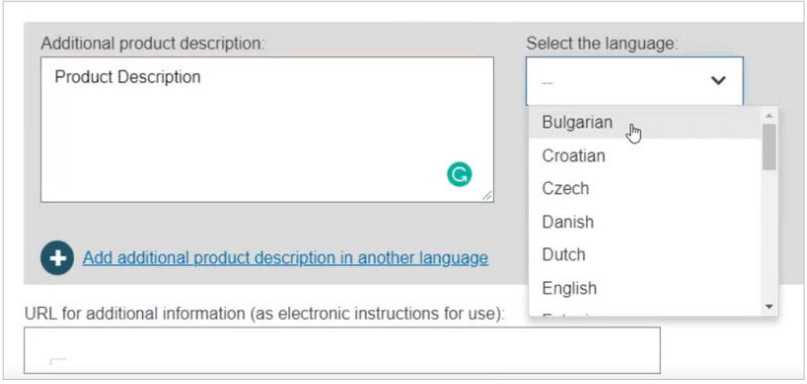


NOTE
For a Master UDI-DI, please indicate the maximum number of devices for the *Quantity of Device*:



9. Select the *Type of* UDI-PI. The UDI-PI is the production identifier for each unit. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date, depending on how the device is produced.

10. Enter any additional pertinent information about the device, select the language in which the additional information is provided and enter a URL (web address) for additional information online if applicable:



IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

11. Specify the status of the device by selecting whether it is *On the EU market*, *Not intended for the EU market* or *No longer placed on the EU market* and click **Save** or **Save & Next**:



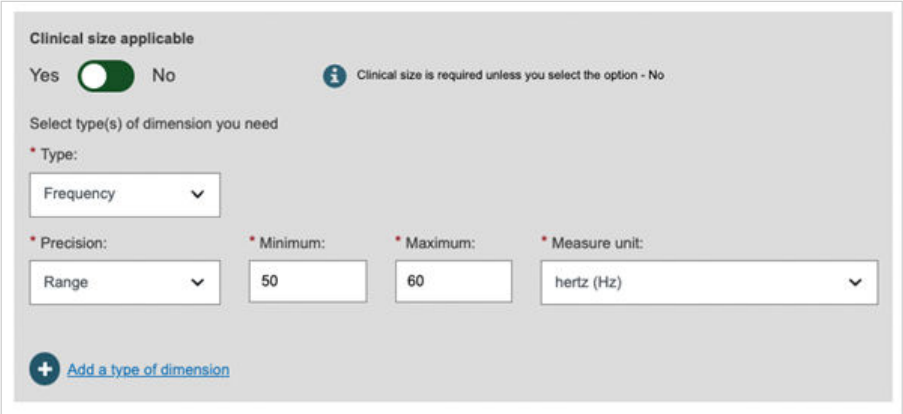
NOTE
A device *not intended for the EU market* may also be registered in EUDAMED.

3.1.4 Step 4: Enter UDI-DI characteristics

1. Specify clinical size for the device if applicable 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 of description. 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 provided in the same languages.



You must provide one of the following precision types:

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

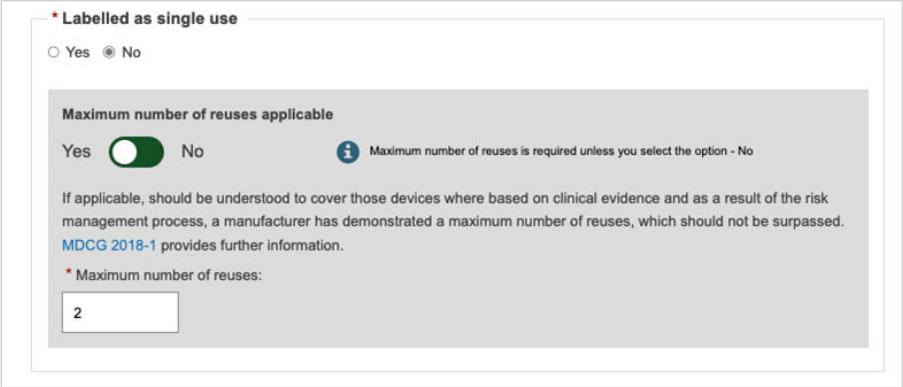
You may add several clinical sizes by adding different types of dimensions, but only one dimension for a given type.

2. Specify if the device is labelled as *single use*.

Single use device

When the device is not labelled *single use* you must provide the number of reuses if applicable:

- If the *Maximum number of reuses* is not applicable, then the device is considered as *non-single use Device* and it 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)

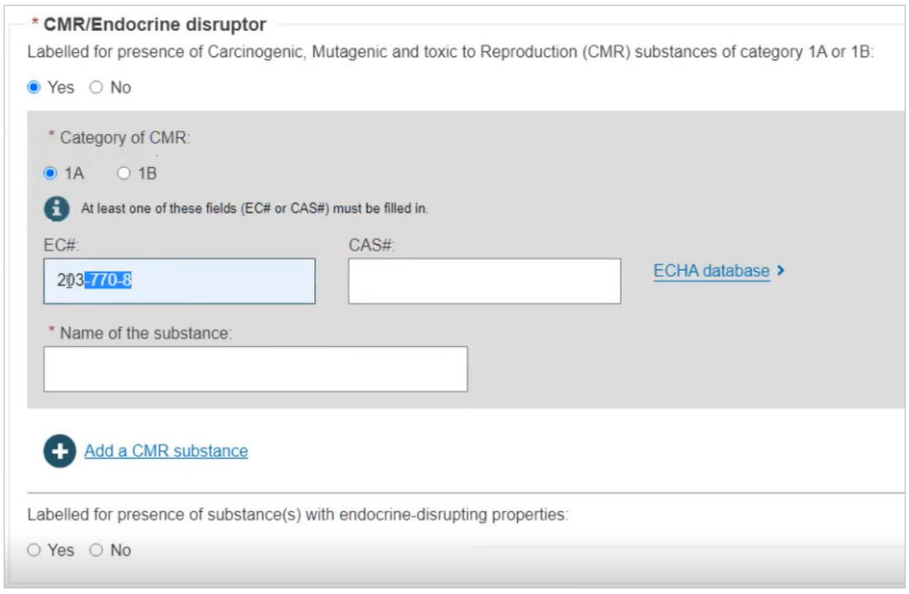


3. Select **Yes** or **No** for each of the options below:

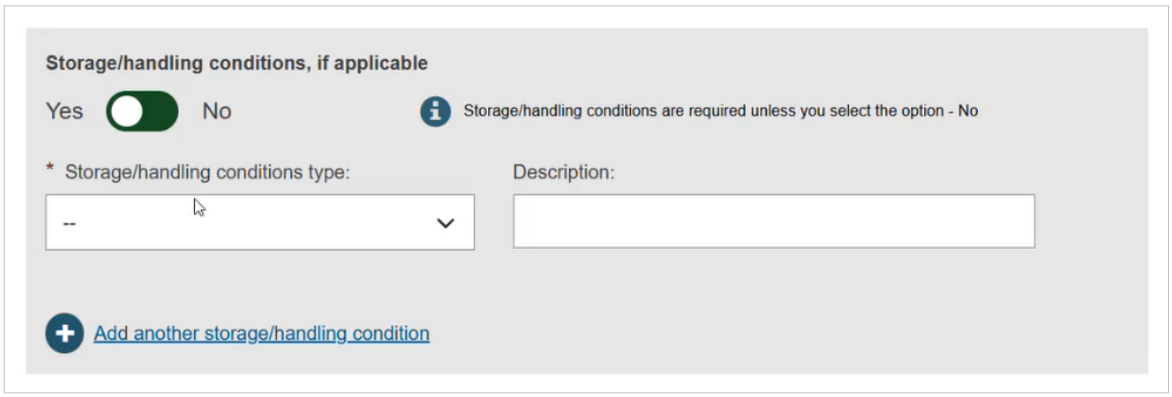


NOTE
Containing latex is only for MDR, not applicable for IVDR.

4. For MDR devices, enter the information on whether the device contains any substance which could be CMR (carcinogenic, mutagenic, or toxic for reproduction) and/or Endocrine disruptor substances if applicable. When specifying CMR and/or Endocrine disruptor substances you may provide the EC# or CAS#. If you do provide them, only the *Name of substance* is required (the language is no longer required):

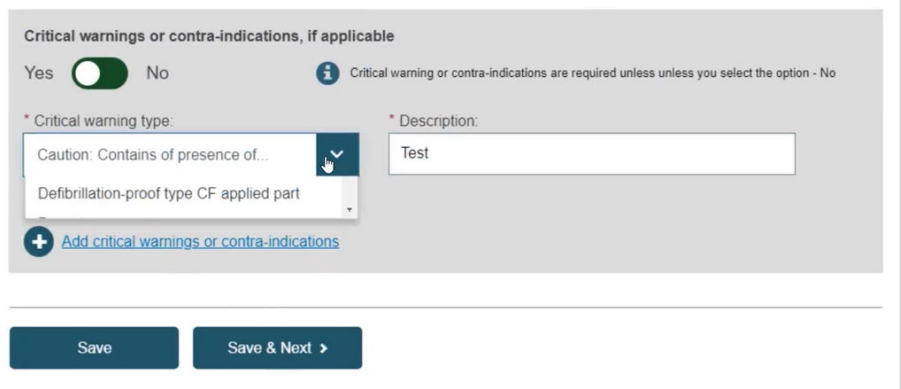


5. Fill in the *Storage/handling conditions* section:



NOTE
For Storage/handling conditions type *Other*, users must enter the Description of the *Storage/handling condition type* and the description's language.

6. Fill in *Critical warnings or contra-indications*, and click **Save** or **Save & Next**:



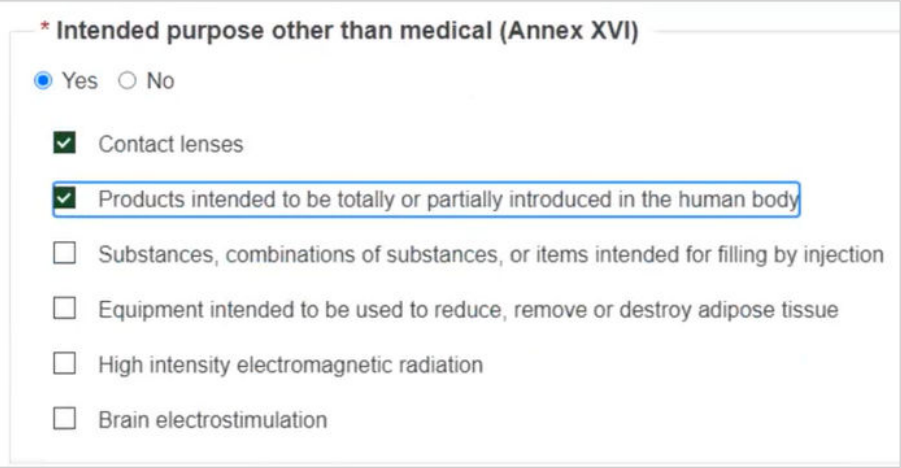
NOTE
For Critical warning or contra-indications type *Other*, users must enter the Description of the Critical warning or contra-indications *type* and the description's language.

3.1.5 Step 5: Enter additional device information

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

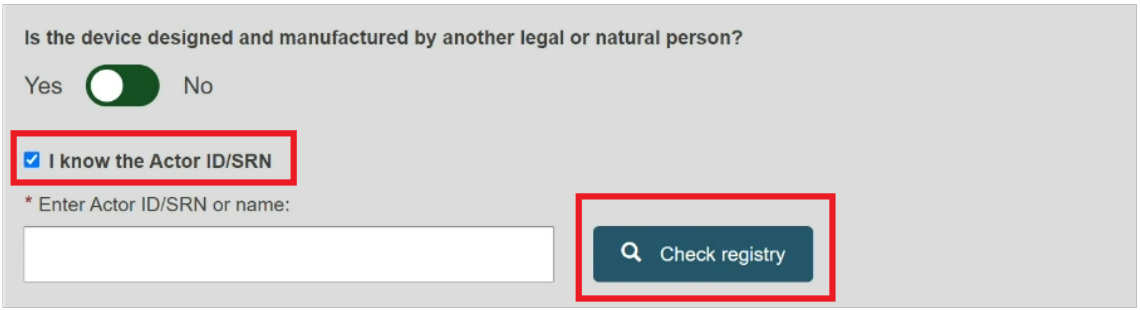


2. If you select *Yes* for the *Intended purpose*, select the relevant purpose(s):



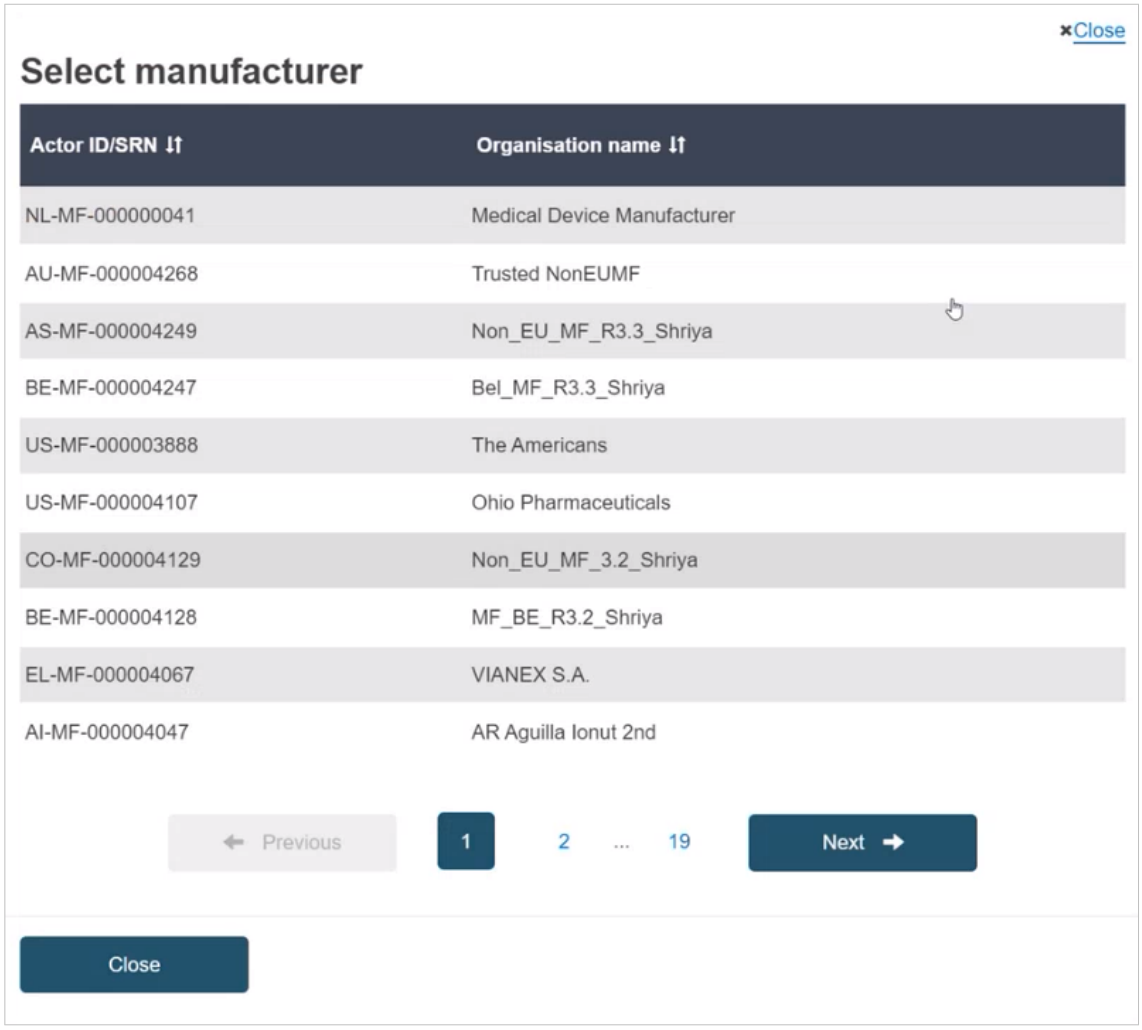
NOTE
When registering a Master UDI-DI for contact lenses, if you select *Yes* for Annex XVI, the list of possible choices will not be displayed, as it is already predefined.

3. The (legal) manufacturer may use another natural or legal person(s) for design and manufacturing activities. However, the (legal) manufacturer, as defined by MDR and IVDR always bears the sole responsibility for device compliance.
   Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person.
   If *Yes*, there are two ways to find the *Product original manufacturer* of the device:
   - Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRN or name of the *Product original manufacturer* of the device and click **Check registry**:



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

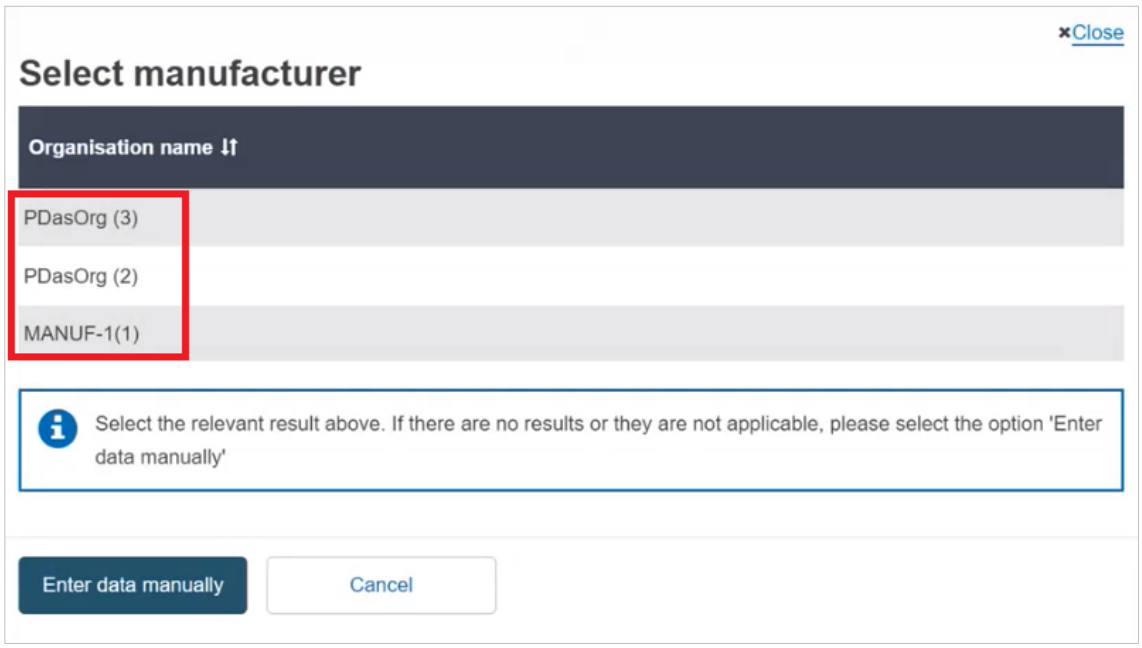
Select the Actor from the list:



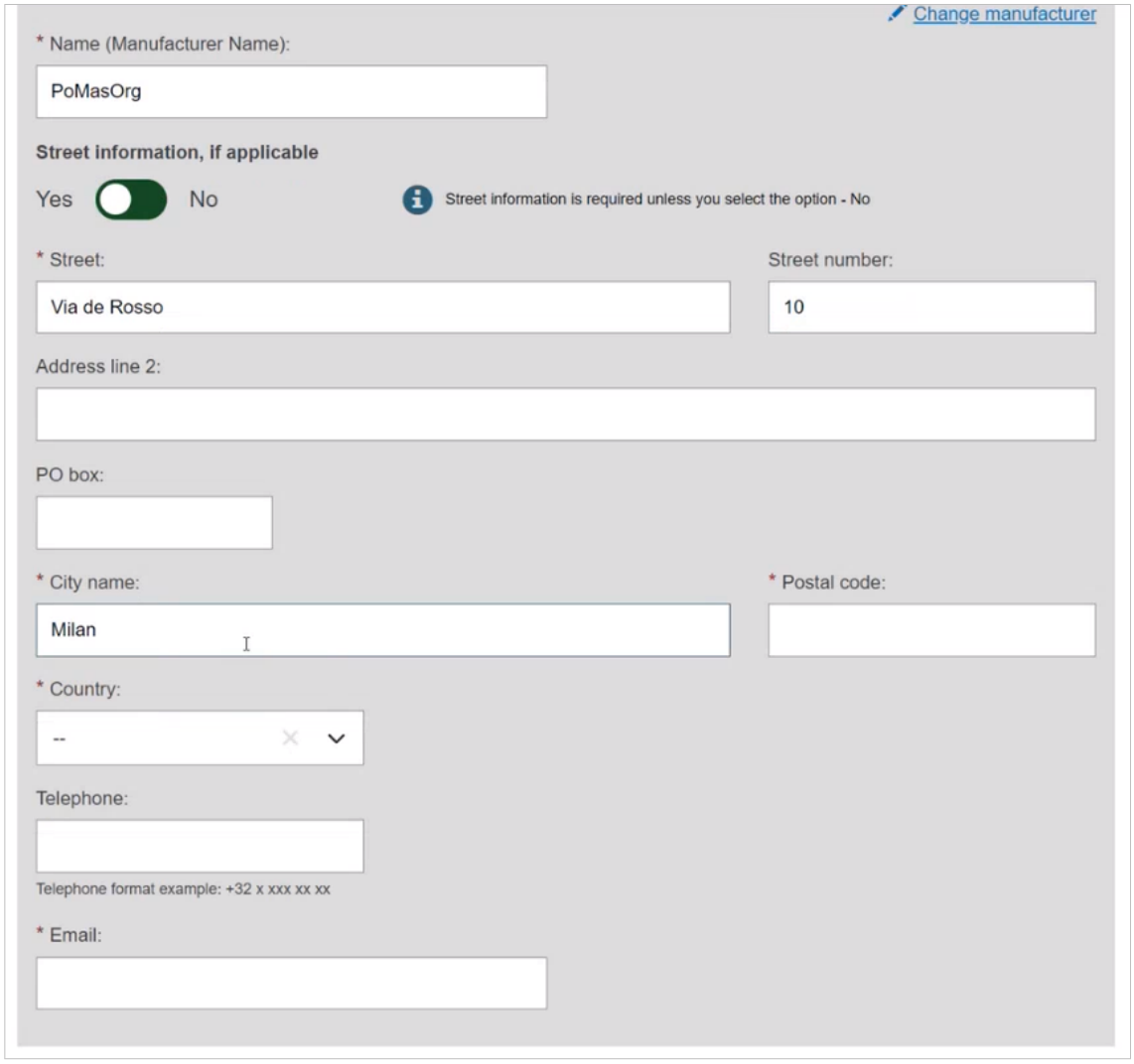
- Enter the name of the *Product original manufacturer organisation name* and click on **Check registry**:



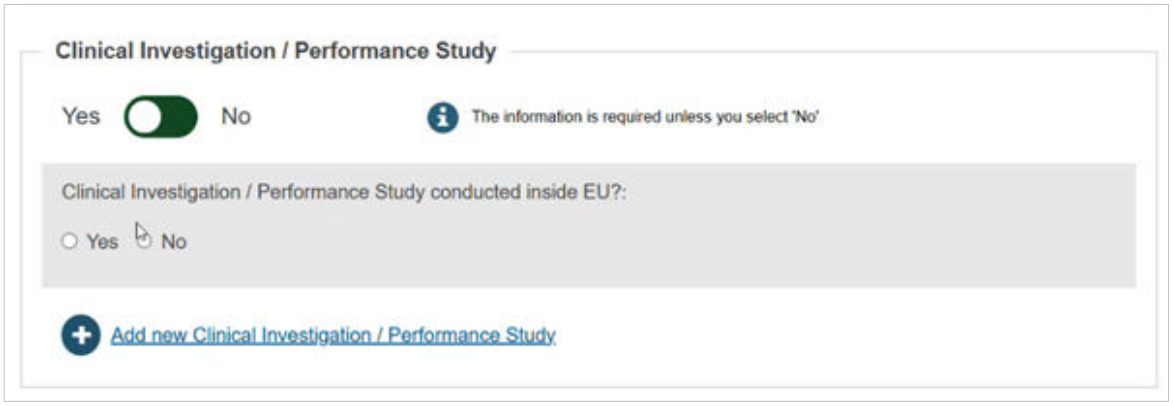
Select the Organisation name from the list:



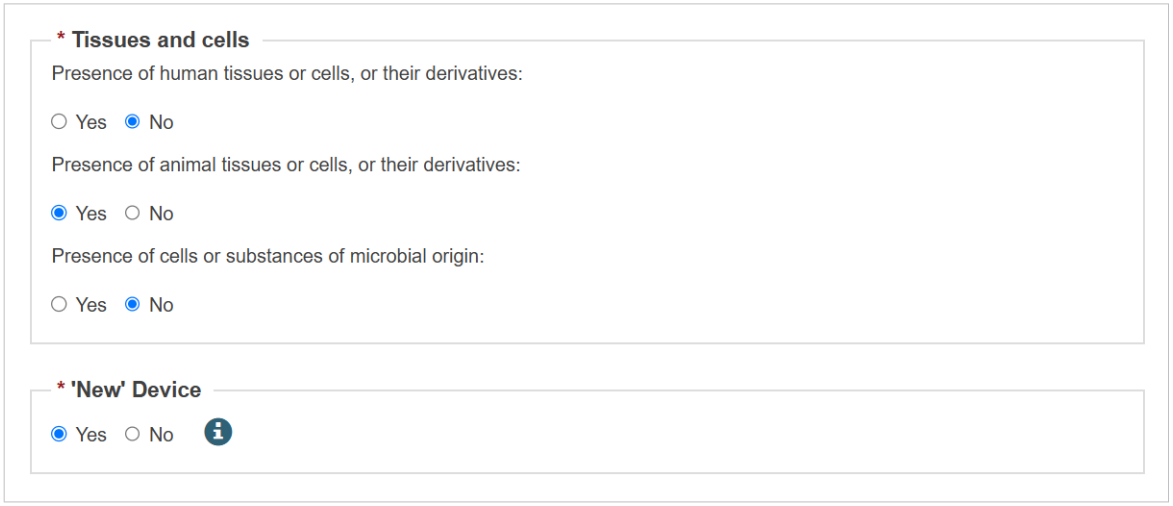
If the Organisation name is not on the list, click on **Enter data manually** and fill in the required fields with the details on the *Product original manufacturer* of the device:



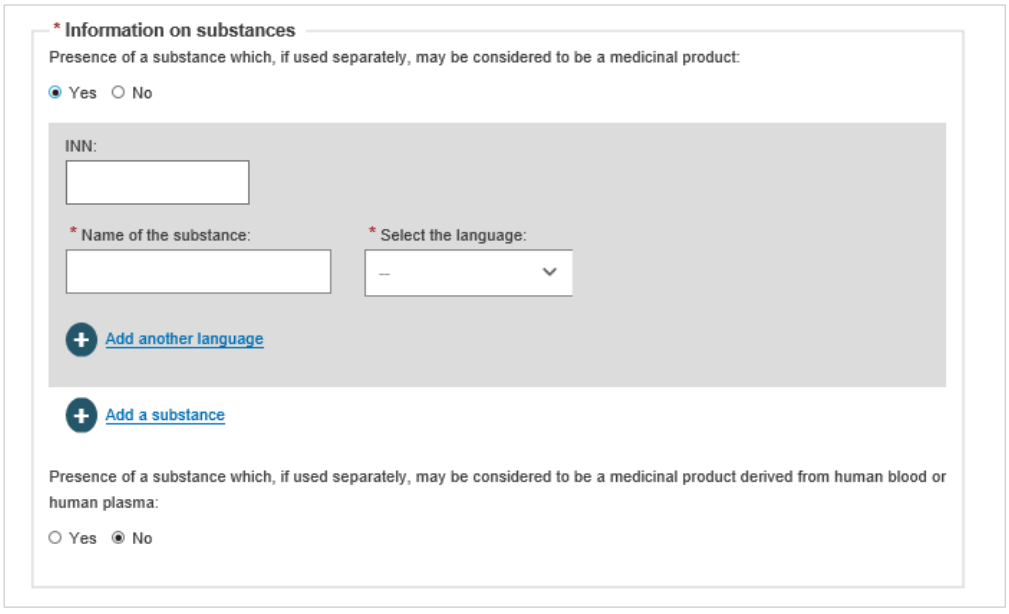
4. Select **Yes** or **No** to provide the Clinical Investigation/Performance study reference for the current device:



5. When registering the devices under MDR, select **Yes** or **No** to fill information on tissues and cells, and information on substances:



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

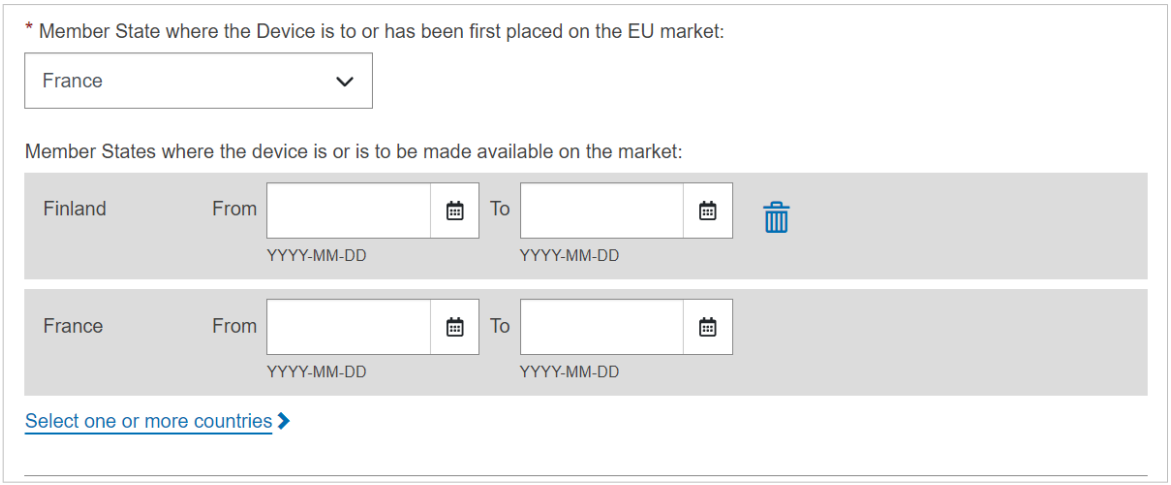


For IVDR, select **Yes** or **No** to fill information on tissues and cells and specify if the device is new.

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.

6. Choose a Member State in the dropdown 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)**.

NOTE
It is possible to enter this information for all risk classes and this may be helpful for users searching for information on devices available in a particular MS.

3.1.6 Step 6: Enter container package details

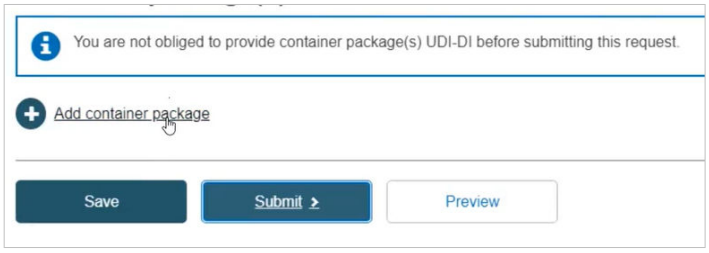
VIDEO: UDI carrier placing

Please note that this video does not contain sound.

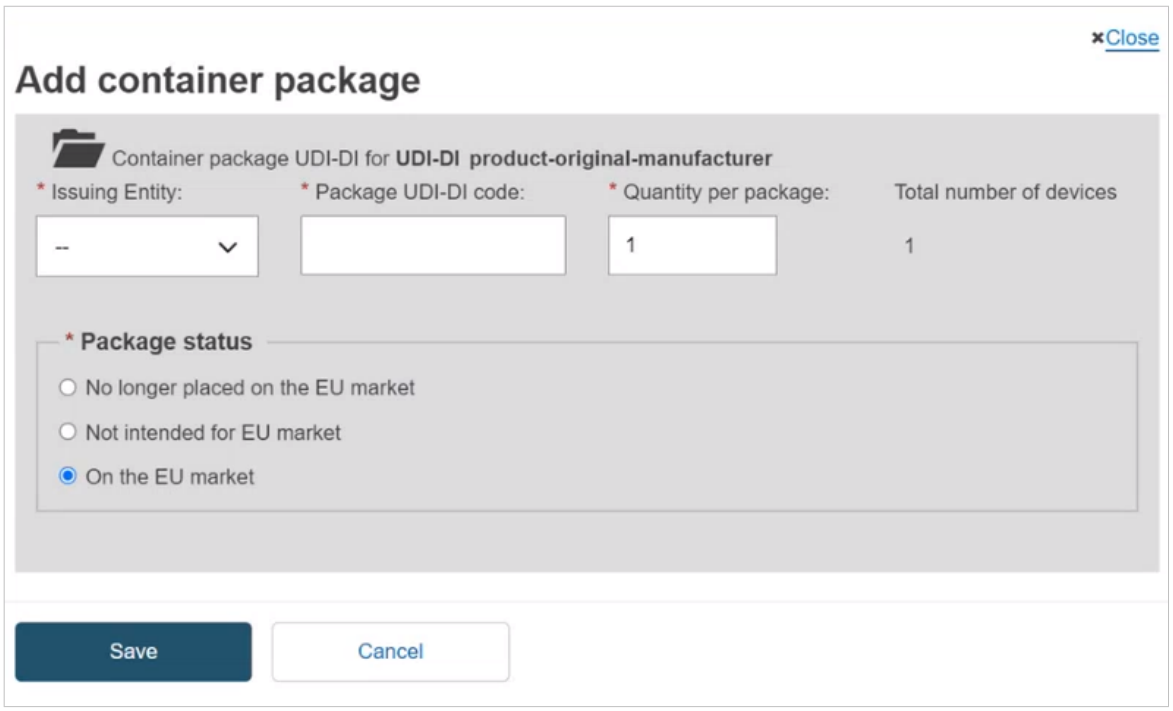


NOTE
Some devices may have more than one packaging level. In that case, each higher level of packaging shall have its own unique UDI. MDR and IVDR define packaging levels as the various levels of device packaging that contain a defined quantity of devices, such as a carton or case.

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.
Start by registering the container package associated with the root UDI-DI (also known as the primary UDI-DI). You may add multiple levels and container packages. Input the *Issuing Entity*, UDI-DI code for the package, *Quantity per package*, select the *Package status* and then click **Save**:



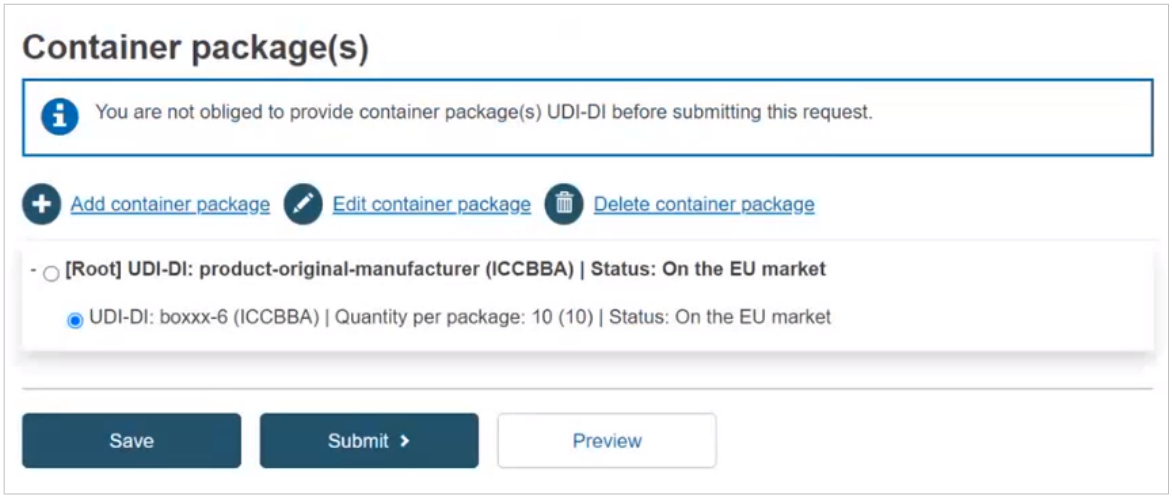
NOTE
If the UDI-DI already exists in EUDAMED, the system will prevent you from saving.

NOTE
If the status of the device for this container package is either *No longer placed on the EU Market* or *Not intended for the EU Market*, the *Package status* options are greyed out and any container package added to this device will automatically have the same *Package status* as the device.

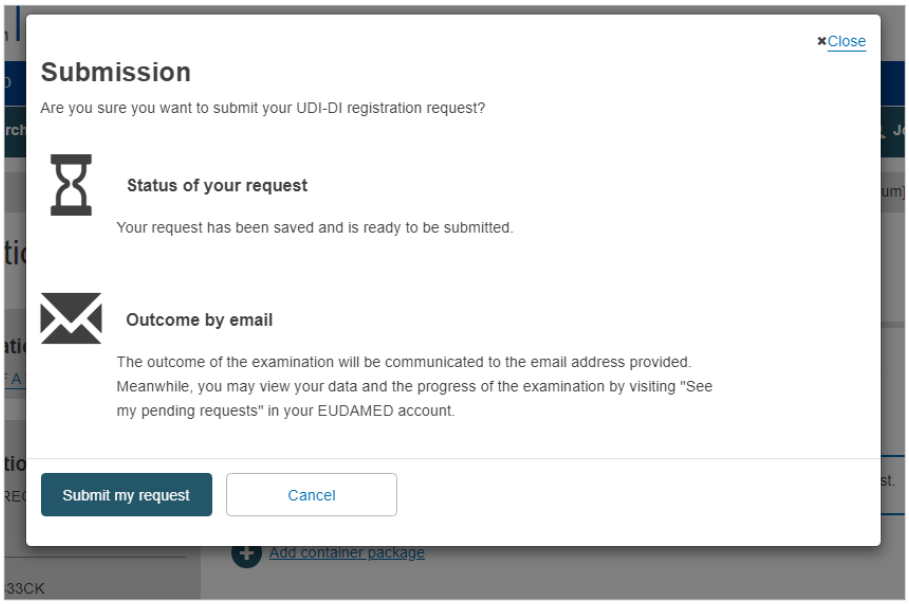
NOTE
When registering a Master UDI-DI code, a specific format validation algorithm is applied when the issuing entity is GS1:

- For **Standard soft contact lenses** and **Standard Rigid Gas Permeable (RGP) contact lenses** the system applies the GMN format validation algorithm.
- For **Made-to-order soft contact lenses** and **Made-to-order Rigid Gas Permeable (RGP) contact lenses** the system applies the GTIN format validation algorithm.

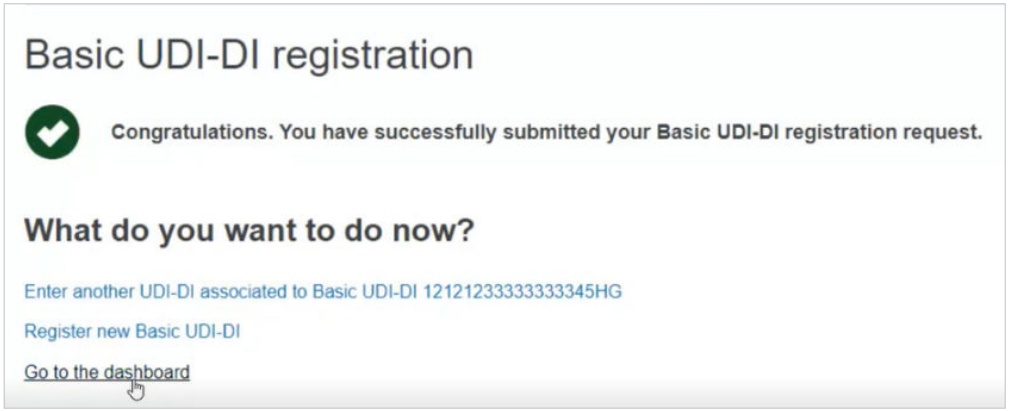
2. Select the generated information and click **Submit**:



3. Users with *Confirmer* profile can submit the device registration in the pop-up window. The device will be then registered and publicly available:



4. The screen will display a success message:

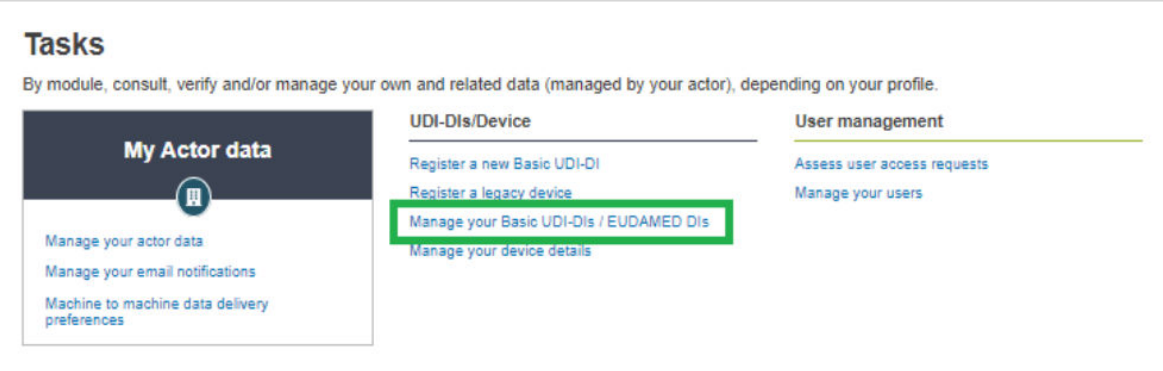


IMPORTANT
After submitting the Device, the state of the Device (Basic UDI-DI and UDI-DI) will be:

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

3.2 Register a regulation device and its UDI-DI for an existing Basic UDI-DI

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

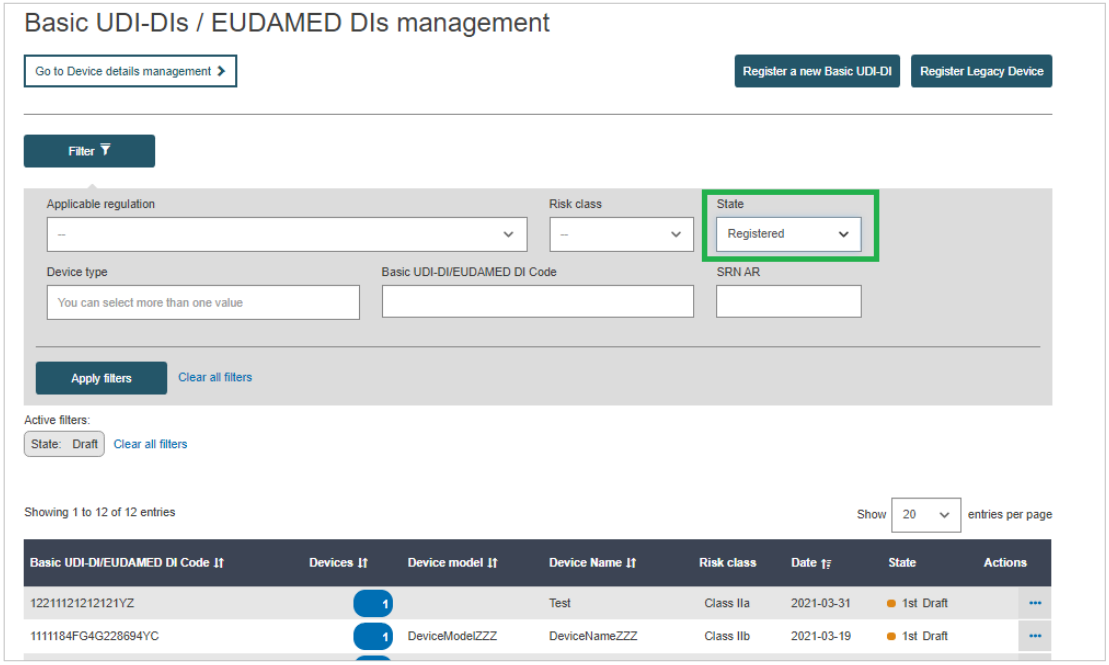


NOTE
If you wish to register a regulation device, belonging to Basic UDI-DI already registered, the registration process is simplified, since some device details are already available in EUDAMED. Therefore, the registration starts by selecting the Basic UDI-DI.

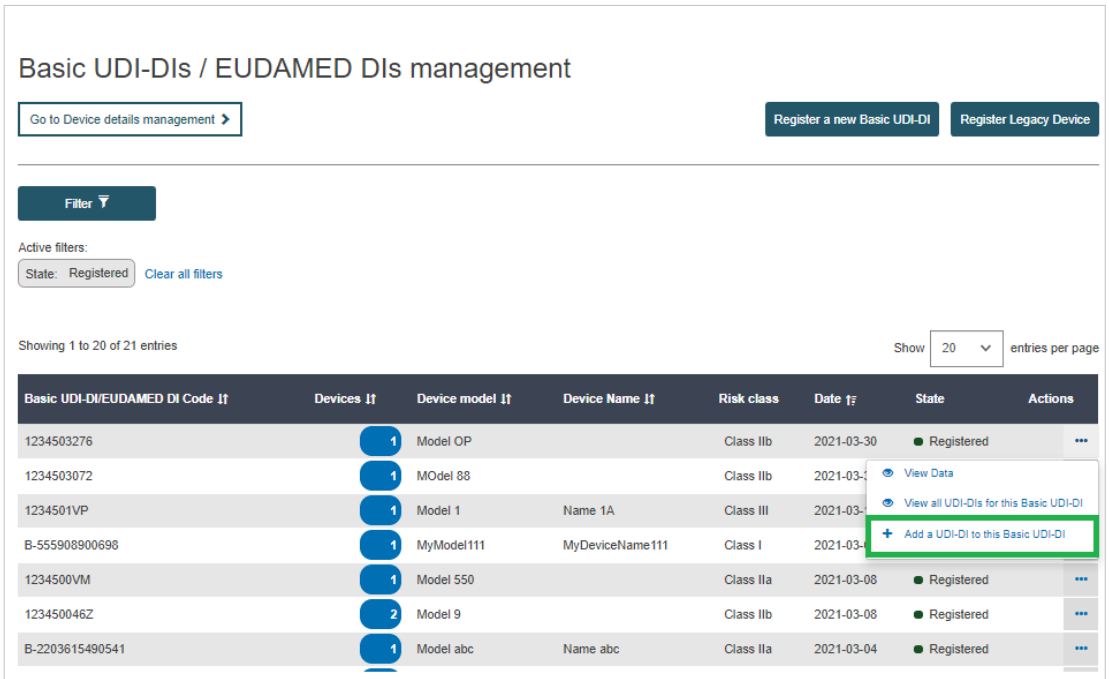
2. Filter the Basic UDI-DIs/ EUDAMED DIs in state *Submitted* or *Registered*:

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

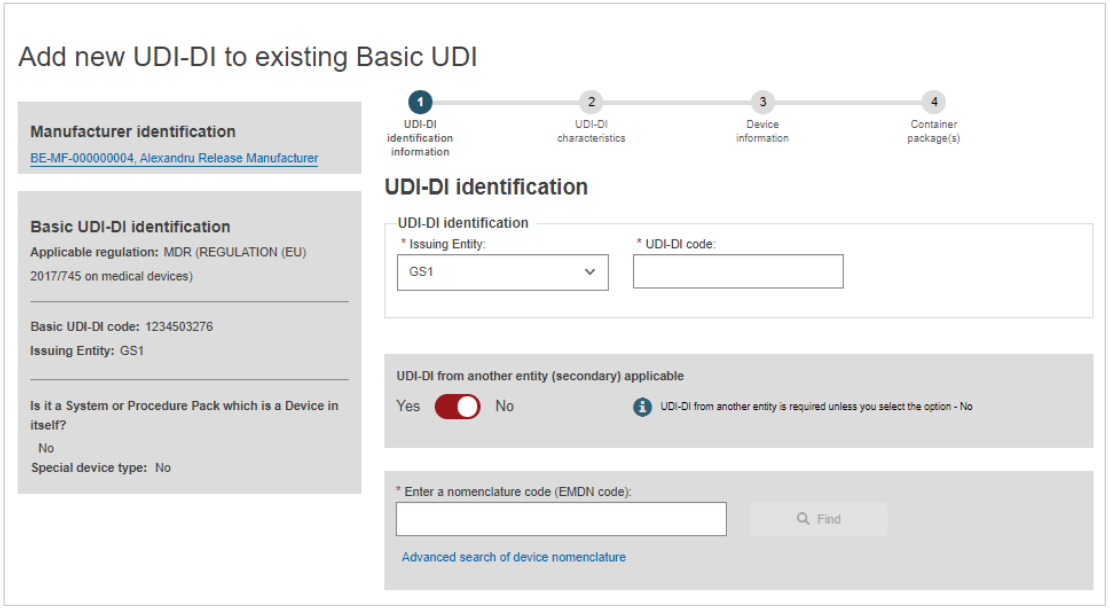
New devices and their UDI-DIs can be added only to Basic UDI-DIs that are in state *Registered* or *Submitted*:



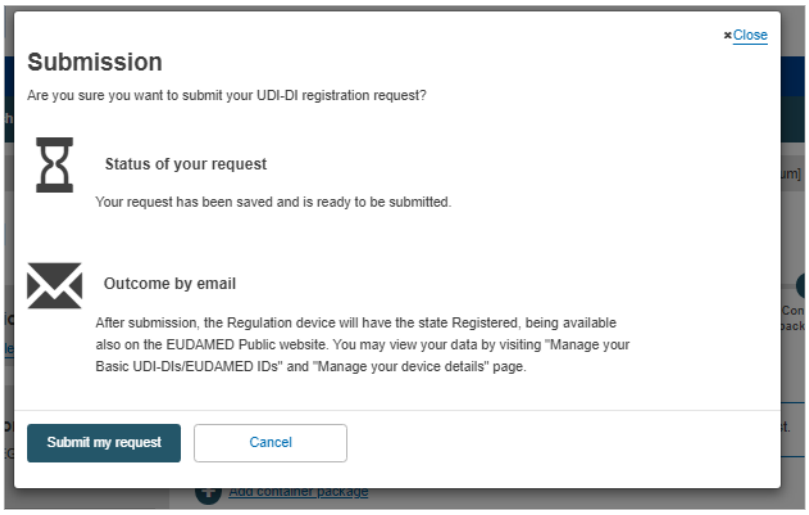
3. From the results, find the Basic UDI-DI for which you wish to add a new device and its UDI-DI. Click on the three dots on the right and click on *Add a UDI-DI to this Basic UDI-DI* / *Add a Master UDI-DI to this Basic UDI-DI*:



4. Complete the steps required for the registration of a UDI-DI for an existing Basic UDI-DI (*Step 3:* UDI-DI identification information [12], *Step 4:* UDI-DI Characteristics [19], *Step 5:* Device information [22], *Step 6:* Container Package Details [27]):



5. When you have completed all steps, click **Submit my request** to submit the new device registration request:



IMPORTANT
After Submitting the device registration request, its state will be:

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

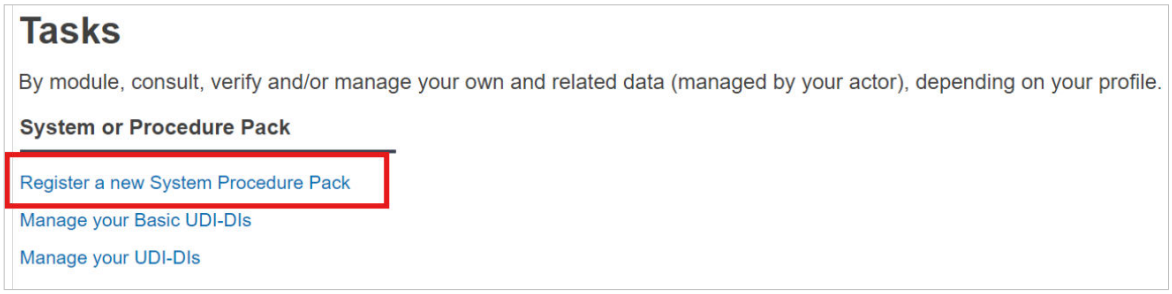
4 Register System or Procedure Packs (SPP)

4.1 Register Basic UDI-DI together with a UDI-DI for a System or Procedure Pack

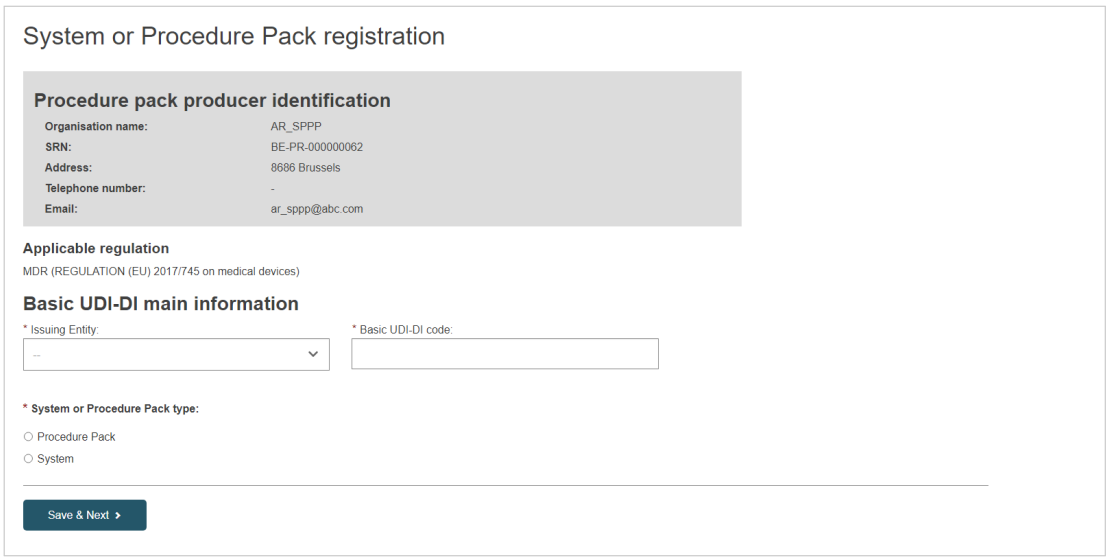
Registering System or Procedure Packs is only possible for users belonging to an actor that is a System and Procedure Pack producer.

4.1.1 Step 1: Enter SPP and Basic UDI-DI main information

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



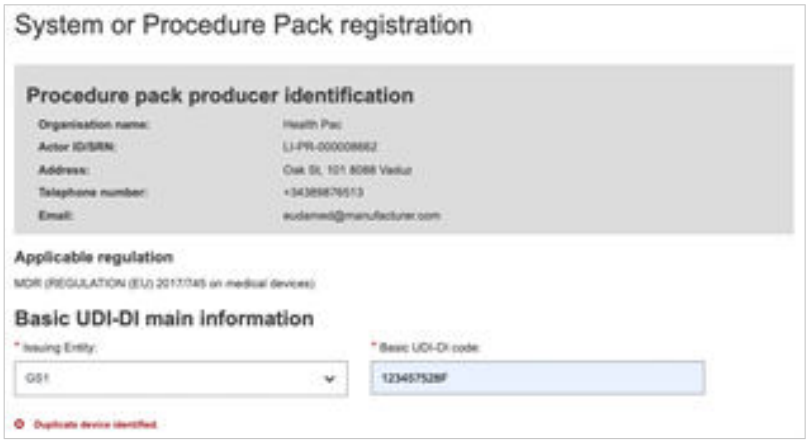
2. Next, specify the *Issuing Entity* and the *Basic UDI-DI code*:



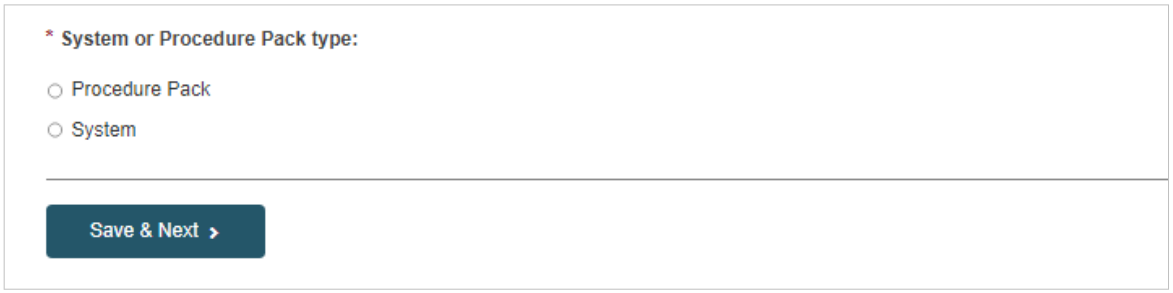
NOTE
Only legislation MDR (Regulation (EU) 2017/745 on medical devices) is possible for system and procedure packs (selected by default).

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. However, EUDAMED cannot verify that the code is correct beyond the format.

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

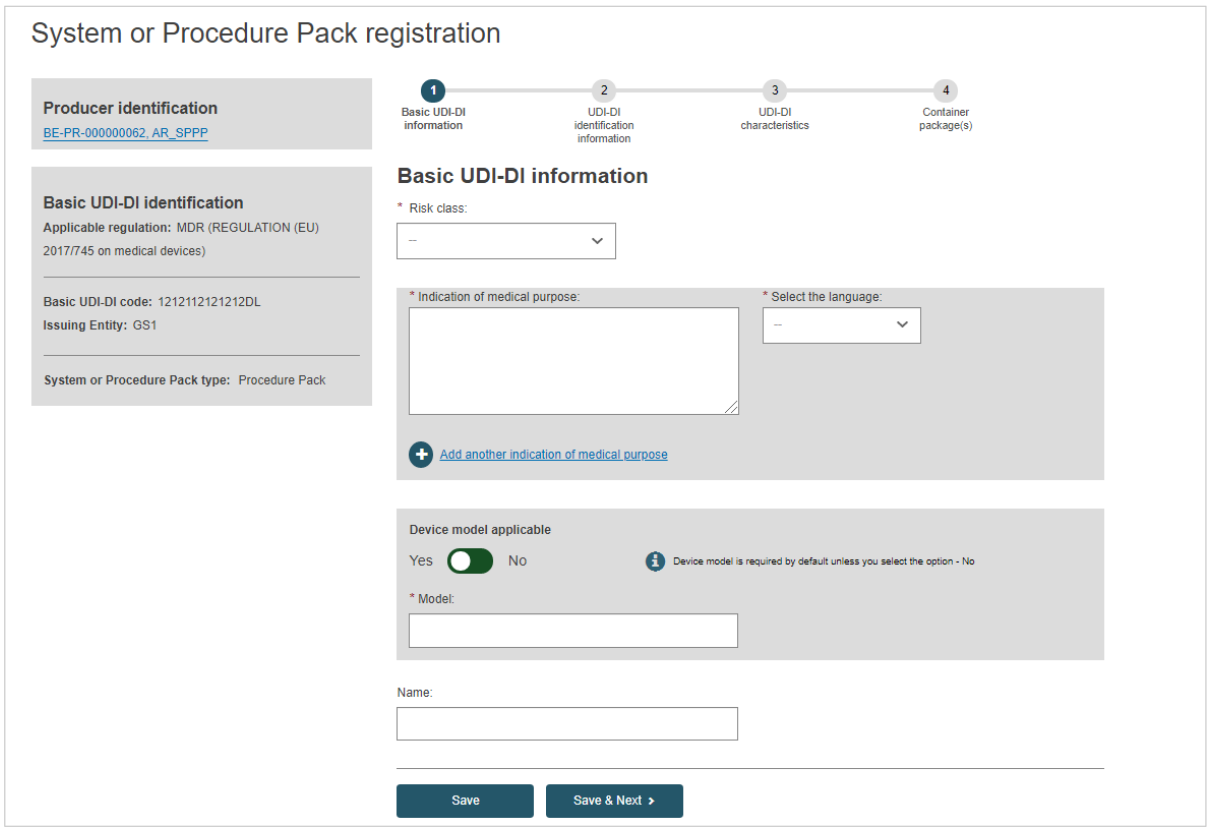


3. Choose if you are registering a system or procedure pack and click on **Save & Next** to save your registration as a draft and move on to the next steps:

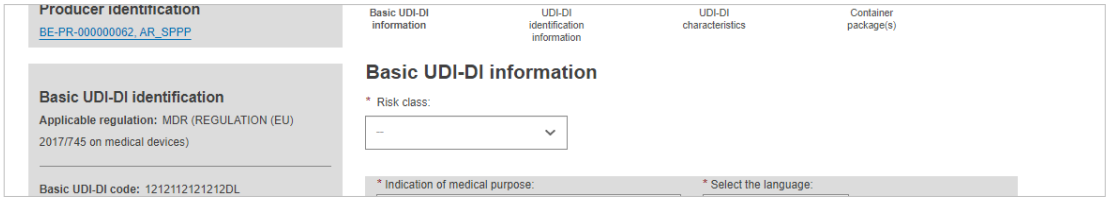


4.1.2 Step 2: Basic UDI-DI information

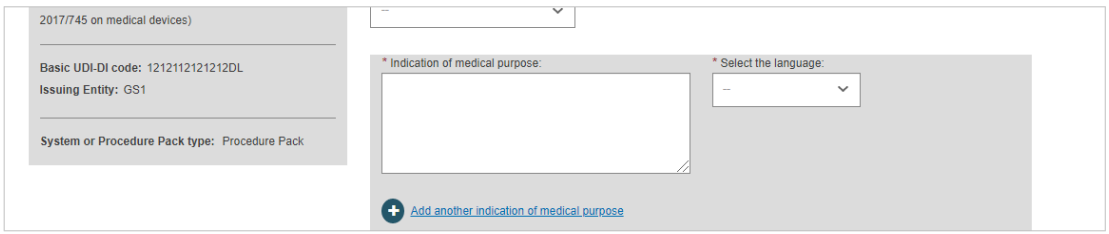
Enter the Basic UDI-DI information:



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

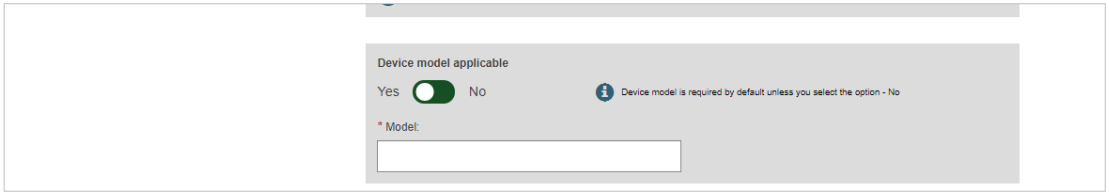


2. Fill in the indication of medical purpose and select the related language from the dropdown list.



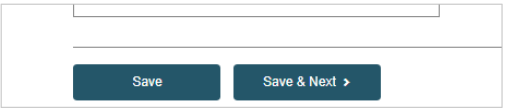
If you add the indication in multiple languages, click on *Add another indication of medical purpose* and select its language.

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



IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

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



4.1.3 Step 3: UDI-DI identification information

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



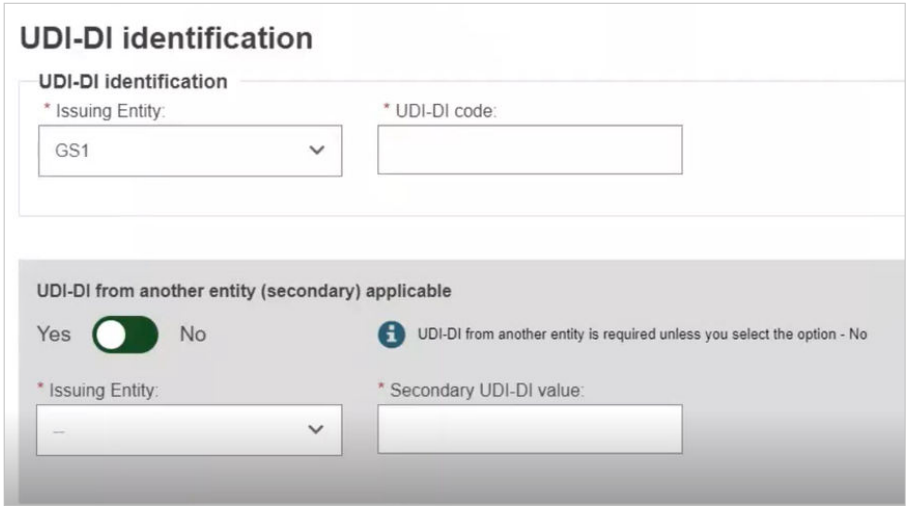
IMPORTANT
The UDI-DI code must be unique. If it already exists in EUDAMED, you will not be able to save.

NOTE
In case your chosen Issuing Entity is GS1, 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 shorter than 14 digits (check digit included), when populating EUDAMED field please add leading zero(s) until you reach 14 digits.

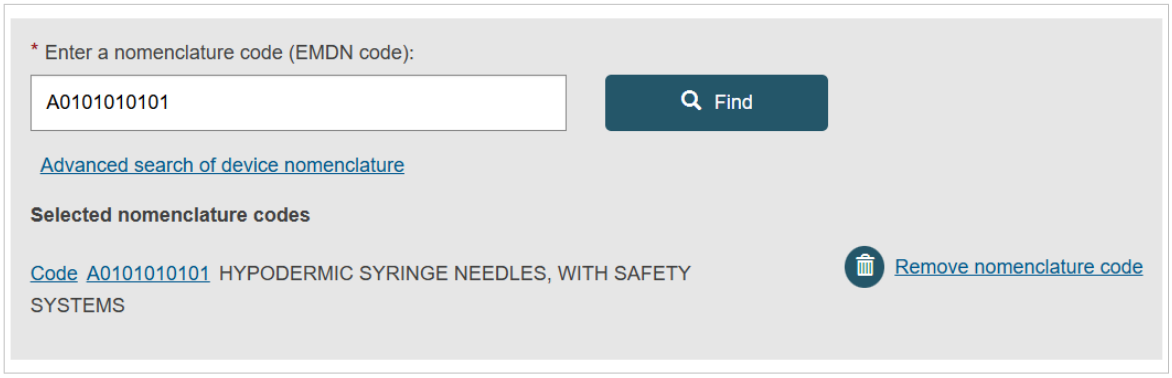
For example:

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

2. Enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI if applicable:

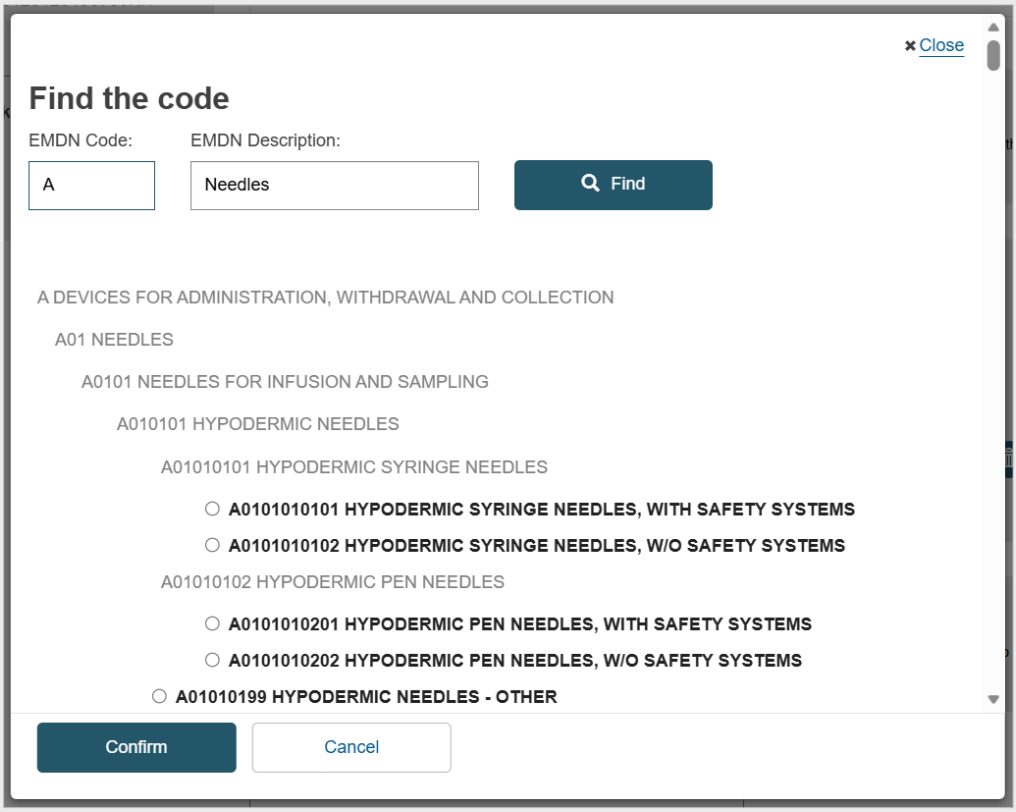


3. Enter the EMDN code, click **Find** and select the correct one from the list:



NOTE
Search for Nomenclature codes (EMDN)

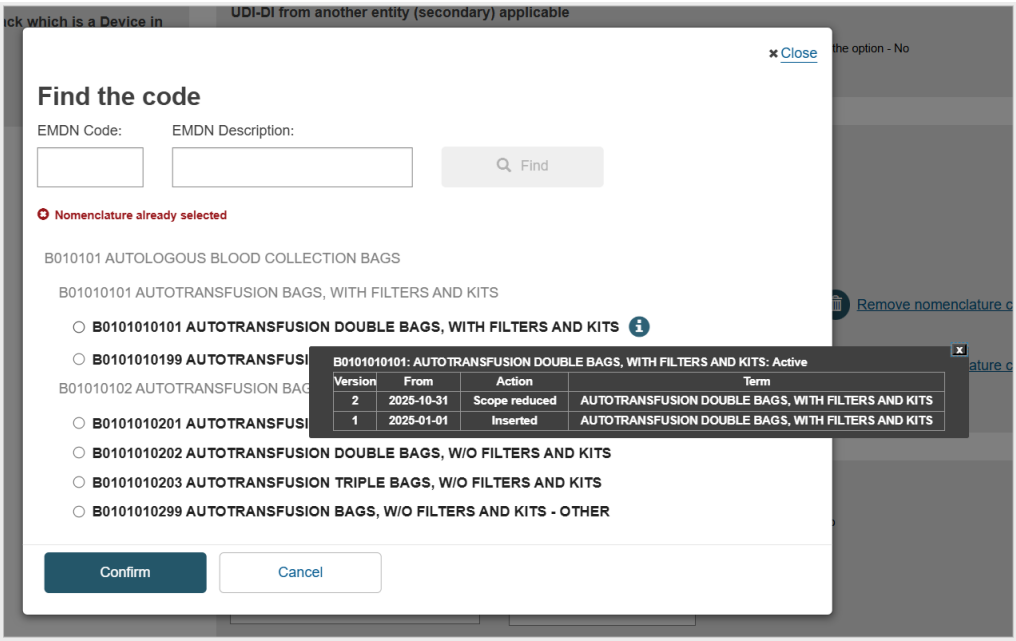
Click on **Advanced search of device nomenclature** to search by partial code name and view the list of codes alphabetically:



EMDN Code updates

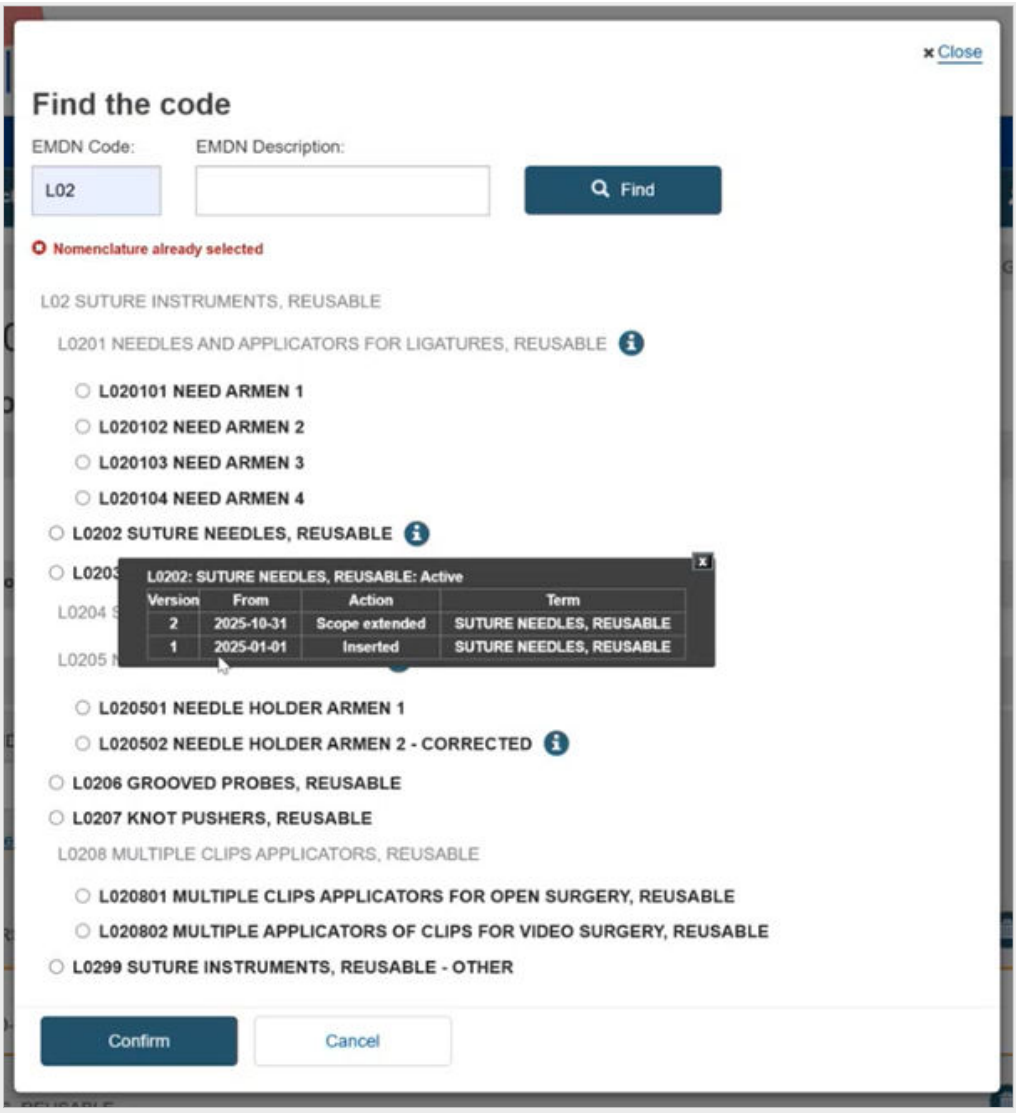
EMDN codes may get updated and therefore have a version history, which is indicated by an *information* icon.

Click on the *information* icon to view details about a code's versions and status:

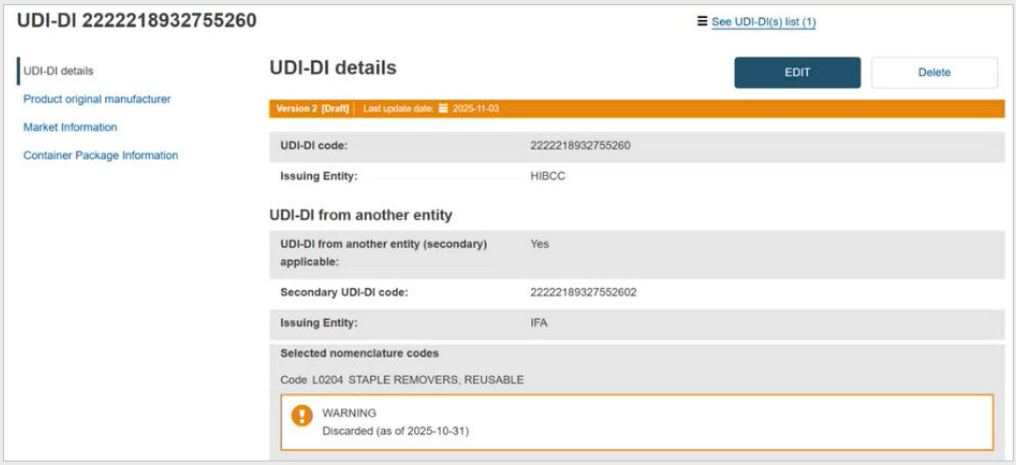


How does an EMDN code update affect my device?

1. If an EMDN code gets *scope-extended* or *corrected*, the device entry is not affected and no action is necessary.

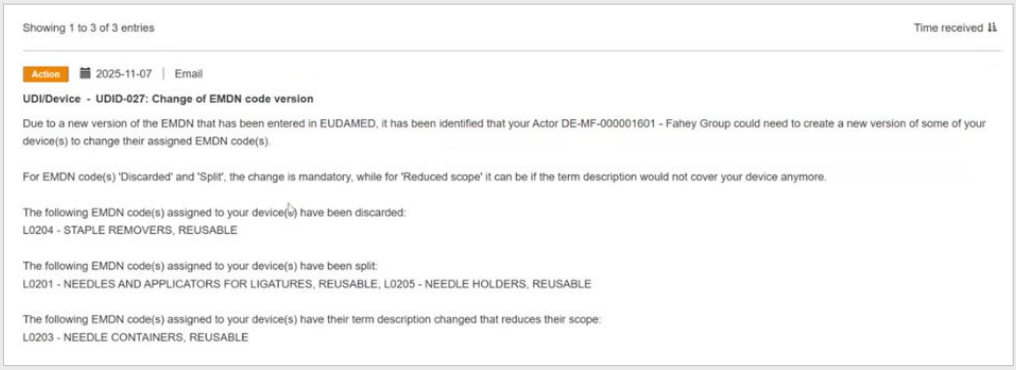


2. If an EMDN code gets *discarded* (*inactive* status), *split* or *scope-reduced*, the system will issue a warning (*UDI details* section):

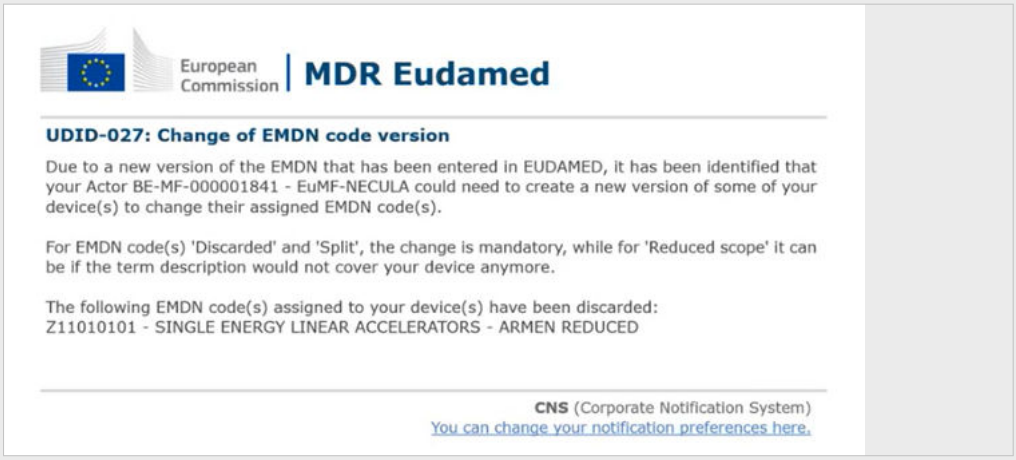


Depending on the specific case, the system may prompt the user to remove the obsolete EMDN code before creating a new device version with the correct EMDN code. In such cases, the user will receive EUDAMED and email notifications.

EUDAMED Notification



Email Notification



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):

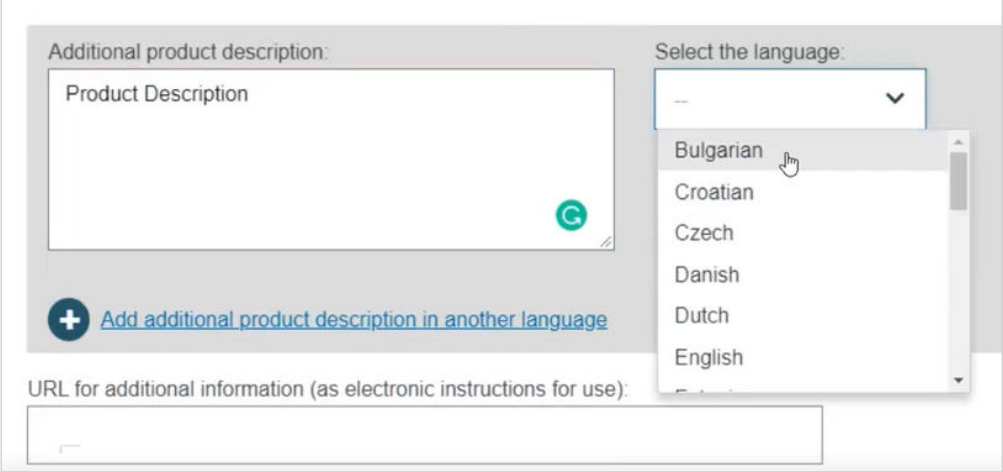


5. Enter the *Reference/Catalogue number*.

IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

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

7. Enter any additional pertinent information about the System or Procedure Pack, select the language of the additional information and enter a URL (web address) for additional information online, if applicable:



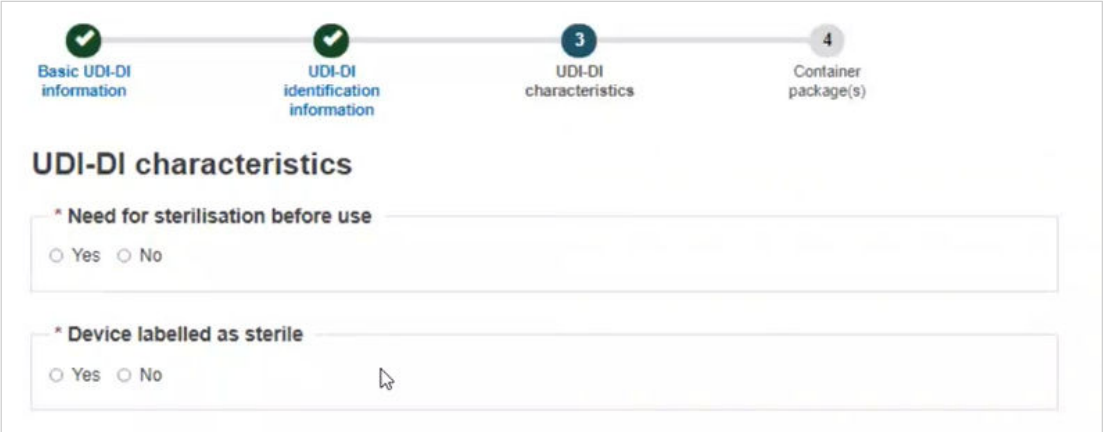
IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

8. Specify the *UDI-DI status* in selecting whether it is *On the EU market*, *Not intended for the EU market* or *No longer placed on the EU market* and click **Save** or **Save & Next**:

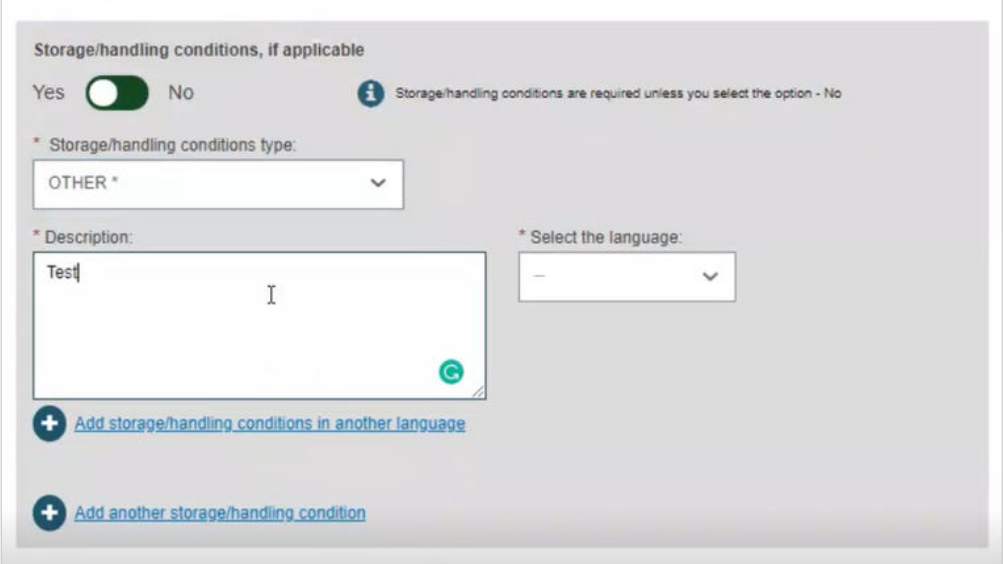


4.1.4 Step 4: UDI-DI characteristics

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

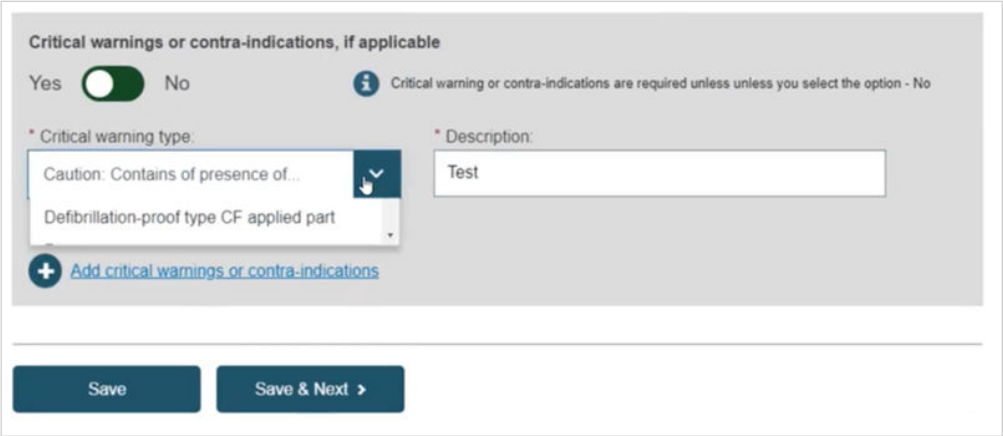


2. If Storage/handling conditions are applicable, slide the toggle to **Yes**. Choose the correct information from the list and provide a description where relevant:



> **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 description's language.

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 description's language.

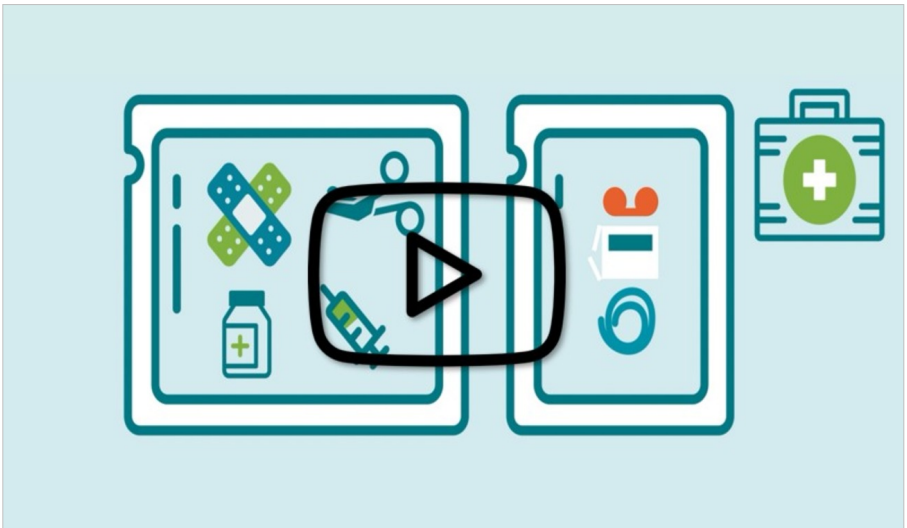
4. Click **Save** to save draft and finish later or **Save & Next** to move directly to the next step of the process:



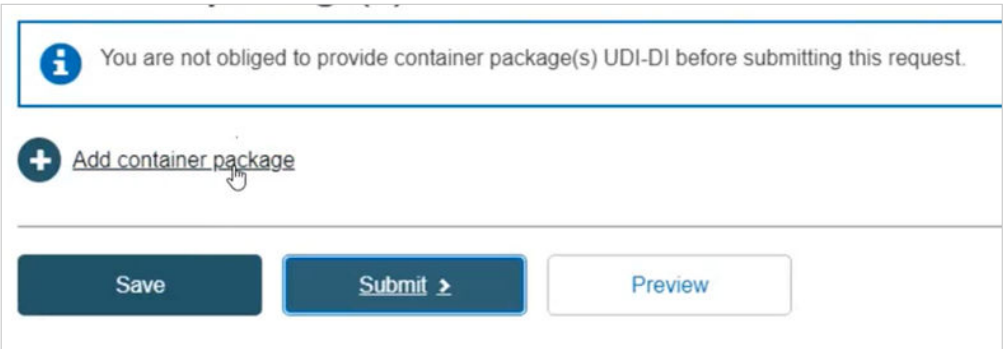
4.1.5 Step 5: Container package details

VIDEO: UDI and Systems and Procedure Packs

Please note that this video contains sound.

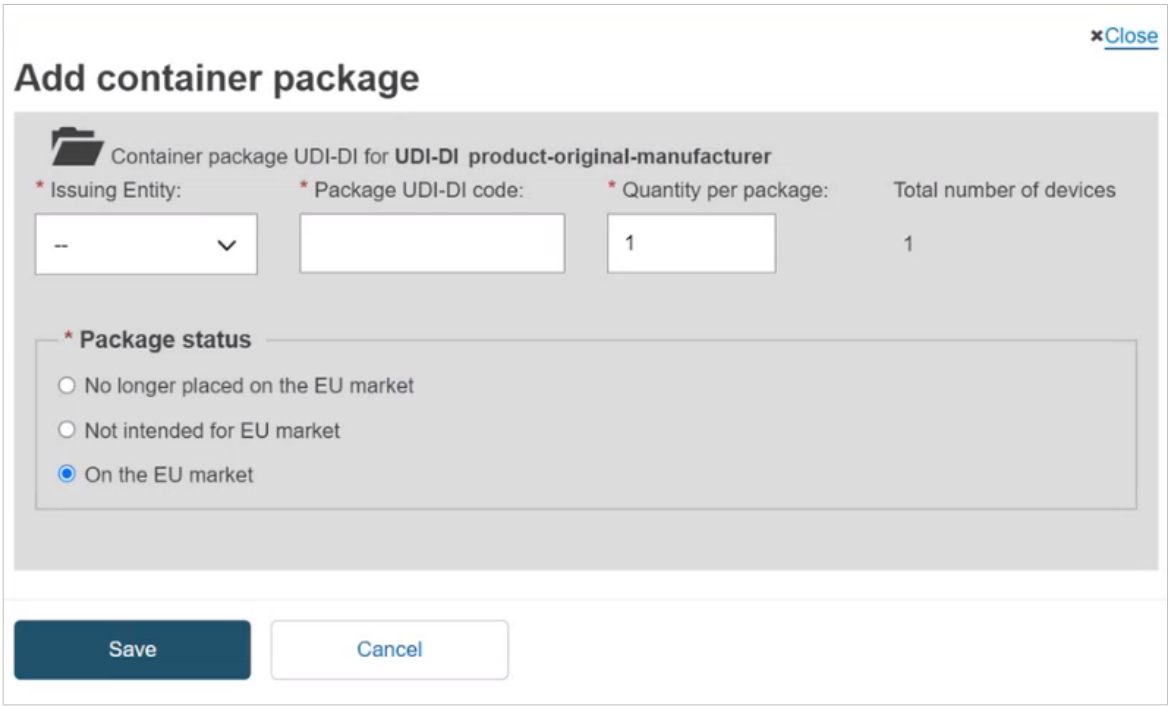


1. Click on *Add container package* when there is a higher packaging level for the root UDI-DI:



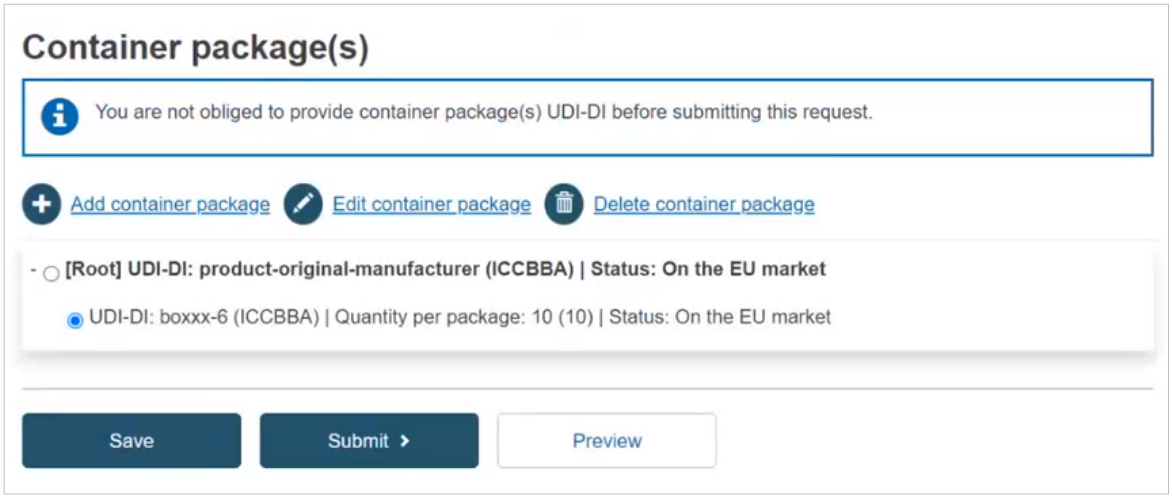
A unique UDI-DI must be assigned to each package level. You add a higher container package to the root UDI-DI if there is no container package UDI-DI yet, or to the selected UDI-DI (you can add as many levels and as many container packages per level as you have). Add the *Issuing Entity*, *Package UDI-DI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

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

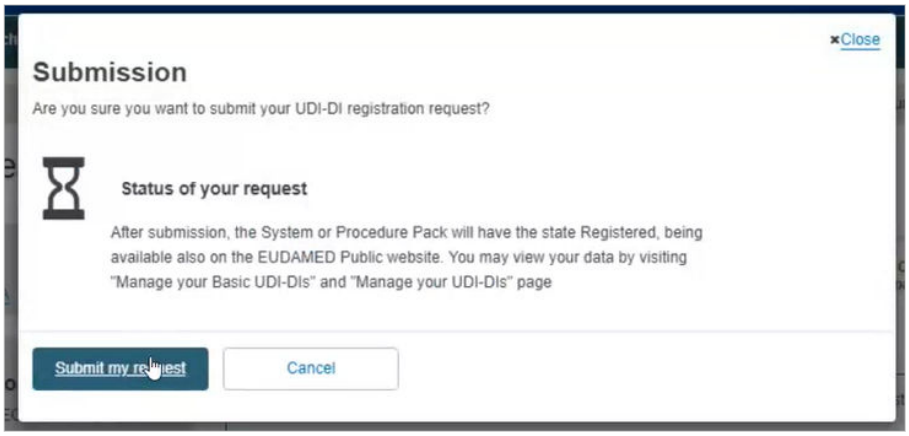


NOTE
If the status of the device for this container package is either *No longer placed on the EU Market* or *Not intended for the EU Market*, the *Package status* options are greyed out and any container package added to this device will automatically have the same *Package status* as the device.

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



3. On the pop-up window, click on **Submit my request**:

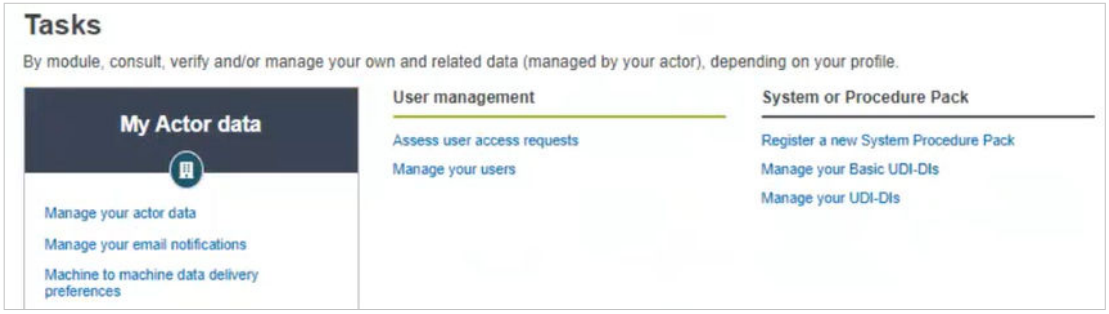


Upon submission, a success message will be displayed on the screen:

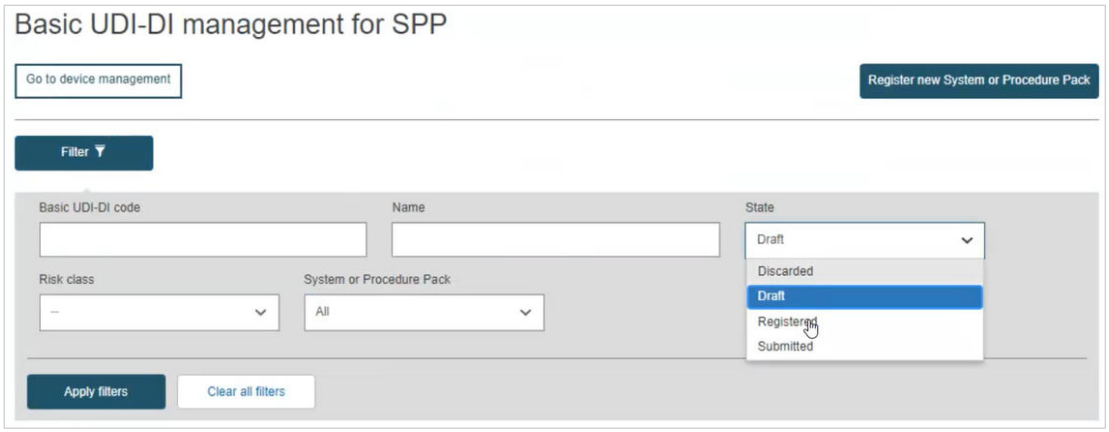


4.2 Register a new System or Procedure Pack UDI-DI for an existing Basic UDI-DI

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 filters**:



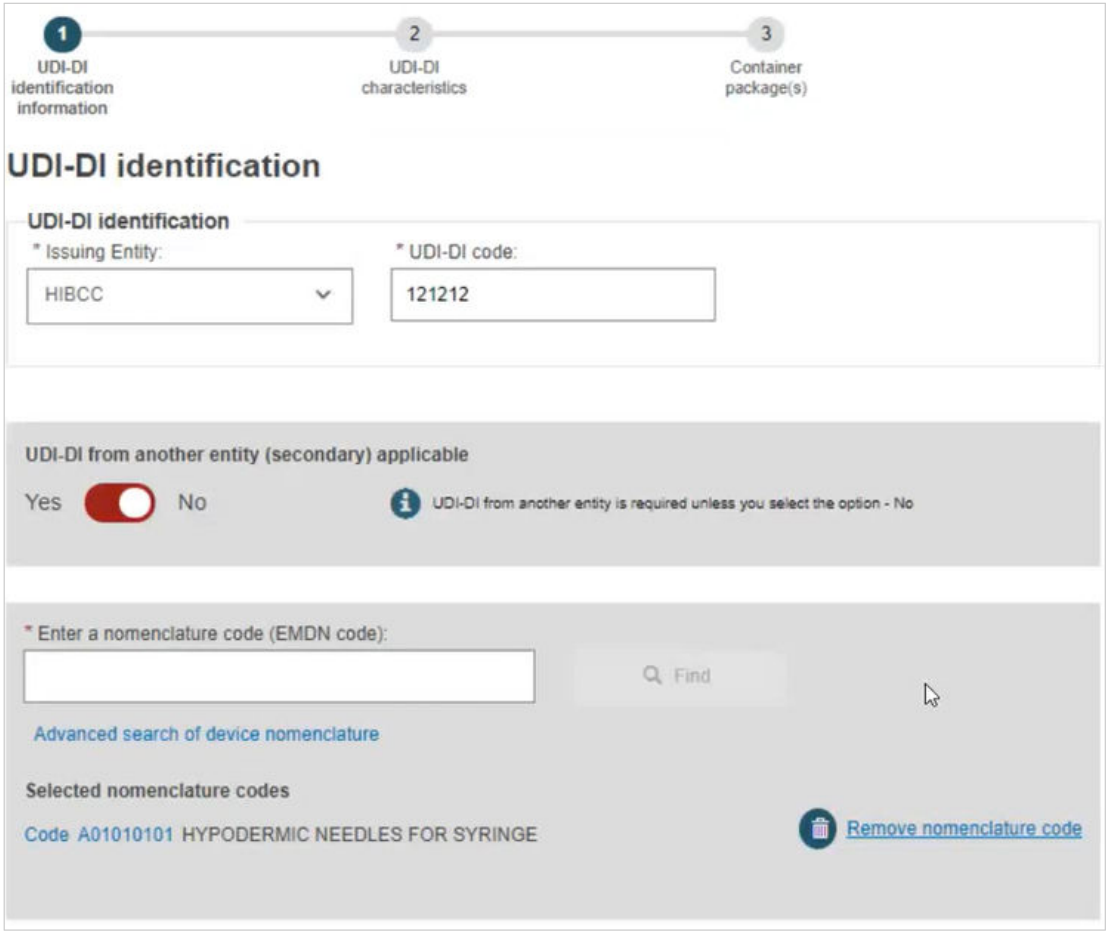
   New UDI-DIs can be added only for Basic UDI-DIs in state *Registered* or *Submitted*.

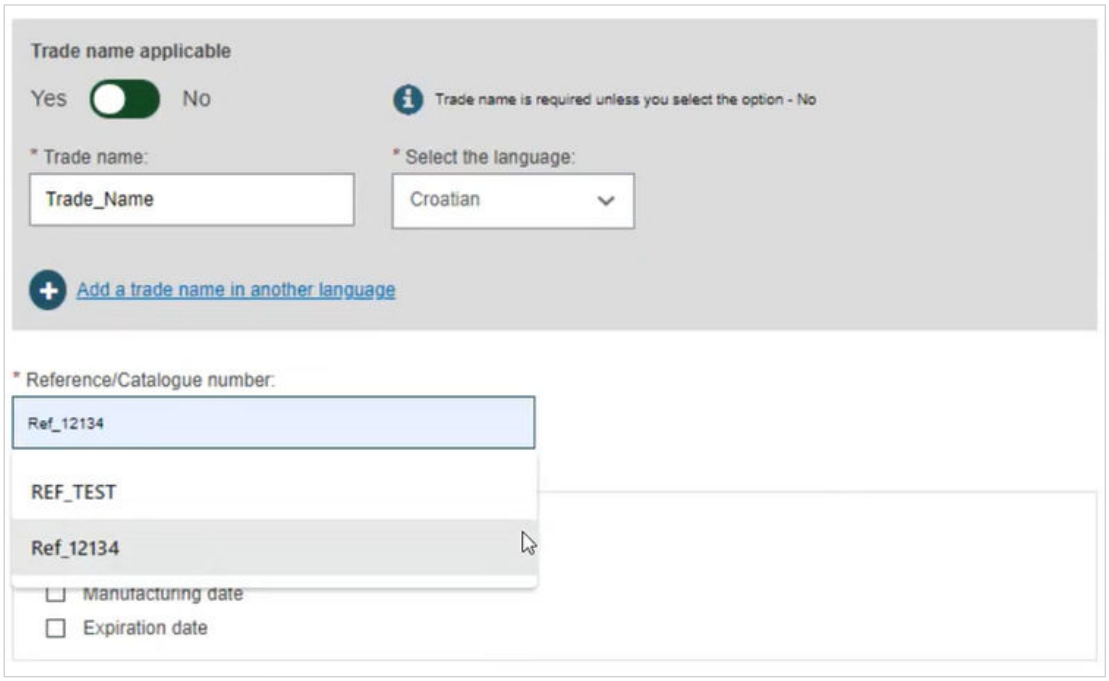
3. Identify the Basic UDI-DI for which you would like to add a new UDI-DI and click on the ellipsis symbol to add it:



4.2.1 Step 1: UDI-DI identification information

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


1
UDI-DI identification information
2
UDI-DI characteristics
3
Container package(s)
UDI-DI identification
UDI-DI identification
* Issuing Entity:
HIBCC
* UDI-DI code:
121212
UDI-DI from another entity (secondary) applicable
Yes
No
UDI-DI from another entity is required unless you select the option - No
* Enter a nomenclature code (EMDN code):
Find
Advanced search of device nomenclature
Selected nomenclature codes
Code A01010101 HYPODERMIC NEEDLES FOR SYRINGE
Remove nomenclature code


Trade name applicable
Yes
No
Trade name is required unless you select the option - No
* Trade name:
Trade_Name
* Select the language:
Croatian
Add a trade name in another language
* Reference/Catalogue number:
Ref_12134
REF_TEST
Ref_12134
Manufacturing date
Expiration date

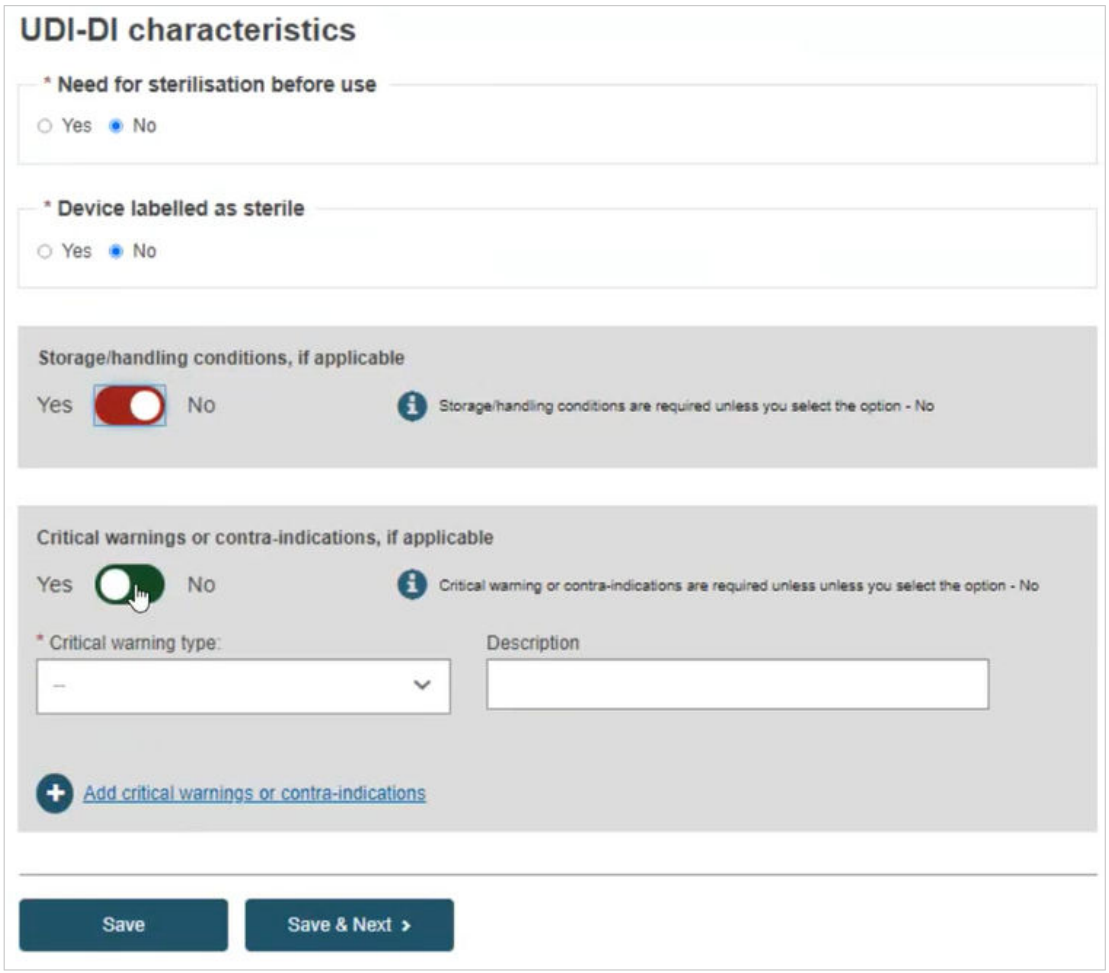
IMPORTANT
The information to be added here should **not** include any third-party nomenclature codes, descriptions or other terms (including GMDN Codes) which are proprietary to the owners of the relevant nomenclatures and should not be used for these purposes.

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



4.2.2 Step 2: UDI-DI characteristics

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



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

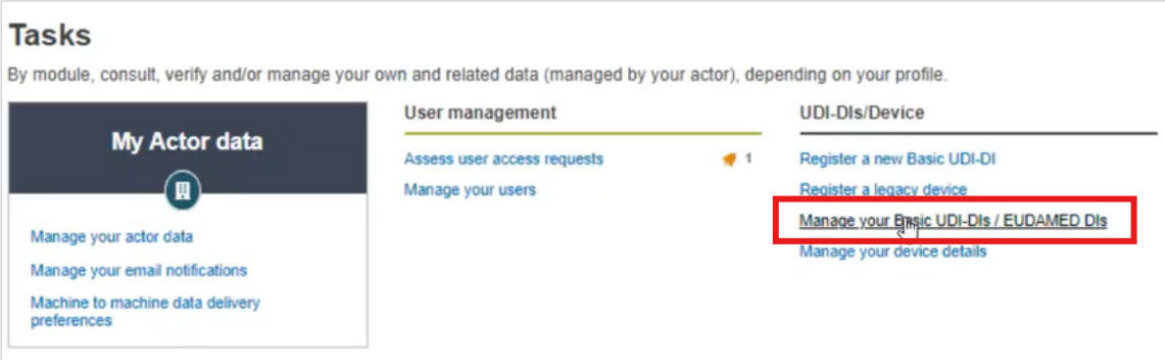
4.2.3 Step 3: Container package details

To complete this step, please consult *Container Package Details [45]* of this guide.

5 Manage your Device information

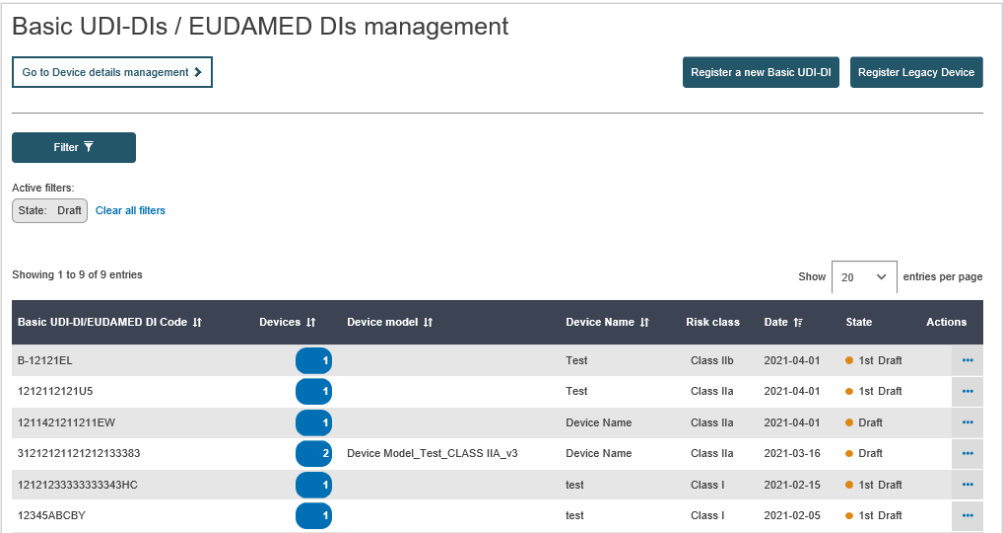
5.1 Manage your device details and Basic UDI-DI/EUDAMED DI

1. On the dashboard, click *Manage your Basic UDI-DI/EUDAMED DIs*:

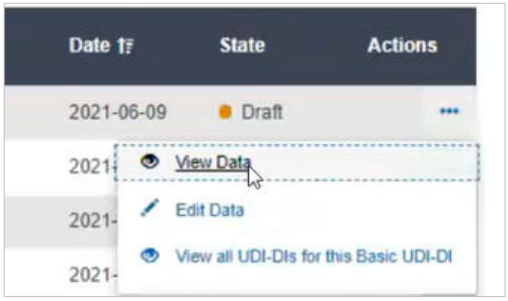


2. You will see a list with all of the Basic UDI-DIs /EUDAMED DIs registered to the current actor:

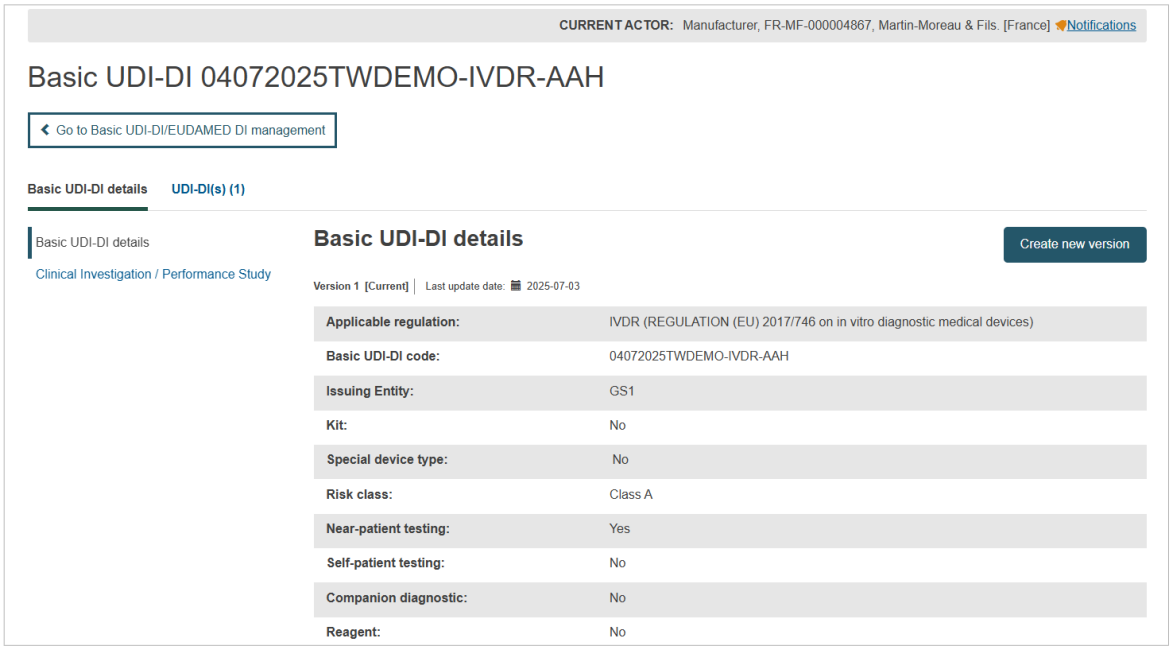
> **NOTE**
> By default, the devices listed are the ones in *draft* state (not yet *submitted*, nor *registered*). To retrieve devices in other states, use the filters.



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



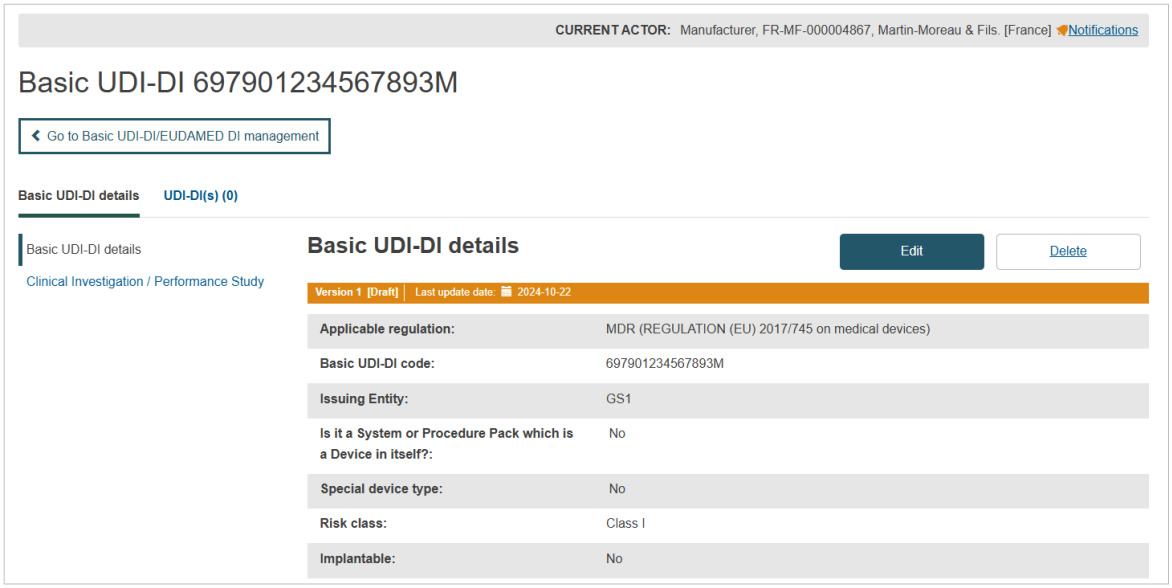
4. You will see a summary of the details concerning your device and its Basic UDI-DI/ EUDAMED DI:



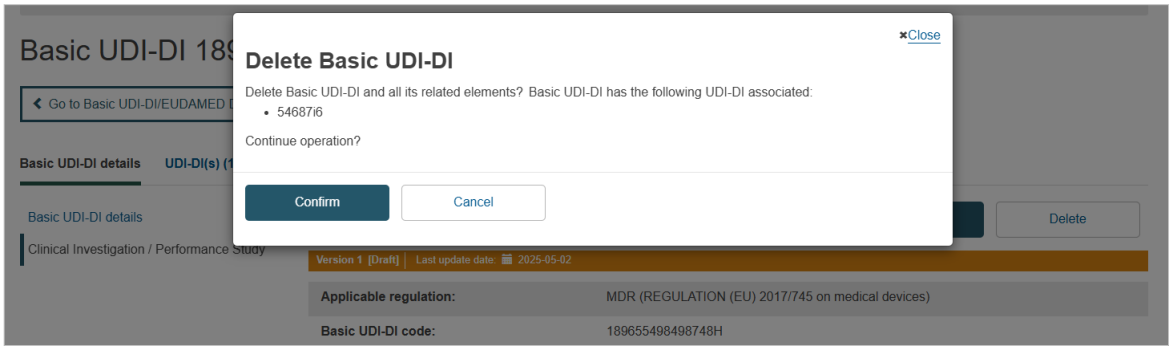
5.1.1 Delete draft Basic UDI-DI/EUDAMED DI

After following steps 1, 2 and 3 from *Manage your device Basic UDI-DI/EUDAMED DI details* [51] to view a Draft Basic UDI-DI/EUDAMED DI in state *1st draft*, you have the option to delete this draft.

1. Inside the *View details* page of the desired 1st draft, click **Delete**:



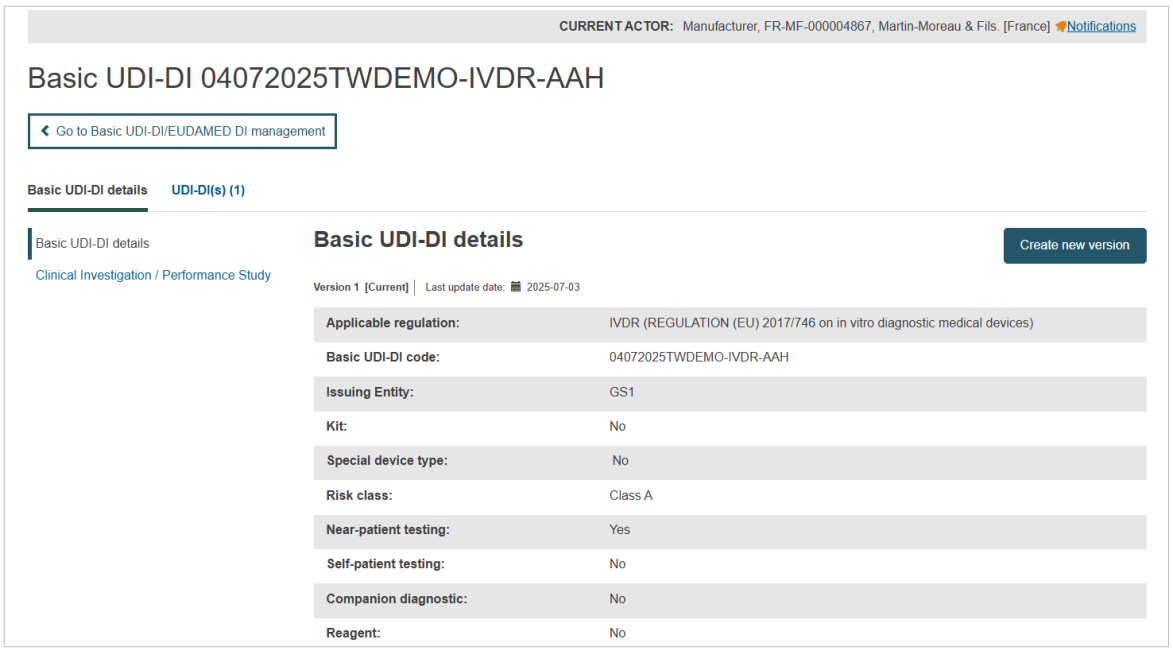
2. A pop-up window will ask you to confirm the deletion.
   The system also warns about simultaneous deletion of any associated device *1st draft* UDIs:



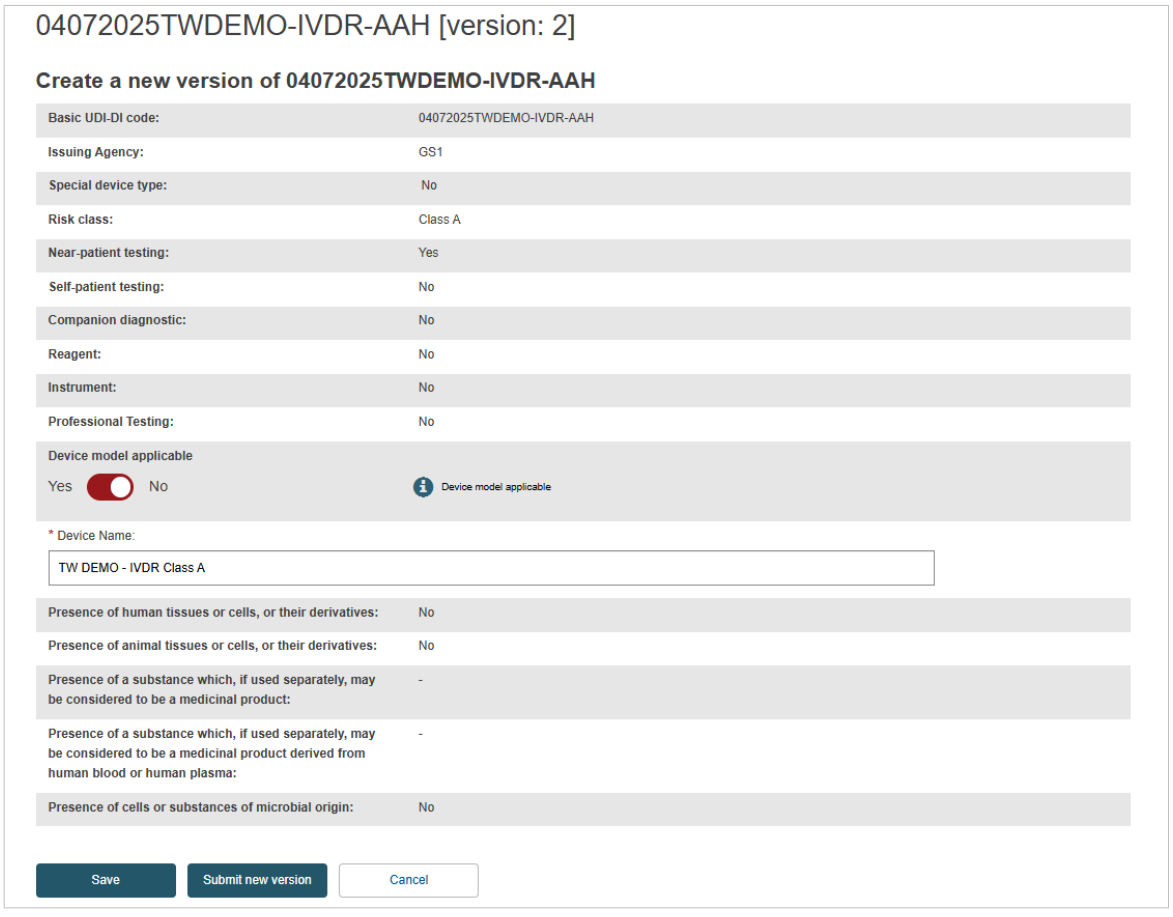
5.1.2 Update (create new version of the record) for Basic UDI-DI/EUDAMED DI

Follow the steps in section *Manage your device Basic UDI-DI/EUDAMED DI details* [51] to view a device and its Basic UDI-DI/EUDAMED DI.

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



2. Update the desired details:



3. To complete the action:
   - Click **Save** to save to your registration as a draft and continue later.
   - Click **Submit new version** if you are certain about the update and wish to submit it.

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

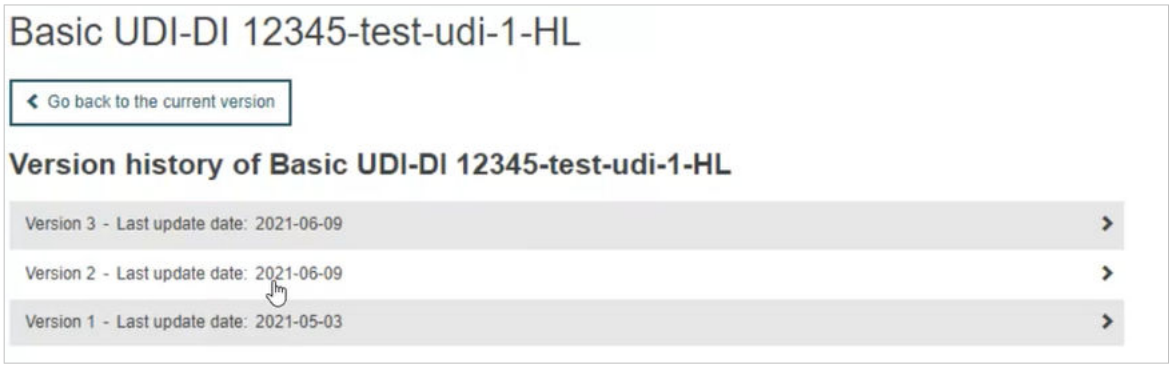
5.1.3 View historical versions of device data and its Basic UDI-DI/EUDAMED DI

Follow the steps in section *Manage your device Basic UDI-DI/EUDAMED DI details* [51] to view data on a device and its Basic UDI-DI/EUDAMED DI.

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



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

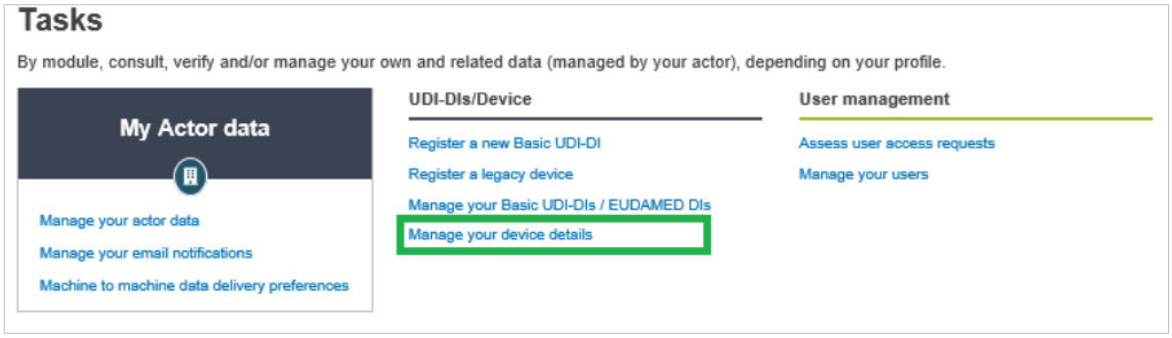


3. Inside a version, you can browse through the different versions by clicking on the arrows at the top right corner:

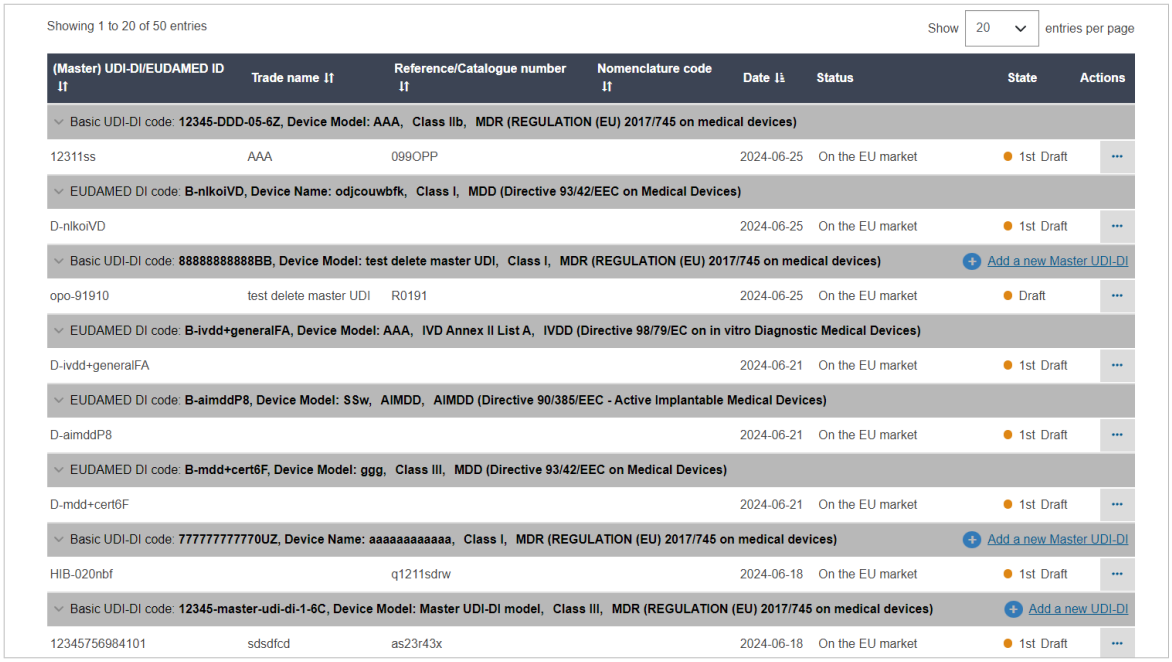


5.2 Manage your device UDI-DI/EUDAMED ID details

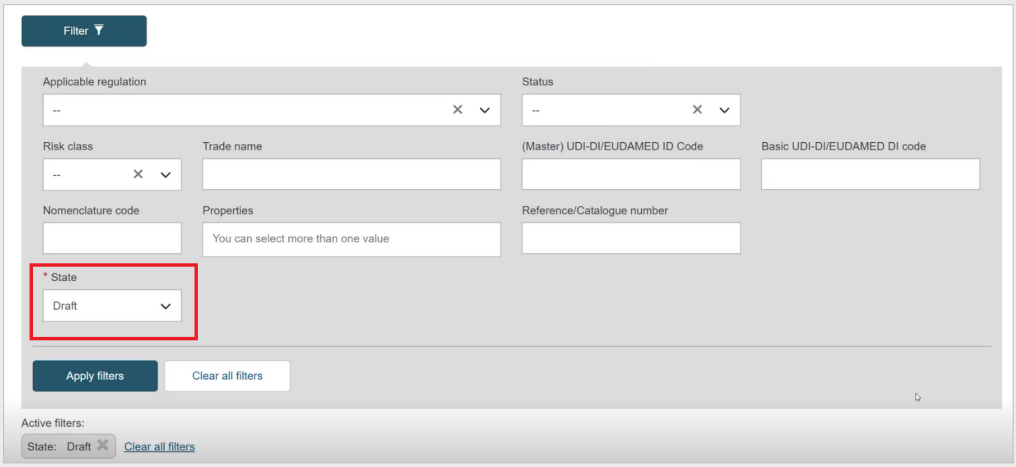
1. On the EUDAMED dashboard, click on *Manage your device details*:



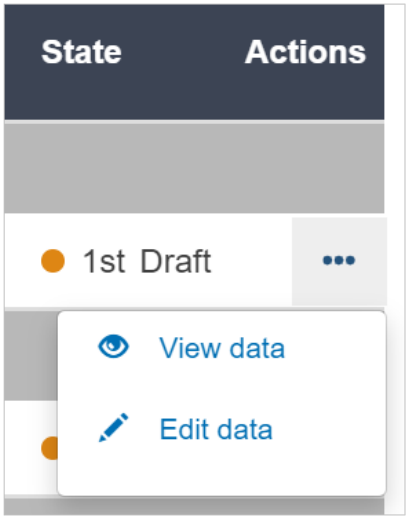
2. You will see a list:



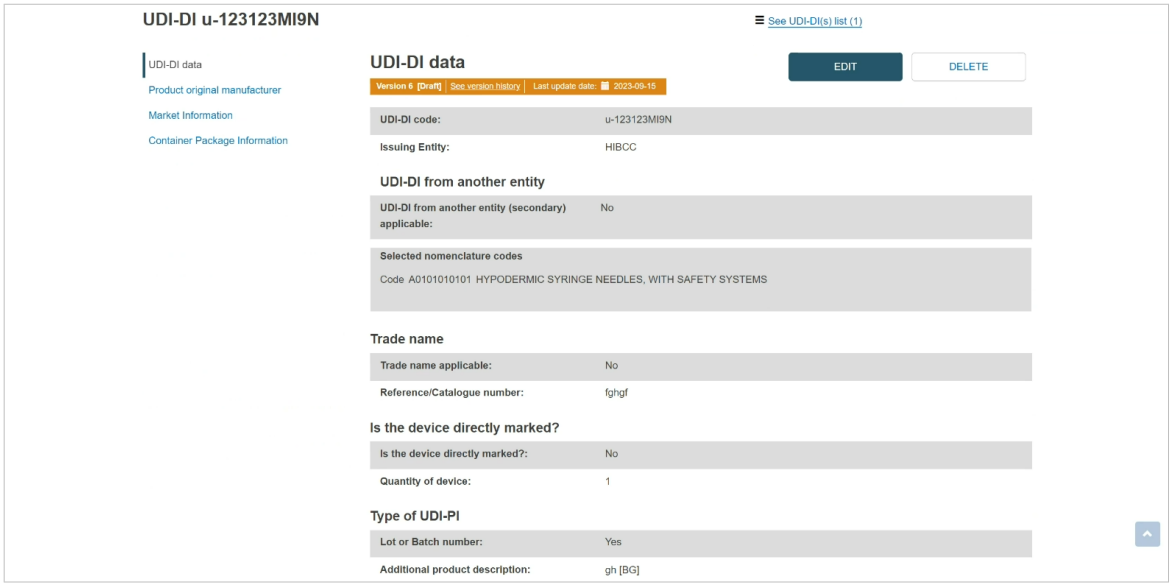
NOTE
By default, the system lists the devices in *draft* state. To retrieve other states use the filters:



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



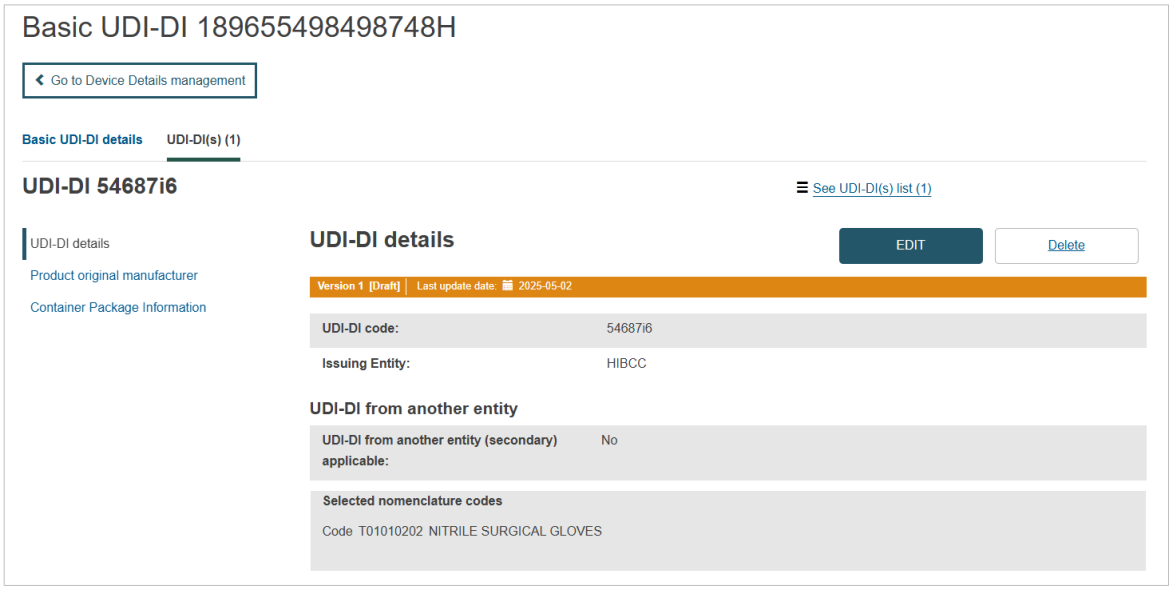
4. You will see a summary of the details of your device:



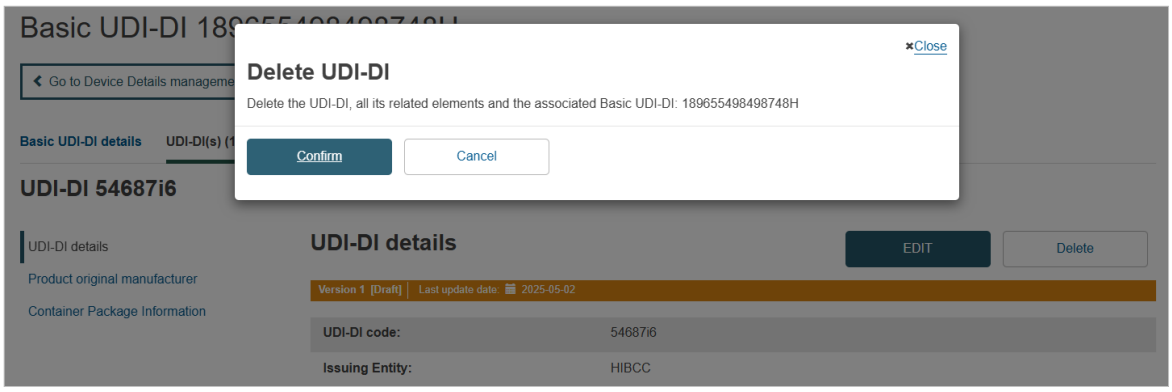
5.2.1 Delete draft UDI-DI/EUDAMED ID

Follow the steps in *Manage your device UDI-DI/EUDAMED ID details* [56] to view a draft UDI-DI.

1. Once inside the desired device's Draft UDI-DI, click **Delete**:

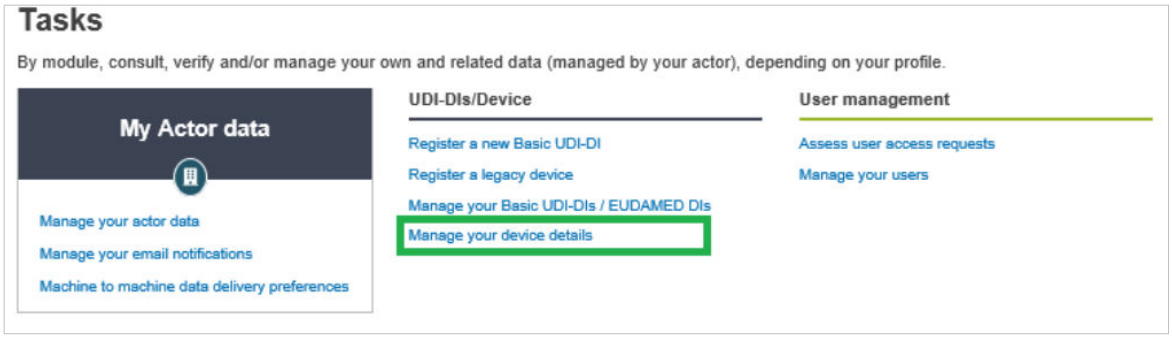


2. A pop-up message will ask you to confirm the deletion.
   The system will also warn about simultaneous deletion of the associated Basic UDI-DI, in case there is only this single device under it:

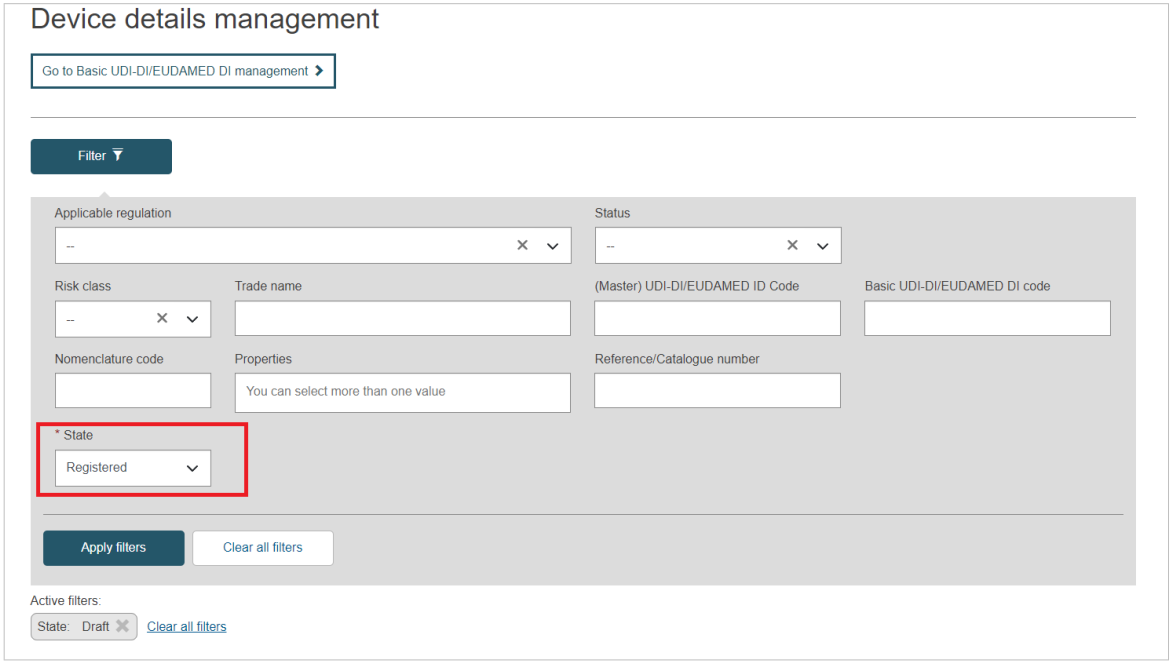


5.2.2 View details of a registered device and its UDI-DI/ EUDAMED ID details

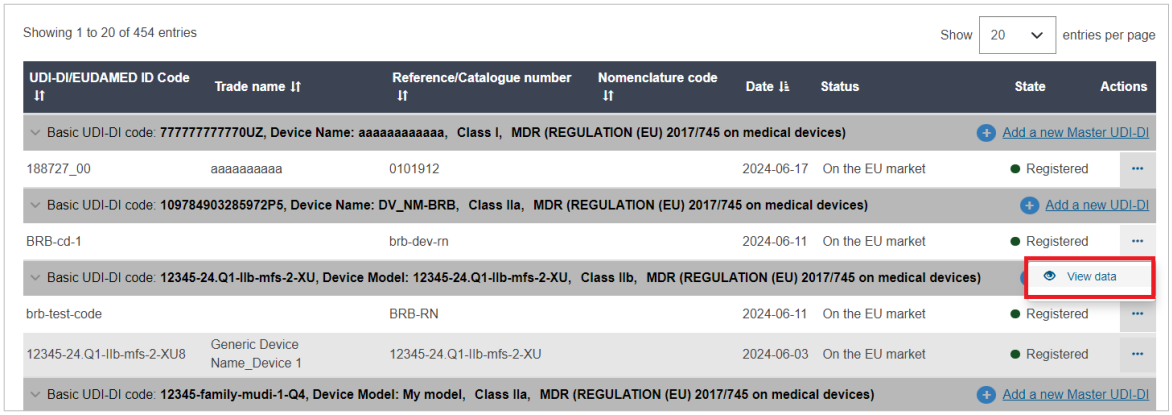
1. On the dashboard, click *Manage your device details*:



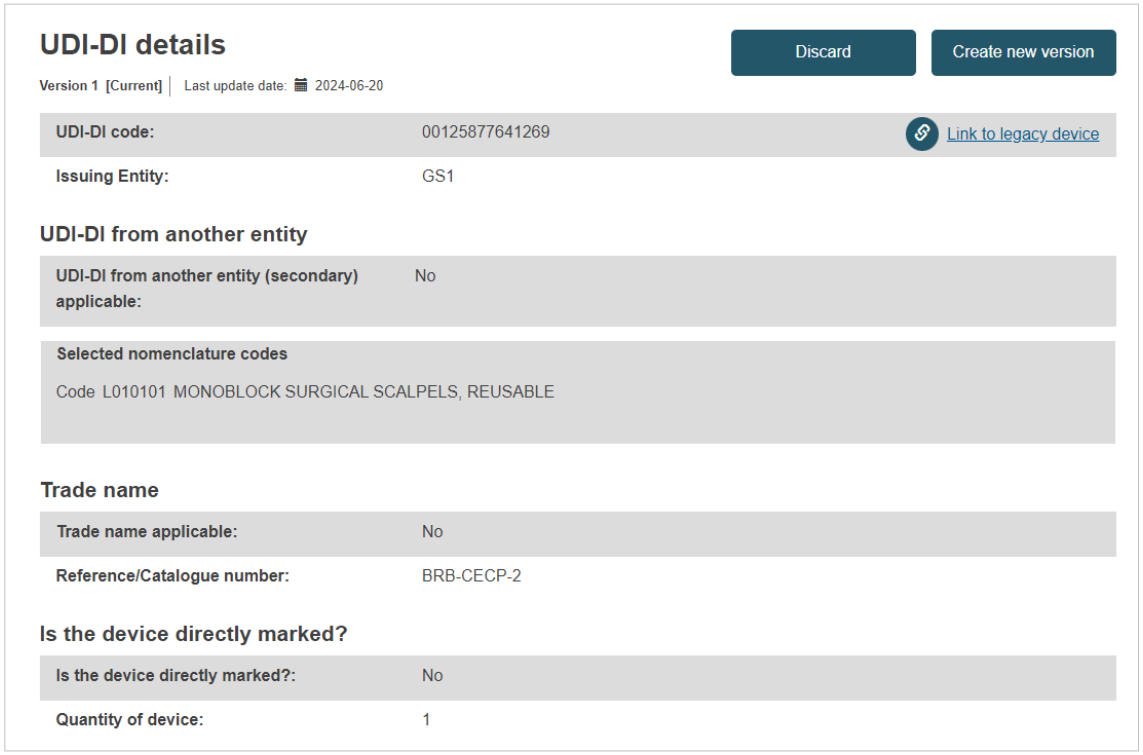
2. Select the option *Registered* in the *State* field and click **Apply filters**:



3. A list of devices will be displayed. Click *View data* under the three dots of the relevant entry:

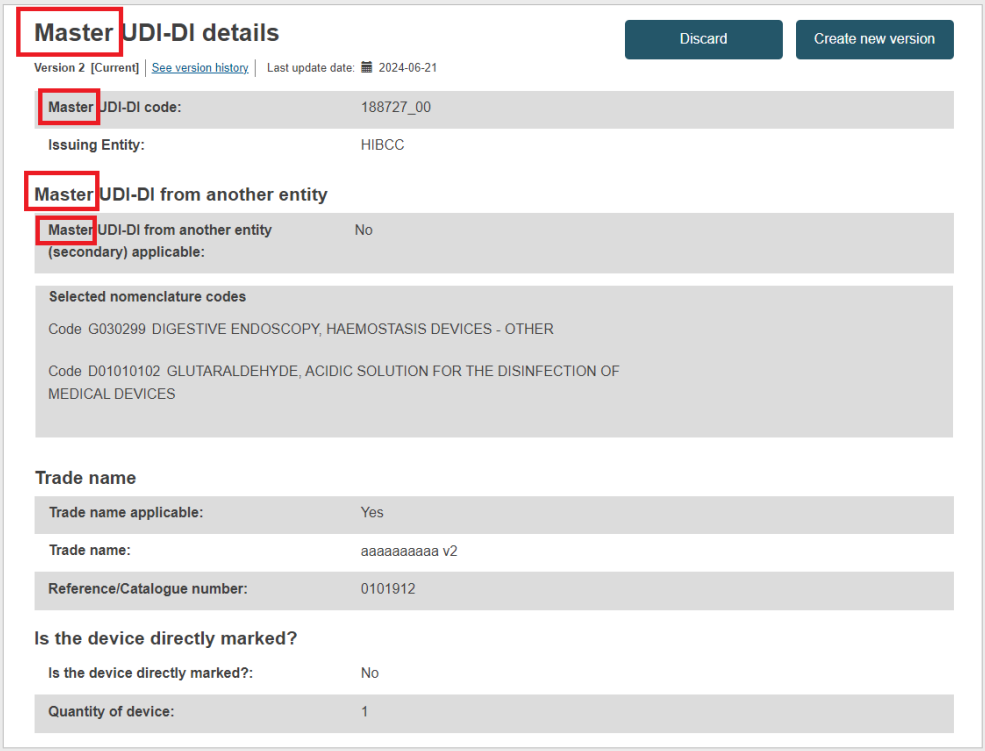


4. You will see a summary of your device details, divided into the following subsections:
   - UDI-DI details:



NOTE

See below for the devices where Master UDI-DI replaces UDI-DI, the *Details* section for a registered device and its Master UDI-DI:



Type of UDI-PI

Expiration date:	Yes
Additional product description:	Description_Generic_EN [EN], Description_FR [FR]
URL for additional information (as electronic instructions for use):	www.yoursite.com/

Status of the UDI-DI/Device

UDI-DI/Device status:	On the EU market

Clinical size

Clinical size applicable:	Yes
Clinical size #1:	**(Type):** Acidity, **(Precision):** Value, **(Value):** 4.0, **(Measure unit):** Adult

Labelled as single use

Labelled as single use:	No
Maximum number of reuses applicable:	No
Maximum number of reuses:	-
Need for sterilisation before use:	No
Device labelled as sterile:	No
Containing latex:	No

CMR/Endocrine disruptor

Labelled for presence of Carcinogenic, Mutagenic and toxic to Reproduction (CMR) substances of category 1A or 1B:	Yes

CMR substances

Category of CMR:	1A
EC#:	-
CAS#:	-
Name of the substance:	Device_Substance_Endocrine [EN]

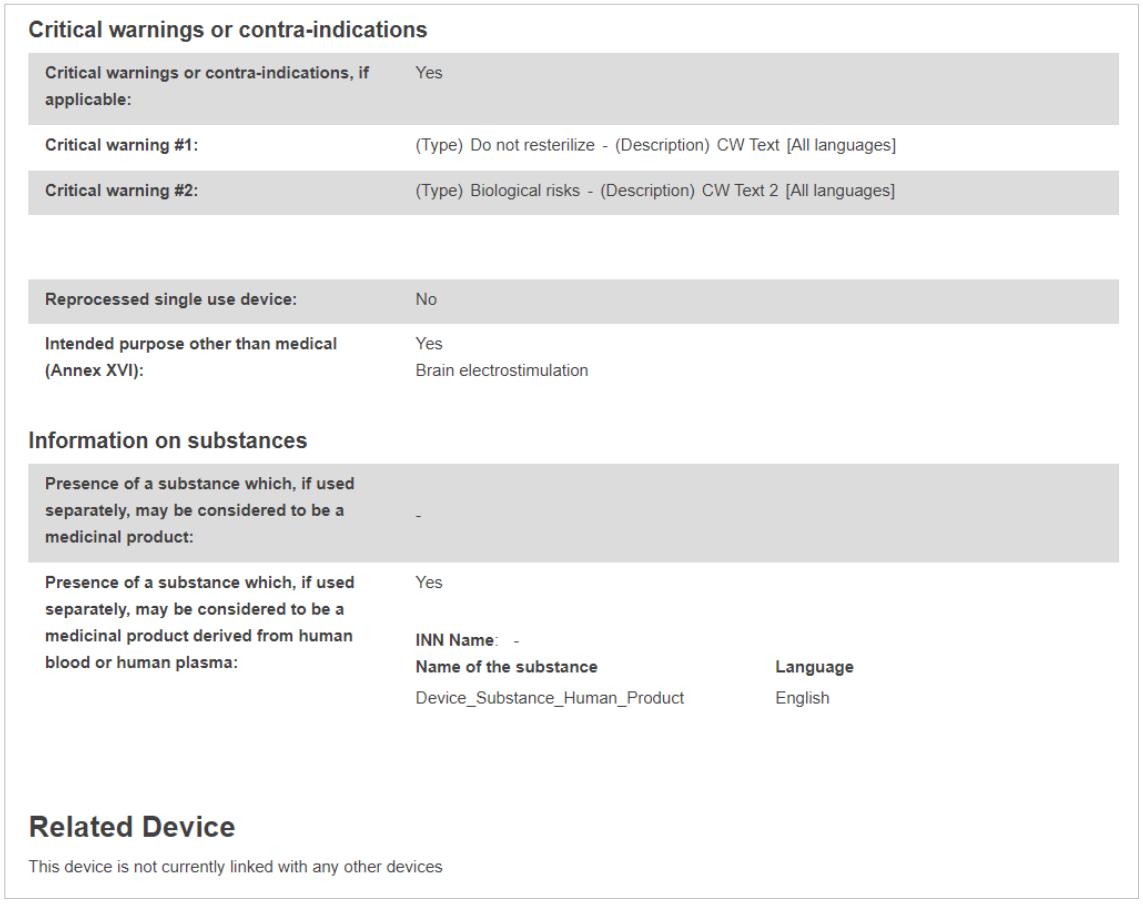
Labelled for presence of substance(s) with endocrine-disrupting properties:	Yes

Endocrine-disrupting properties

EC#:	-
CAS#:	-
Name of the substance:	Device_Substance_Endocrine [EN]

Storage/handling conditions

Storage/handling conditions, if applicable:	Yes
Storage/handling condition #1:	(Type) Protect from heat and radioactive sources - (Description) Text EN_1 [All languages]



Critical warnings or contra-indications

Critical warnings or contra-indications, if applicable:	Yes
Critical warning #1:	(Type) Do not resterilize - (Description) CW Text [All languages]
Critical warning #2:	(Type) Biological risks - (Description) CW Text 2 [All languages]
Reprocessed single use device:	No
Intended purpose other than medical (Annex XVI):	Yes Brain electrostimulation

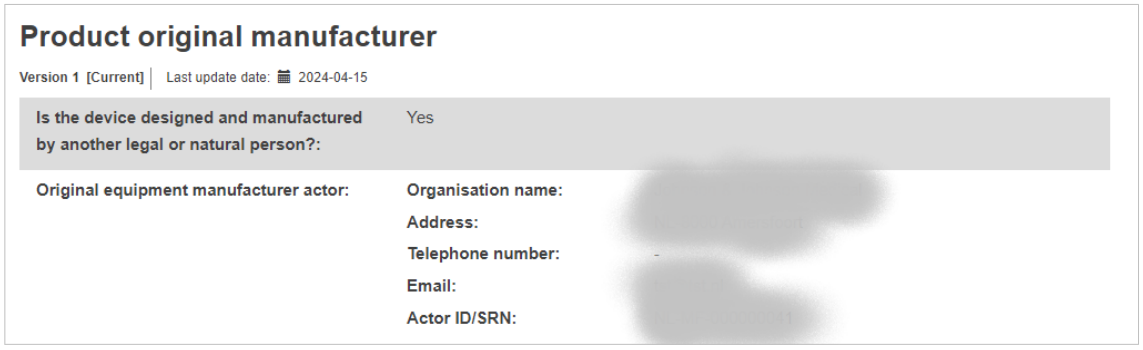
Information on substances

Presence of a substance which, if used separately, may be considered to be a medicinal product:	-	
Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:	Yes **INN Name**: - **Name of the substance** Device_Substance_Human_Product	**Language** English

Related Device

This device is not currently linked with any other devices

- Product original manufacturer:

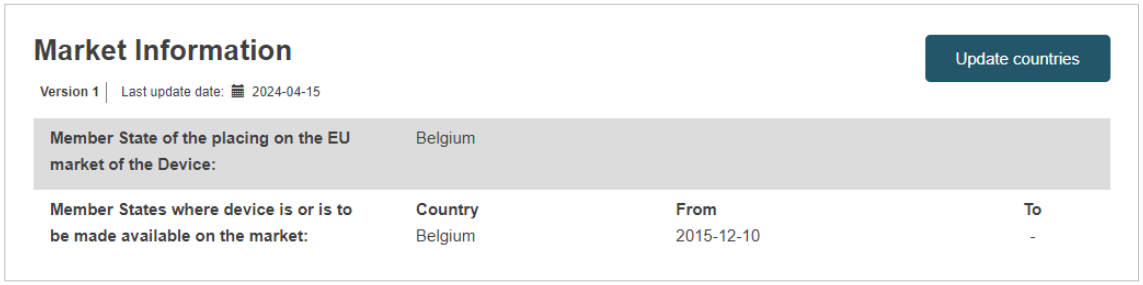


Product original manufacturer

Version 1 [Current] | Last update date: 2024-04-15

Is the device designed and manufactured by another legal or natural person?:	Yes
Original equipment manufacturer actor:	**Organisation name:** **Address:** **Telephone number:** - **Email:** **Actor ID/SRN:**

- Market Information:



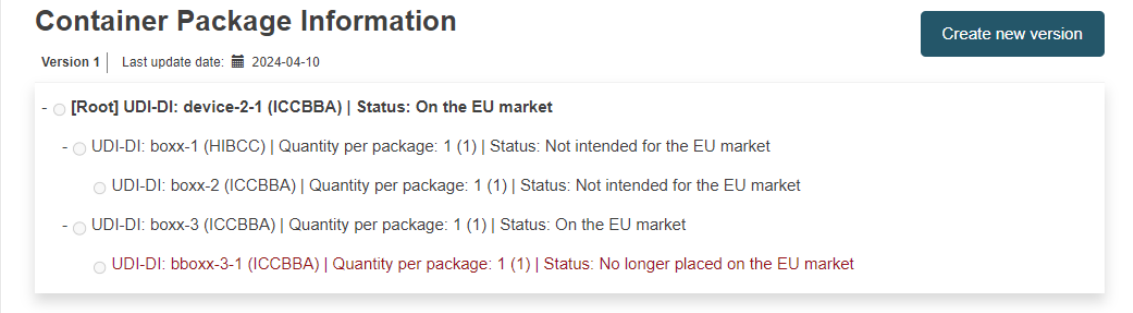
Market Information

Update countries

Version 1 | Last update date: 2024-04-15

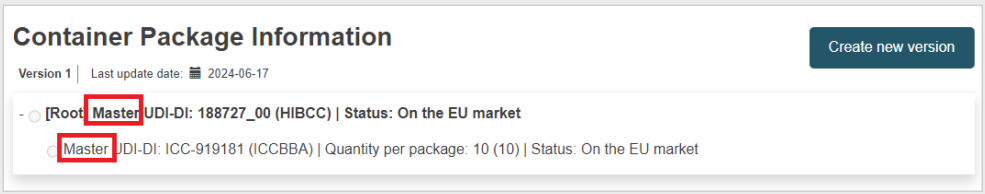
Member State of the placing on the EU market of the Device:	Belgium		
Member States where device is or is to be made available on the market:	**Country** Belgium	**From** 2015-12-10	**To** -

- Container Package Information:



NOTE

Container Package Information section for a registered Master UDI-DI:



5.2.3 Update (create a new version) for a device and its UDI-DI/EUDAMED ID

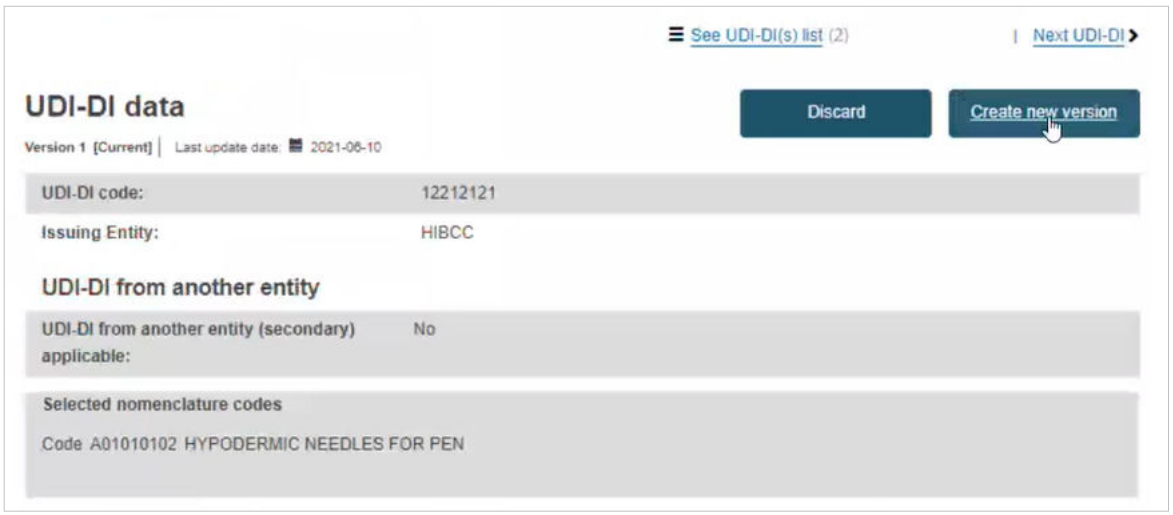
VIDEO: UDI assignment and updates

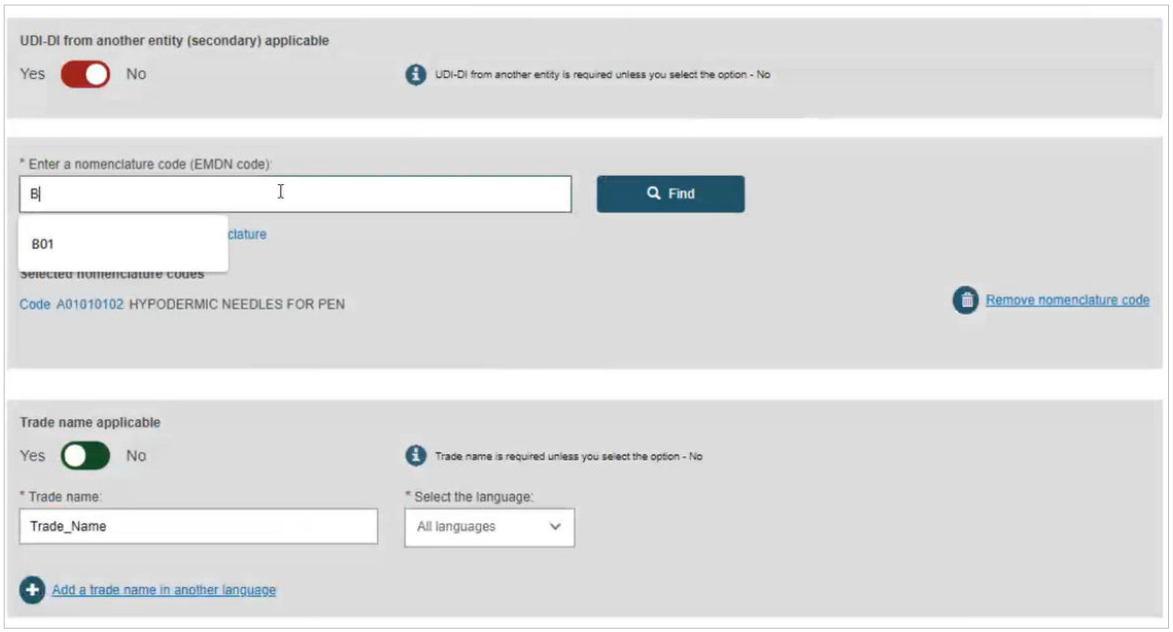
Please note that this video does not contain sound.

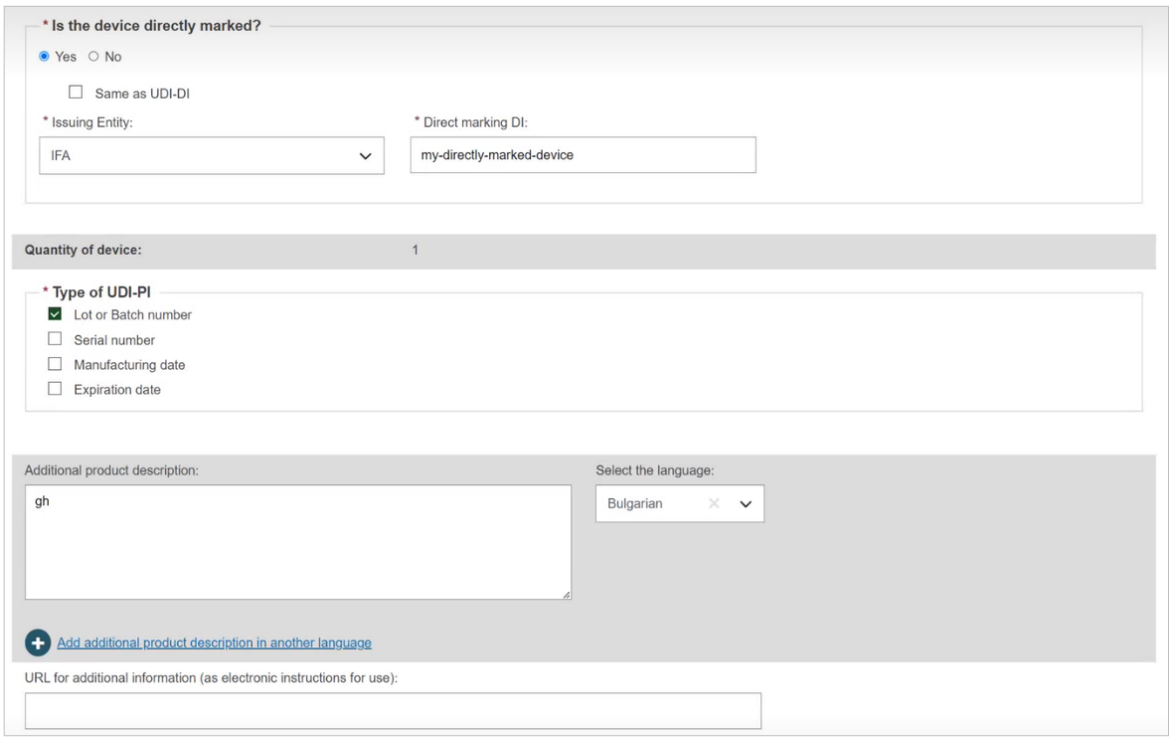


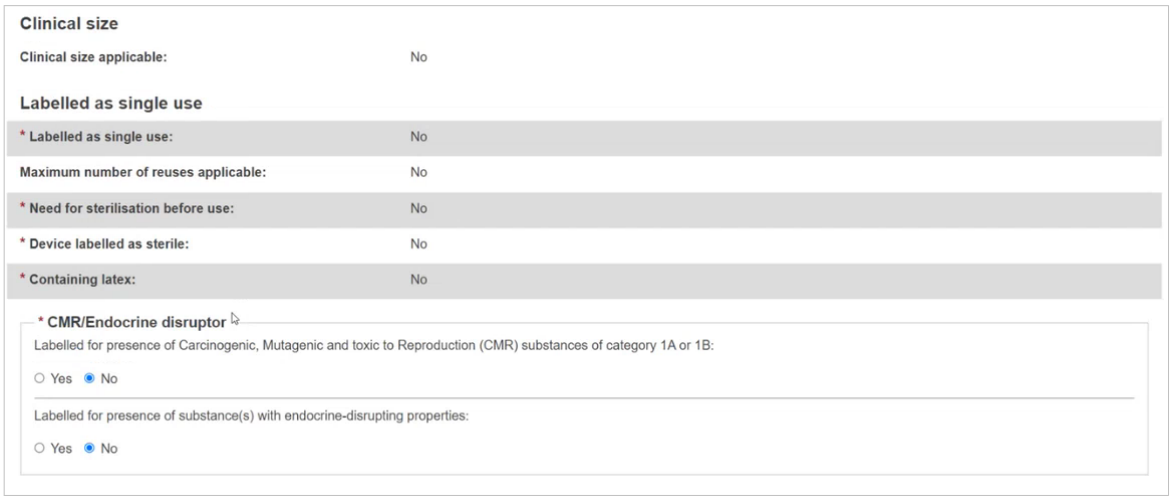
Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [56] to view a device and its UDI-DI/EUDAMED ID.

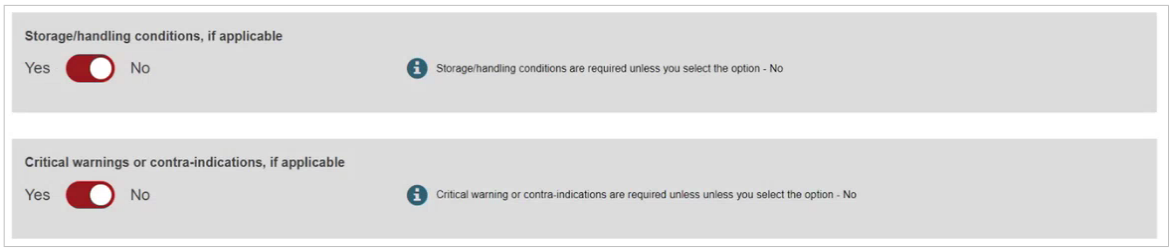
1. Once inside the details of the selected UDI-DI, click **Create new version** and proceed to update:

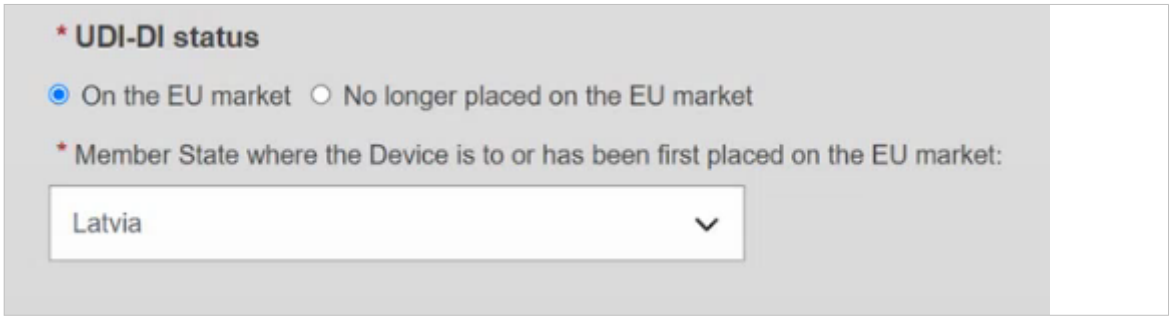

See UDI-DI(s) list (2)
Next UDI-DI
UDI-DI data
Discard
Create new version
Version 1 [Current] | Last update date: 2021-06-10
UDI-DI code: 12212121
Issuing Entity: HIBCC
UDI-DI from another entity
UDI-DI from another entity (secondary) applicable: No
Selected nomenclature codes
Code A01010102 HYPODERMIC NEEDLES FOR PEN


UDI-DI from another entity (secondary) applicable
Yes No
UDI-DI from another entity is required unless you select the option - No
* Enter a nomenclature code (EMDN code):
B
Find
B01
Code A01010102 HYPODERMIC NEEDLES FOR PEN
Remove nomenclature code
Trade name applicable
Yes No
Trade name is required unless you select the option - No
* Trade name:
Trade_Name
* Select the language:
All languages
Add a trade name in another language


* Is the device directly marked?
Yes
No
Same as UDI-DI
* Issuing Entity:
IFA
* Direct marking DI:
my-directly-marked-device
Quantity of device:
1
* Type of UDI-PI
Lot or Batch number
Serial number
Manufacturing date
Expiration date
Additional product description:
gh
Select the language:
Bulgarian
Add additional product description in another language
URL for additional information (as electronic instructions for use):


Clinical size
Clinical size applicable:
No
Labelled as single use
* Labelled as single use:
No
Maximum number of reuses applicable:
No
* Need for sterilisation before use:
No
* Device labelled as sterile:
No
* Containing latex:
No
* CMR/Endocrine disruptor
Labelled for presence of Carcinogenic, Mutagenic and toxic to Reproduction (CMR) substances of category 1A or 1B:
Yes
No
Labelled for presence of substance(s) with endocrine-disrupting properties:
Yes
No

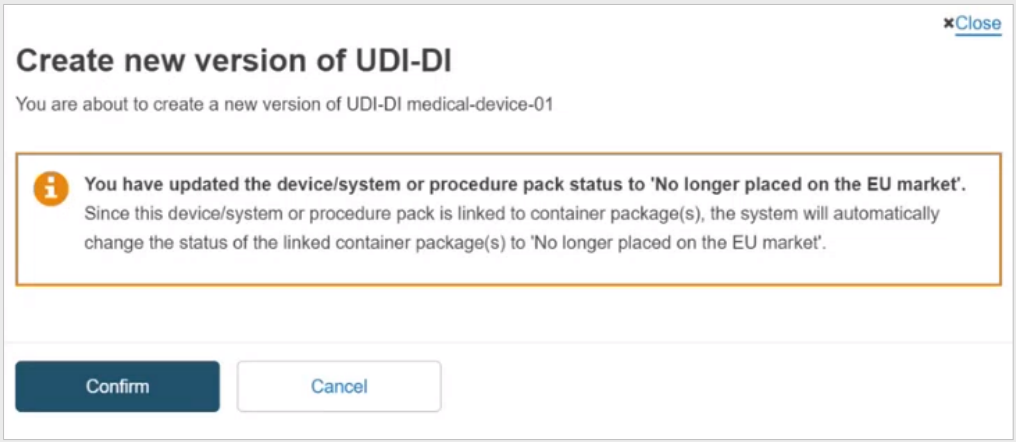

Storage/handling conditions, if applicable
Yes
No
Storage/handling conditions are required unless you select the option - No
Critical warnings or contra-indications, if applicable
Yes
No
Critical warning or contra-indications are required unless unless you select the option - No


* UDI-DI status
On the EU market
No longer placed on the EU market
* Member State where the Device is to or has been first placed on the EU market:
Latvia

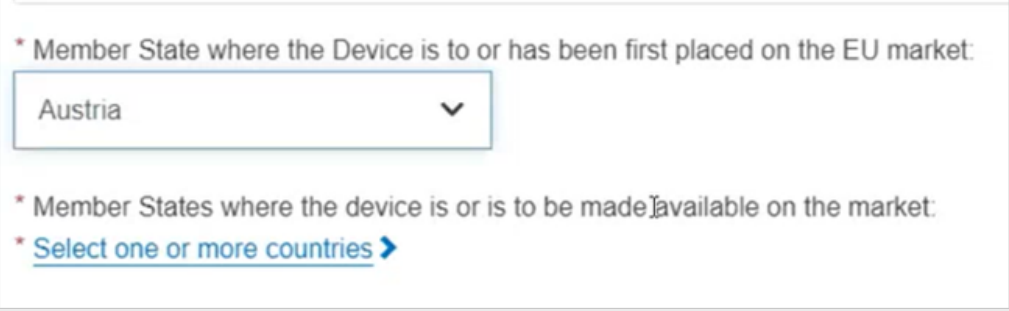
NOTE
The available options for the device status depend on the initial status of the device.

- If the initial UDI-DI status of the device is either *On the EU market* or *No longer placed on the EU market*, when updating the UDI-DI status of the device, you can select either the *On the EU market* or the *No longer placed on the EU market* status.
- If the initial UDI-DI status of the device is *Not intended for the EU market*, when updating the UDI-DI status of the device you can only select the *On the EU market* status.

NOTE
In the *UDI-DI status* field, if you select the *No longer placed on the EU market* status, the Market information will no longer be displayed and all container packages linked to this device will automatically be updated to the same status as the device.



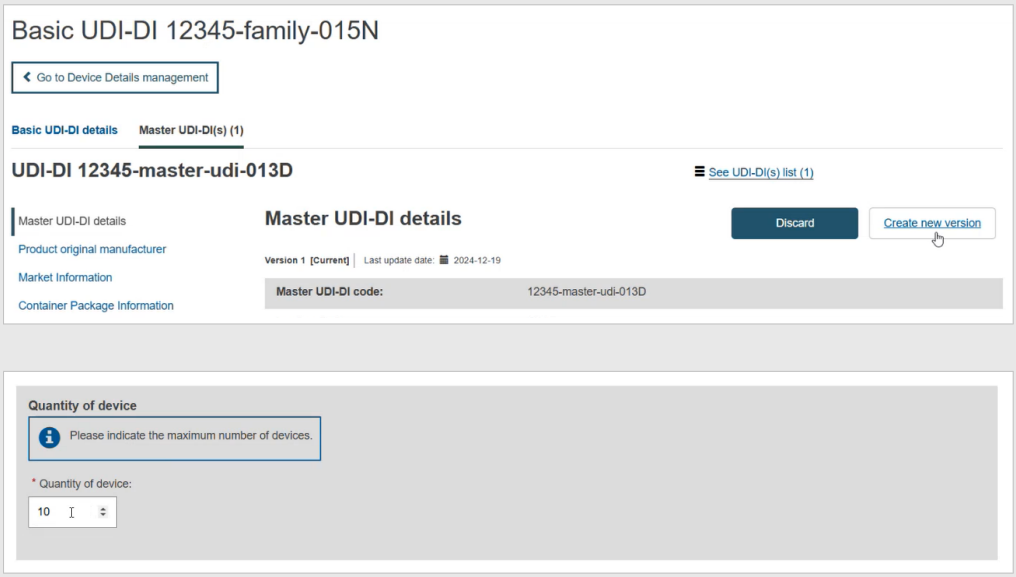
Otherwise, if you select the *On the EU market* status, you must select a Member State in the drop-down list where the device is or has been first placed on the EU market and the Member State(s) where the device is or is to be made available. You must also manually update all container packages linked to this device.



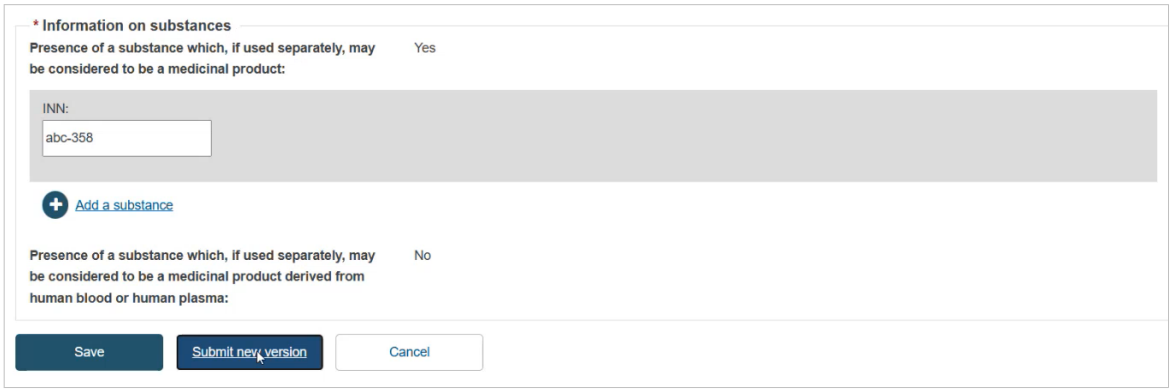
TIP

Master UDI-DI update variation

When creating a new version of a Master UDI-DI, the *Quantity of device* field is editable, whereas for the UDI-DI, it is not.



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



Once you have submitted the new version, click **Confirm** in the pop-up window to finalise the update:



5.2.4 Update Product original manufacturer

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

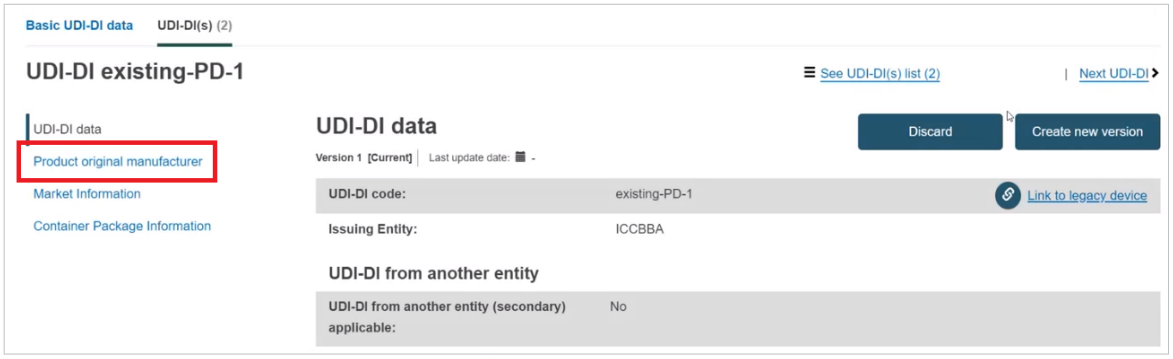
NOTE

Product original manufacturer information can be updated if it was initially provided with details of an Organisation that is not a registered Actor with an Actor ID/SRN.

It **cannot** be updated if it was initially marked as *Not applicable*, or if it was specified with an Actor ID/SRN.

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [56] to view a UDI-DI/EUDAMED ID.

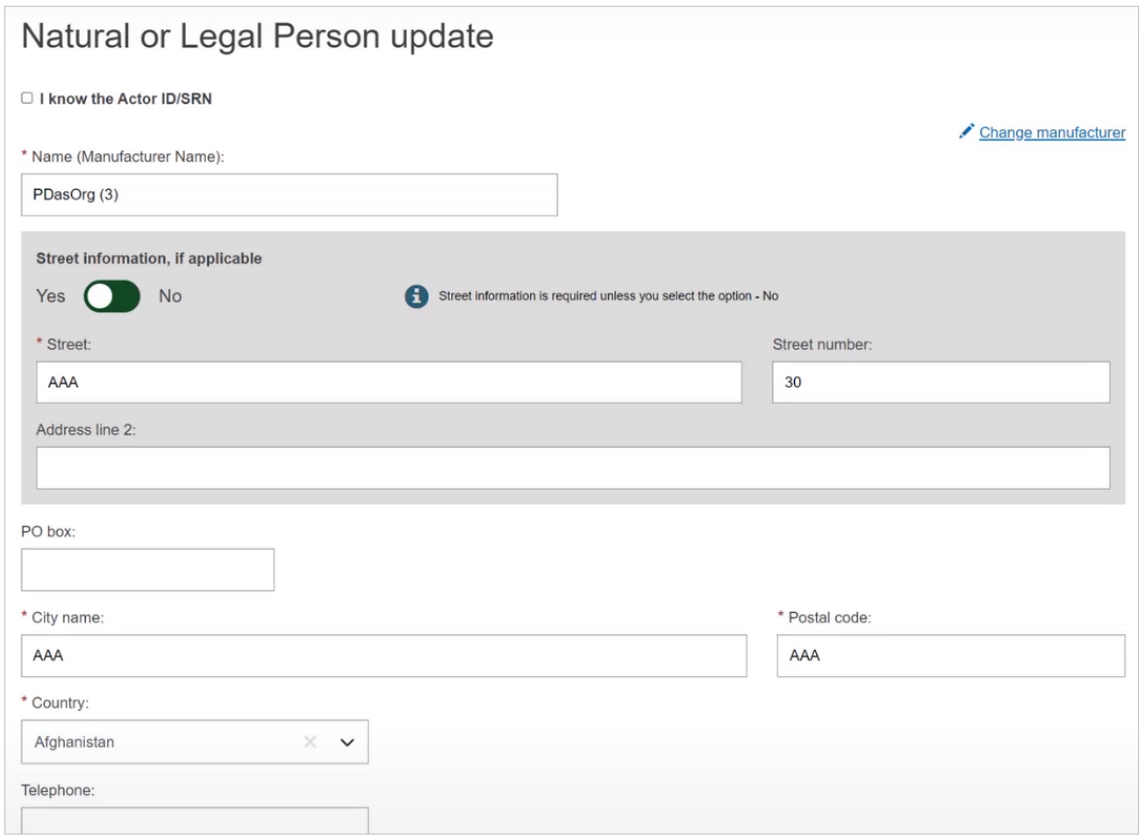
1. Once inside the details of the selected UDI-DI, click **Product original manufacturer** from the list on the left (or scroll down to *Product original manufacturer*):



2. Click **Update** to access the *Product original manufacturer* page:

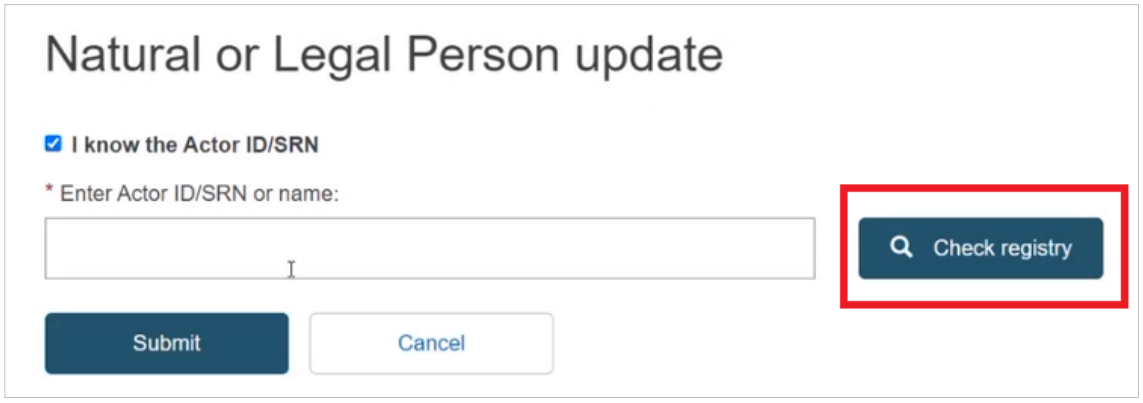


- You can **either** update the details on *Product original manufacturer*:

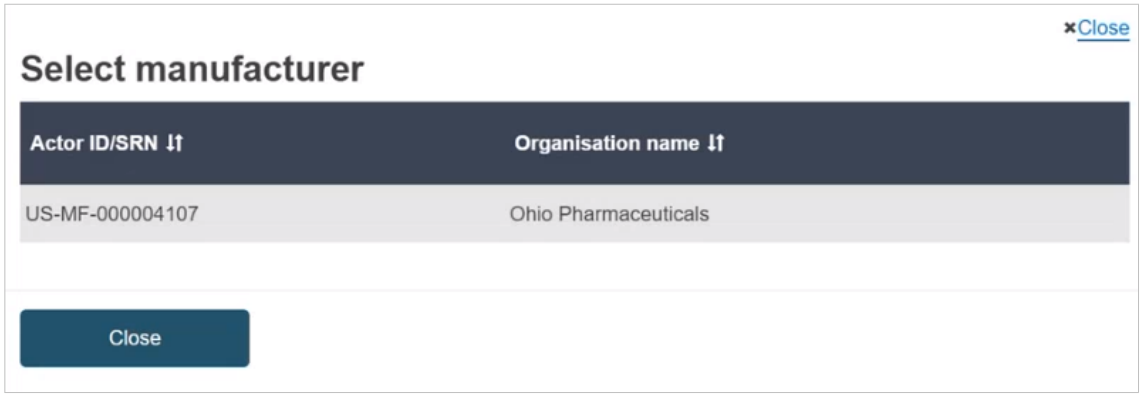


Or

- You can update the *Product original manufacturer* to an actor that is already registered in EUDAMED.
  Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRNor name of the *Product original manufacturer* of the device and click on **Check registry**:



  In the pop-up window, select the *Product original manufacturer* from the list:



3. Click **Submit** at the bottom of the screen to finalise the update.
   You will be able to see the new version created for the *Product original manufacturer* information.

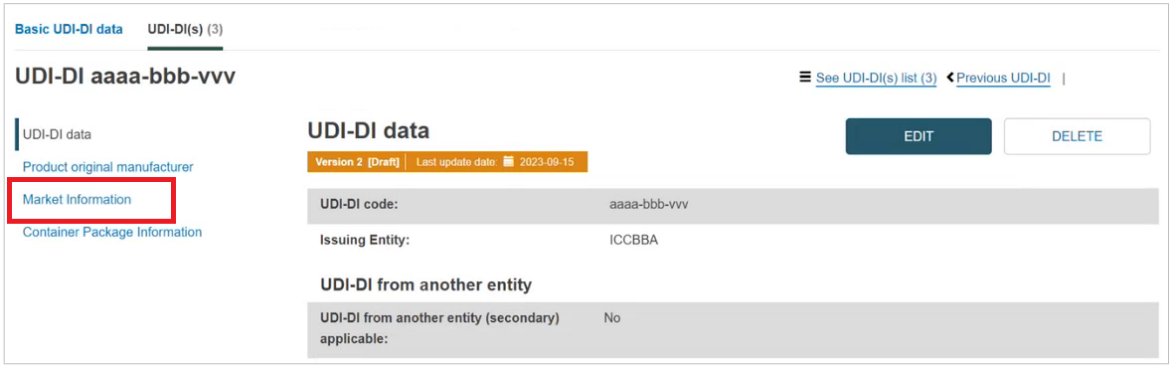
NOTE
Once you update the *Product original manufacturer* to an actor that is already registered in EUDAMED, you will not be able to perform any further update to the Product original manufacturer via the UDI/Devices module.

5.2.5 Update Market Information

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

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [56] to view a UDI-DI/EUDAMED ID.

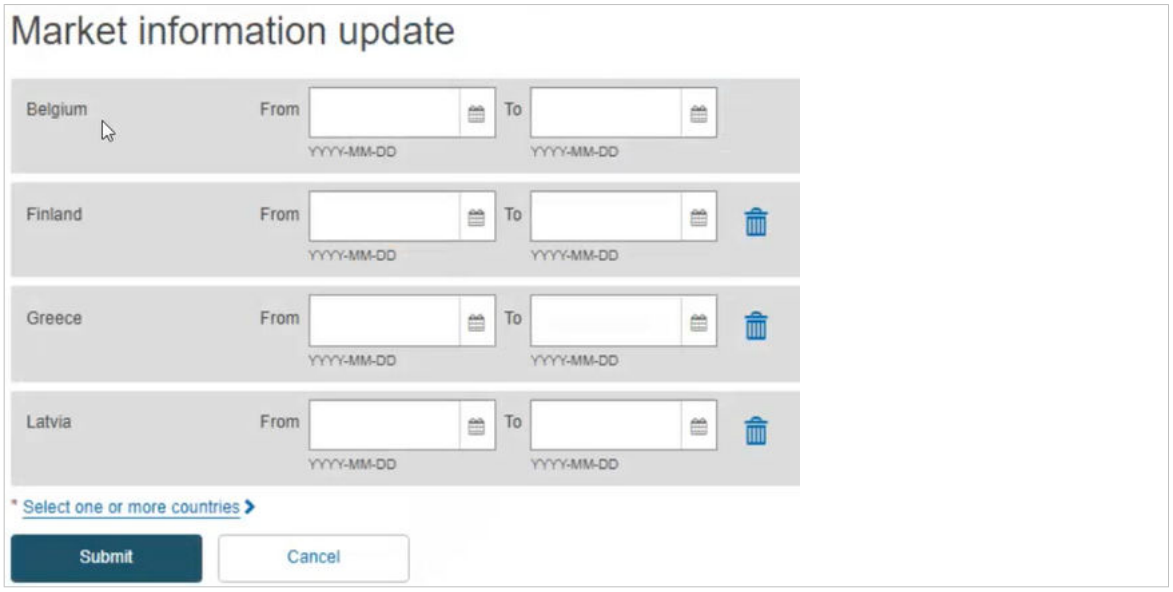
1. Once inside the details of the selected UDI-DI, click **Market Information** from the list on the left (or scroll down to *Market Information*):



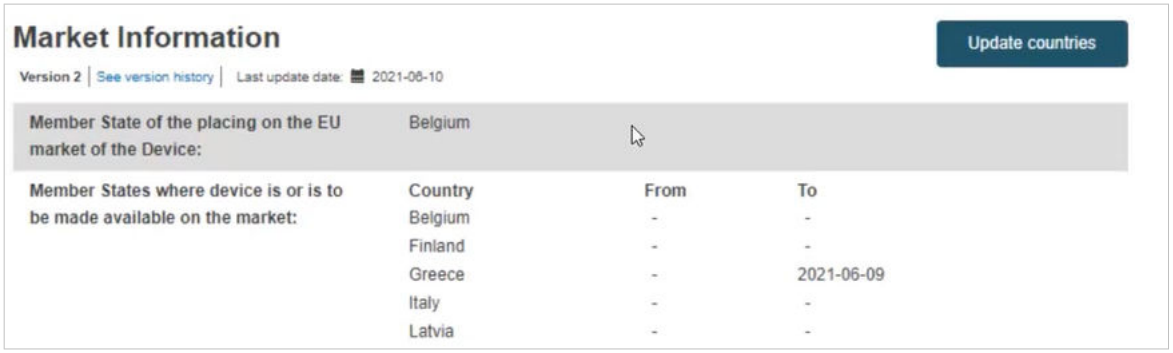
2. Click **Update countries**:



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



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

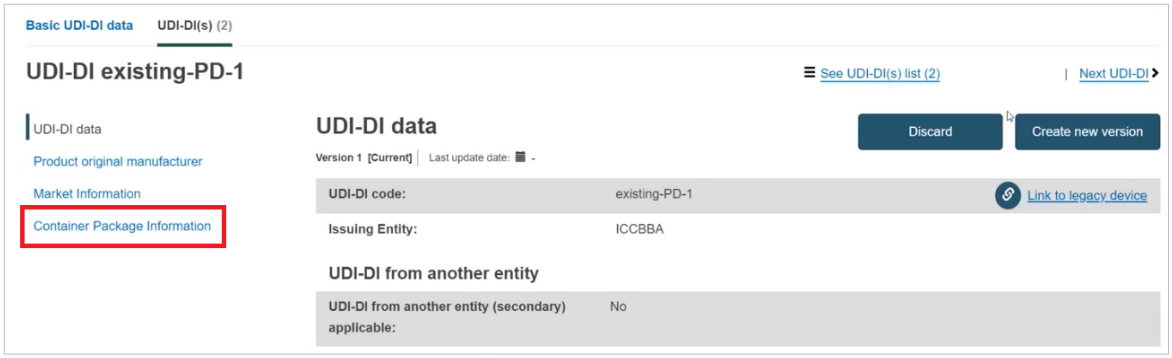


5.2.6 Update Container Packages

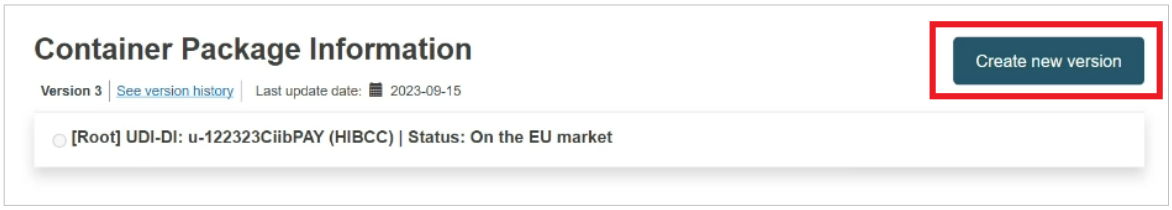
The Container Packages information can be updated independently of other data in a device UDI-DI record.

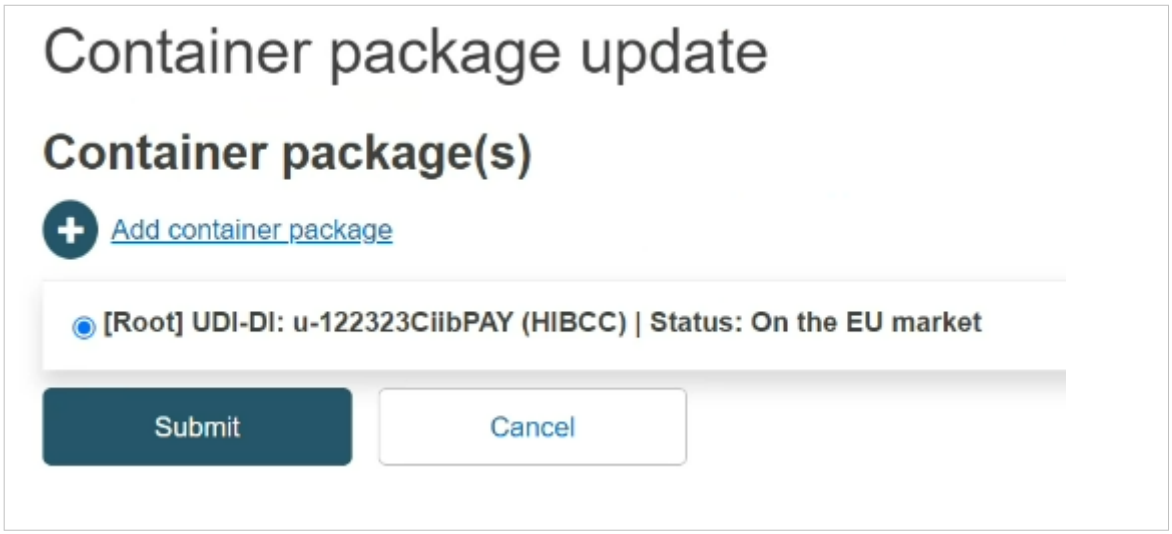
Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [56] to view a UDI-DI/EUDAMED ID.

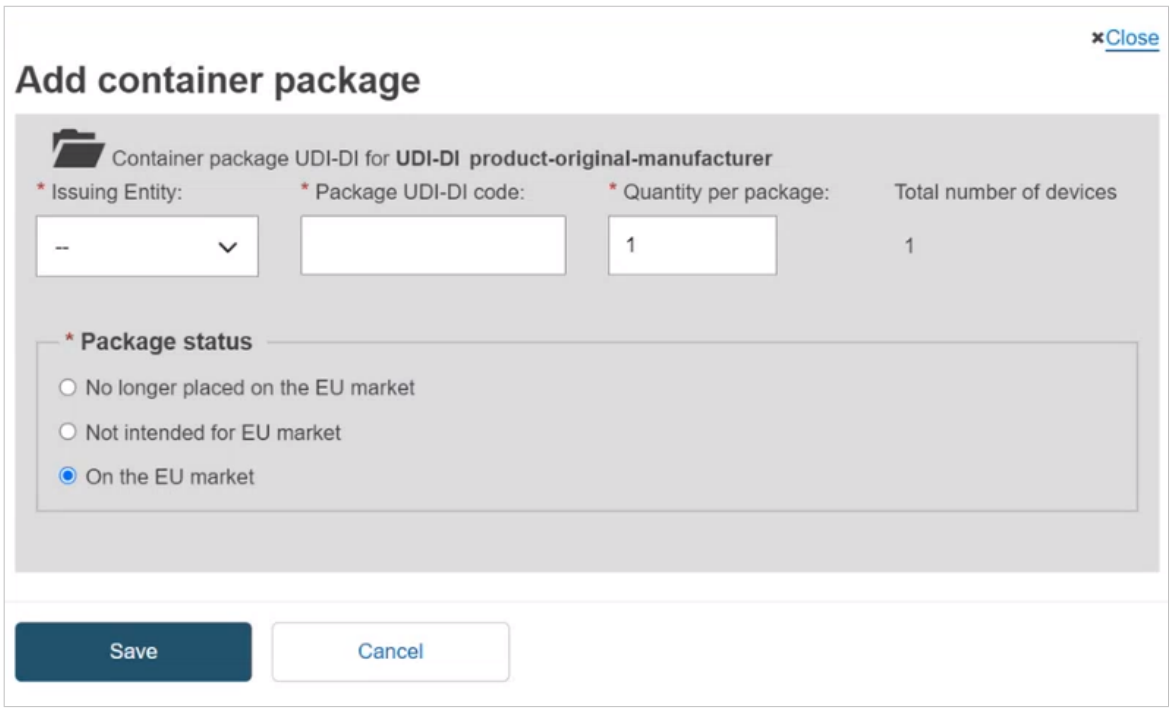
1. Once inside the details of the selected UDI-DI, click on *Container Package information* from the list on the left (or scroll down to the relevant section):

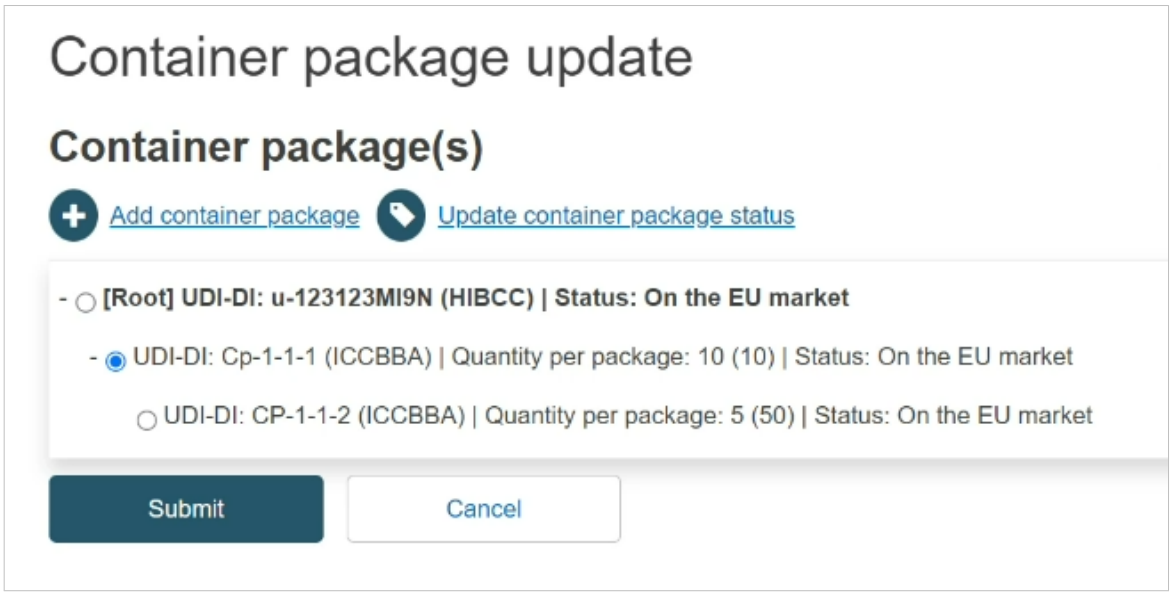


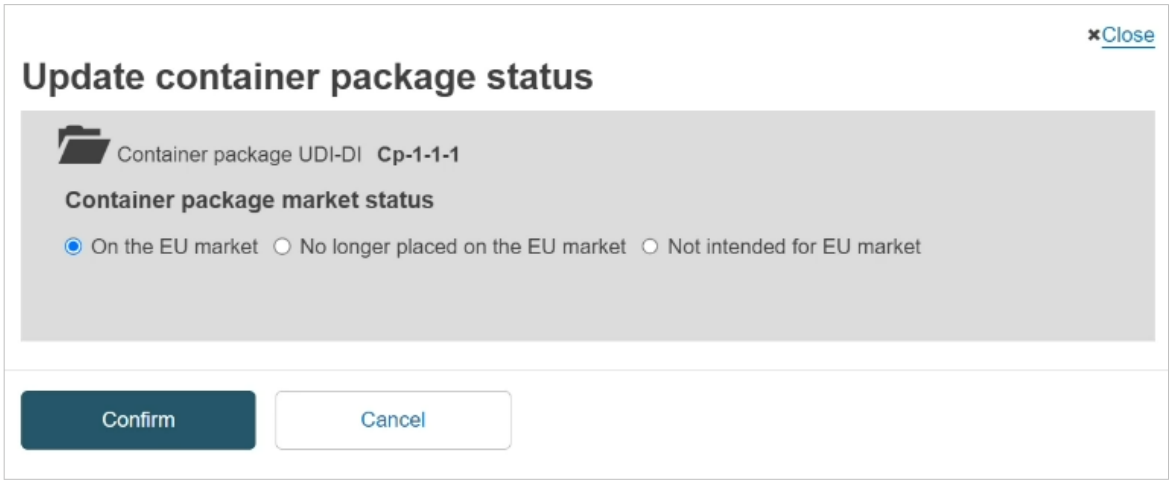
2. Click **Create new version** in the *Container Package* section and proceed to update:





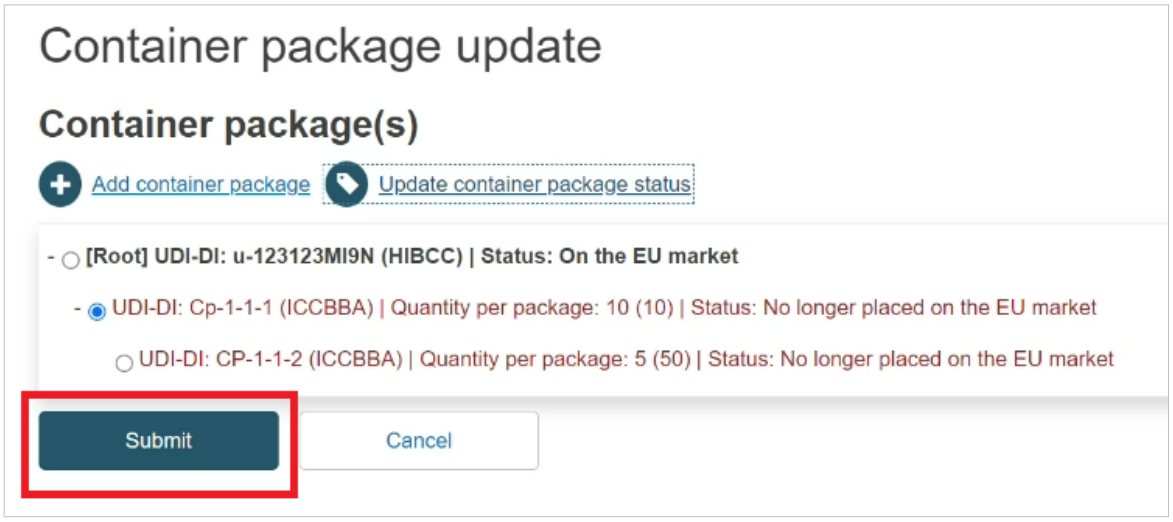

Close
Add container package
Container package UDI-DI for UDI-DI product-original-manufacturer
* Issuing Entity:
* Package UDI-DI code:
* Quantity per package:
Total number of devices
--
1
1
* Package status
No longer placed on the EU market
Not intended for EU market
On the EU market
Save
Cancel


Container package update
Container package(s)
Add container package
Update container package status
- [Root] UDI-DI: u-123123MI9N (HIBCC) | Status: On the EU market
- UDI-DI: Cp-1-1-1 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market
UDI-DI: CP-1-1-2 (ICCBBA) | Quantity per package: 5 (50) | Status: On the EU market
Submit
Cancel


Close
Update container package status
Container package UDI-DI Cp-1-1-1
Container package market status
On the EU market
No longer placed on the EU market
Not intended for EU market
Confirm
Cancel

NOTE
Only if the status of the selected UDI-DI is *On the EU market*, will you be able to update the status of the container package. Otherwise, the options will be greyed out and you will not be able to update the status of the container package for the selected UDI-DI.

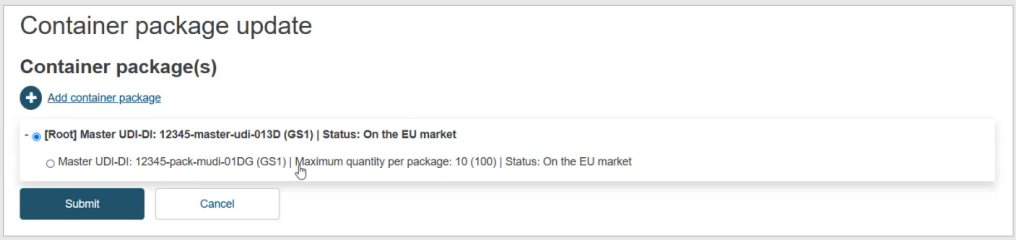
3. Click **Submit** to finalise the container package update:

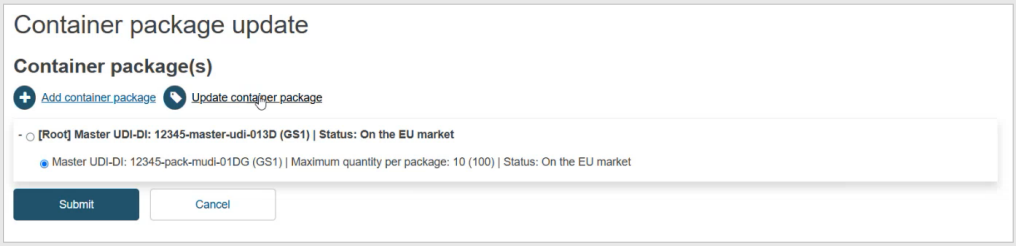


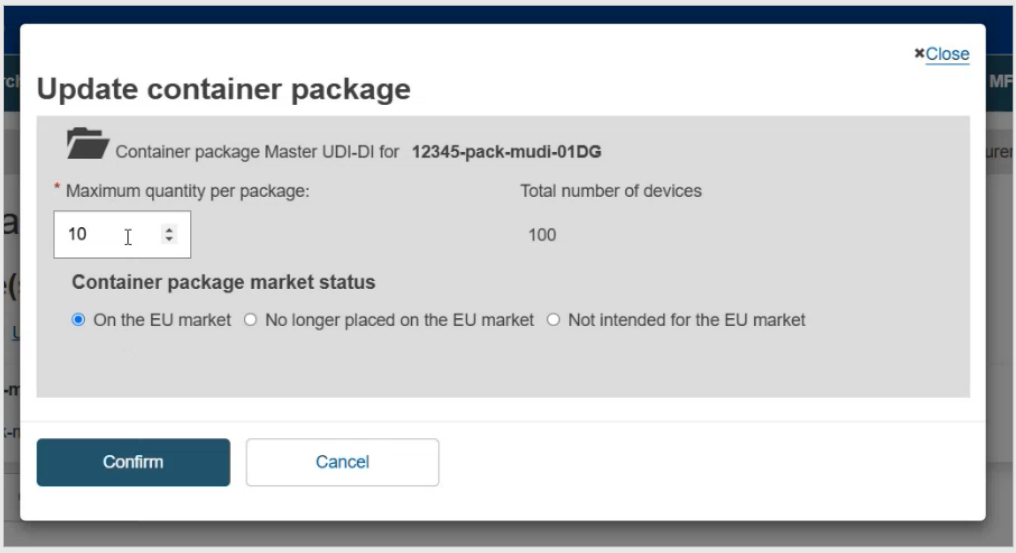
TIP

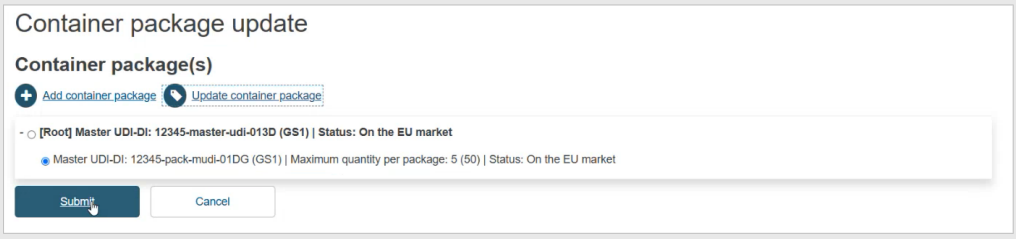
Master UDI-DI update variation

When creating a new version of a Master UDI-DI container package, the *Maximum quantity per package* field is editable, whereas for the UDI-DI container package, it is not:









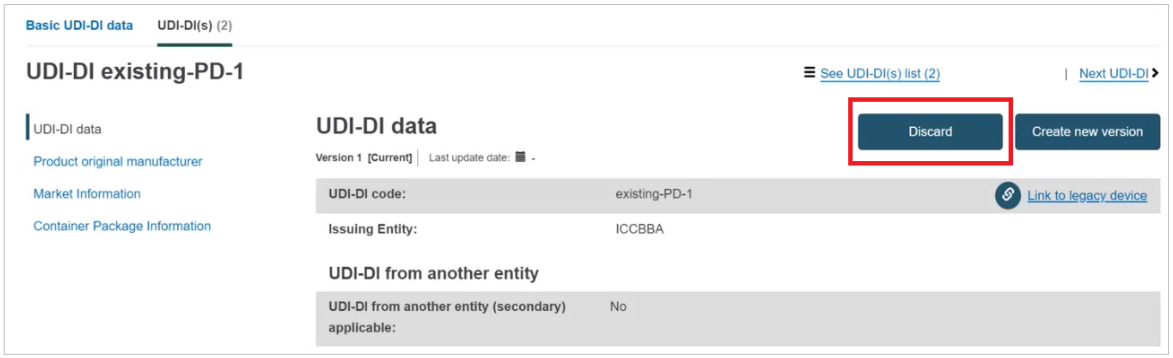
5.2.7 Discard registered devices and their UDI-DIs/ EUDAMED-IDs (and their Basic UDI-DI/EUDAMED-DI

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 device and its UDI-DI in case you discover errors that cannot be corrected.

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details* [56] to view a registered UDI-DI/EUDAMED ID.

1. Only a user with *Confirmer* profile can discard. Once inside the details page of the selected UDI-DI, click **Discard** at the top right corner:



2. Confirm your intention to discard the registered UDI-DI:



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

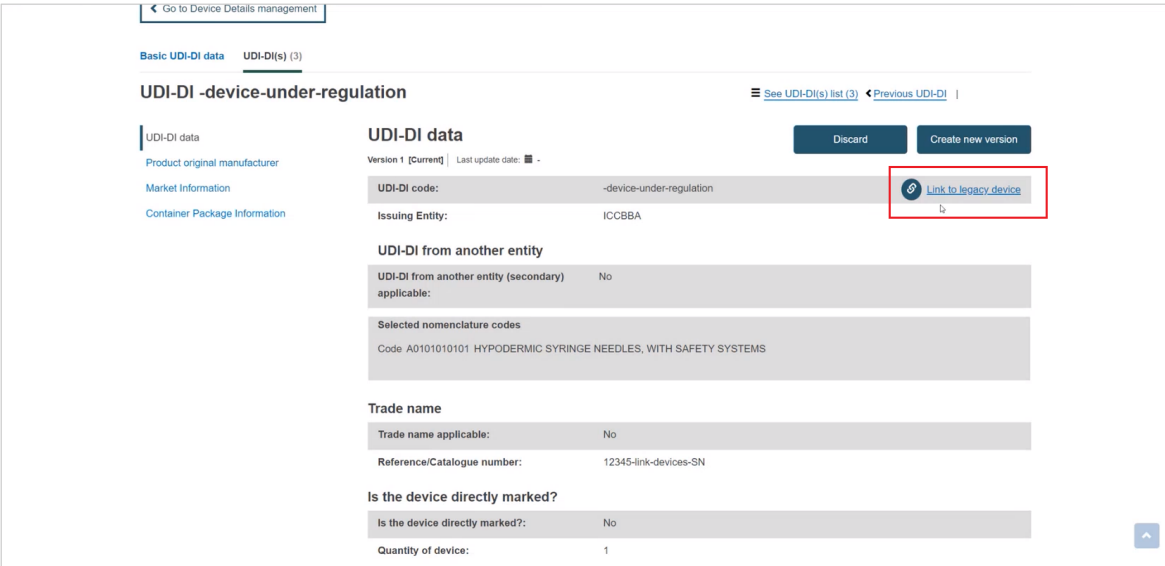
CAUTION
If the UDI-DI is the only one in this Basic UDI-DI category, the *discard* action will also discard the Basic UDI-DI. The system will alert you accordingly:



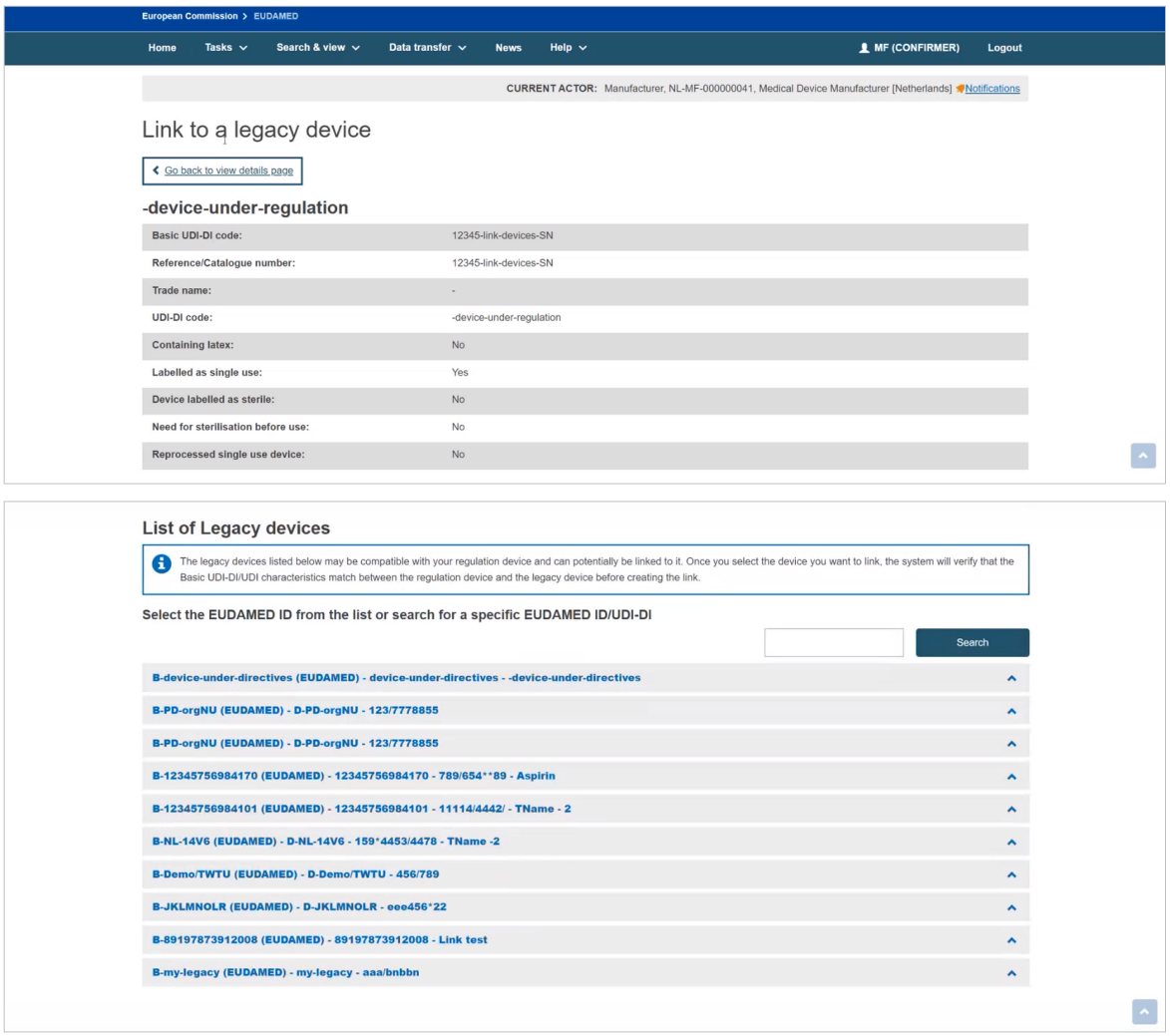
5.2.8 Link registered Regulation Device to registered Legacy Device

Follow the steps in Manage your device UDI-DI/EUDAMED ID details [56] and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

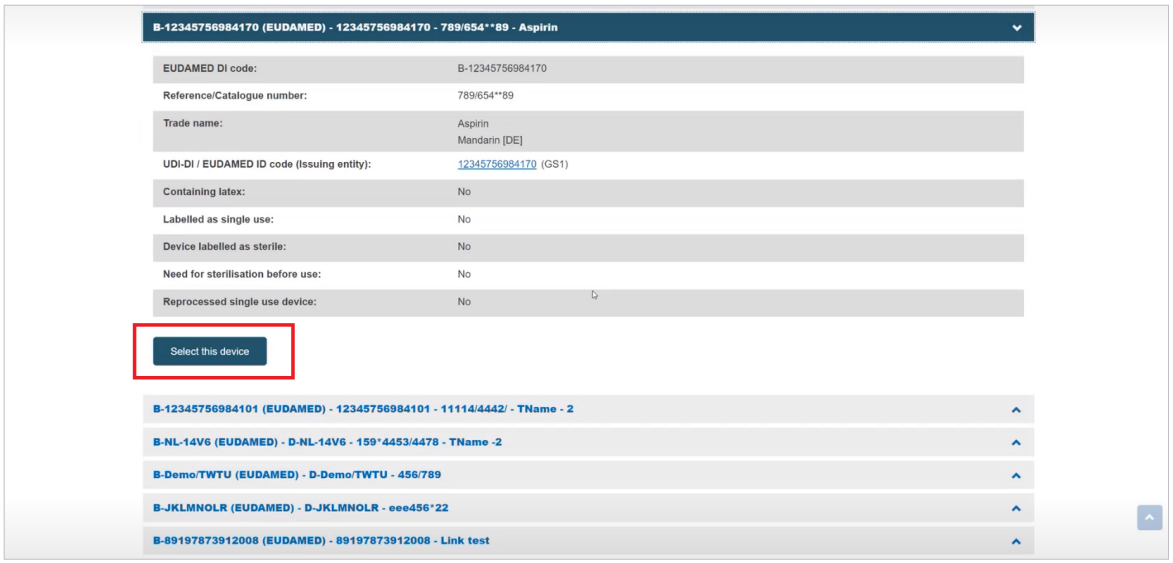
1. Once inside the relevant registered regulation device click on *Link to legacy device*:



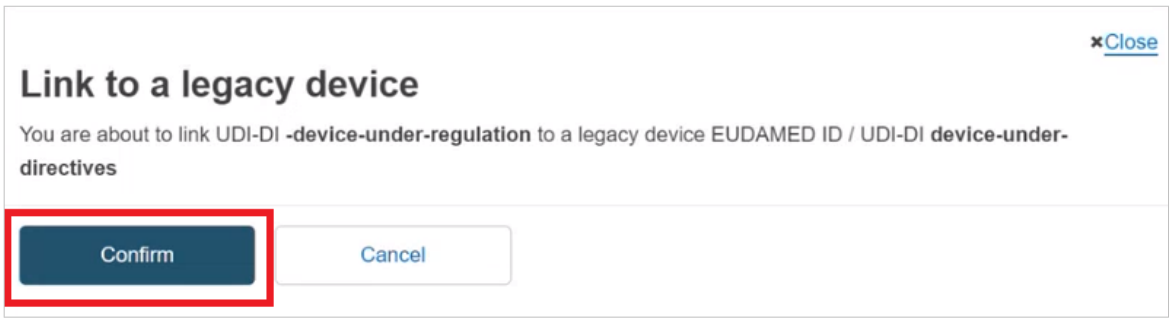
2. The page next contains details on the selected registered regulation device and a list with all possible compatible legacy devices to be linked to:



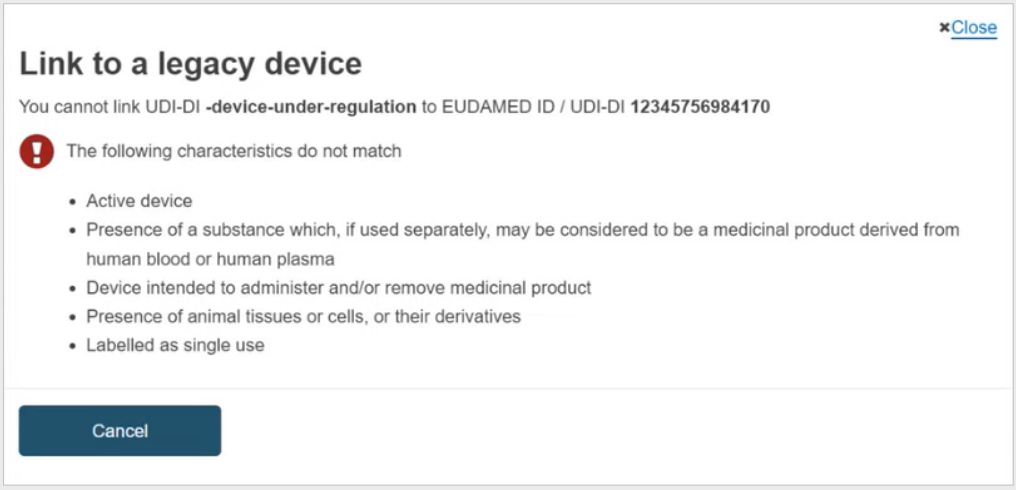
3. You can either select the desired legacy device using the search box or you can select it from the list. Select the device and click **Select this device**:



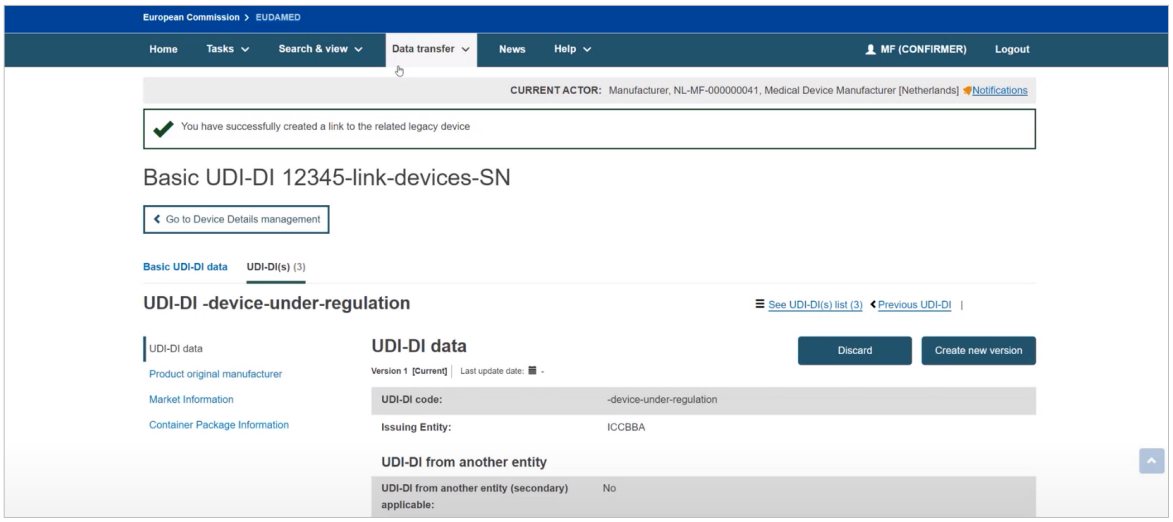
4. Click **Confirm** in the pop-up window:



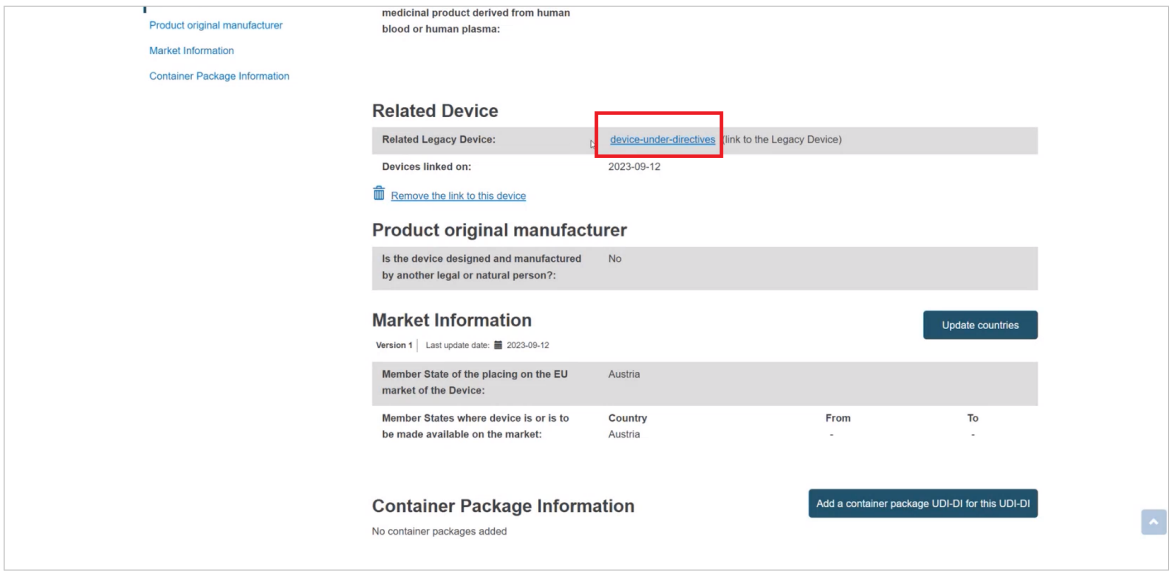
NOTE
If some characteristics don't match, then you will not be able to link the registered regulation device to the selected legacy device:



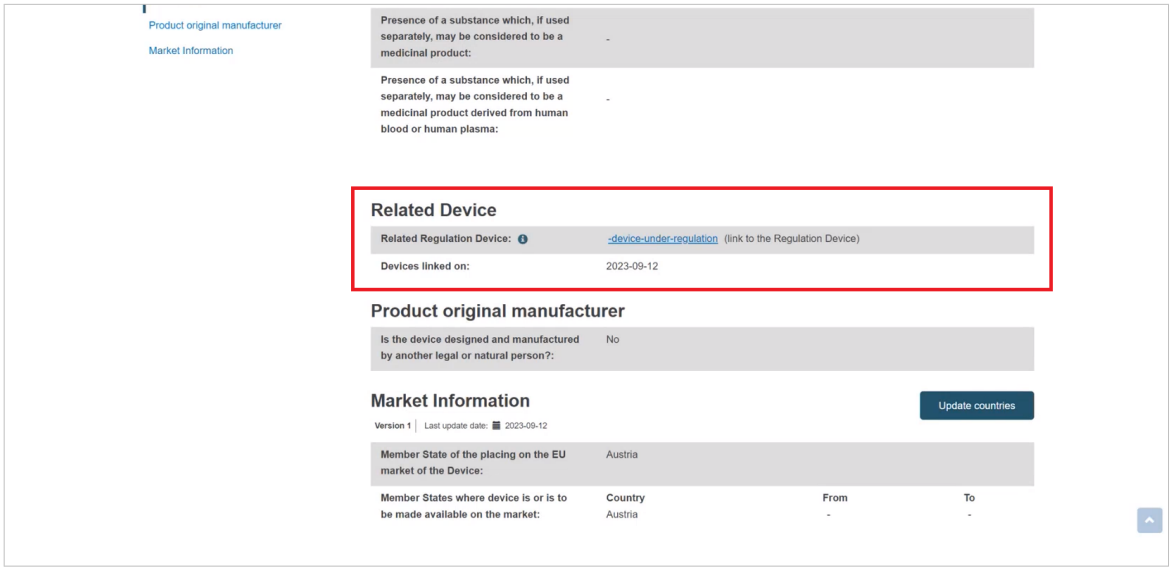
5. The system will redirect you back to the regulation device's page:



6. You can view details on the linked legacy device by selecting the link to the legacy device under the *Related Device* section:



7. The legacy device's page will appear. You can view the linked regulation device under the *Related Device* section:

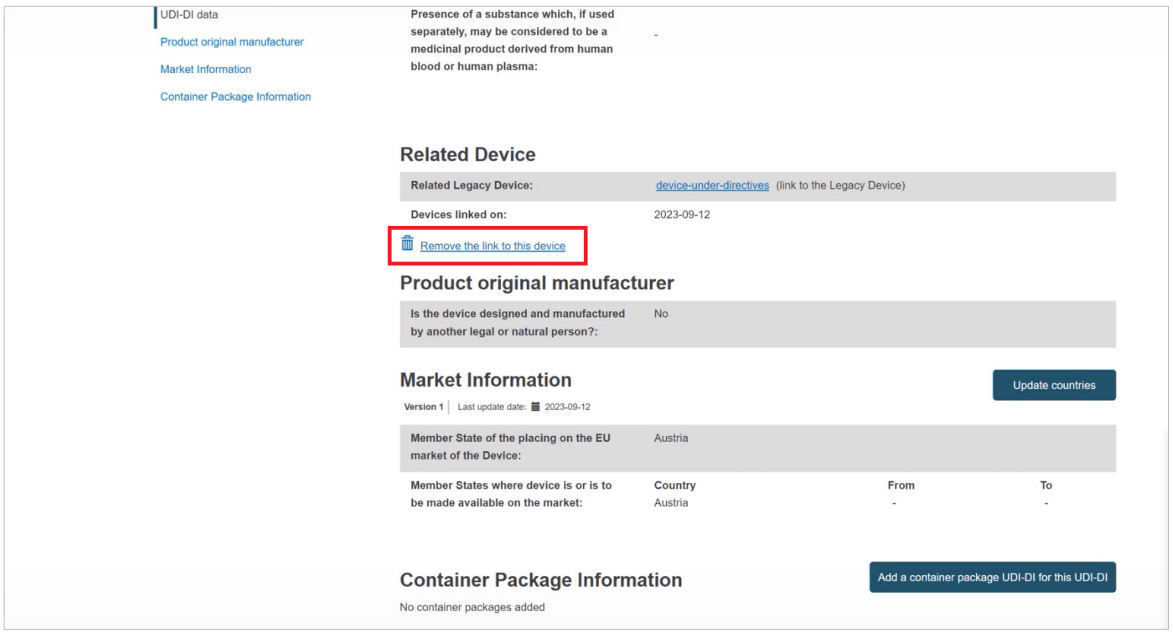


NOTE
See the Legacy Devices - user guide for further details on Legacy Devices.

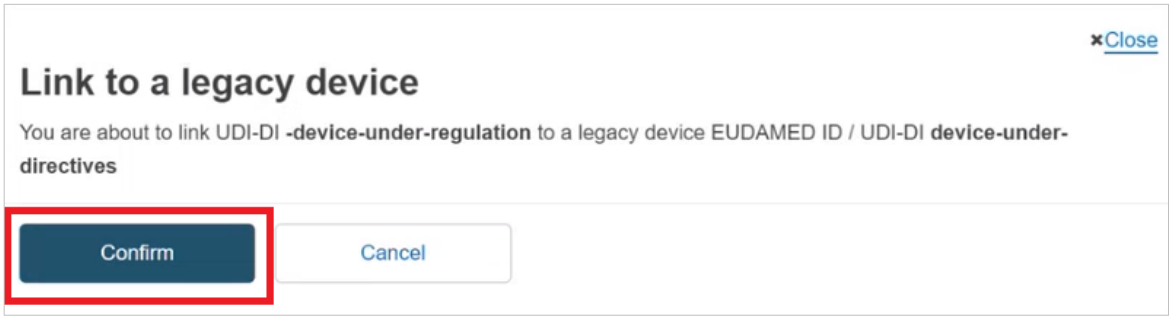
5.2.9 Delete link between Regulation Device and Legacy Device

Follow the steps in Manage your device UDI-DI/EUDAMED ID details [56] and select the *Registered* option in the *State* field.

1. Once inside the relevant registered regulation device click on *Remove the link to this device* under the *Related Device* section:



2. Click **Confirm** on the pop-up window:



NOTE
See the Legacy Devices - user guide for further details on Legacy Devices.

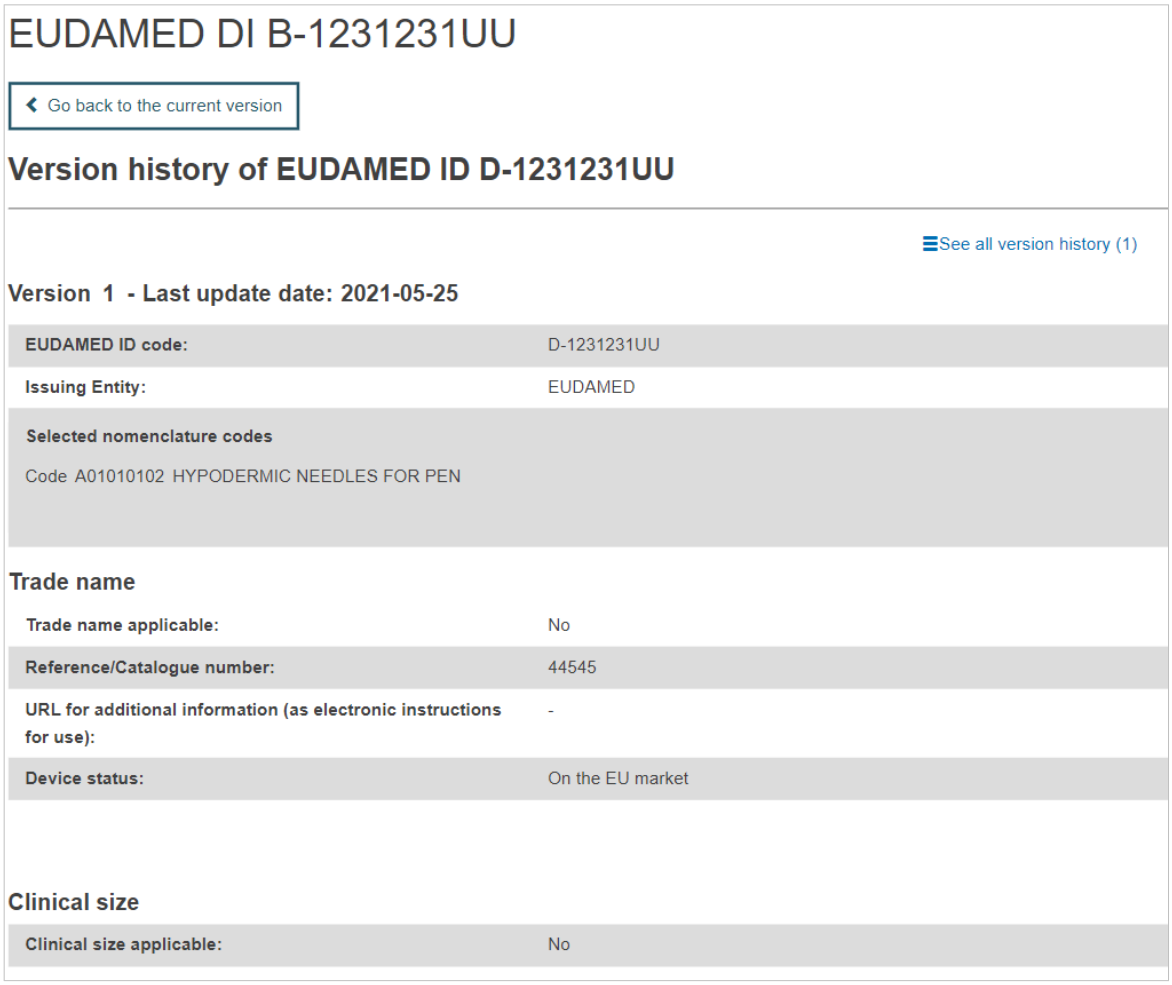
5.2.10 View historical versions of a device and its UDI-DI/EUDAMED-ID and associated entities

Follow the steps in section *Manage your device UDI-DI/EUDAMED ID details [56]* to view a UDI-DI/EUDAMED ID.

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



2. In the list of versions displayed, click on the version you wish to access:

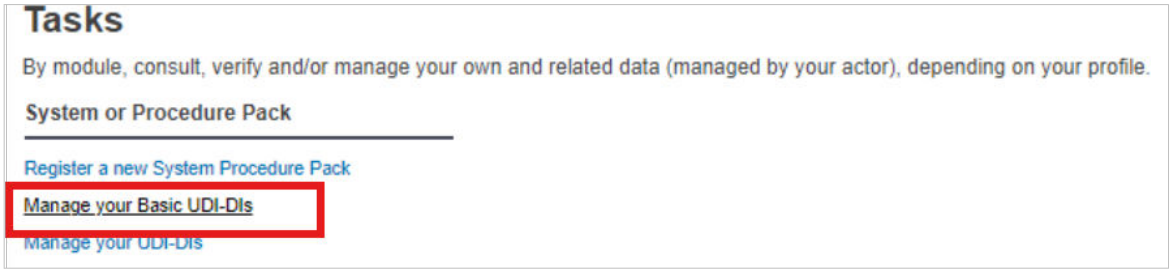


3. You can return to the version history list, by clicking on *See all version history* at the top right corner.

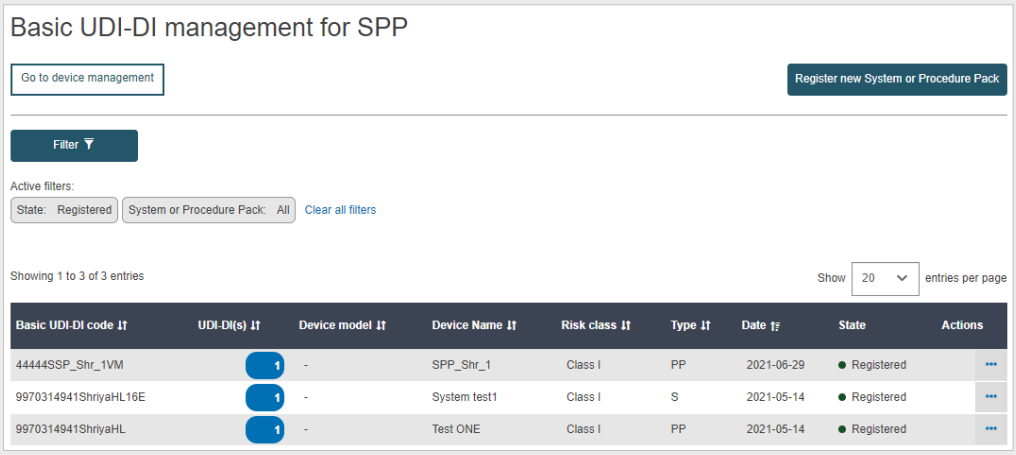
6 Manage your own System or Procedure Pack (SPP) information

6.1 Manage your SPP Basic UDI-DI details

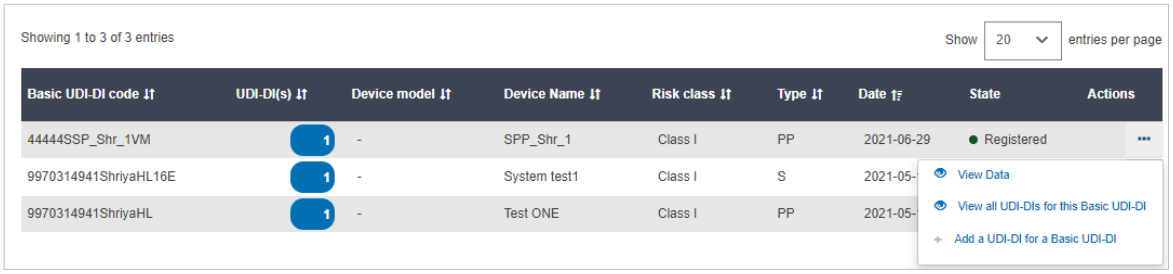
1. On the EUDAMED dashboard, click on *Manage your Basic UDI-DIs* to see a list of all your Basic UDI-DIs:



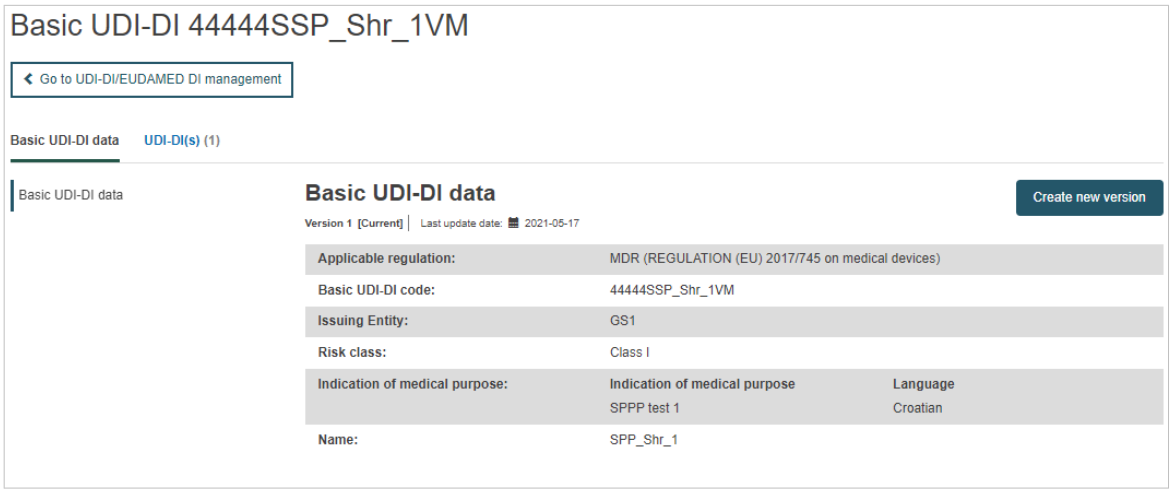
NOTE
By default, the system displays the System or Procedure Packs in state *draft*. To see other states, use the filters.



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

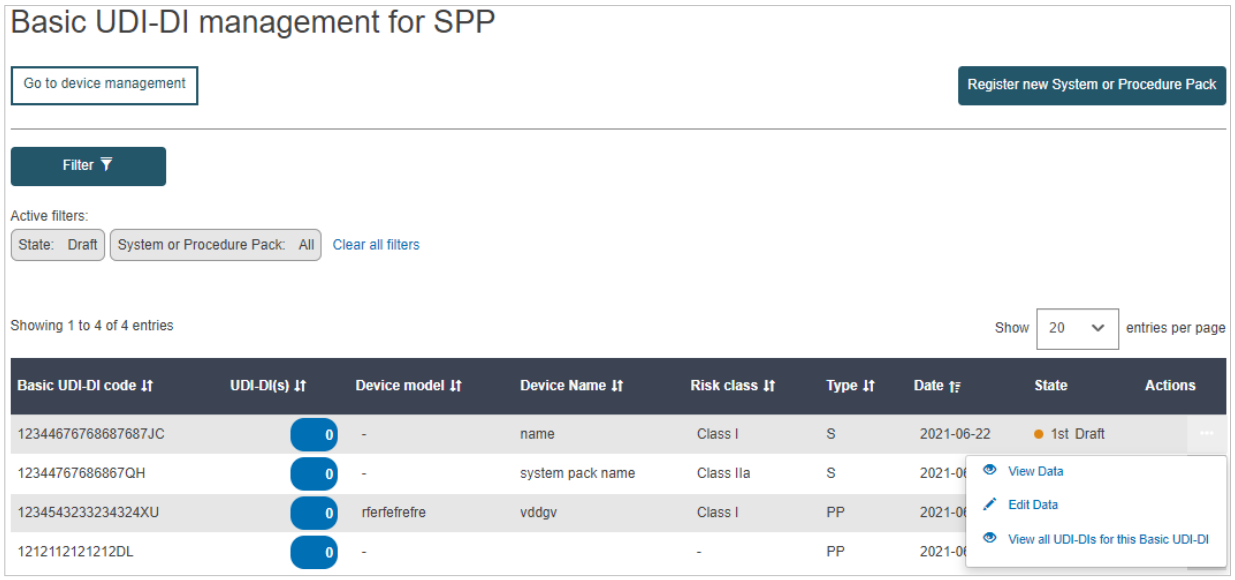


3. A *Details* summary of your System or Procedure Pack is displayed:

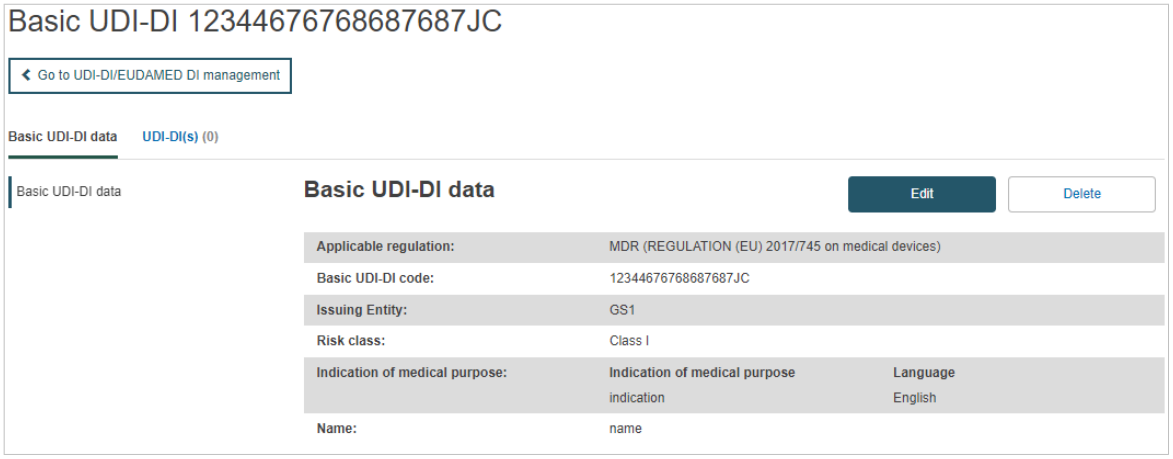


6.1.1 Delete a SPP draft Basic UDI-DI

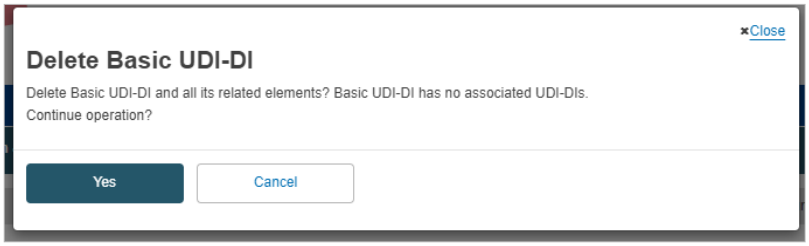
Follow the steps in section *Manage your SPP Basic UDI-DI details* [85] to view a Draft Basic UDI-DI:



1. Once inside the draft, click **Delete**:

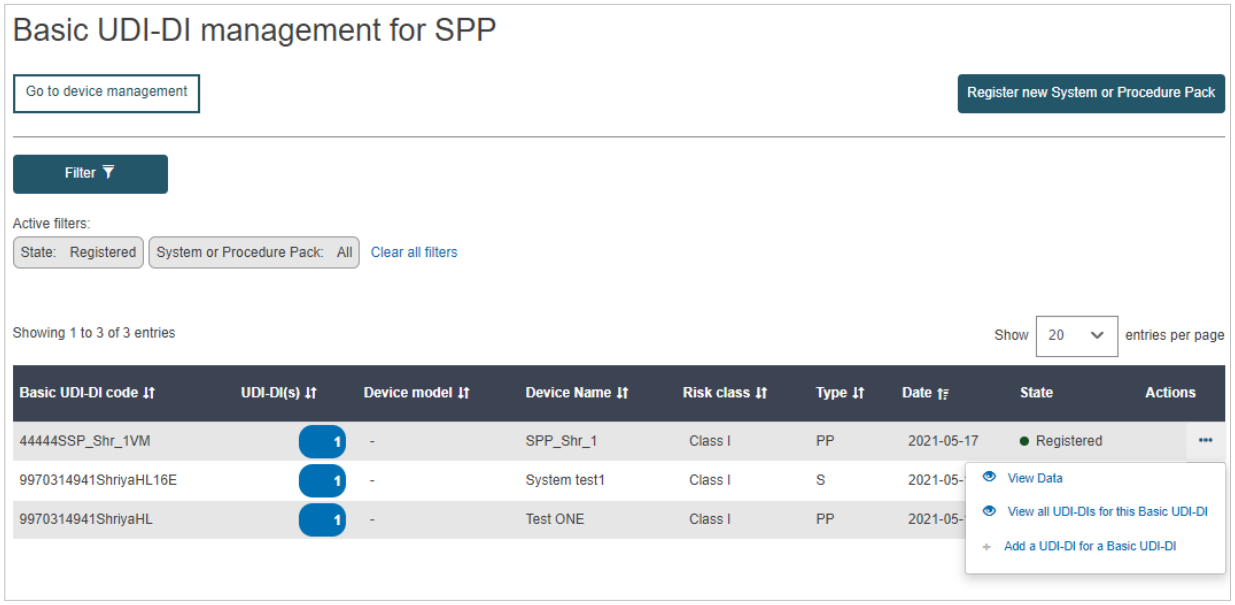


2. Confirm the deletion in the pop-up window:

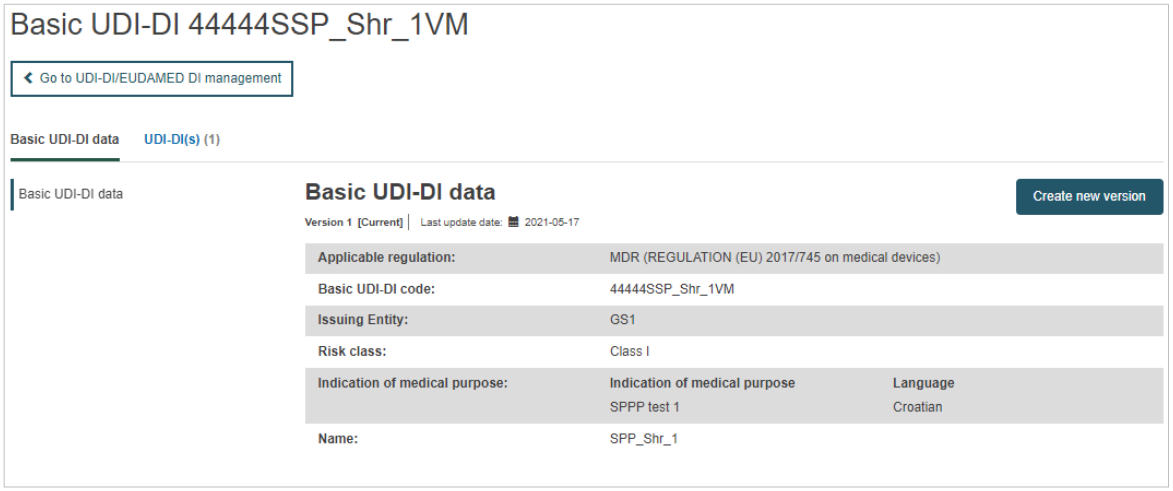


6.1.2 Update SPP Basic UDI-DI

Follow the steps in section *Manage your SPP Basic UDI-DI details* [85] to view a Basic UDI-DI:



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



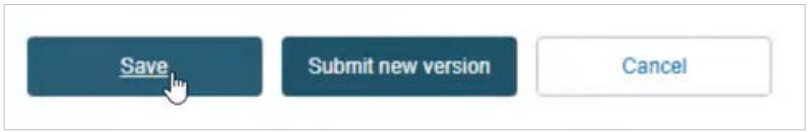
2. Update the desired details.

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

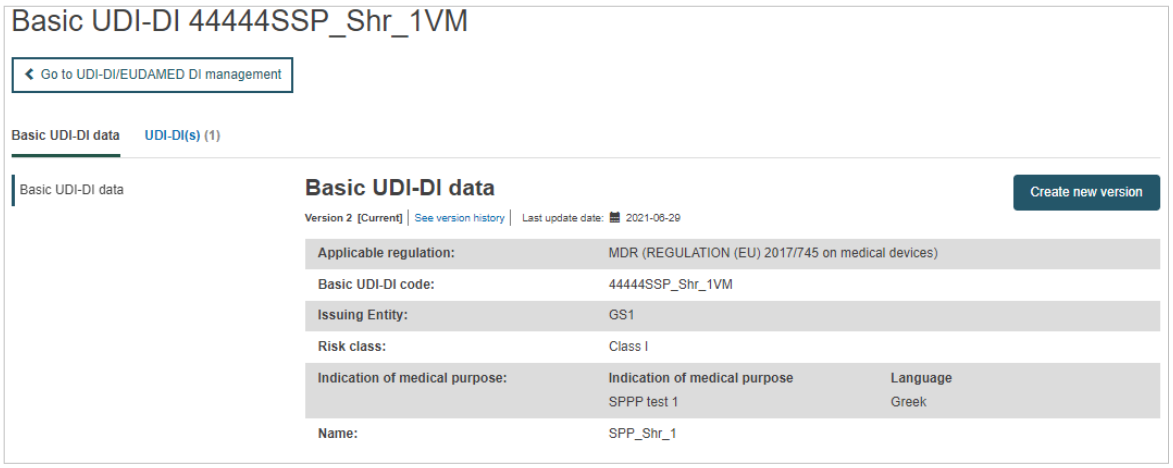


3. To finish the action you have two options:
   - Click **Save** to save the updated details without submitting the new version.
   - Click **Submit new version** if you wish to submit it.

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



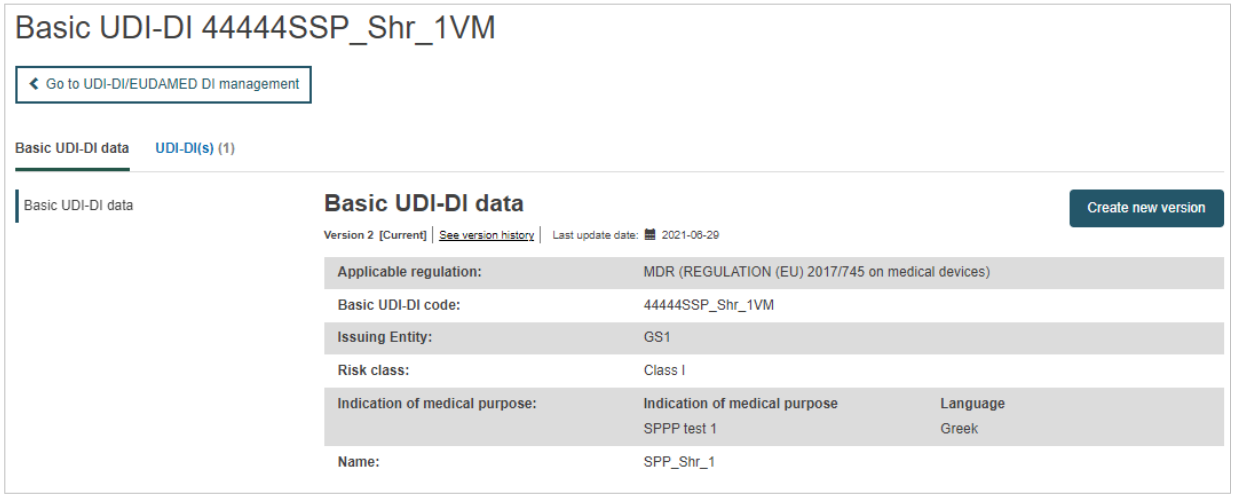
4. After you have submitted the new version, you can see the update under the Basic UDI-DI details:



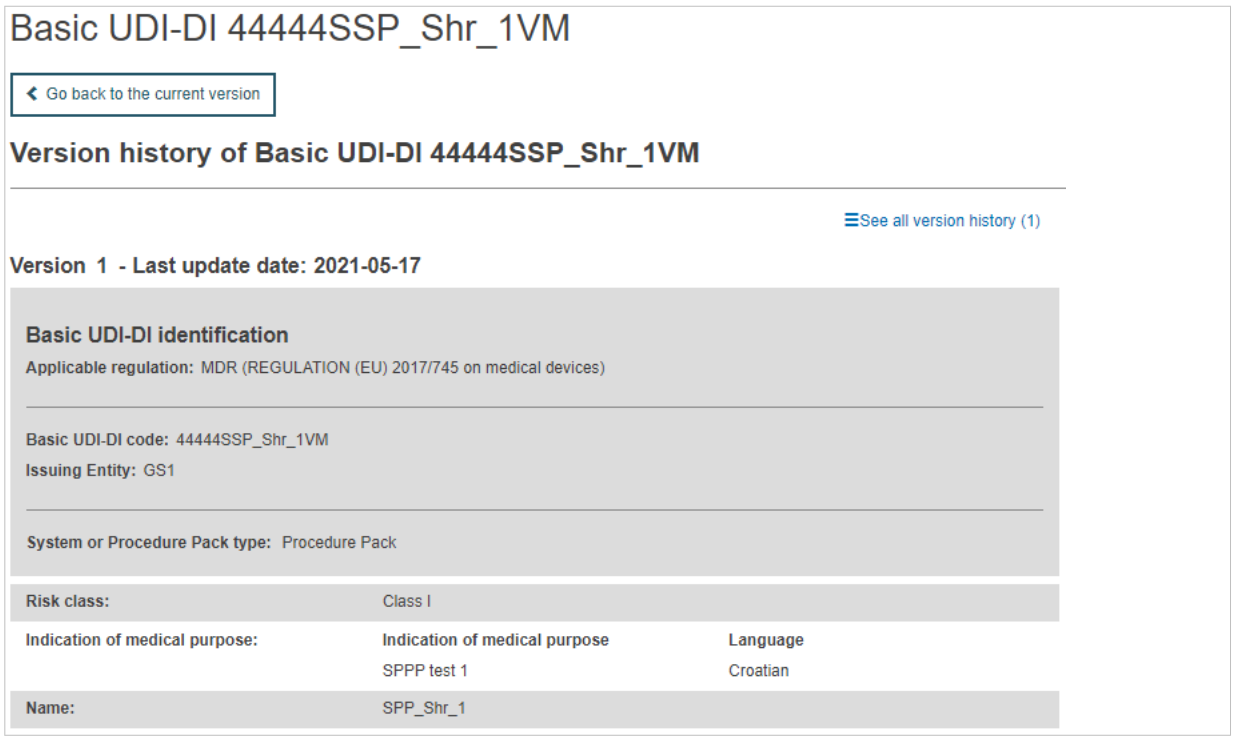
6.1.3 View SPP Basic UDI-DI historical versions

Follow the steps in section *Manage your SPP Basic UDI-DI details* [85] to view a Basic UDI-DI.

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

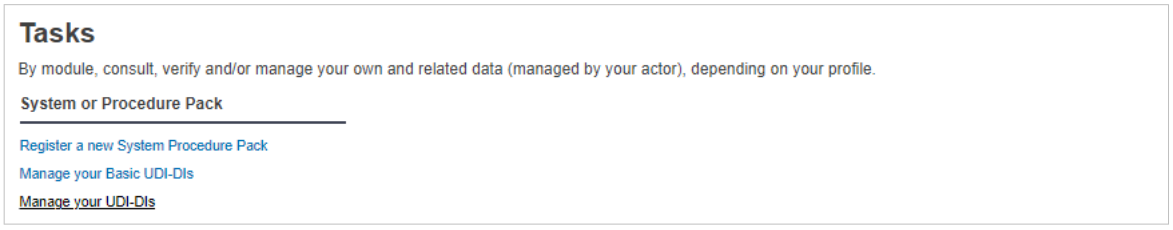


To return, click **Go back to the current version**:

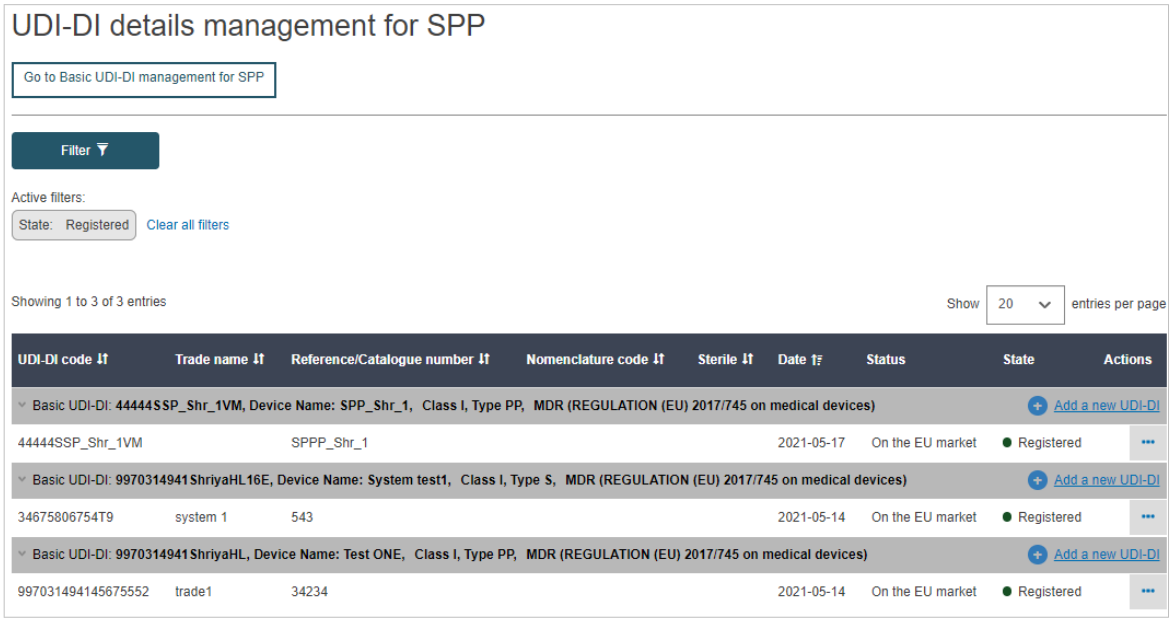


6.2 Manage your SPP UDI-DI details

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

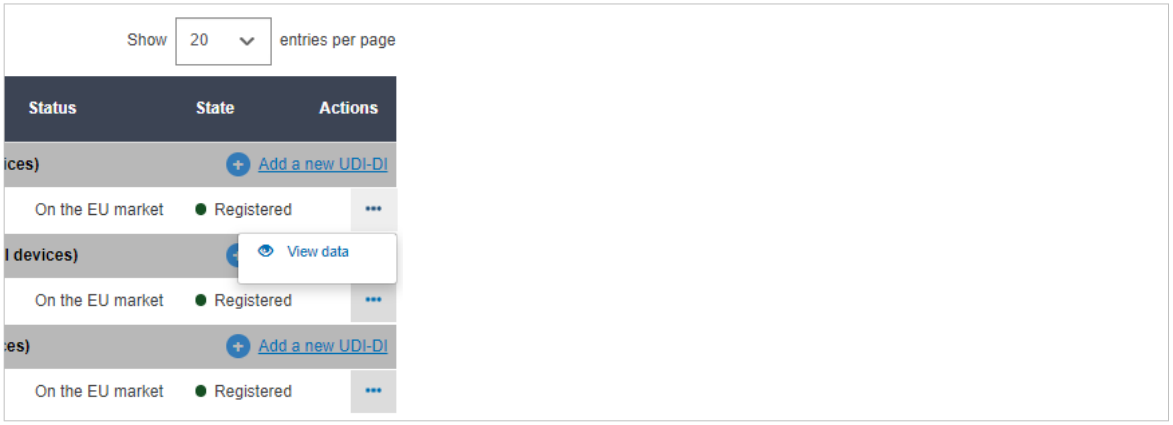


2. To find the relevant UDI-DI, click the **Filter** button and choose the right parameters:

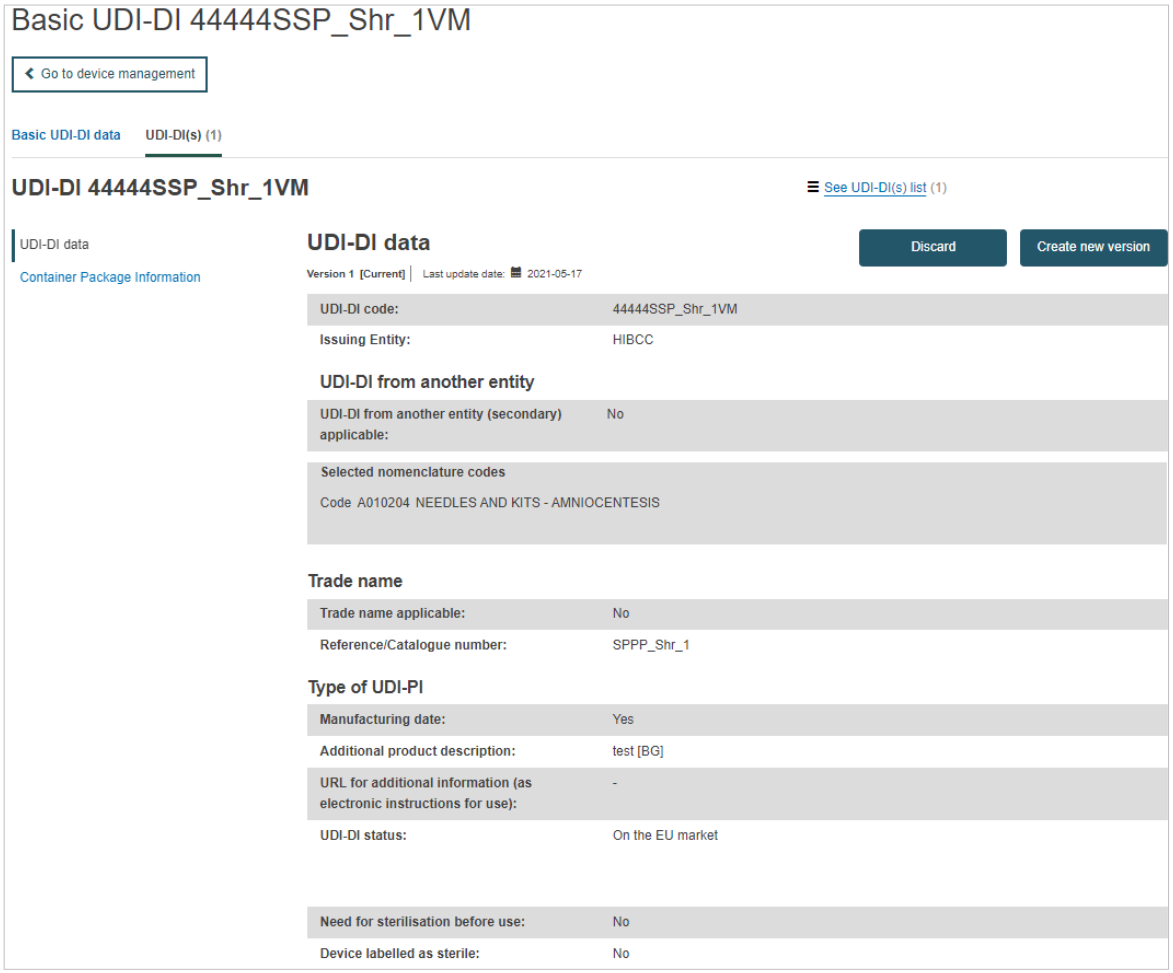


NOTE
By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in *draft* state. To retrieve other states, use the filters.

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



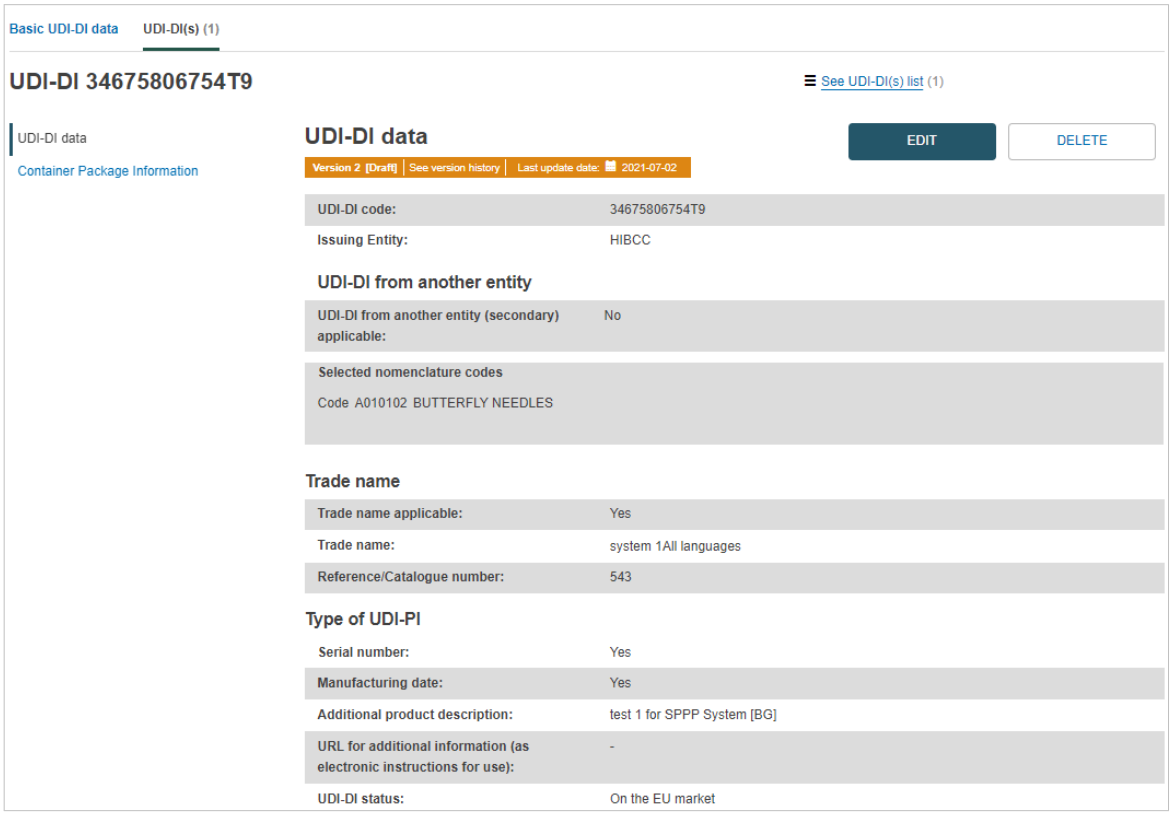
4. A summary of the details concerning your chosen SPP UDI-DI will be displayed:



6.2.1 Delete SPP draft UDI-DI

Follow the steps in section Manage your SPP UDI-DI details [90] to view a draft UDI-DI.

1. Once inside the draft, click **Delete**:

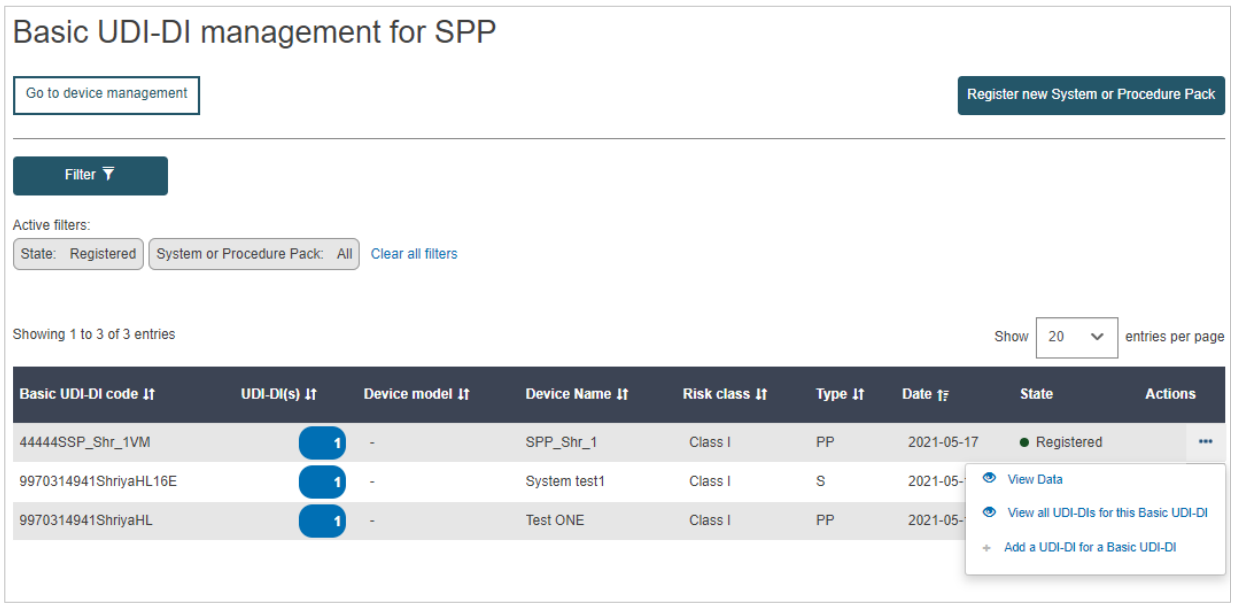


2. Confirm the deletion in the pop-up window:

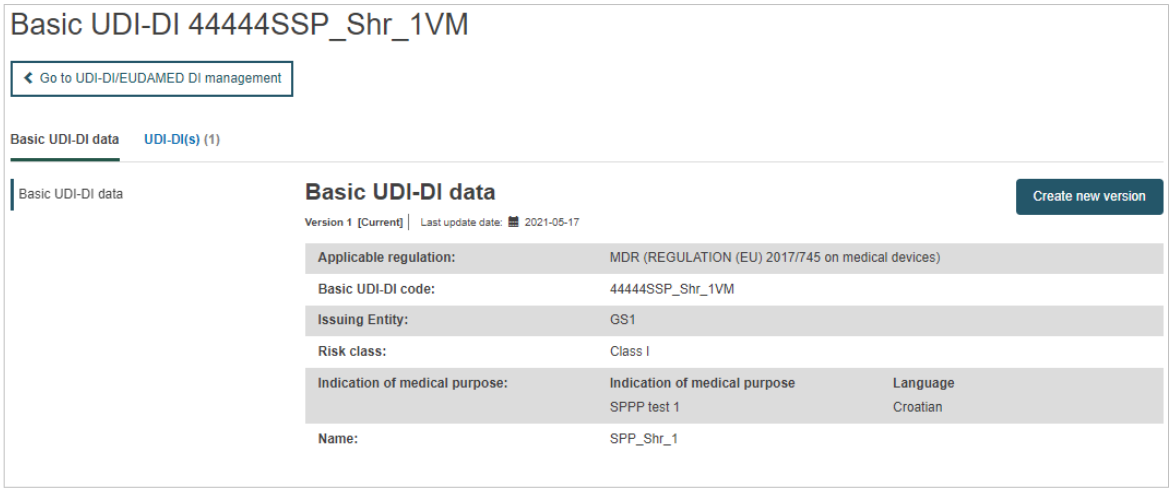


6.2.2 Update SPP UDI-DI

Follow the steps in Manage your SPP UDI-DI details [90] to view a UDI-DI:

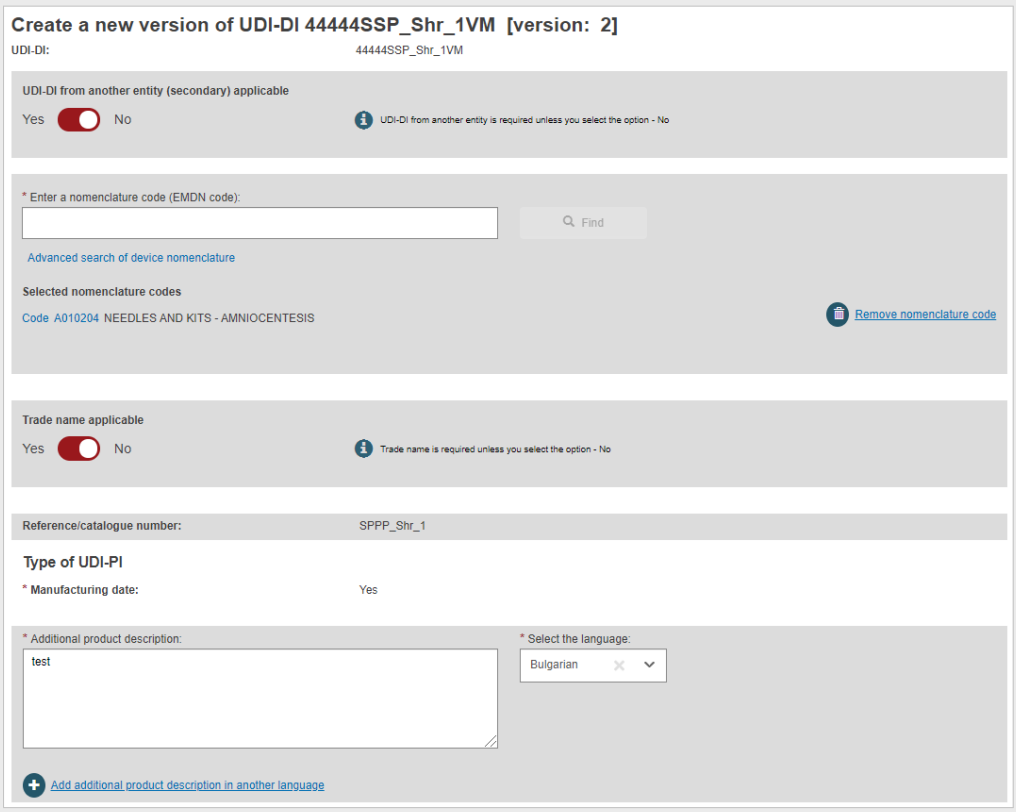


1. Once inside the details of the chosen UDI-DI, click **Create new version** at the top right corner:



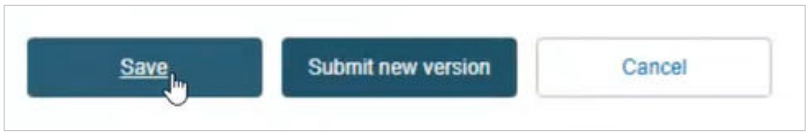
2. Update the necessary details.

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



3. To finish the action you have two options:
   - Click **Save** to save the updated details without submitting the new version.
   - Click **Submit new version**, if you wish to submit it.

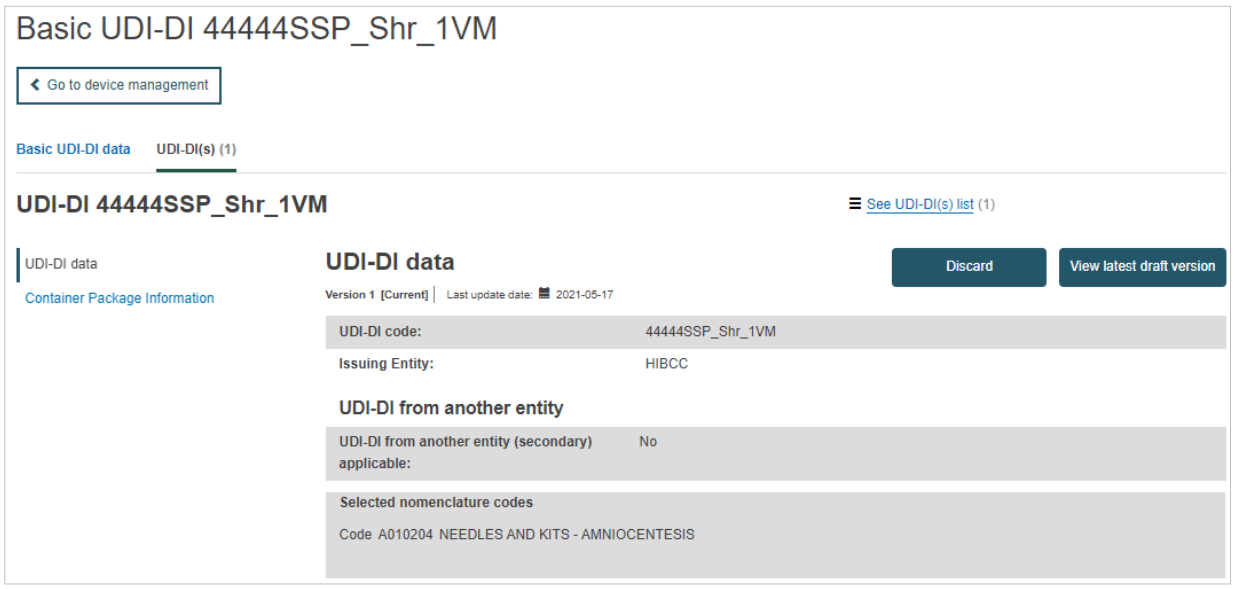
   Otherwise click **Cancel** to cancel the update.



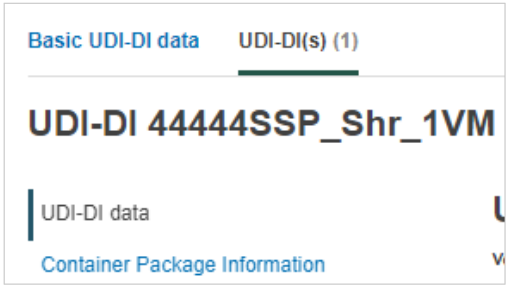
6.2.3 Update SPP Container Packages

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

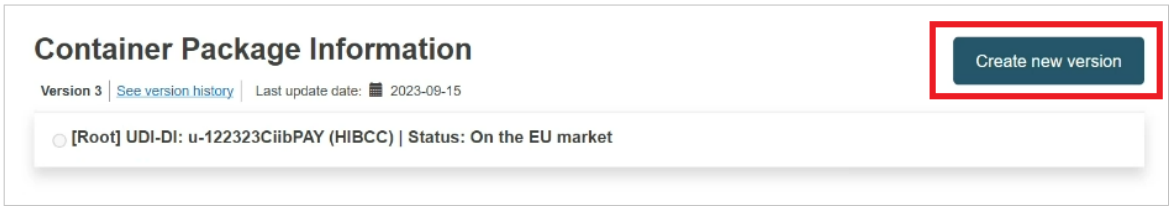
Follow the steps in section Manage your SPP UDI-DI details [90] to view a specific UDI-DI:



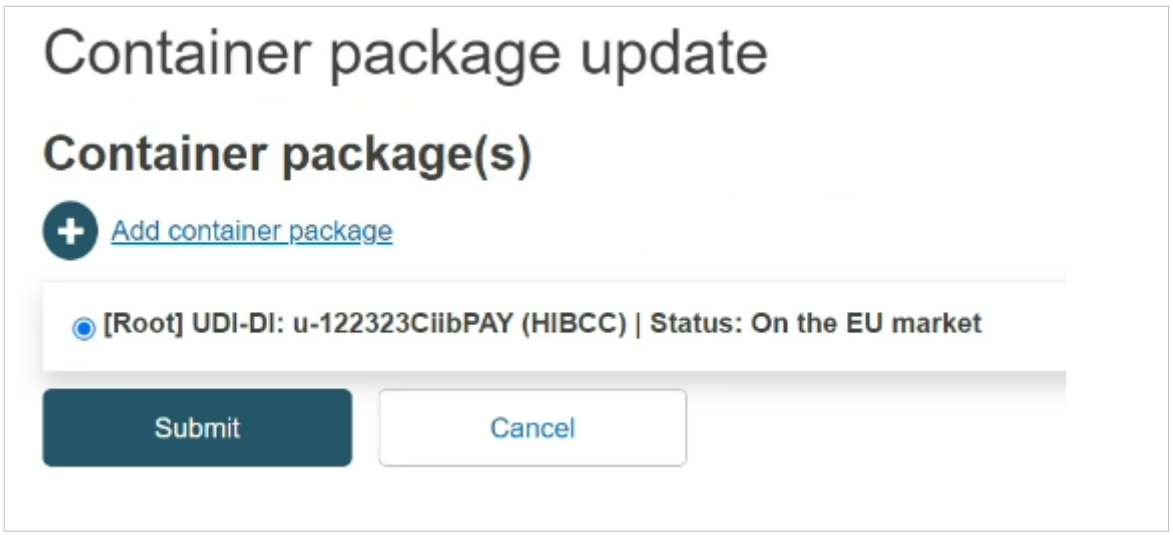
1. Click *Container Package information* from the list on the left (or scroll down to the relevant section):



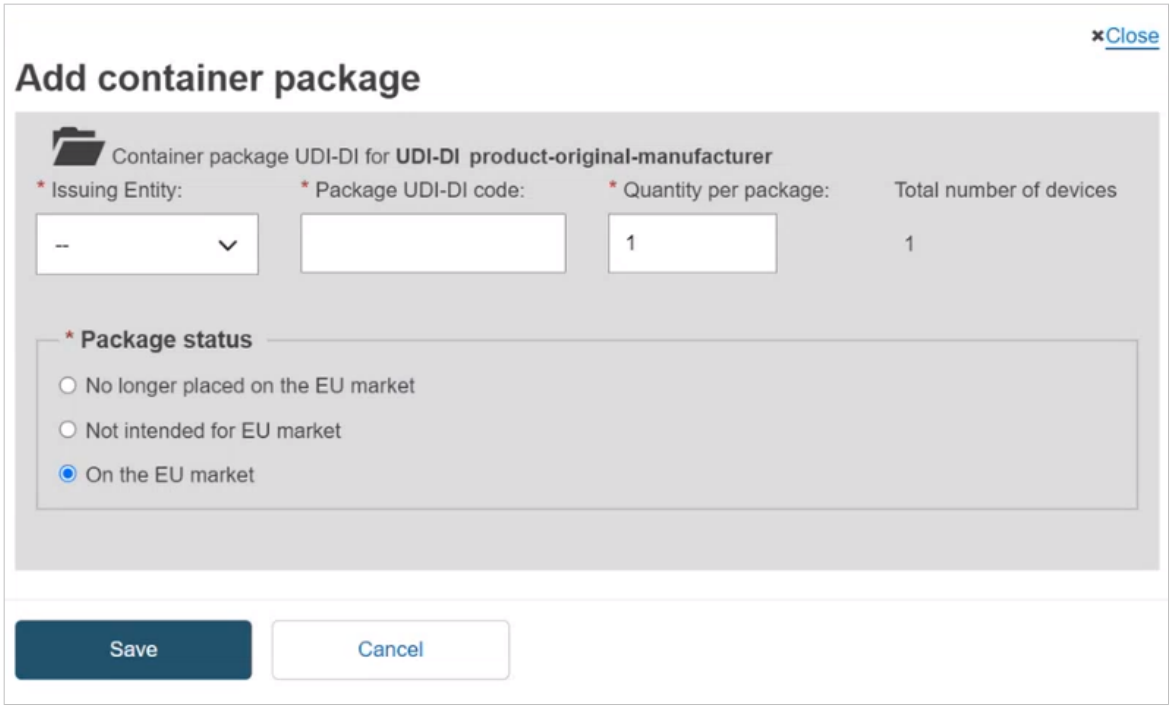
2. Click **Create new version** in the *Container Package* section:



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

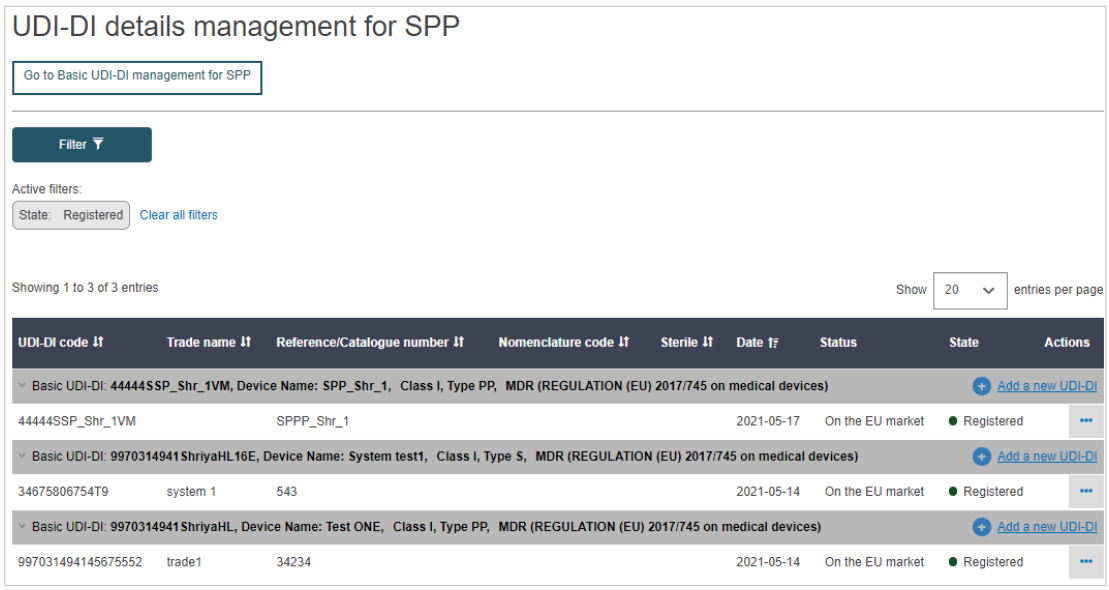


4. Insert the package details in the pop-up window and click **Save**:

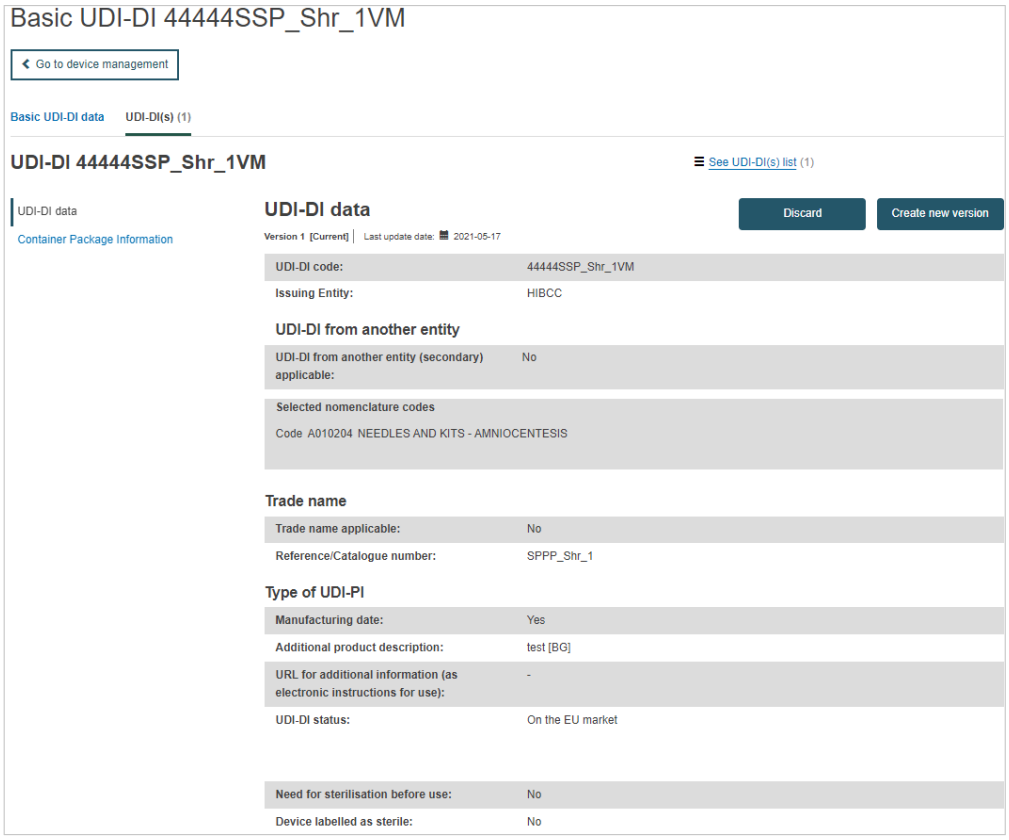


6.2.4 Discard SPP registered UDI-DIs

Follow the steps in section Manage your SPP UDI-DI details [90] to view a chosen Registered UDI-DI:



1. Once inside the *Details* page of the chosen UDI-DI, click **Discard** at the top right corner:





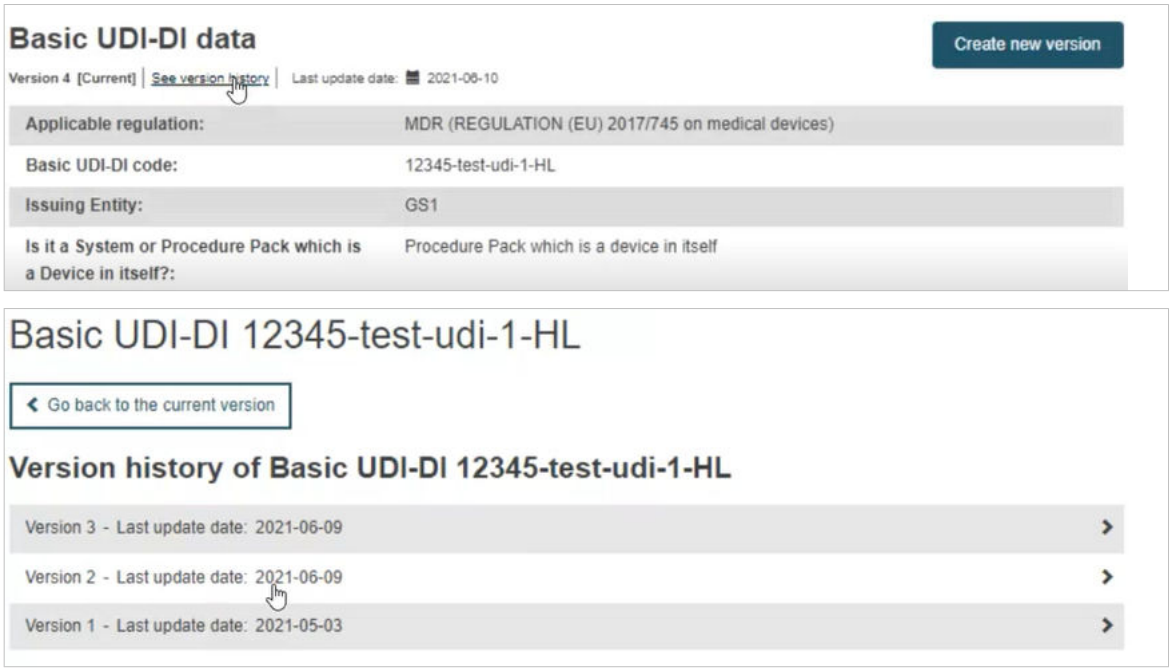
2. Confirm your intention to discard the record in the pop-up window:



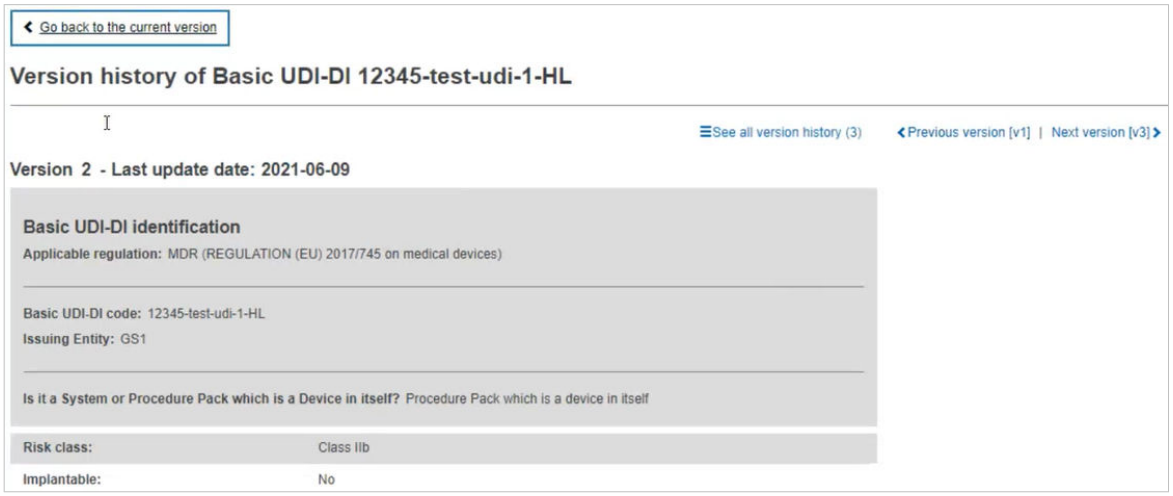
6.2.5 View SPP historical versions for UDI-DI and associated entities

Follow the steps in section *Manage your SPP UDI-DI details* [90] to view a UDI-DI for the SPP.

1. Once inside the details of the chosen UDI-DI, click *See version history* at the top of the table to view a list of all past versions:



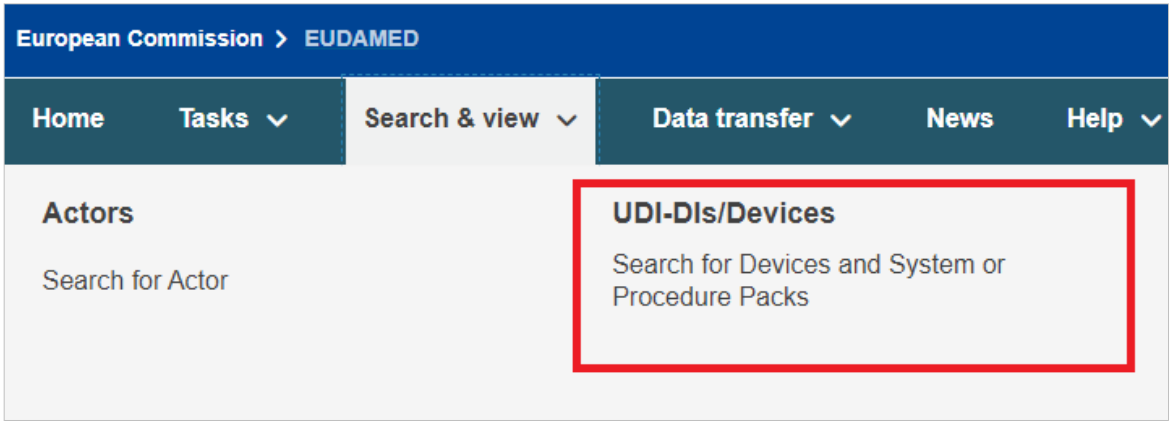
2. Click on the version you wish to access to view its detailed summary:



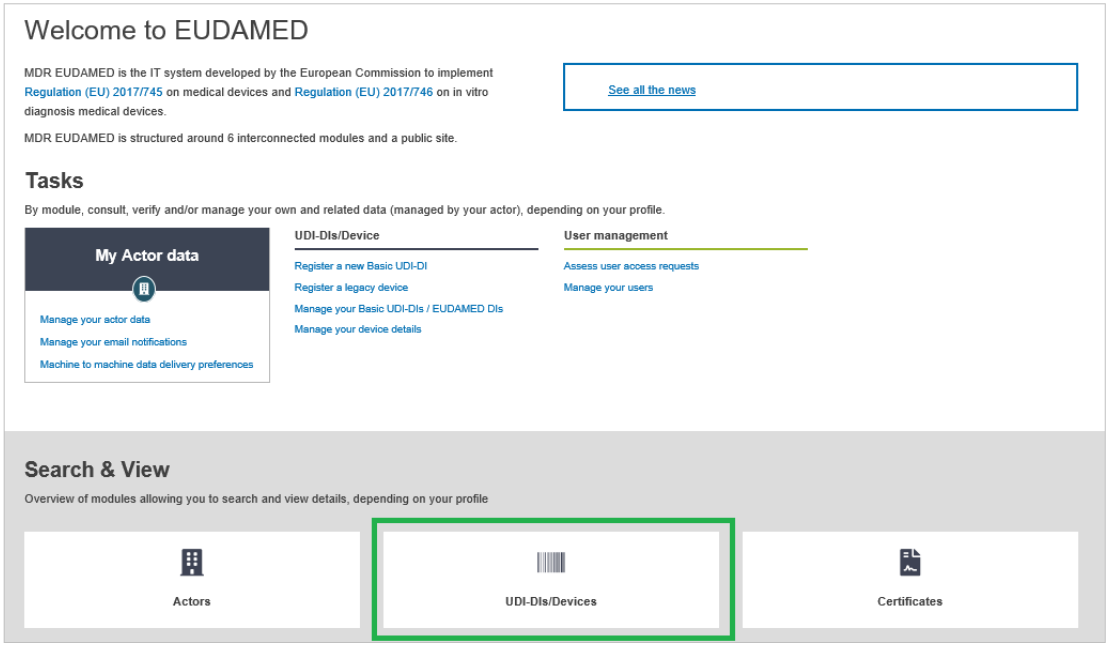
You can return to the version history list by clicking on *See all version history* at the top right corner.

7 Search & View Devices and Systems or Procedure Packs

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



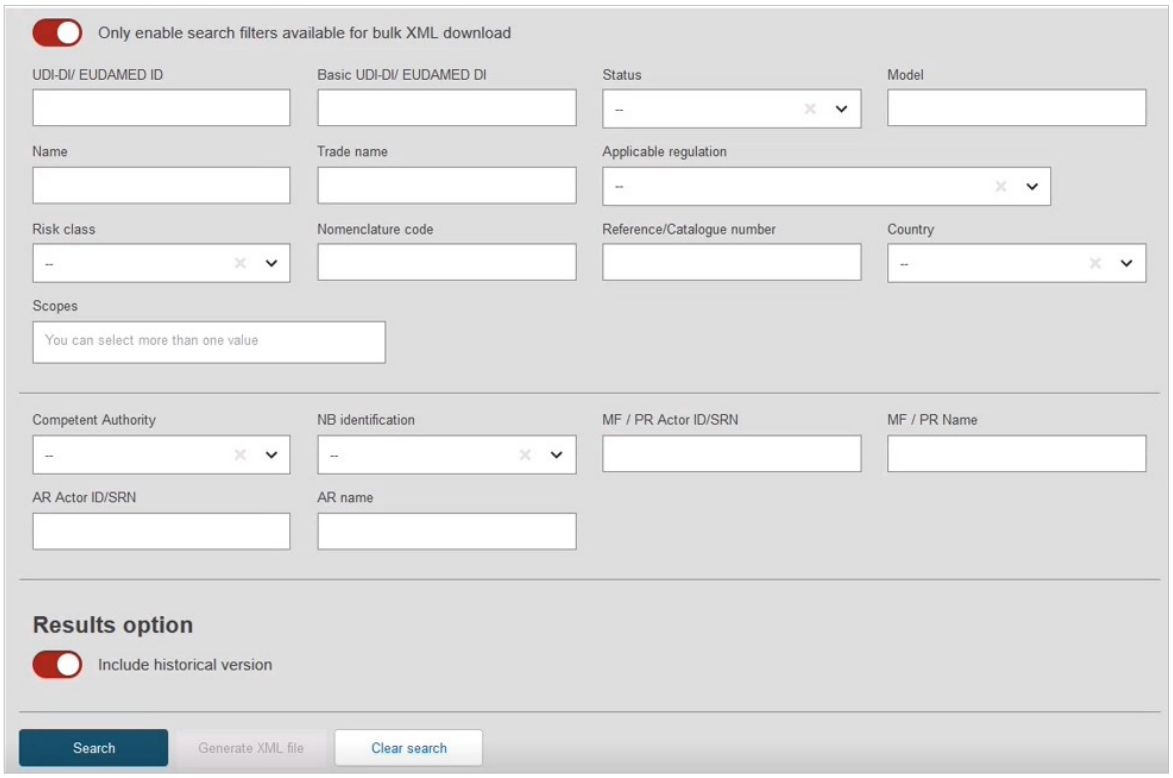
Alternatively, use the *Search & View* option available on the dashboard:



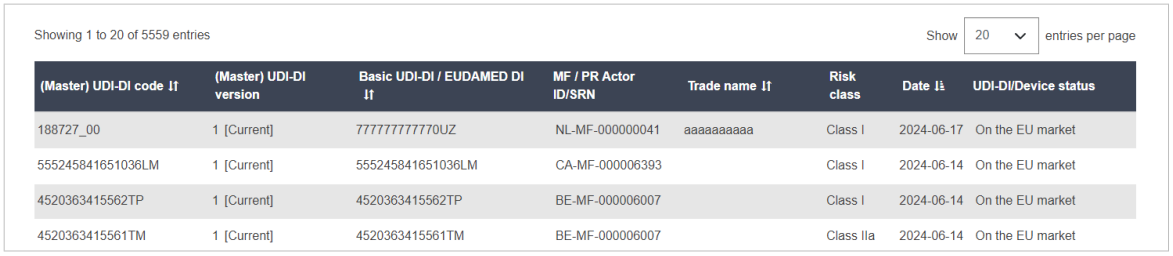
NOTE

Search and view can be accessed by all users, regardless of profile. It is possible to search and view device and SPP data from all actors in EUDAMED.

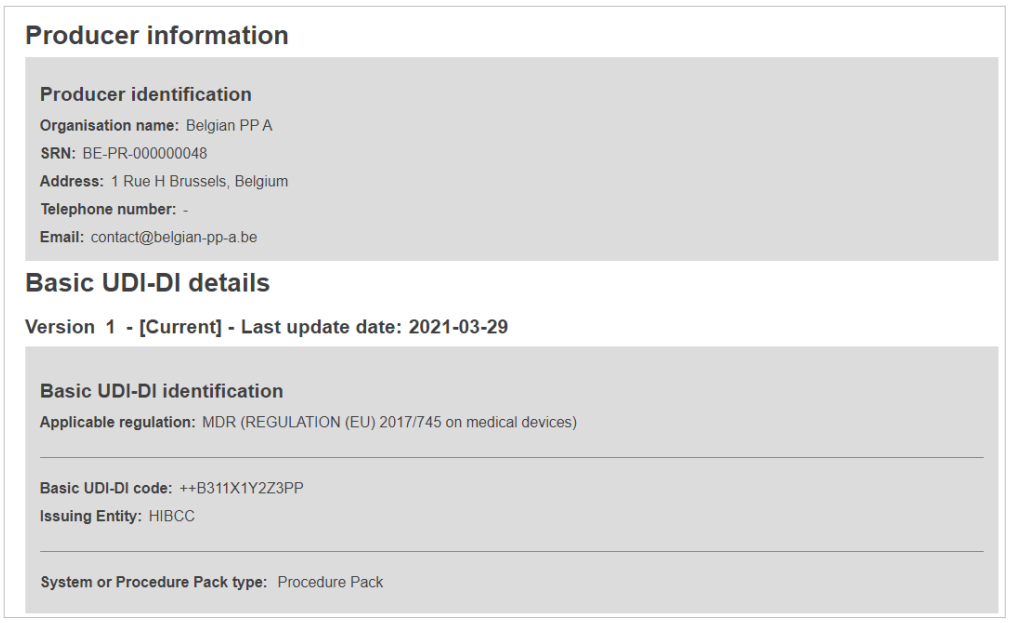
2. You can use the filters to search for *Devices*, *Systems* and/or *Procedure Packs (SPP) registered* in EUDAMED, or, in the case of Competent Authorities and Notified Bodies, those *submitted* or *discarded*:



3. Once you have entered your search filters, click **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):



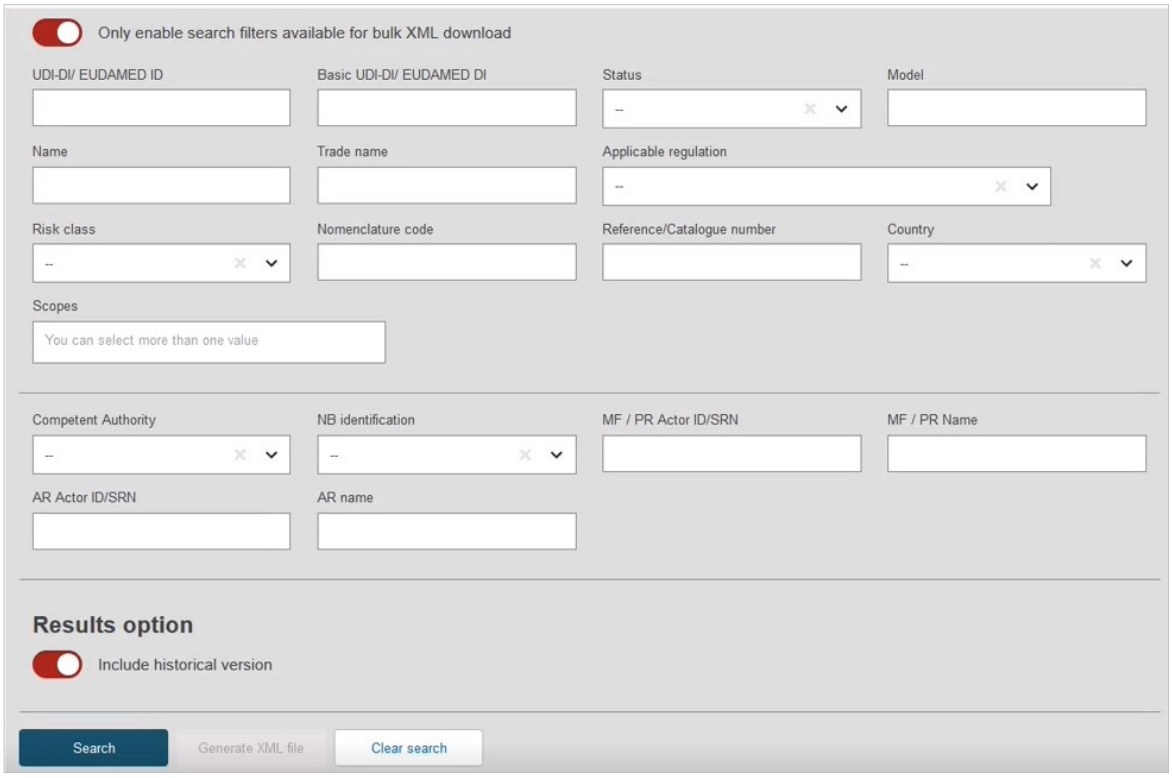
4. Click on the UDI-DI/EUDAMED ID row of your choice to see the details:



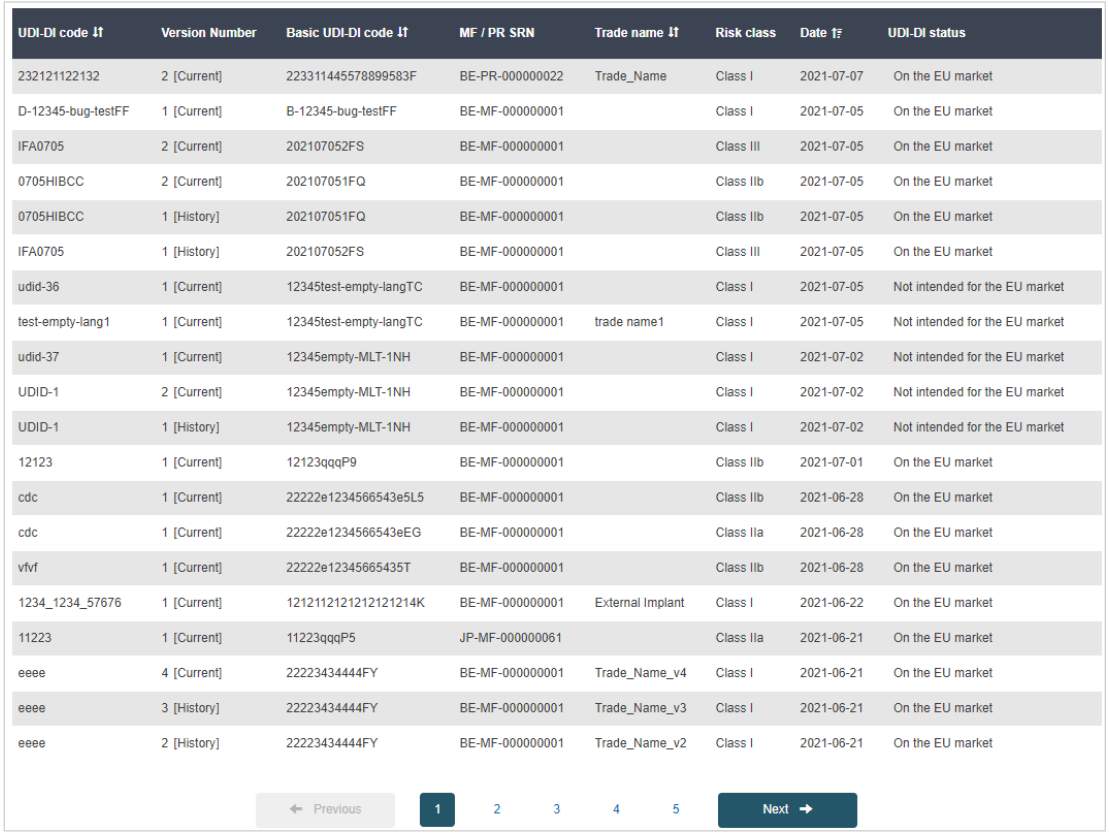
7.1 Search & View historical versions of Devices or SPPs

Follow the steps in Search & View Devices, Systems and/or Procedure Packs [99] to search and view a Device or System or Procedure Pack.

1. 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 **Search**:



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



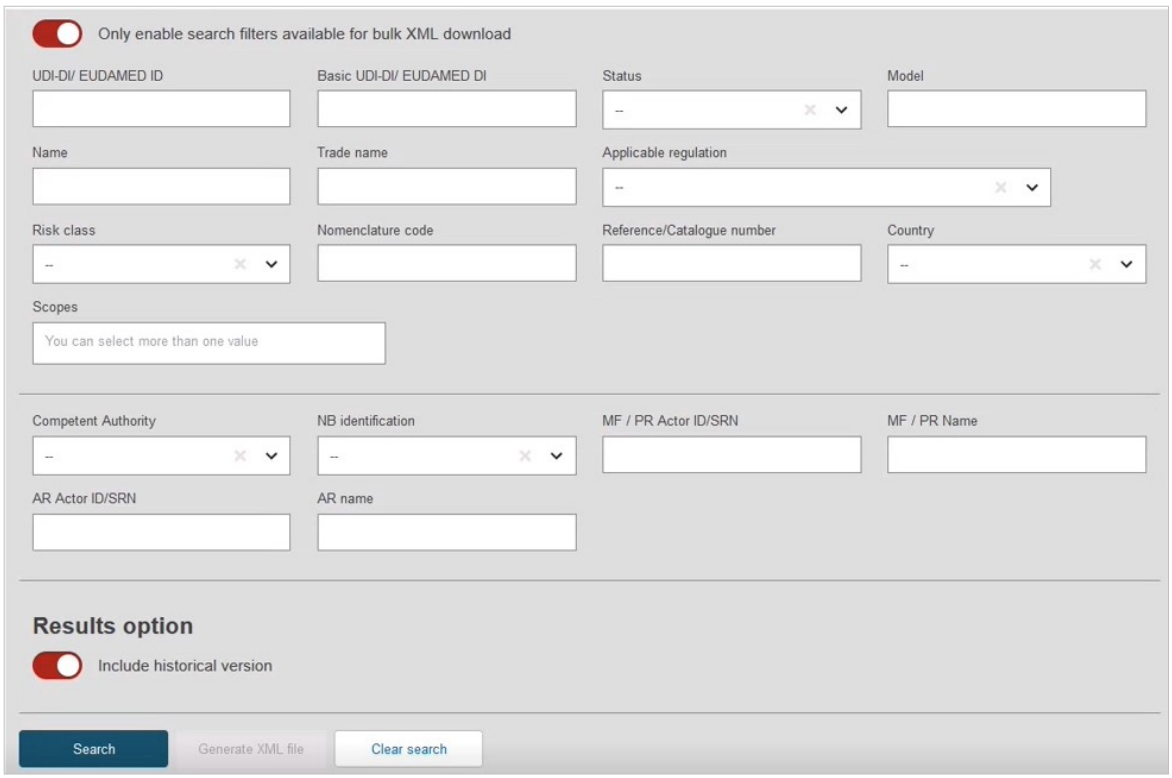
UDI-DI code	Version Number	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
232121122132	2 [Current]	2233114455788995 83F	BE-PR-000000022	Trade_Name	Class I	2021-07-07	On the EU market
D-12345-bug-testFF	1 [Current]	B-12345-bug-testFF	BE-MF-000000001		Class I	2021-07-05	On the EU 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

7.2 Download Devices or SPPs 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.

Follow the steps in Search & View Devices, Systems and/or Procedure Packs [99] to search and view a device or a system or procedure pack.

1. On the *Search* page, activate the top filter (**Only enable search filters available for bulk XML download**) and enter your search criteria.
   Enter the search criteria of your choice, and click **Search**:



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

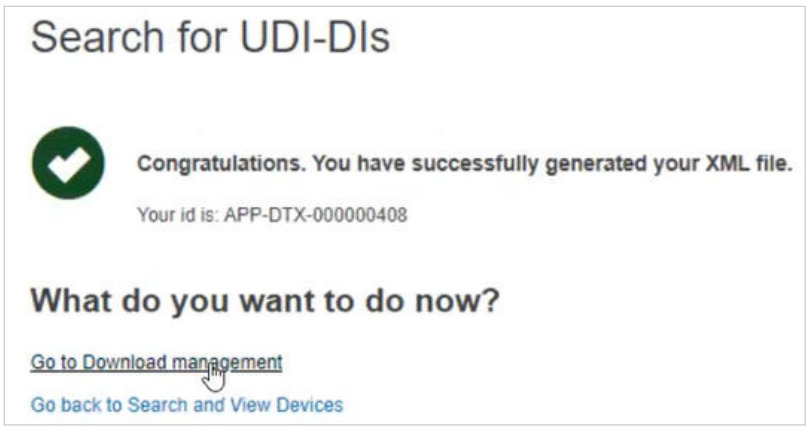


NOTE
Only what is shown on the result list will be included in the generated file and not all the results of your search. If the search yields multiple pages of results, you will need to download an XML file for each page to capture all the data.

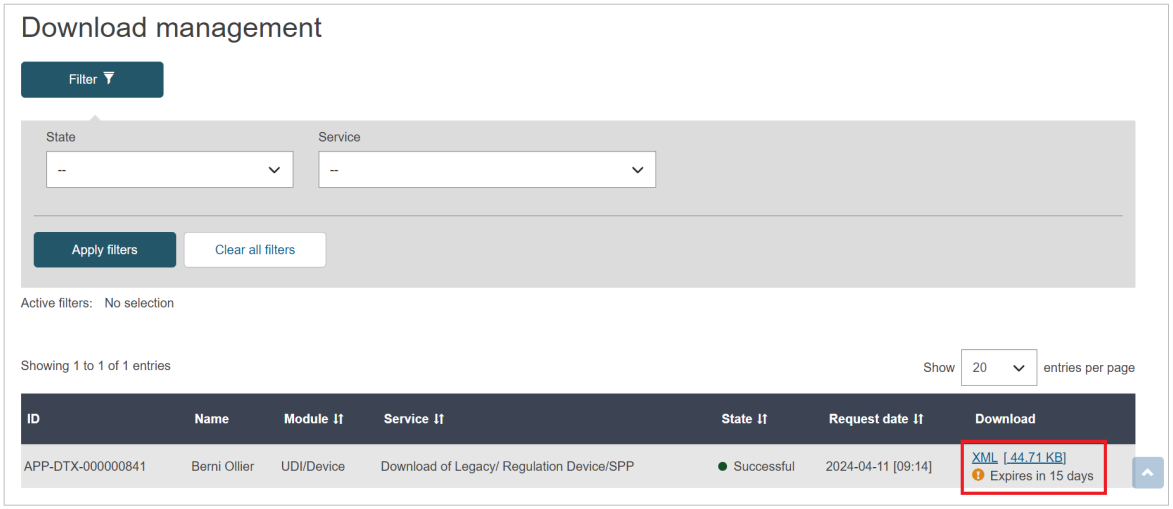
3. Confirm your action in the pop-up window:



4. The system will display a success message. Click **Go to Download Management** under the question *What do you want to do now?*:



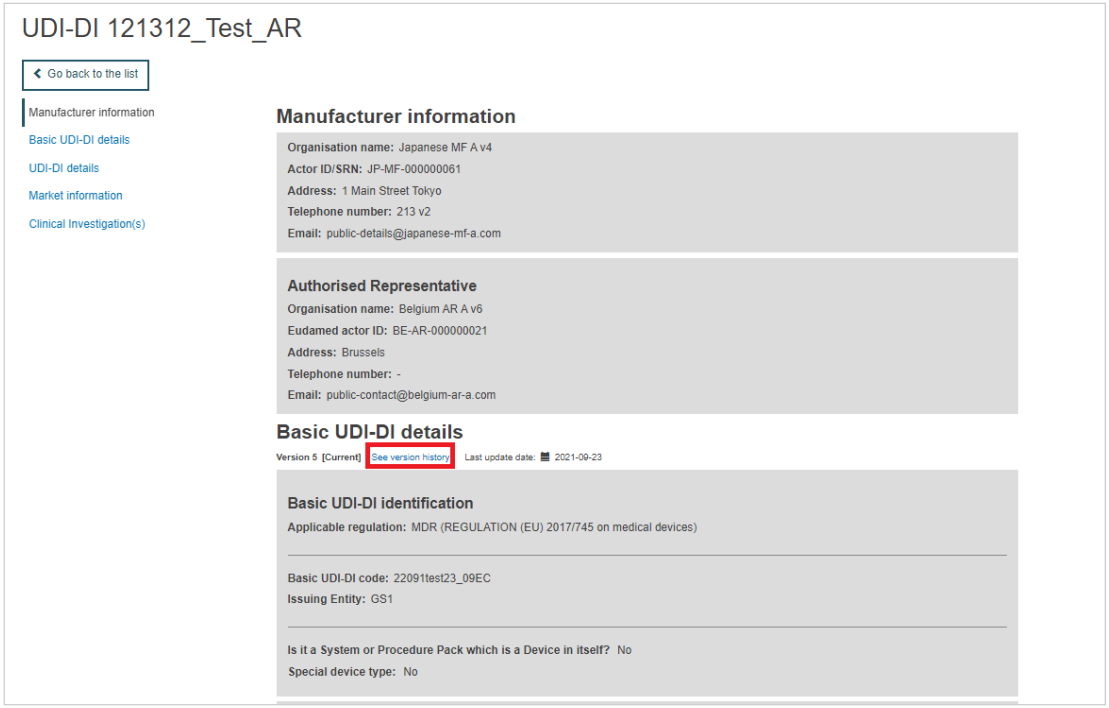
5. You can download the generated XML file by clicking on it under the **Download** column:

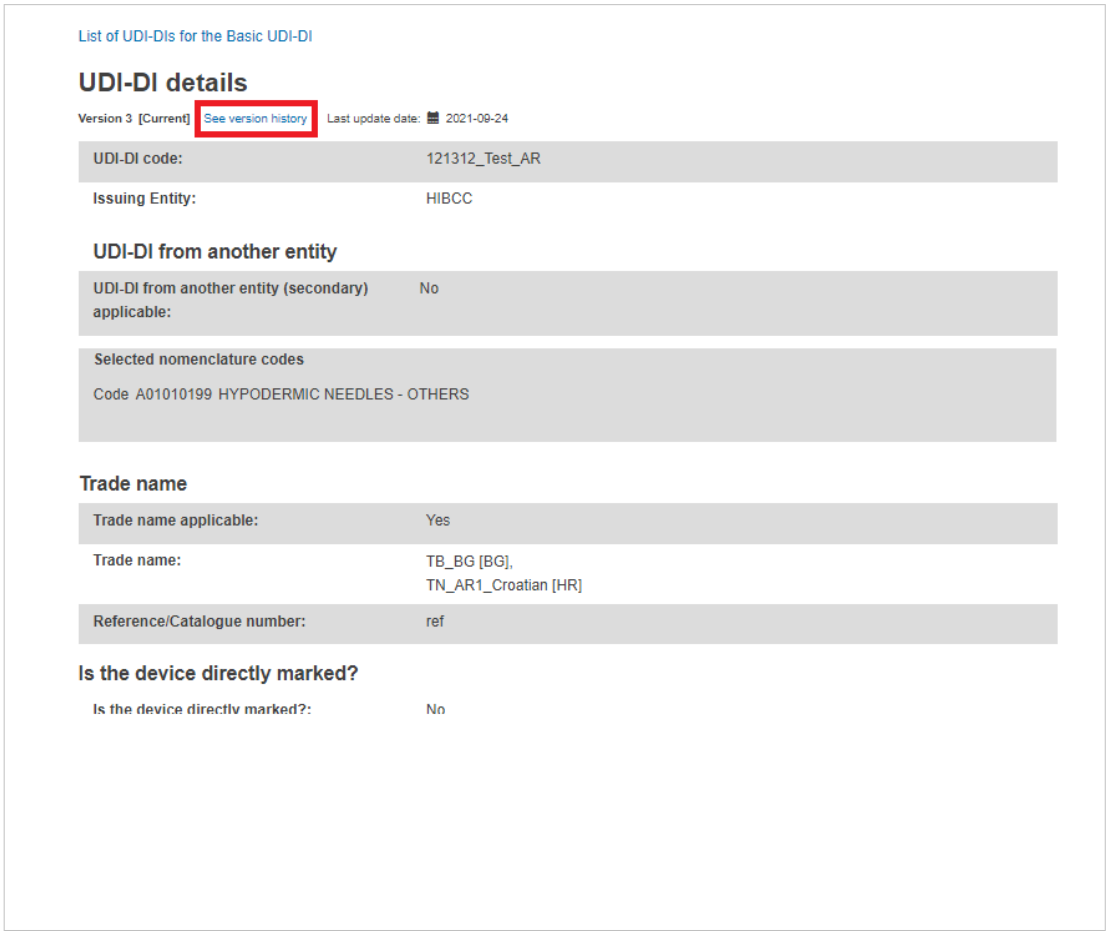


7.3 View historical versions of Basic UDI-DI/EUDAMED DI, UDI-DI/EUDAMED ID and associated entities

Follow the steps in Search & View historical versions of Devices, System and/or Procedure Packs [101] to view the details of a Device or System or Procedure Pack.

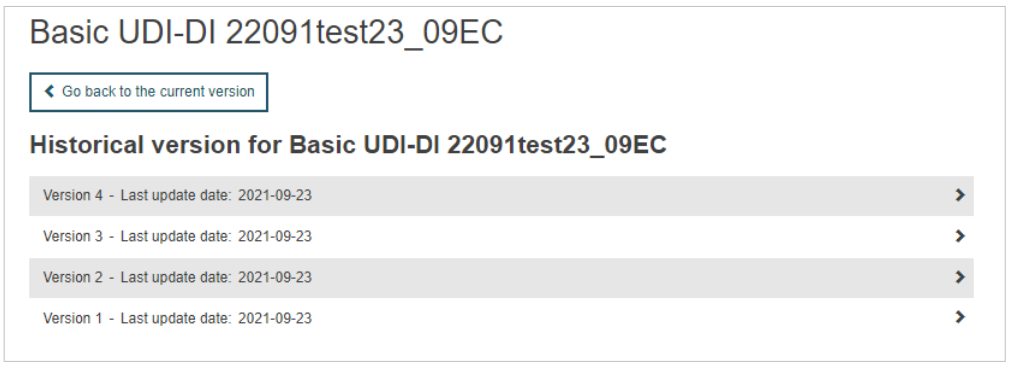
1. Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product original manufacturer or Container Package) and click on *See version history*:


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

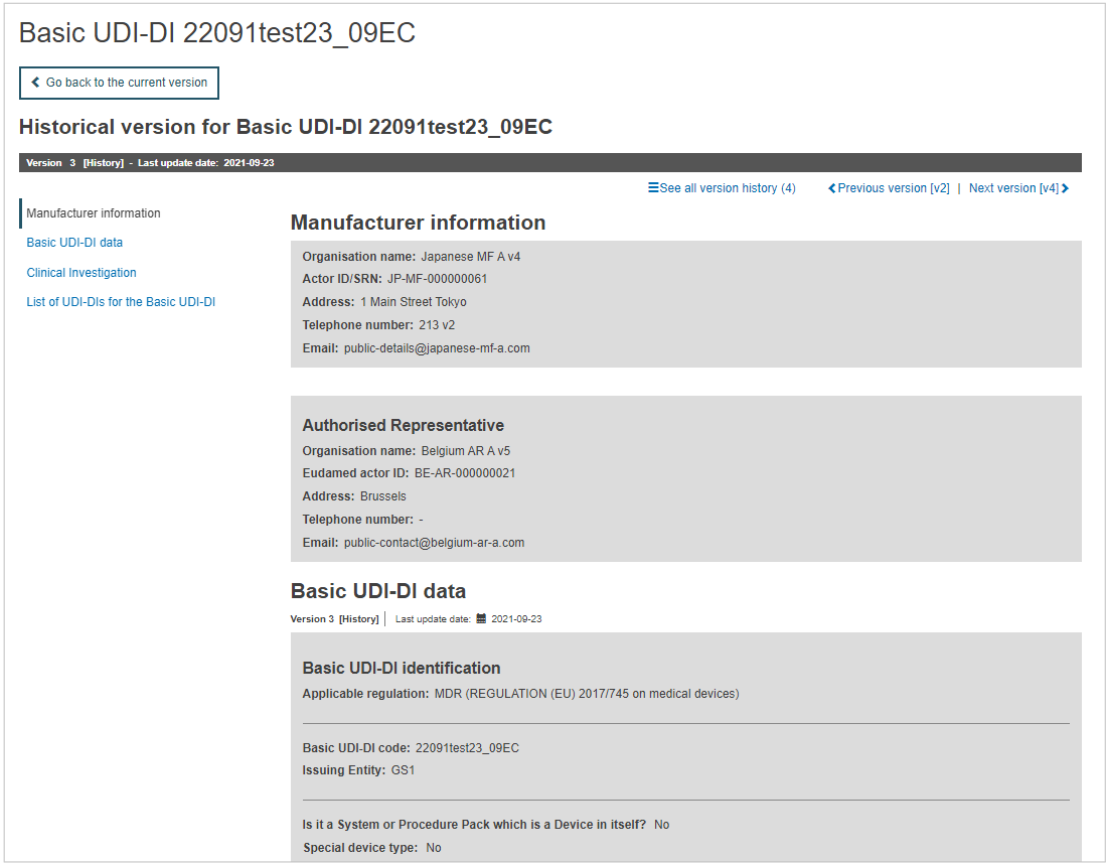

List of UDI-DIs for the Basic UDI-DI
UDI-DI details
Version 3 [Current] See version history Last update date: 2021-09-24
UDI-DI code: 121312_Test_AR
Issuing Entity: HIBCC
UDI-DI from another entity
UDI-DI from another entity (secondary) applicable: No
Selected nomenclature codes
Code A01010199 HYPODERMIC 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



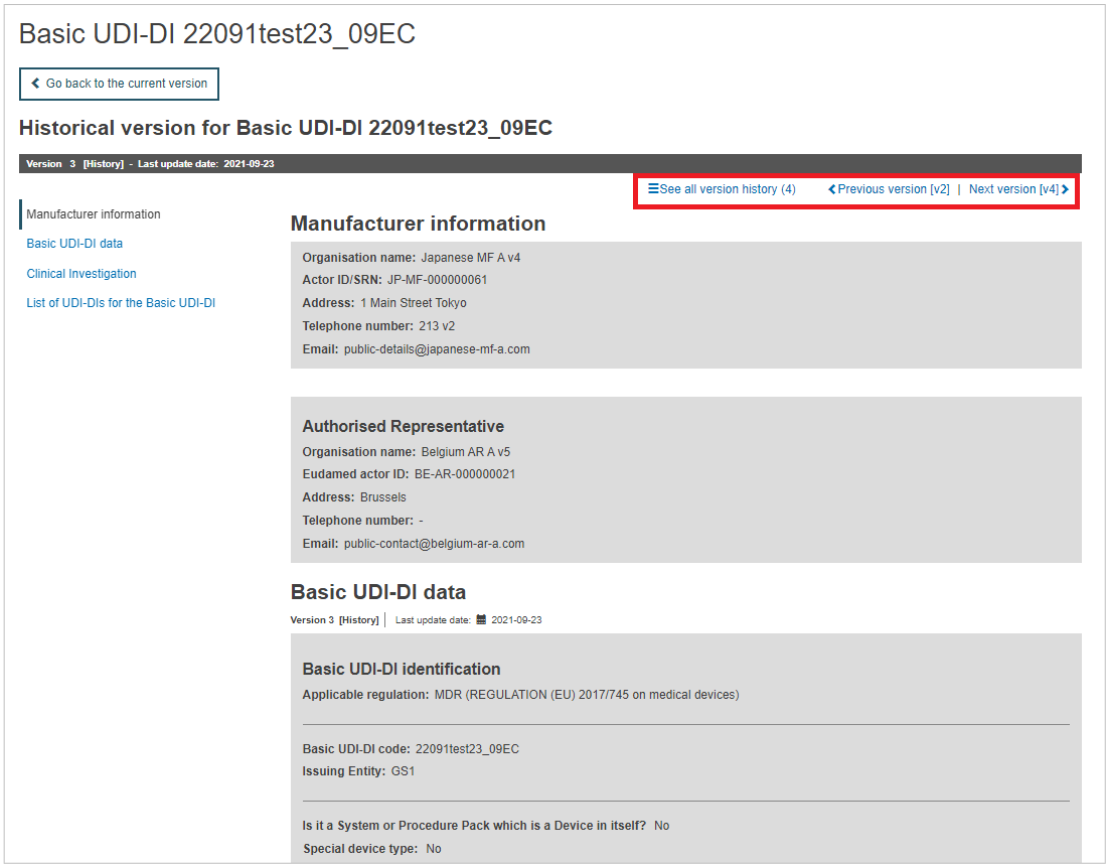
2. You will see, if any, a list of all old versions for the selected entity, e.g. version history of the Basic UDI-DI:



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



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



8 Annex – 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 to be provided based on the properties of the device.

The updated versions of the tables below can also be consulted here: Notified Bodies and Certificates module - Documentation

IVDR Conformity assessments table

IVD: Device class & Certificate type		EU QMS Device or Group	EU TDA Device	EU TE Device	EU PQA Device or Group
Class D		✓ (NB)	✓(NB, SSP, scrutiny)		
				✓ (SSP, scrutiny)	✓
Class C	Self/near patient testing devices	✓(NB)	✓(NB, SSP)		
				✓ (SSP)	✓
	Companion diagnostics	✓(NB)	✓(NB, SSP)		
				✓ (SSP)	✓
	All other class C devices	✓ (SSP)			
				✓ (SSP)	✓
Class B	Self/near patient testing devices	✓(NB)	✓(NB)		
	All other class B devices	✓			
A sterile		✓			
					✓

29.3 par #1: MF assigns a Basic UDI-DI before it applies to a NB
29.3 par #2: NB confirms the concerned device data in registering the certificate in Eudamed.
As a pre-requisite the MF provides the NB identification and certificate type information with submission of Basic UDI-DI data in Eudamed.
(NB) = Same NB carries the conformity assessments.

MDR Conformity assessments table

MDR: Applicable conformity assessments per device class (and characteristics of the device class) Each line represents a different path for assessing the conformity of a device.			**EU QMS** (scope is defined using devices and/or device groups)	**EU TDA** (certificate scope is defined using devices)	**EU TE** (certificate scope is defined using devices)	**EU QA** (scope is defined using devices and/or device groups)	**EU PV** (certificate scope is defined using devices)
III	Implantable		✓ (NB)	✓ (NB, CECP, SSCP)			
					✓ (CECP, SSCP)	✓	
					✓ (CECP, SSCP)		✓
	Non implantable		✓ (NB)	✓ (NB, SSCP)			
					✓ (SSCP)	✓	
					✓ (SSCP)		✓
IIb	IIb implantable	NON sutures/staples/dental fillings/…	✓ (NB)	✓ (NB, SSCP)			
					✓ (SSCP)	✓	
					✓ (SSCP)		✓
		sutures/staples/dental fillings/…	✓ (SSCP)	sample/generic device group			
					✓ (SSCP)	✓	
					✓ (SSCP)		✓
	IIb non implantable	- Active devices intended to administer and/or remove a medicinal product	✓ (CECP)	sample/generic device group			
					✓ (CECP)	✓	
					✓ (CECP)		✓
		- Non active devices - Active devices NOT intended to administer and/or remove a medicinal product	✓	sample/generic device group			
					✓	✓	
					✓		✓
IIa	Implantable		✓ (SSCP)	sample/device category			
						✓ (SSCP)	
							✓ (SSCP)
	Non implantable		✓	sample/device category			
						✓	
							✓
I sterile condition/measuring function/reusable surgical instrument)			✓				
						✓	
III custom-made implantable (a certificate is needed only for impantable devices)			✓				
						✓	
System/Procedure pack (SPP sterilisation)			✓			✓	

29.3 par #1: MF assigns a Basic UDI-DI before it applies to a NB

29.3 par #2: NB confirms the concerned device data in registering the certificate in Eudamed. As a pre-requisite the MF provides the certificate identification information with submission of Basic UDI-DI data in Eudamed.

Devices that may require a CECP for a QMS certificate (in case there is no EU TDA certificate or EU Type examination certificate)

CECP could apply from MDR but it was agreed that CECP is never to be applied for custom-made devices

(NB) = Same NB carries the conformity assessments.

(CECP) = Should requires a CECP

SSCP is required for implantable and class III devices. If the device needs both a product and a quality certificate then the SSCP is only uploaded with the product certificate.


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