UDI/DEVICES USER GUIDE

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DG SANTE

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1.Introduction

The new MDR 2017/745 and IVDR 2017/746 EU regulations introduce an EU identification system for medical devices based on a Unique Device Identifier (UDI) and require that manufacturers of medical devices submit the UDI/Device information of all devices/products that they place on the market.

The UDI-DI/Device module of EUDAMED is used for this purpose.

MDR 2017/745 further states that '*Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack*'. EUDAMED allows system or procedure pack producers to register their packs in a similar manner as manufacturers register their devices.

A step-by-step wizard will guide you through the respective registration processes. Please make sure that you understand all concepts and have all information at hand before starting to register a new UDI/device or a system or procedure pack.

1.1. Basic Concepts

The UDI (Unique Device Identification) system is a new feature introduced by the MDR 2017/745 and IVDR 2017/746 EU regulations. It will improve the traceability of medical devices, enhance post-market safety-related activities and allow for better monitoring by competent authorities.

- **BASIC UDI-DI**
  This is the main access key for device-related information in the EUDAMED database. It is referenced in various other documents [e.g. certificates (including certificate of free sale), EU declaration of conformity, technical documentation and summary of safety and (clinical) performance)]. All devices with the same Basic UDI-DI share the same core characteristics such as intended purpose, risk class, essential design and manufacturing characteristics. The Basic UDI-DI information entered in EUDAMED includes this core information plus a unique Basic UDI-DI code issued by an officially designated issuing entity. It is independent/separate from the packaging/labelling of the device and does not appear on any trade item.

- **UDI-DI**
  The UDI is the *main* identifier of a medical device used on its label. It identifies the specific device within a given product family. The UDI-DI is a numeric or alphanumeric code relating to a medical device.

- ***(PACKAGE UDI-DI)***
  If applicable, each device may have an additional, higher-level UDI-DI assigned to its higher package. Package UDI-DIs identify each package configuration, including quantities of items at each package level.

A Basic UDI-DI always references at least one UDI-DI, while multiple UDI-DIs can be referencing the same Basic UDI-DI.

Legacy Devices

Legacy devices are defined as medical devices, active implantable medical devices and in vitro diagnostic medical devices - covered by a valid Directive certificate - that will continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR). Legacy devices shall be registered in some cases in EUDAMED without a Basic UDI-DI and without a UDI-DI.

A Legacy Device has to have an assigned EUDAMED DI (instead of a Basic UDI-DI), and in some cases (when no UDI-DI was already assigned) a EUDAMED ID (instead of the UDI-DI), and has to be registered in the 'UDI/Device module' of EUDAMED, allowing EUDAMED to work as close as possible like Regulation Devices.

- **EUDAMED DI**
  The EUDAMED DI corresponds to the Basic UDI-DI. It can either be entirely generated by EUDAMED if a UDI-DI has already been assigned to the legacy device, or the DI code can be partly assigned by the manufacturer (EUDAMED is the issuing entity for a EUDAMED DI)

- **EUDAMED ID**
  The EUDAMED ID corresponds to the UDI-DI. In case a UDI-DI has not already been assigned, the EUDAMED ID will always be automatically and fully generated by EUDAMED from the EUDAMED DI.

2.Getting Started

Prerequisites to access EUDAMED:

EU Login (ECAS) account

If you do not have an EU account, please follow the instructions for creating an account and requesting access from the competent authority before attempting to use the database.

For information on how to gain access to EUDAMED, please consult the User's Guide for Economic Operators available for download on the EUDAMED Playground.

Every user in EUDAMED is granted the profile "Viewer" and can search and view registered devices. In order to register a device in EUDAMED, you must request access to the Device module as:

- A "Proposer" profile may create and delete draft records in the Device module
- A "Confirmer" profile may also submit and discard records in the Device module

If you have already registered as a user in EUDAMED prior to the release of this version, in order to create and submit records you must submit a profile change request to upgrade your user profile in the Device module to "Proposer" or "Confirmer".

Important: The Local Actor Administrator (LAA) must approve your user access request before you may enter any devices for your actor. As a user cannot approve their own profile change requests, these requests must be approved by a **different** Local Actor/User Administrator.

Before you start entering details of a UDI/device in EUDAMED, please make sure that you have all requested information at hand, including the Basic UDI-DI and UDI-DI codes.

3.Registering Regulation Devices

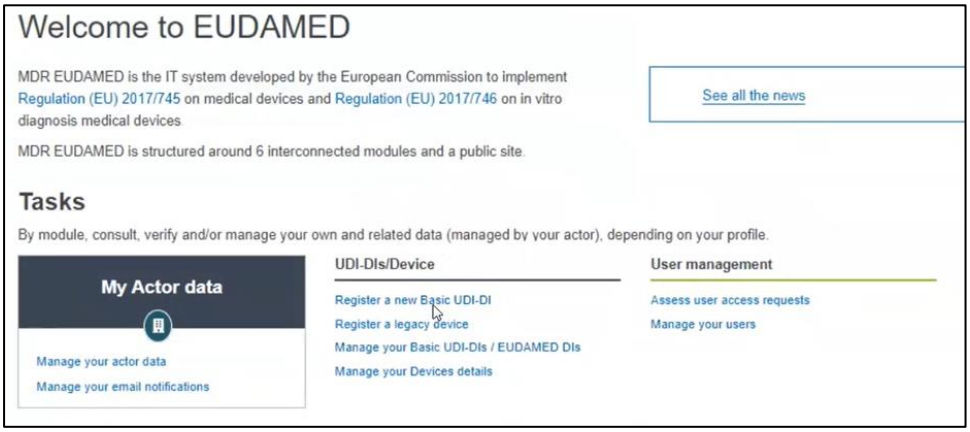
Click on the following link to arrive to EUDAMED Playground:
https://webgate.training.ec.europa.eu/eudamed-play/.

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

3.1. Registration of Basic UDI-DI together with the first UDI-DI

3.1.1 Step 1: Basic UDI-DI identification information

1. Start by clicking on “Register a new Basic UDI-DI”:



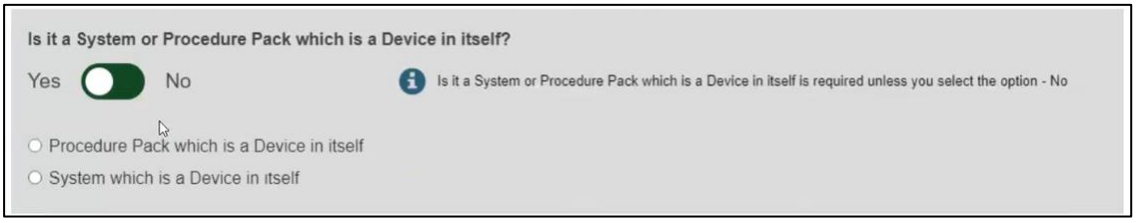
2. On the next page, you may start entering the Basic UDI-DI information for your device. Select the applicable legislation for your Basic UDI-DI, from the two following options:

Note: For the rest of the procedure, we will assume in this quick user guide that you have selected MDR (Regulation (EU) 2017/745).

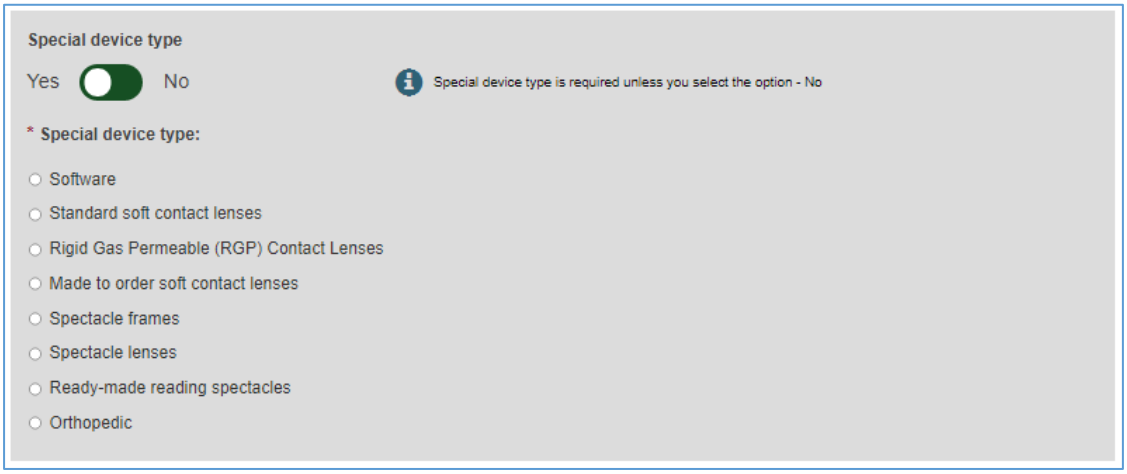
Note: Based on the selected Applicable Legislation, the set of properties (characteristics of the Device) that may be entered will vary.

An additional question appears at the bottom of the page depending on the regulation that you have selected i.e.:

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 you answer '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



Select the correct configuration. If you select “No”, indicating that you are entering a device, prompts for further details about the device (Special Device type) will appear:



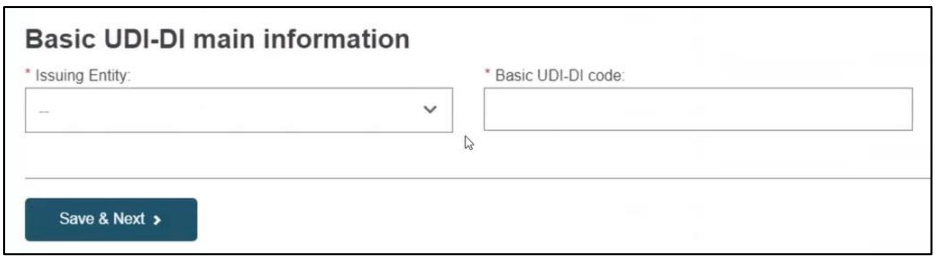
Note :

Registration of Devices having as Device one of the following Special Device types : Standard soft contact lenses, Rigid Gas Permeable (RGP) Contact Lenses, Made to order soft contact lenses, Spectacle frames, Spectacle lenses or Ready-made reading spectacles , is not possible in the current phase.

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

Important: EUDAMED will perform a validation for the Basic UDI-DI code provided based on the specific format provided by each Issuing Entity. Please ensure that you provide the correct value.

Basic UDI-DI duplicates cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value.

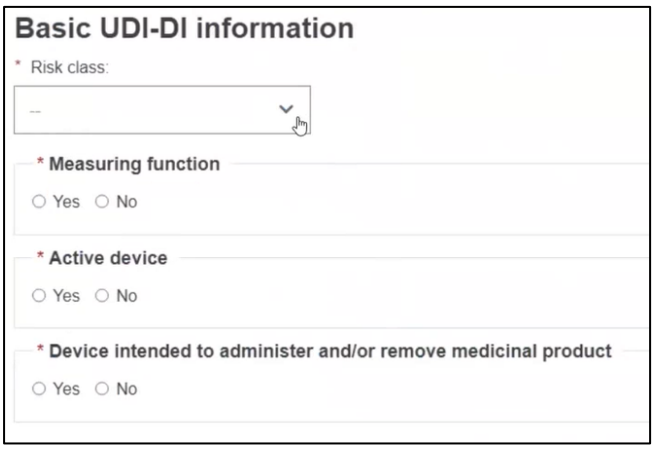


4. Select the authorised representative for the current device (Basic UDI-DI) from the options available (applicable only in case of Non EU Manufacturers).

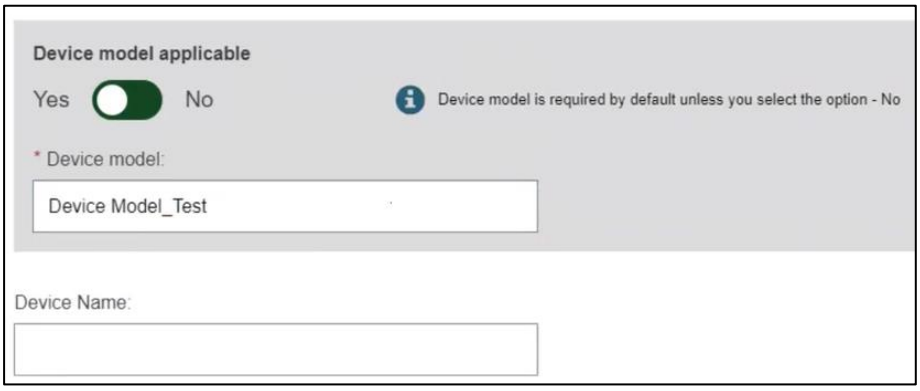
Note: The authorised representative and the manufacturer must have an active Mandate in order to assign the authorised representative for the device.

If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically selected:

5. On the next page, you must choose a Risk Class and select “Yes” or “No” for each option that follows. **Note: these options change depending on your previous selections as the applicable legislation of the device can influence the properties:**



6. Select “Yes” or “No” if a model is applicable and enter the name or number, and enter the device name if available:



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

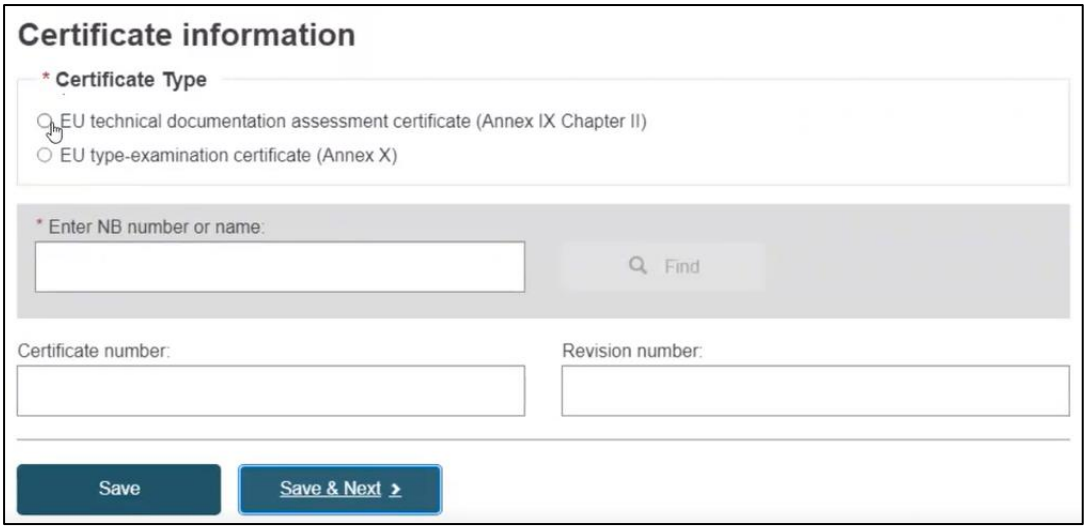
3.1.2 Step 2: Certificate information

Select the certificate type and enter some or all of the Notified Body name(s) or number(s). Click on “Find” and select the correct Notified Body from the new window. Optionally, provide the certificate number and revision number and click on “Save” or “Save & Next”.

Note: Certificate Information must be provided for Basic UDI-DIs which require confirmation from the Notified Body for the data provided in the UDI/Device module.

In Annex 1 to this User Guide you can find the different device cases (different device properties) in which Certificate information is required to be provided for the Device and the type of certificate that should be provided in each case apart.

This section will become active based on the selection made for Risk Class and additional properties in the Basic UDI-DI:


Certificate information
* Certificate Type
EU technical documentation assessment certificate (Annex IX Chapter II)
EU type-examination certificate (Annex X)
* Enter NB number or name:
Find
Certificate number:
Revision number:
Save
Save & Next

3.1.3 Step 3 : UDI-DI identification information

1. Select the “Issuing Entity” from the dropdown list and enter the UDI-DI code.

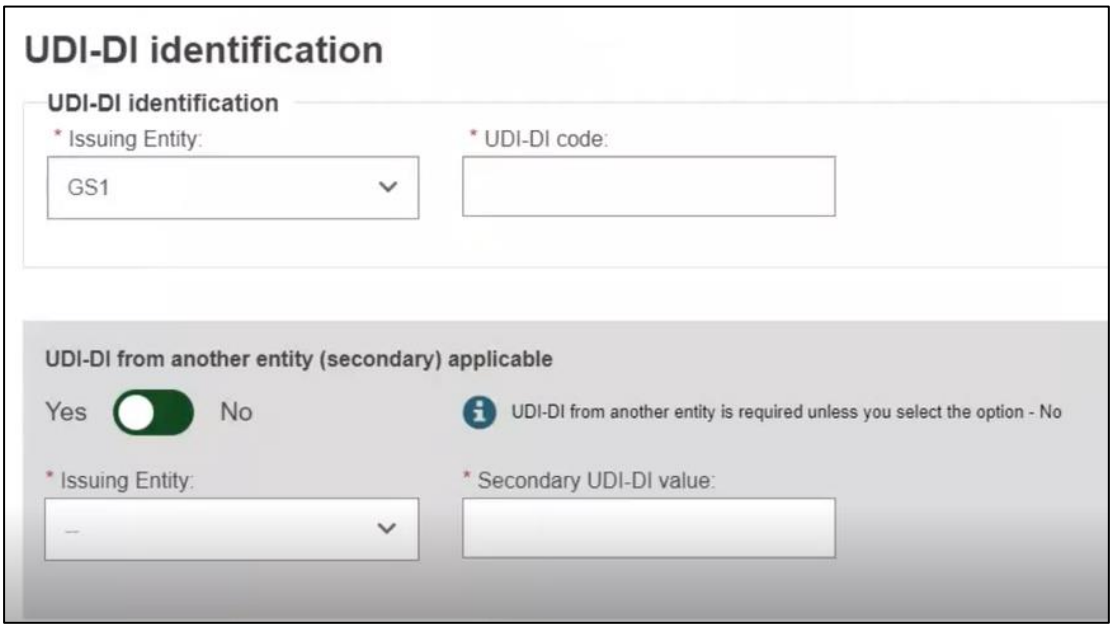
Important: The provided UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Note : In case of GS1 Issuing Entity, the UDI-DI code provided must have 14 characters

As an exception to this rule, the same UDI-DI can be used for different Devices if one is a Legacy Device and one is a Regulation Device, i.e. a device is initially registered under a Legacy Legislation and is later certified under a Regulation Legislation.

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 was created between the two devices (the Regulation and the Legacy Device).

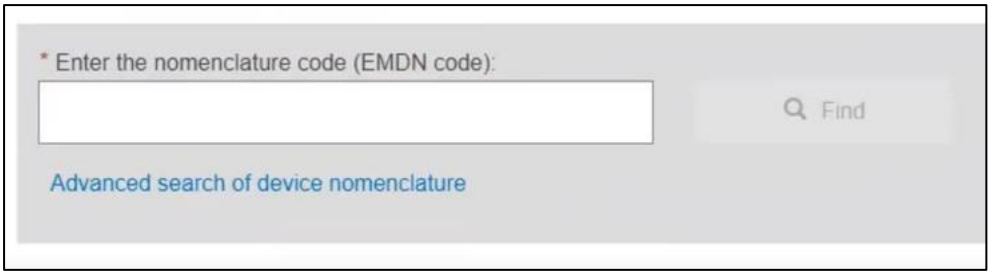
2. Enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI, if applicable:



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

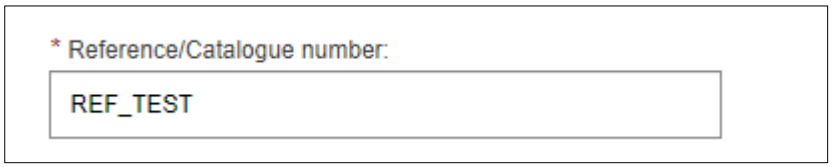
Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time.



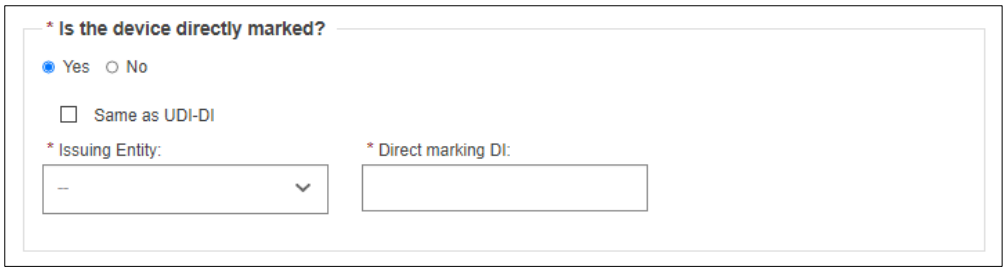
4. Enter the trade name (as it appears on the device label) and select the language, otherwise, select “No”:

5. Enter the Reference number (as found on the device label):



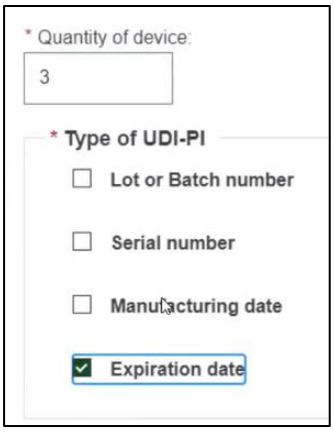
6. Enter details on whether the device is directly marked or not and specify the identifier (Direct Marking DI or Unit of Use DI):

- If the device is directly marked, the Direct marking DI is required. This can be same as the UDI-DI or can be another UDI-DI.
- If the device is not directly marked and the base quantity of the device is greater than one, the Unit of Use DI should be provided. The 'Unit of Use DI' box is used to enter the actual unique DI code assigned to the lowest unit of use that is used for the patient. Issuing entity for this DI Code is the same as the UDI-DI. This can at first registration or later (e.g. when performing an update of the device).
- The same Unit of Use DI can be used for several Devices.

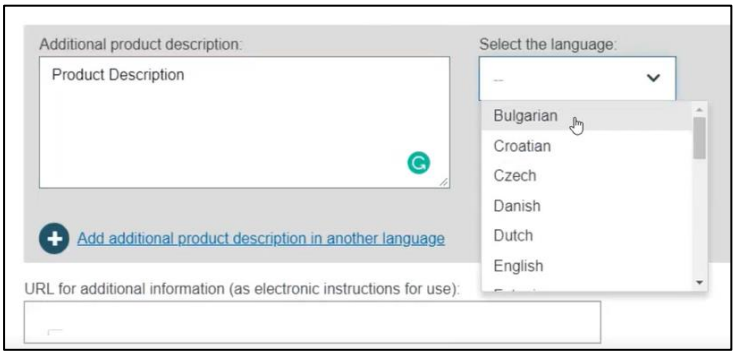


7. Provide the quantity of devices (the number of devices within a package identified by the specified UDI-DI) and select the type of UDI-PI:

Note: UDI-PI describes the manner in which production of the device is controlled.



8. Enter any additional information about the product (any additional information or details about specific features of the device), select the language and enter a URL if you have one for additional information online:



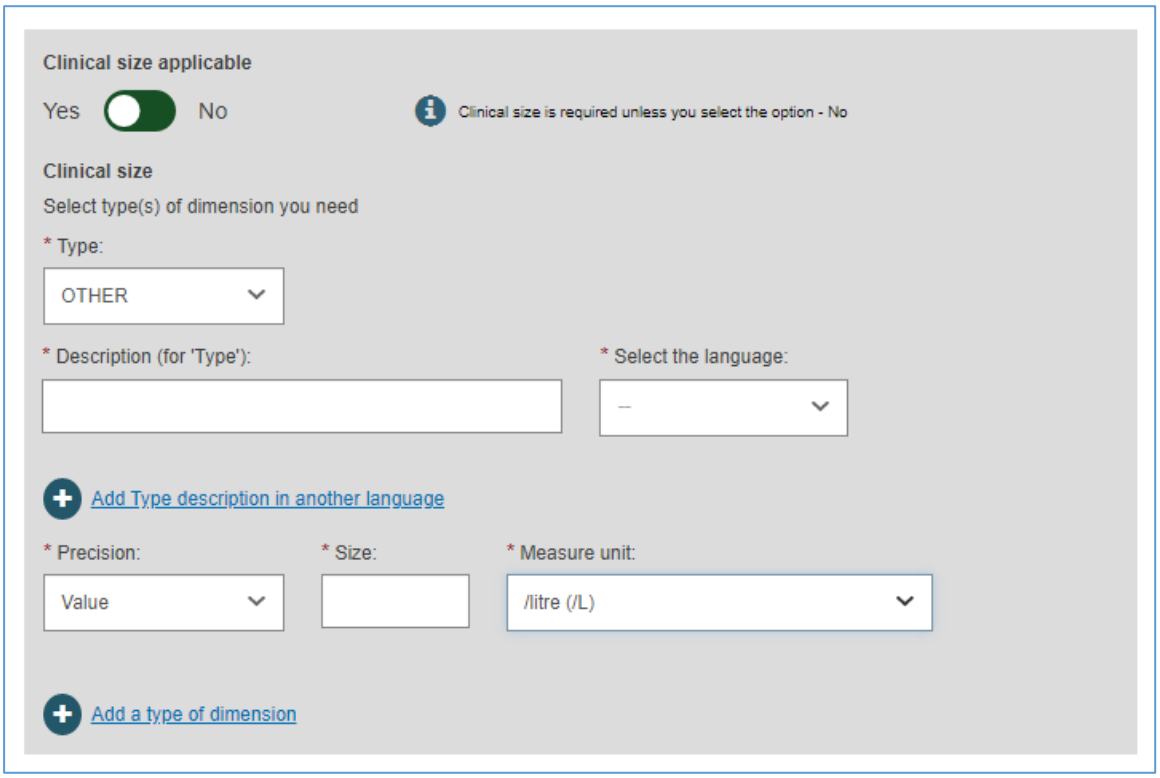
9. Select whether it is on the EU market or not and click on “Save” or “Save & Next”:

3.1.4 Step 4: UDI-DI Characteristics

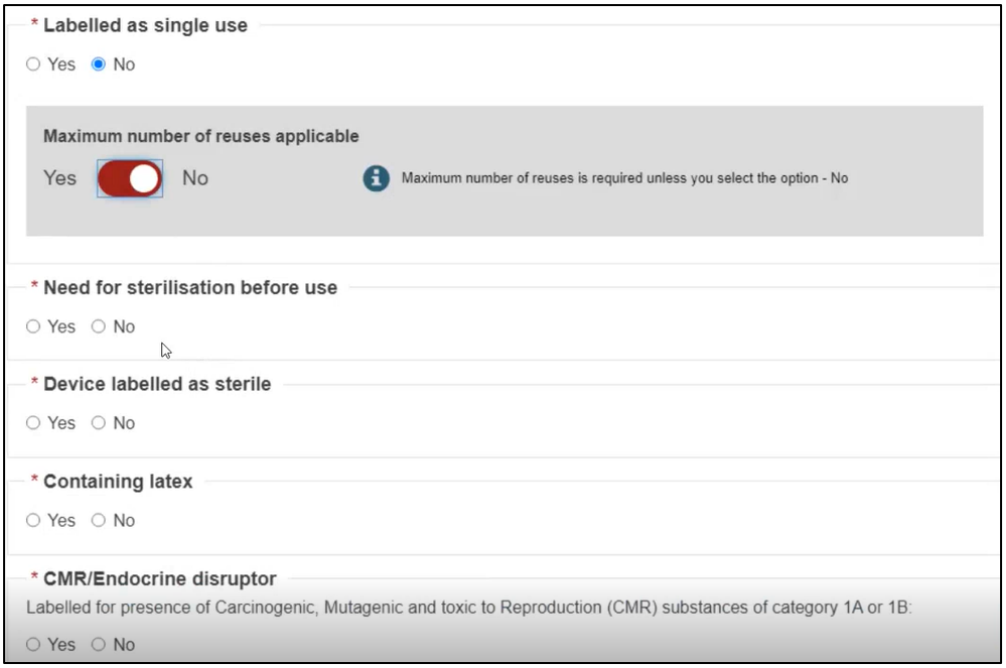
1. Select if the clinical size is applicable for the UDI-DI and choose the correct values in the dropdown lists below:

Note: When the selected Clinical size type has option Other, user will be required to provide the Description of the Clinical size type and the language in which the description is given. Same behaviour applies for Measure unit.

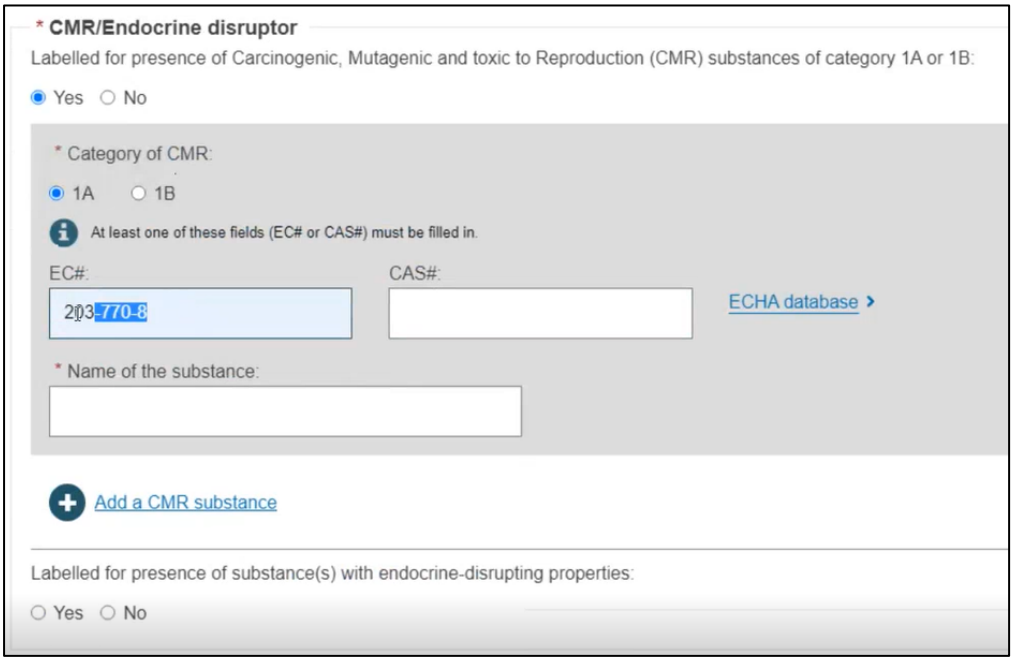
In case both the Clinical size and Measure unit have value Other, the description for the two fields needs to be provided in the same languages.



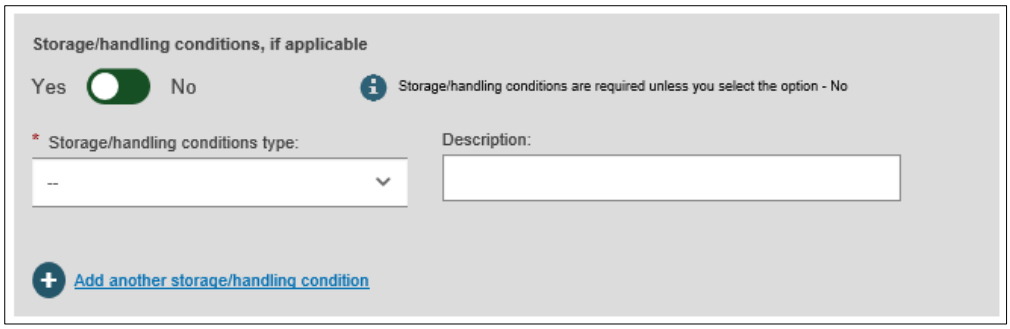
2. Select “Yes” or “No” for each option prompted:



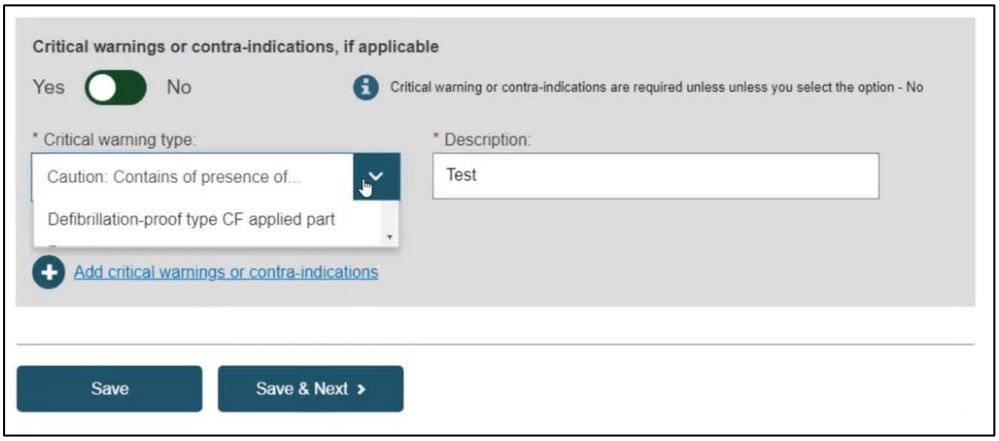
3. Enter the CMR/Endocrine disruptor substances. Select the appropriate option to indicate if the device is labelled with an indication of the presence of substances. When registering CMR or Endocrine substances you may optionally provide the EC# or CAS#. If provided, only the Name of substance is required (i.e. the language is no longer required):



4. Select “Yes” or “No” for the Storage/handling conditions, if applicable, and provide the desired values by selecting from the options provided and by entering a description:

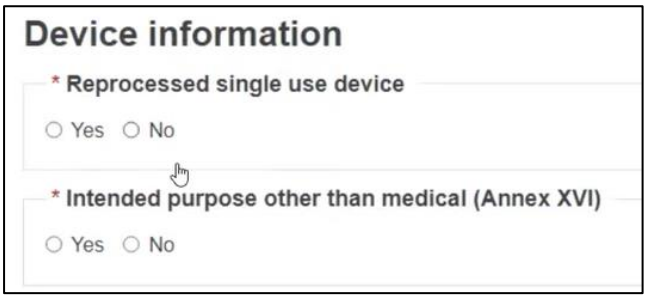


5. Repeat for Critical warnings or contraindications, and click “Save” or “Save & Next”:

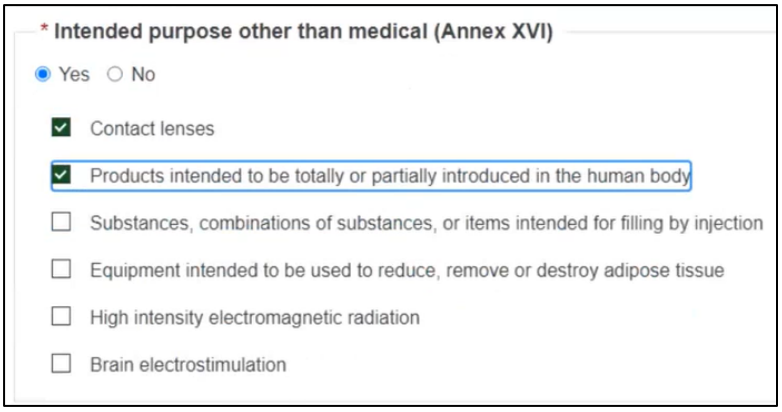


3.1.5 Step 5: Device information

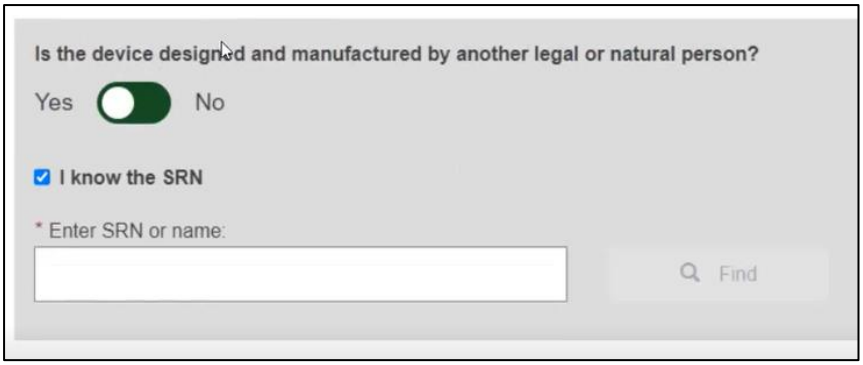
1. Select “Yes” or “No” for the first device information options:



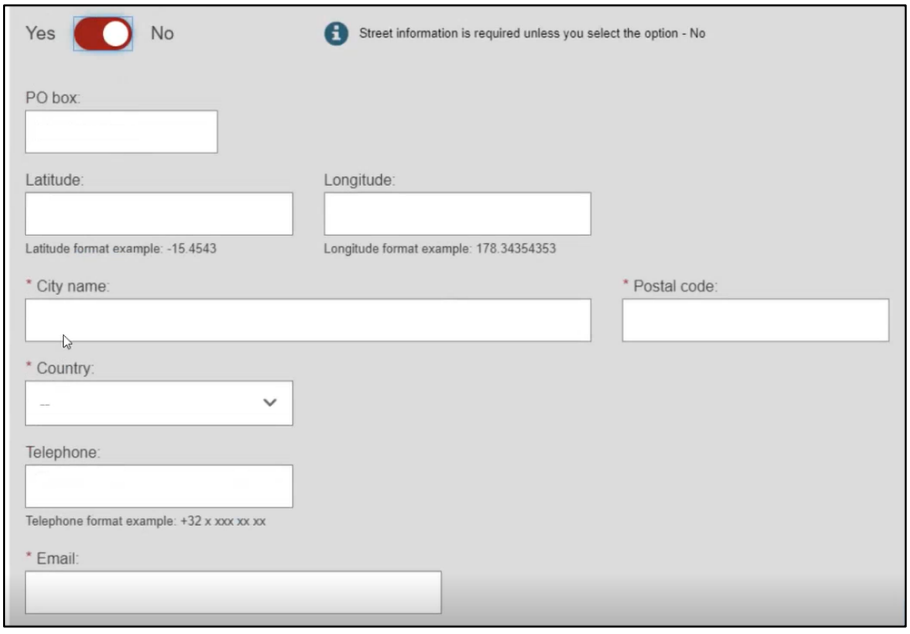
2. If you select “Yes” for the intended purpose other than medical (Annex XVI), options will appear. Select the correct purposes:



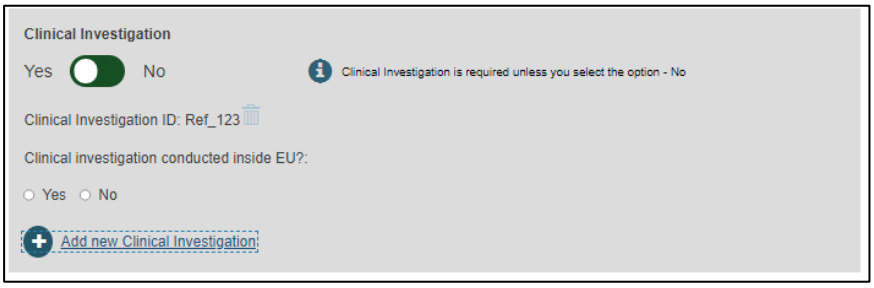
3. Select “Yes” or “No” if the device was designed by another legal or natural person. If you know the SRN, enter here:



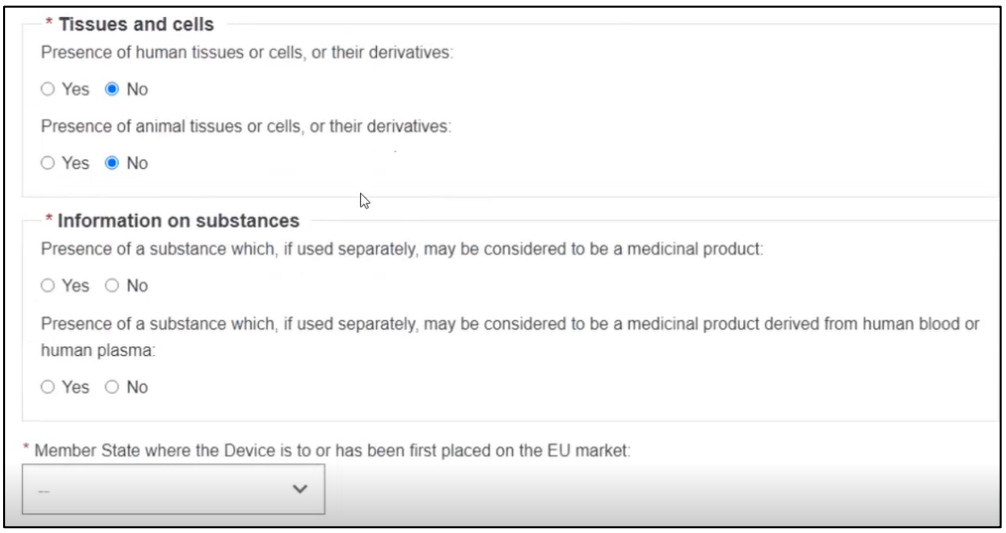
4. If you do not know the SRN, uncheck the box and complete the required fields:



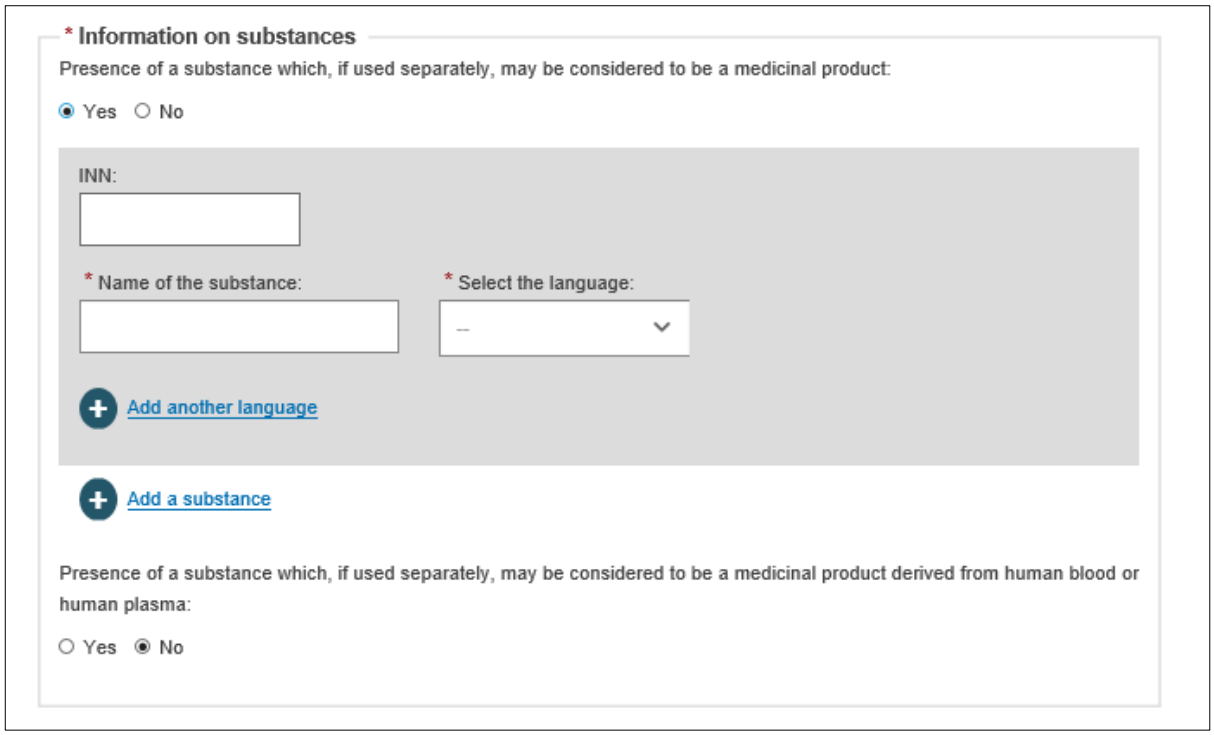
5. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI:



6. Select “Yes” or “No” to complete information on tissues and cells, and information on substances:



7. If you answer “Yes” to the presence of a substance which, if used separately, may be considered to be a medicinal product or a human product derived from human blood or plasma, enter details about the substance name and language in which it is provided and optionally the INN (International Non-proprietary Name):



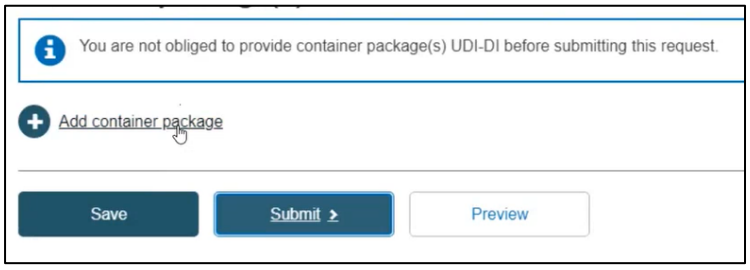
8. Select a Member State from the dropdown list where the device was or will be placed on the EU market, and click “Save” or “Save & Next”:

Note: This field may be optional or required, based on the properties selected earlier for the device (Basic UDI-DI and UDI-DI). If the device (UDI-DI) has the status “Not intended for EU Market”, this information cannot be provided.

3.1.6 Step 6: Container Package details

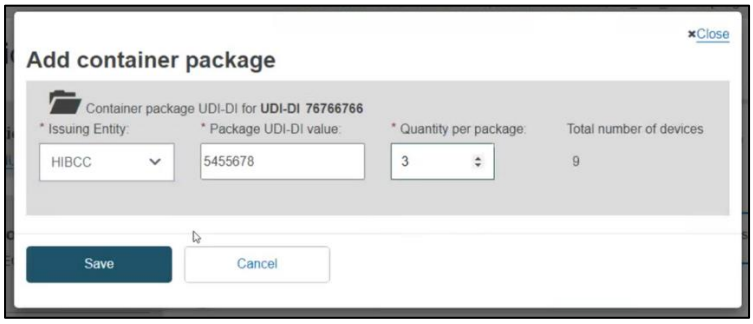
Container Package information is optional to complete. This page allows users to enter the unique UDI-DIs assigned to each package level of the device in order to distinguish between package quantities at each package level, higher level of packaging shall have their own unique UDI:

1. Click on “Add container package” (**Note: this step is not mandatory in order to submit your registration**):

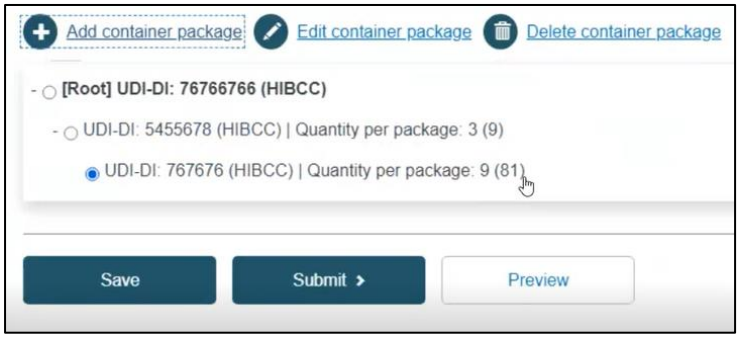


2. Add the Issuing Entity, Package UDI-DI value and the quantity per package, and click “Save”:

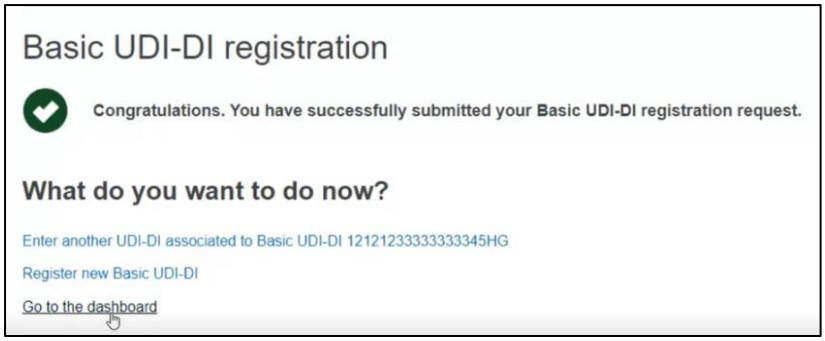
Note: The Package UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value.



3. Select the generated information and click on “Submit”:



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

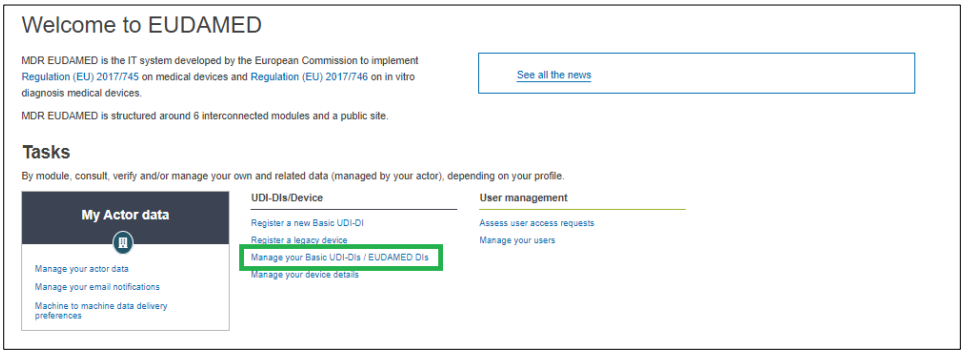


Important: After Submitting the Device, the state of the Device (Basic UDI-DI and UDI-DI) will be:

- **Registered if the Basic UDI-DI data does not require a confirmation from the Notified Body;**
- **Submitted if the Basic UDI- DI data requires a confirmation from the Notified Body before being Registered (and being published on the Public website);**

3.2. Registration of UDI-DI for an existing Basic UDI-DI

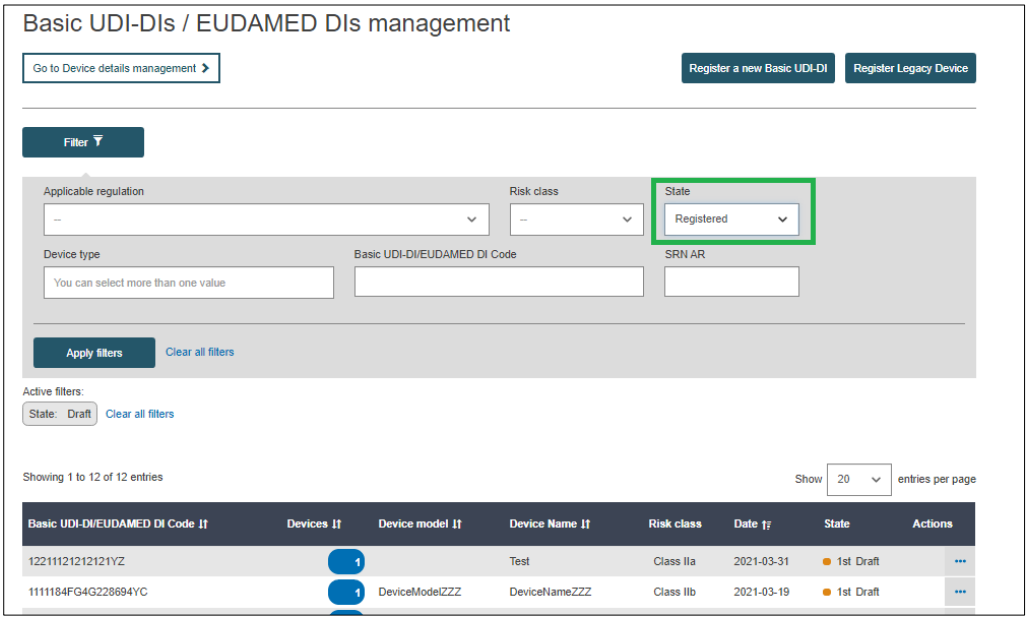
1. From your Dashboard, select “Manage your Basic UDI-DIs/ EUDAMED DIs”:



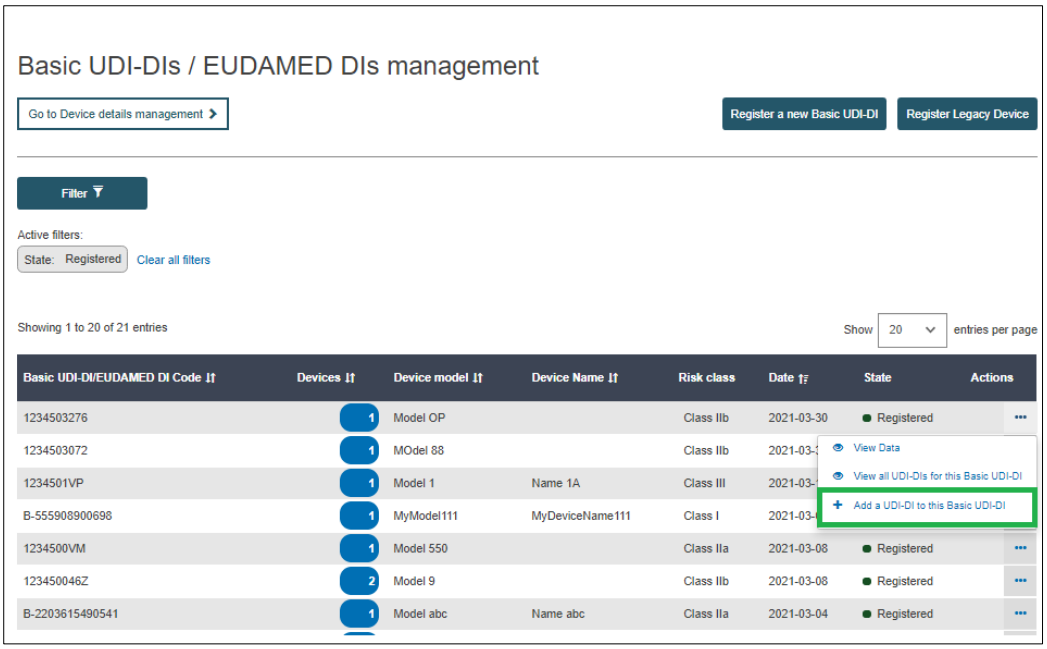
2. Filter the Basic UDI-DIs/ EUDAMED DIs in state Submitted or Registered:

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

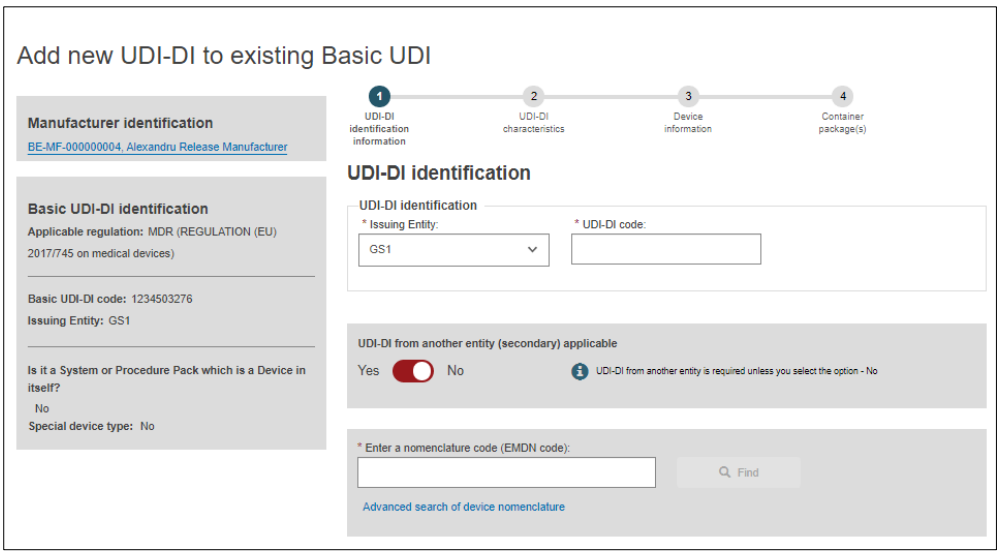
New UDI-DIs can be added only for Basic UDI-DIs being in state Registered or Submitted.



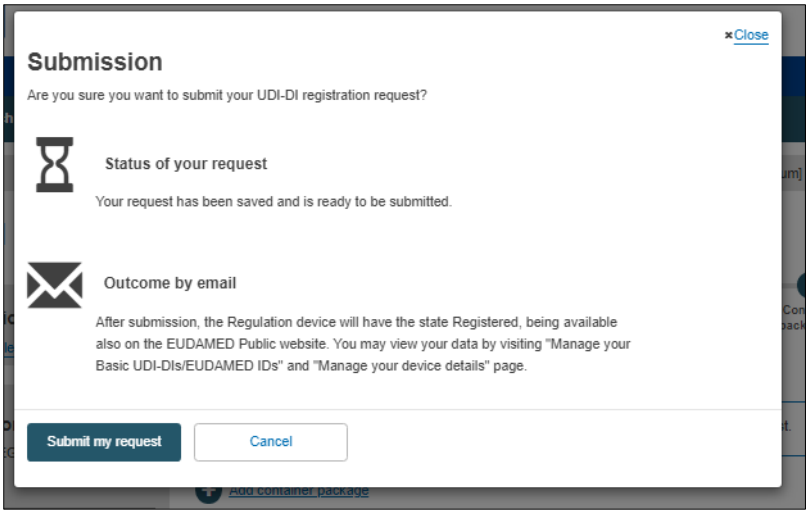
3. Identify the desired Basic UDI-DI for which you would like to add a new UDI-DI and use the functionality to register a new UDI-DI for this UDI-DI:



4. Complete the fields required in the wizard for the registration of a UDI-DI for an existing Basic UDI-DI:



6. Submit the UDI-DI:



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

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

4.Registering Legacy Devices (EUDAMED DI and UDI-DI/EUDAMED ID)

On the dashboard, click on “Register a Legacy device”:

EUDAMED DIEUDAMED DI

4.1. Step 1: EUDAMED DI Identification Information

1. Select an applicable legislation:

Note: Based on the selected applicable legislation, the set of properties (characteristics of the Device) that can be provided will differ.

Note: For the rest of the procedure, we will assume in this quick user guide that you have selected IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices).

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

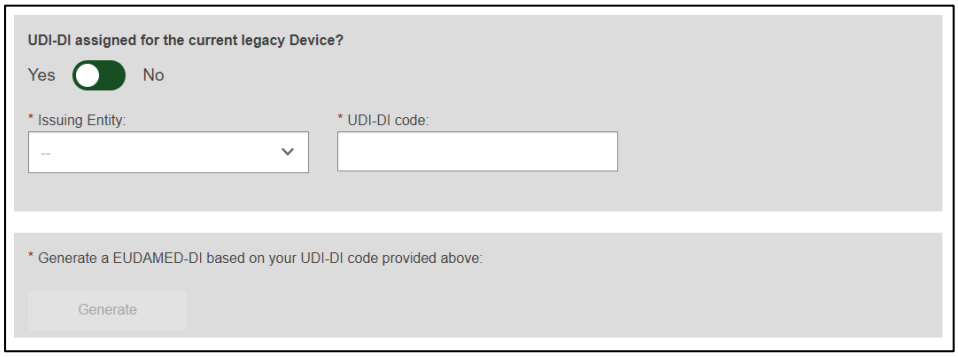
Note: In case no UDI-DI is available, the EUDAMED DI must be provided.

In case UDI-DI is provided for GS1 Issuing Entity, the UDI-DI code provided must have 14 characters.

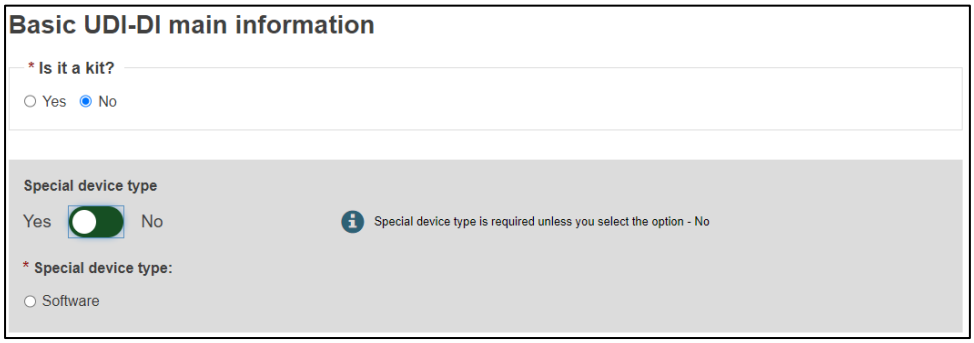
The EUDAMED DI can be generated outside EUDAMED (using the provided algorithm for the generation of EUDAMED DI) or can be generated within the registration process by providing the manufacturer's device identifier and allowing EUDAMED to generate it.

If a UDI-DI is provided, it must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Exception: The same UDI-DI can be used for the same legacy and Regulation device, whereby a device is initially registered under a legacy legislation and is later certified under a Regulation-applicable legislation). In this case, you will be prompted that a link will be created between the two devices (the Regulation and the Legacy Device).



3. Select whether it is a kit or not, if you select "Yes" you can move on to the next step, otherwise fill in the remaining information:



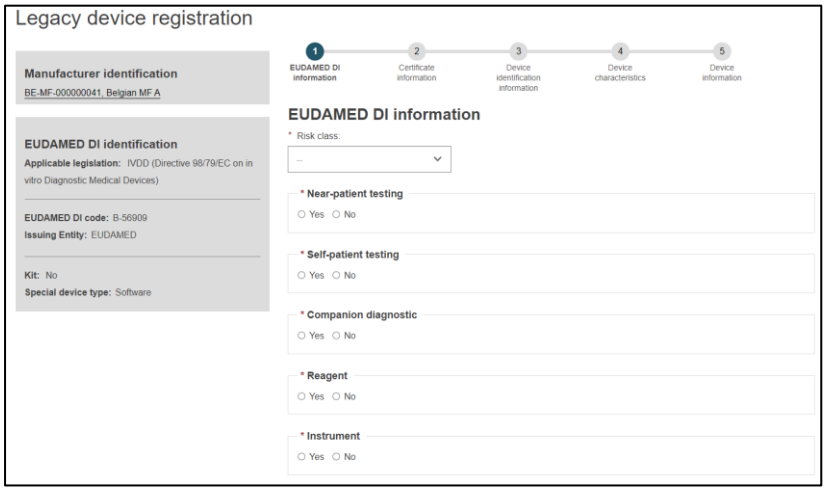
4. Select the authorised representative for the current device (Basic UDI-DI) from the options available (applicable only in case of non-EU manufacturers).

Note: The authorised representative and the manufacturer must have an active Mandate in order to be able to assign the authorised representative to the Device.

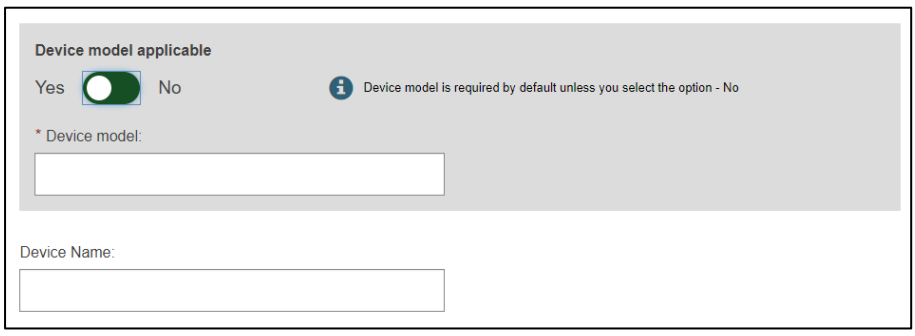
If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically selected:

5. On the side you will be shown a small description of the device. Select a “Risk class” from the list and select “Yes” or “No” for each of the options.

Risk Class options are dependent on the Applicable Legislation of the Device and have an influence over the properties which must be provided later.



6. Select “Yes” or “No” if the device model needs to be specified, and if available enter a Device name:



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

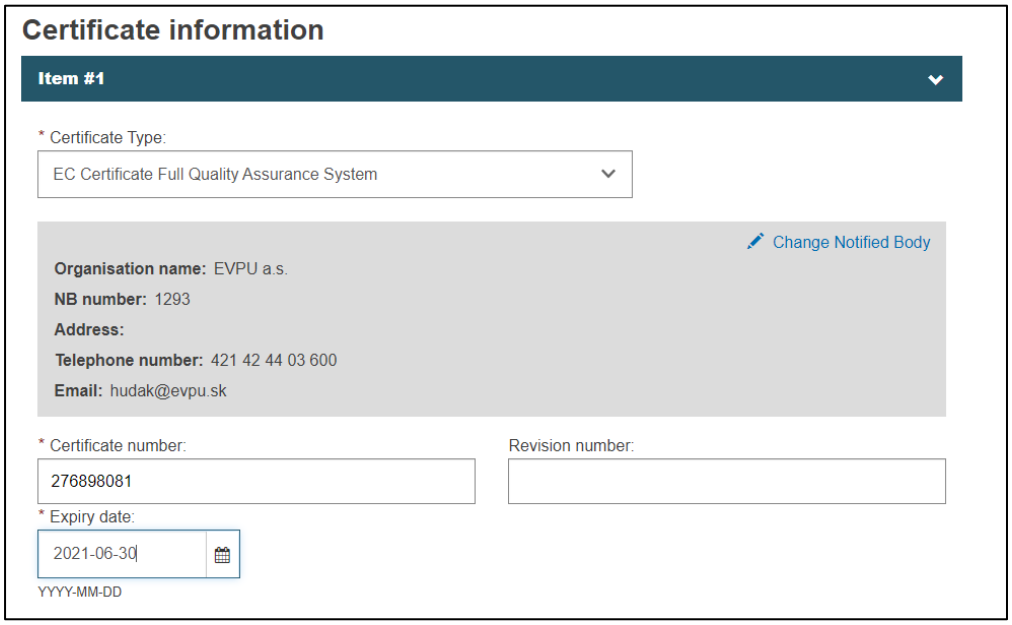
4.2. Step 2: Certificate information

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

Note: Information on active certificates must be provided for Legacy Devices.

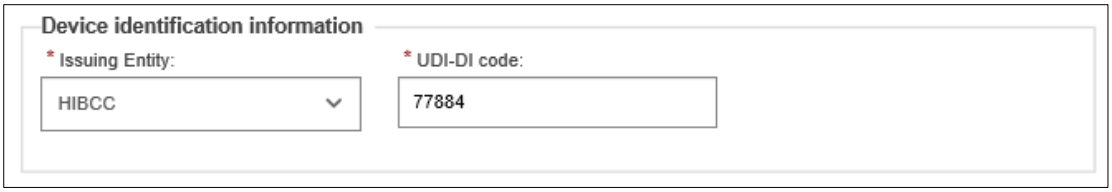
In Annex 2 to this document you may find the Certificate types that can be provided for the Legacy Devices specific for each Applicable legislation of the Device.

Several identification details for several certificates may be provided.



4.3. Step 3: Device identification information

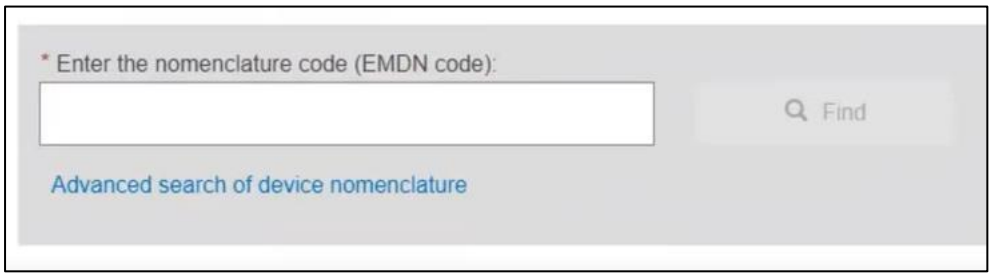
1. EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED ID generated based on the provided/generated EUDAMED DI):



2. Enter the EMDN code. Click on “Find” and select the correct one:

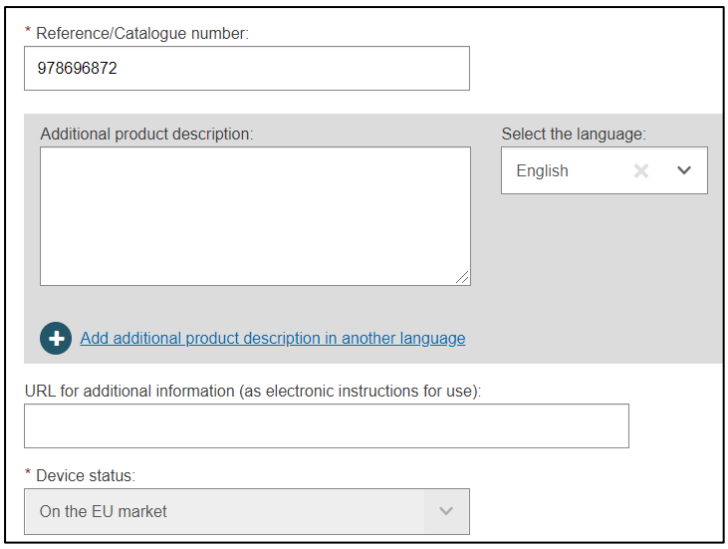
Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time. (The mapping is not fully completed and not reliable and can be used only for facilitating the correct selection of EMDN code)



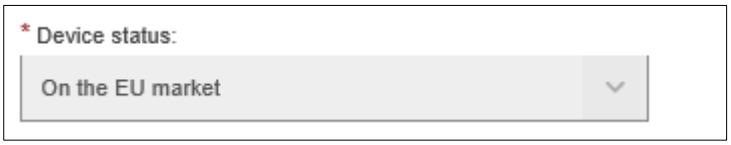
3. Enter the trade name (if there is one) and select the language, otherwise, select “No”:

4. Enter a reference number and any additional information you might have:



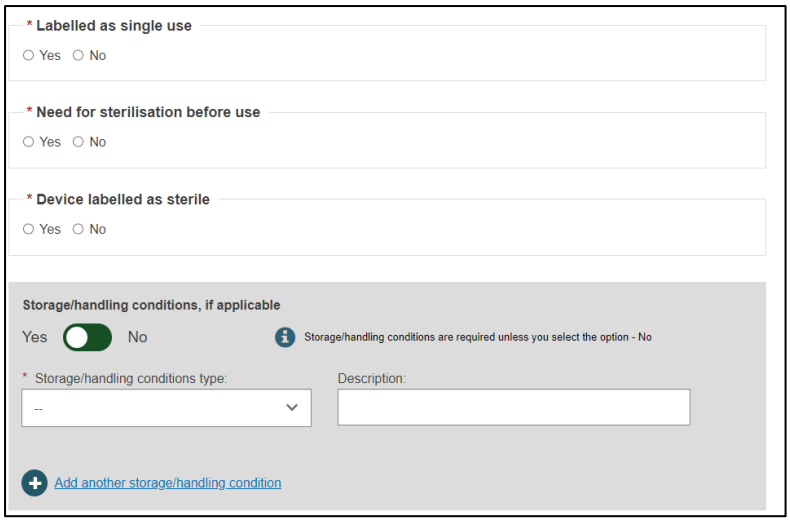
5. EUDAMED will display the status of the Device.

Note: In the case of Legacy Devices, the initial status of the Device is considered to be 'On the market'. If the device is 'No longer on the market', an update of the status can be performed on the Device (UDI-DI/EUDAMED ID):

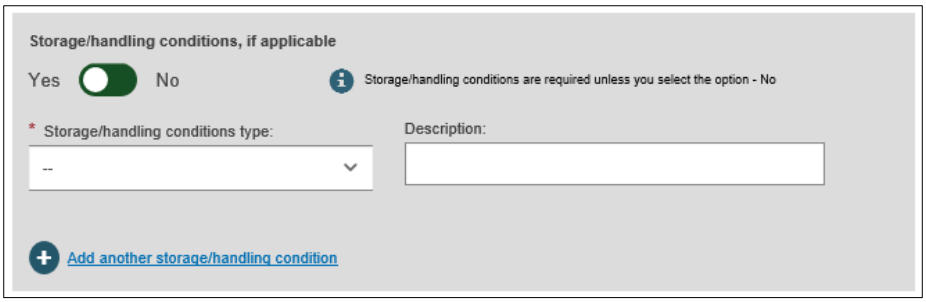


4.4. Step 4: Device characteristics

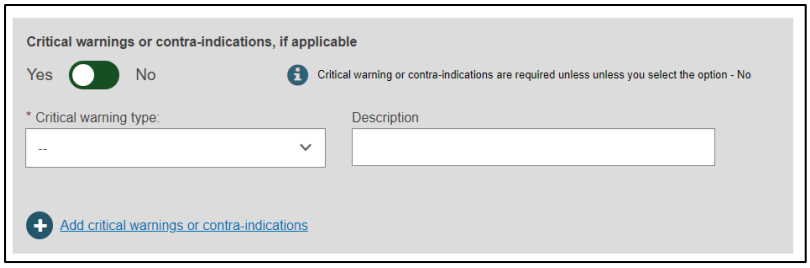
1. Select “Yes” or “No” for the first three options, then select “Yes” or “No” if Storage/handling conditions are applicable:



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

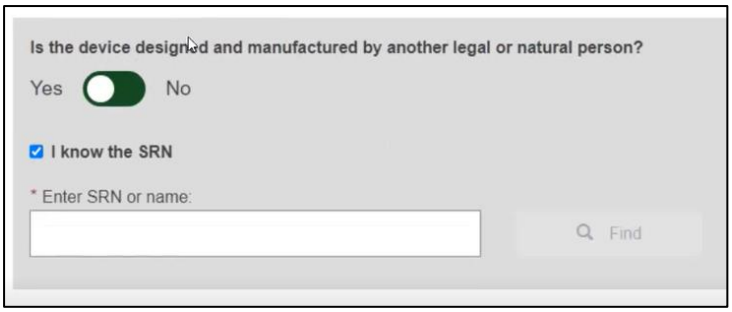


3. Repeat for Critical warnings or contraindications. After completing, click on “Save” or “Save & Next”:

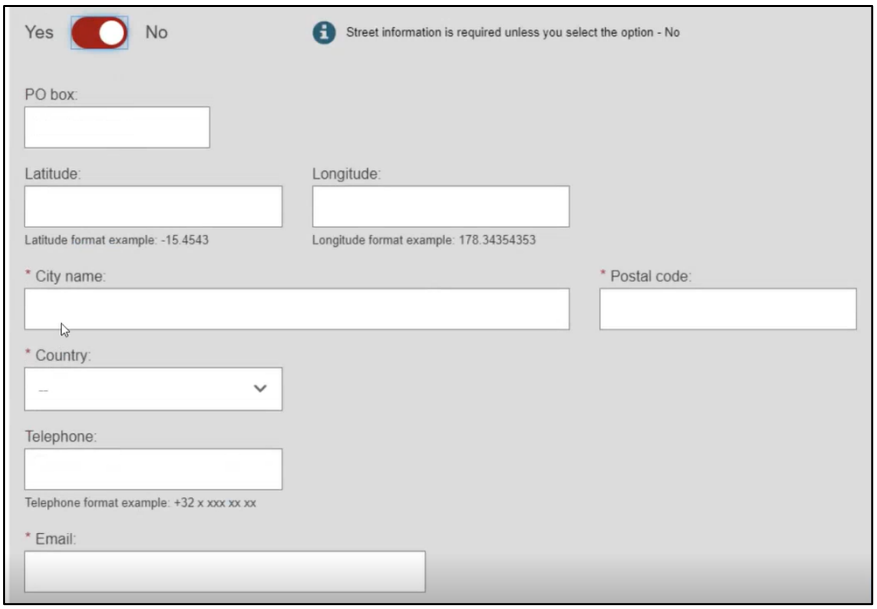


4.5. Step 5: Device information

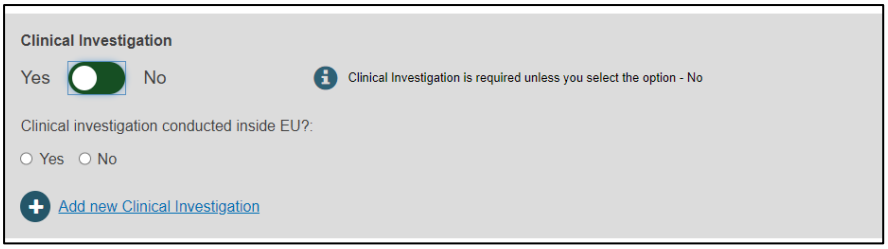
1. Select “Yes” or “No” if the device was designed by another legal or natural person, enter the SRN number if you know it:



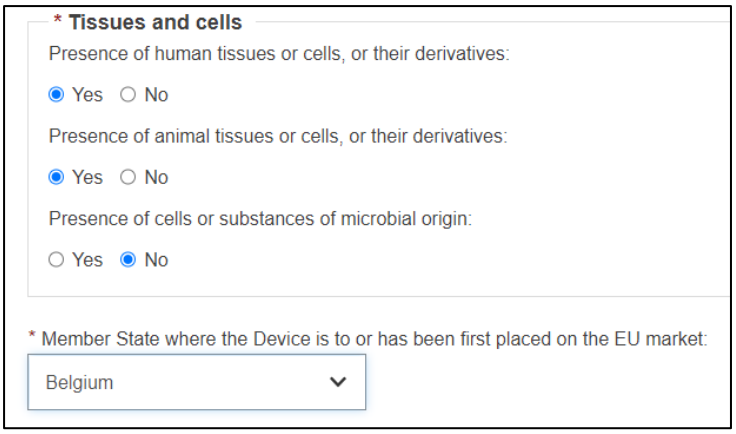
If you select “No”, enter the information manually, fill in all the fields with a red asterisk (the others are optional):



2. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI/EUDAMED ID:

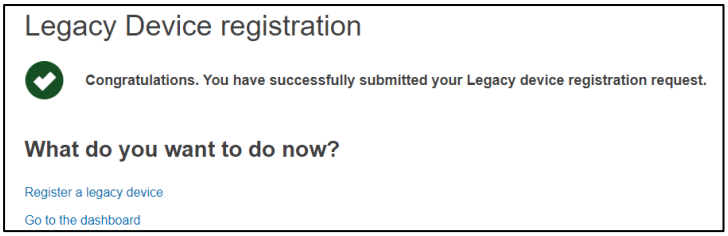


3. Select “Yes” or “No” for the three following options



4. Select a Member State from the dropdown list where the device was or will be placed on the EU market, and click “Submit” or “Preview”:

4. A pop-up window will appear asking you to confirm your submission. Once confirmed, you will be brought to a new page showing you succeeded in registering your Legacy device:

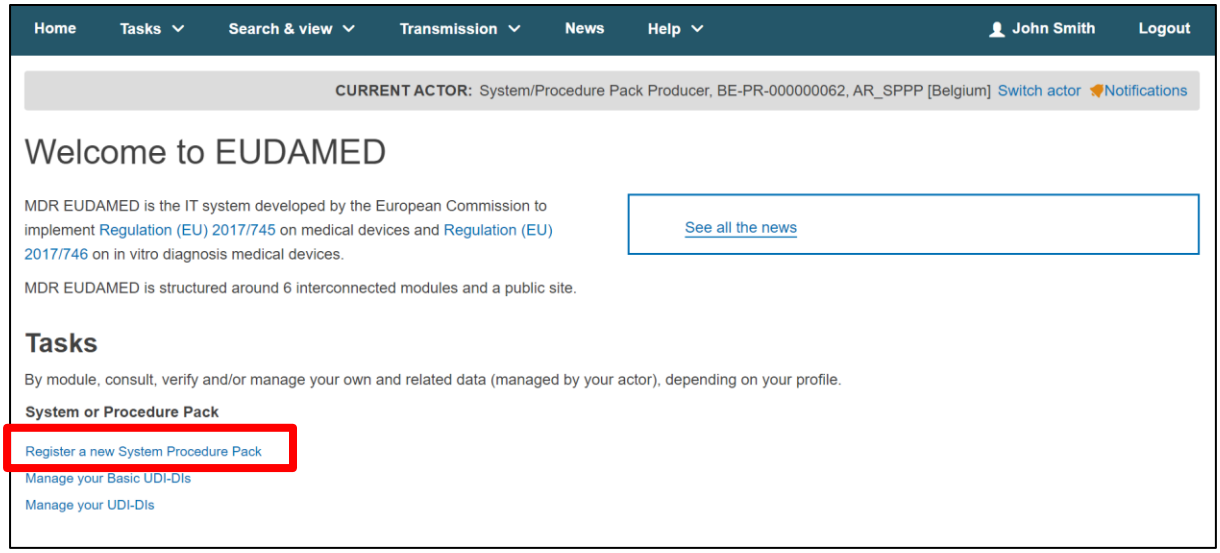


5.Registering System or Procedure Packs

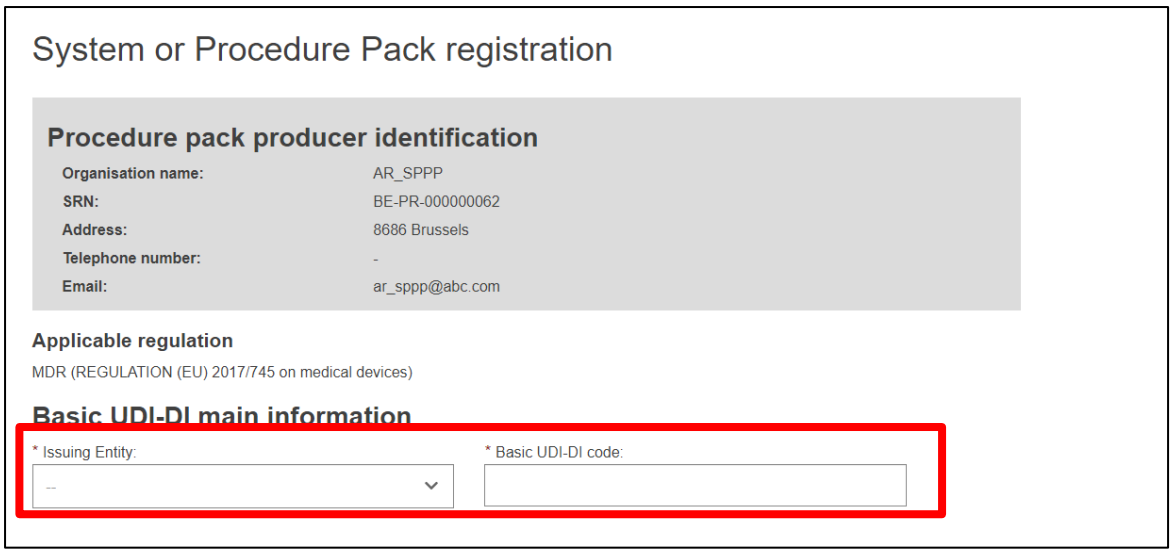
5.1. Registration of Basic UDI-DI together with the first UDI-DI for System or Procedure Packs

5.1.1 Step 1: Basic UDI-DI Identification information

1. On the EUDAMED dashboard, click on “Register a New System Procedure Pack”.



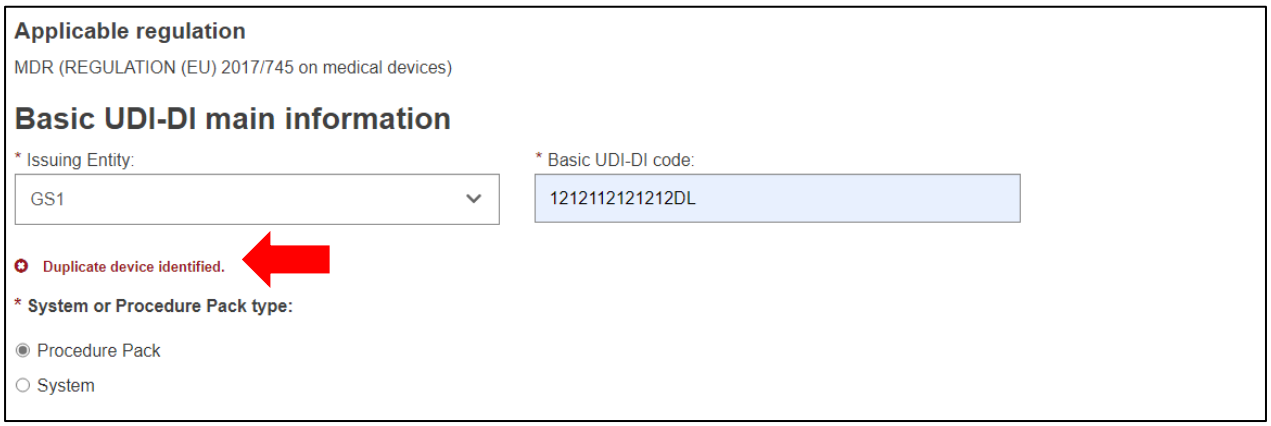
2. On the next page, you may register the Basic UDI-DI information for your system or procedure pack, i.e. the Basic UDI-DI Issuing entity and code.



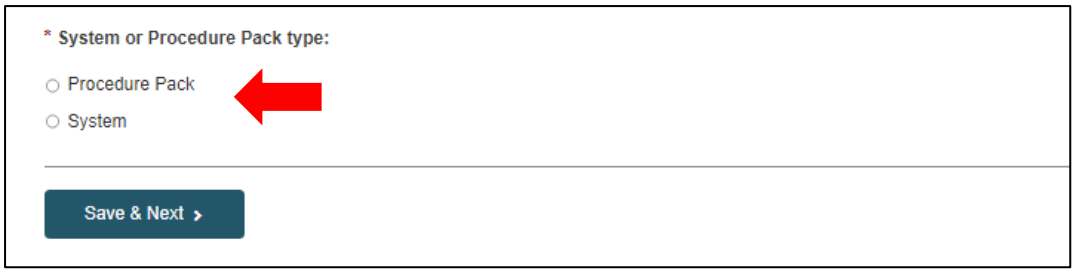
Note: The applicable legislation (MDR) for system and procedure packs will be pre-selected by default.

Important: EUDAMED will perform a validation for the Basic UDI-DI code provided based on the specific format provided by each Issuing Entity. Please ensure that you provide the correct value.

Basic UDI-DI duplicates cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value:



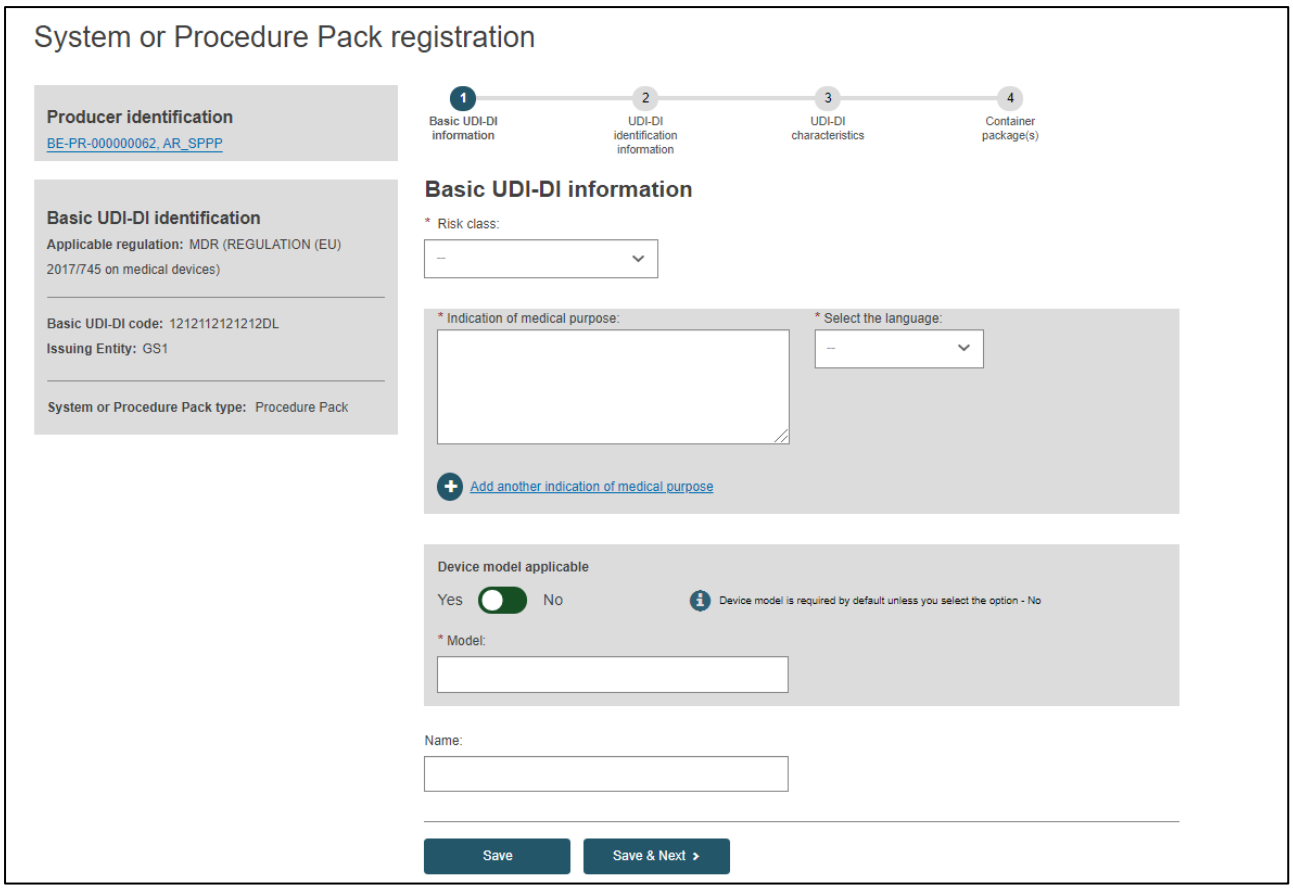
3. Choose whether you are registering a system or procedure pack:



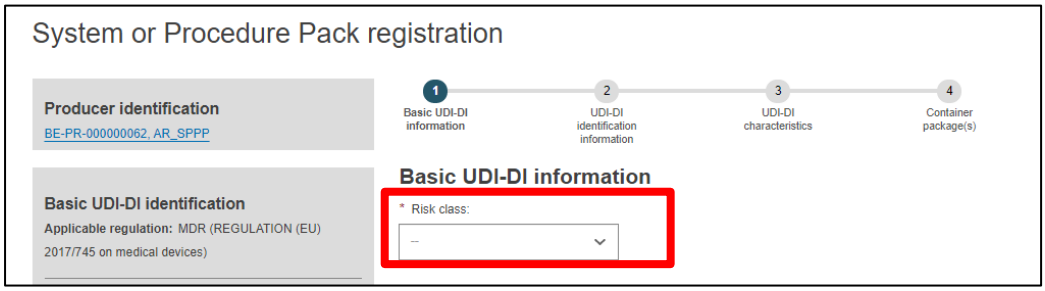
4. Click on “Save & Next” to save your registration as a draft and move on to the next steps.

5.1.2 Step 2: Basic UDI-DI information

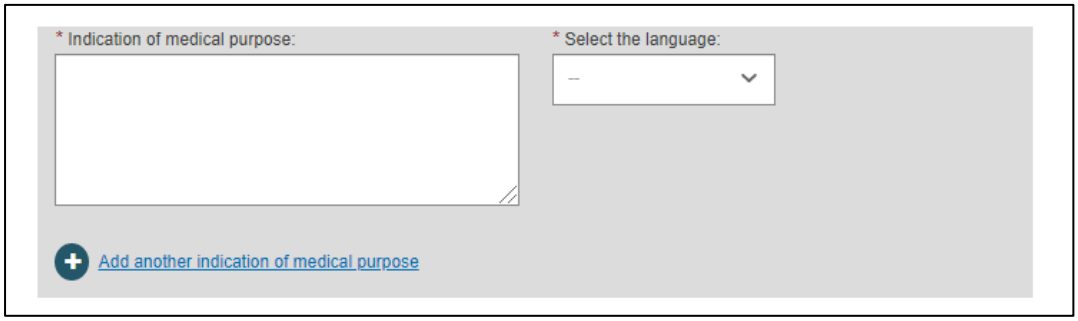
On the next page, you must provide Basic UDI-DI identification information:



1. Choose a Risk Class from the drop-down list:

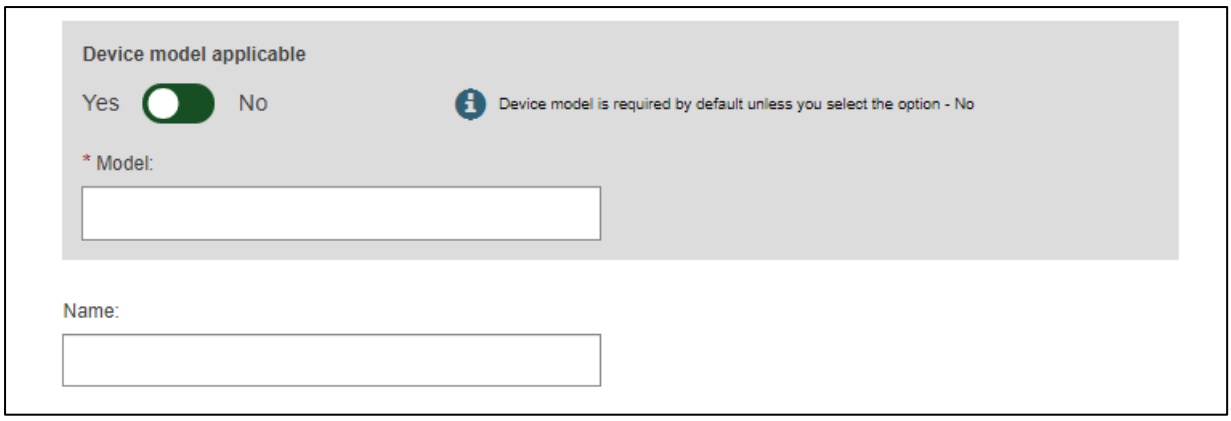


2. Fill in the indication of medical purpose, and select its corresponding language:



You may choose to add the indication in several languages, in which case you have to click on “Add another indication of medical purpose” and select its language from the drop-down list.

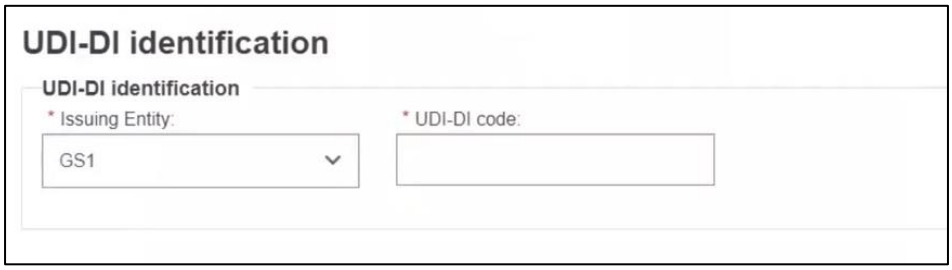
3. Select “Yes” or “No” if a device model is applicable. If you selected “Yes”, enter the device model and the device name if available:



4. Click on “Save” to save your registration as a draft, or click on “Save & Next” to save it as a draft and proceed to the next steps:

5.1.3 Step 3: UDI-DI identification information

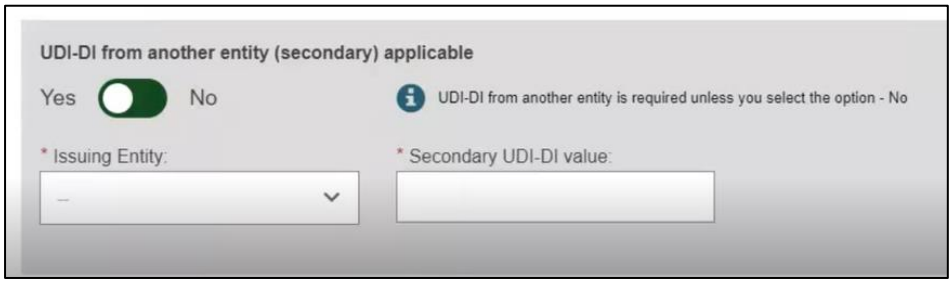
1. Select the “Issuing Entity” from the dropdown list and enter the UDI-DI code:



Important: The provided UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Note : In case of GS1 Issuing Entity, the UDI-DI code provided must have 14 characters

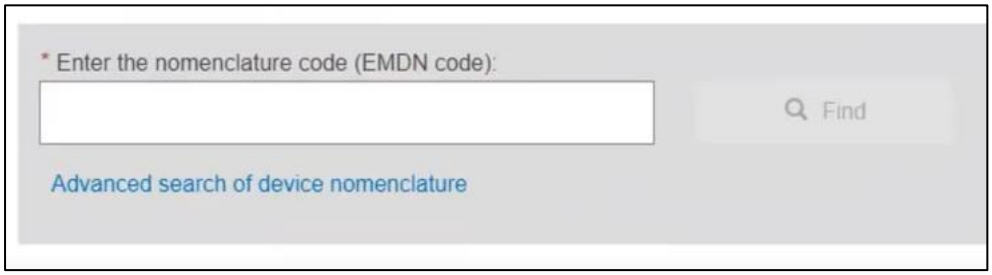
2. Enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI, if applicable:



3. Enter the EMDN code (European Medical Device Nomenclature) and click on “Find”:

Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time. (The mapping is not fully completed and not reliable and can be used only for facilitating the correct selection of EMDN code)

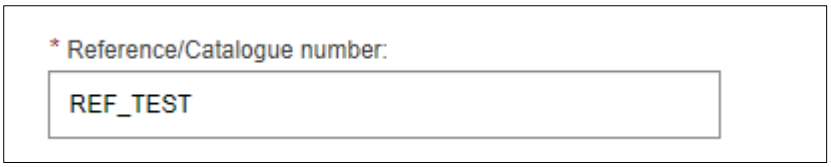


Then select the correct one from the pop-up list and click on “Confirm”. You can add more than one EMDN codes.

4. If applicable, select “Yes” to enter the trade name and select its language:

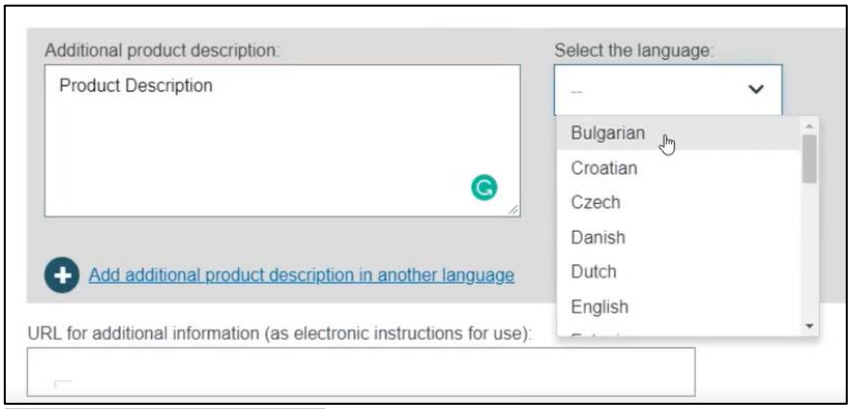
You can provide trade names in several languages; in which case you have to click on “Add a trade name in another language”.

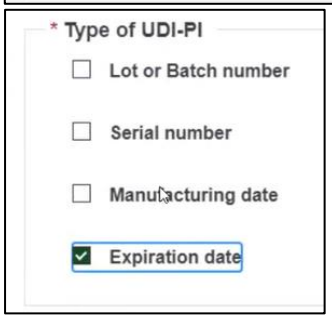
5. Enter the Reference/Catalogue number:



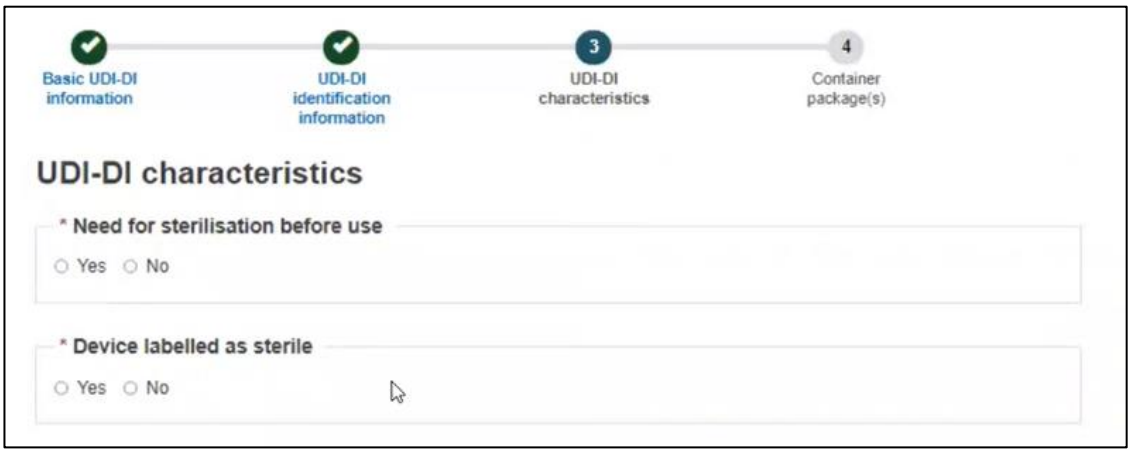
6. Select the type of UDI-PI, which signifies the way in which production is controlled.

You can select more than one type.





7. Enter any additional information about the system or procedure pack, select the language of the additional information and enter a URL if you have one for additional information online:

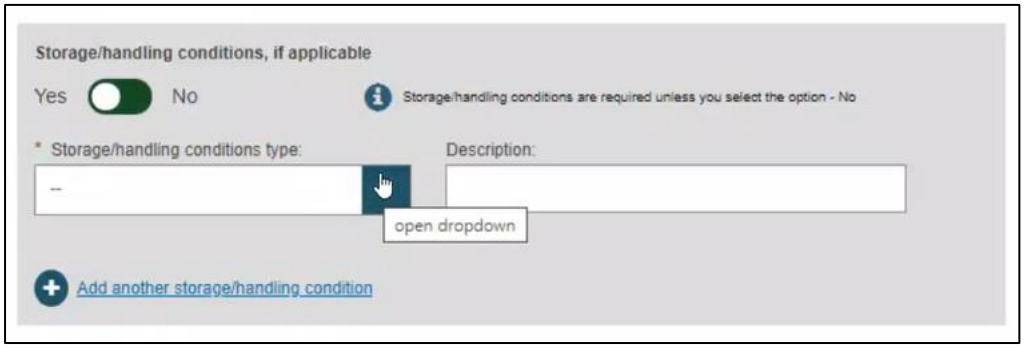


8. Select whether the system or procedure pack is intended for the EU market or not and click on "Save" to save as draft or "Save & Next" to continue to the next steps:

5.1.4 Step 4: UDI-DI Characteristics

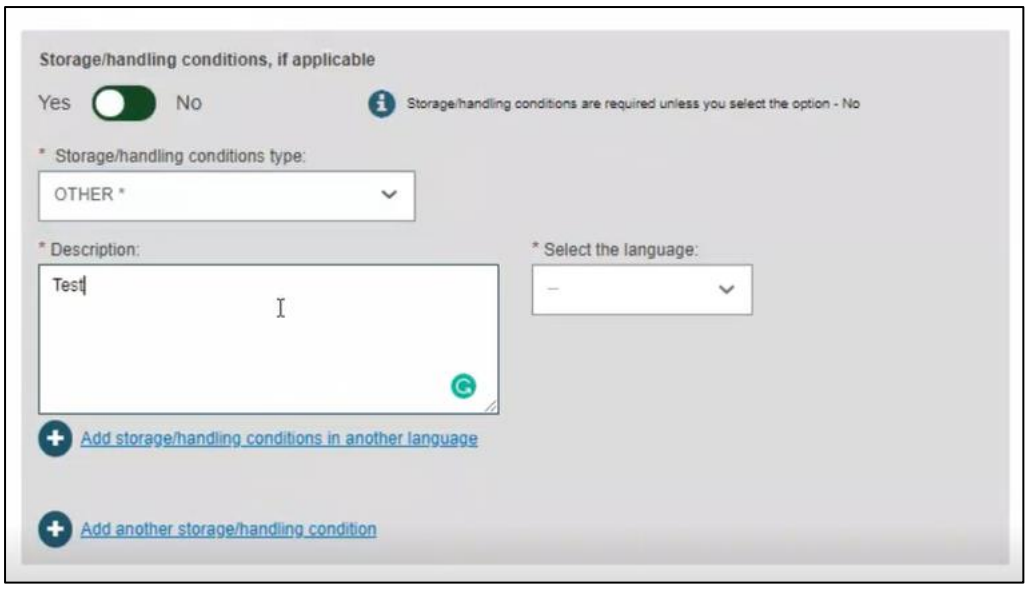
1. Select "Yes" or "No" for each option prompted regarding sterilisation:

2. Select "Yes" or "No" if storage or handling conditions are applicable:

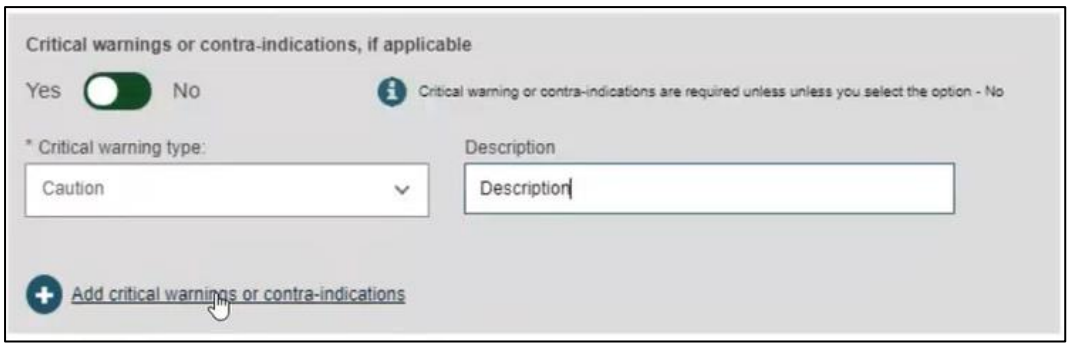


If you choose “Yes”, you have to select the conditions type from a dropdown list. Some of these types require a description, which you can provide in the relevant box. You may add several storage and handling conditions types.

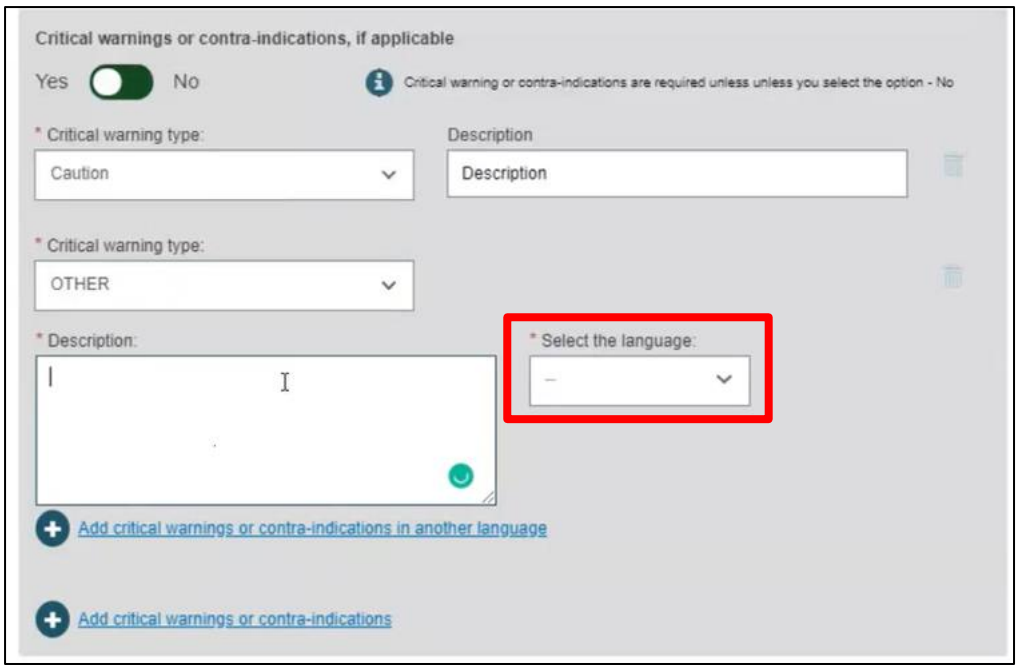
Note: If you select “Other” from the Storage/Handling conditions type list, the system requires the description to be provided in several languages:



3. Select “Yes” or “No” if any critical warnings or contra-indications are applicable (you can add several):



Just like for the previous section, if you choose “Other” for the critical warning type, the system requires you to provide the description in several languages:

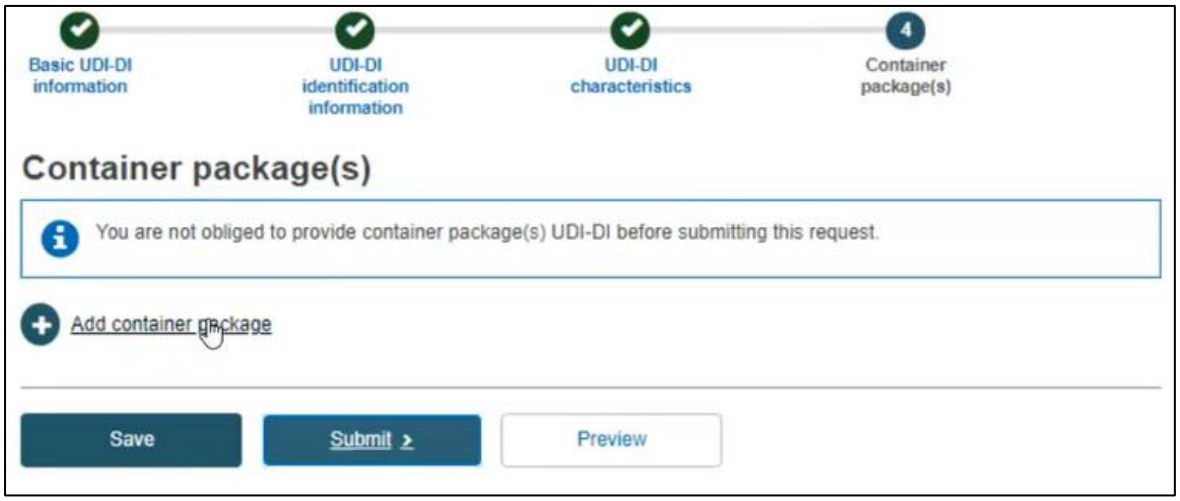


4. Click on “Save” to save draft or “Save & Next” to move to the next step of the process:

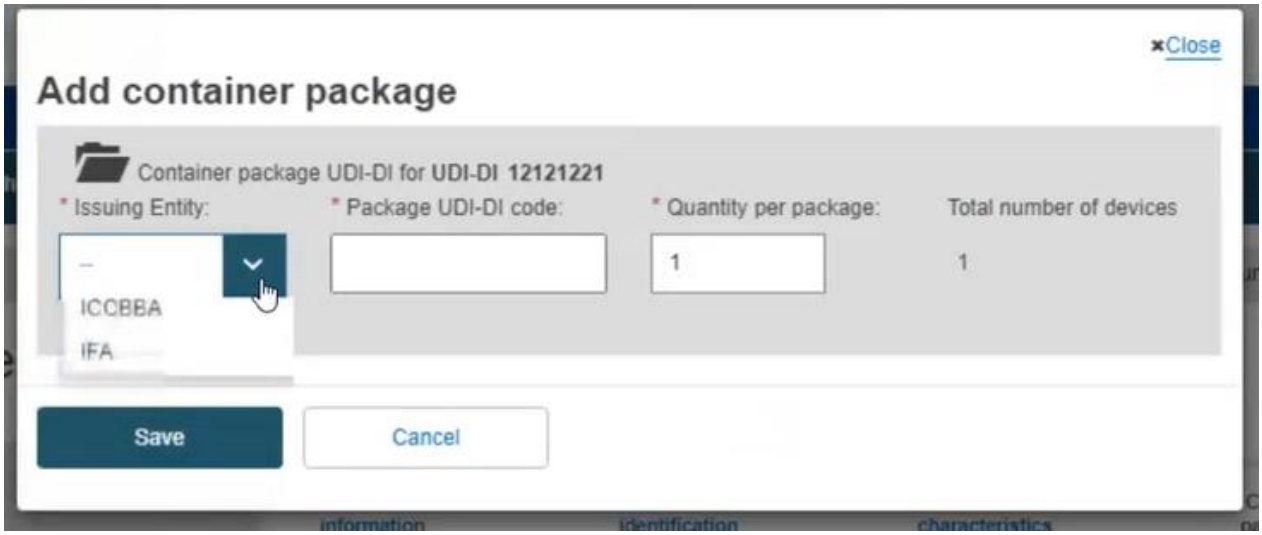
5.1.5 Step 5: Container Package details

This is the last step for registering a System or Procedure Pack.

1. If you wish to provide information about packaging structures for shipping, click on “Add container package”:



A pop-up box will appear for you to make your selection:



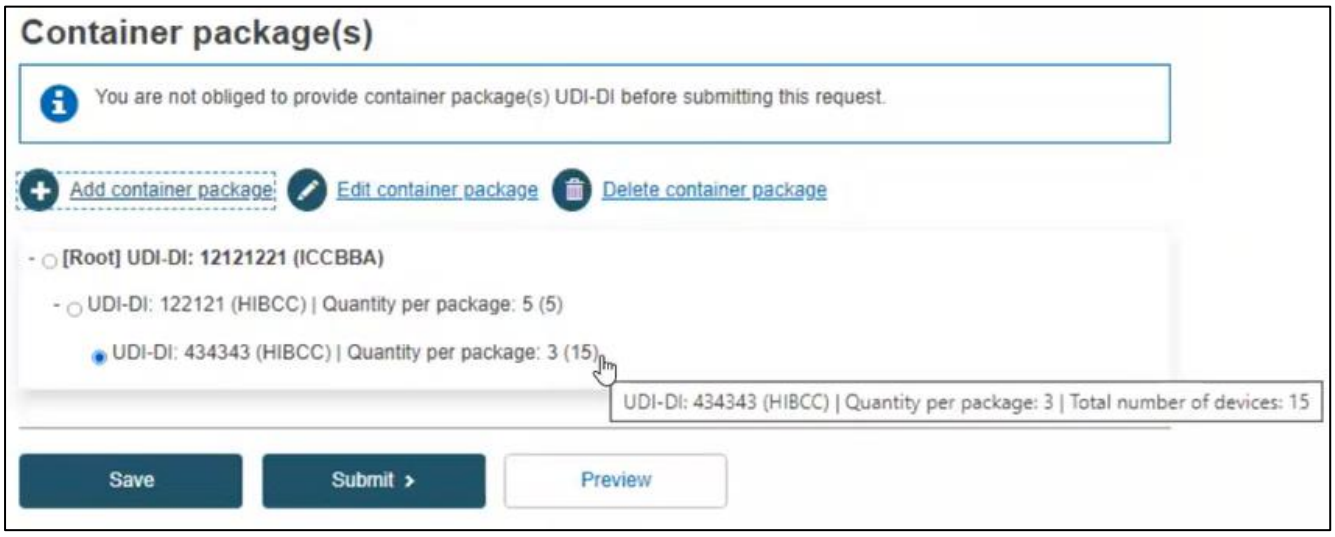
2. From the drop-down list choose the issuing entity.

3. Enter the Package UDI-DI code and the quantity per package in the boxes provided.

4. Click on “Save” to return to the main page.

You can add several container packages, and also edit or delete the container package information you provided.

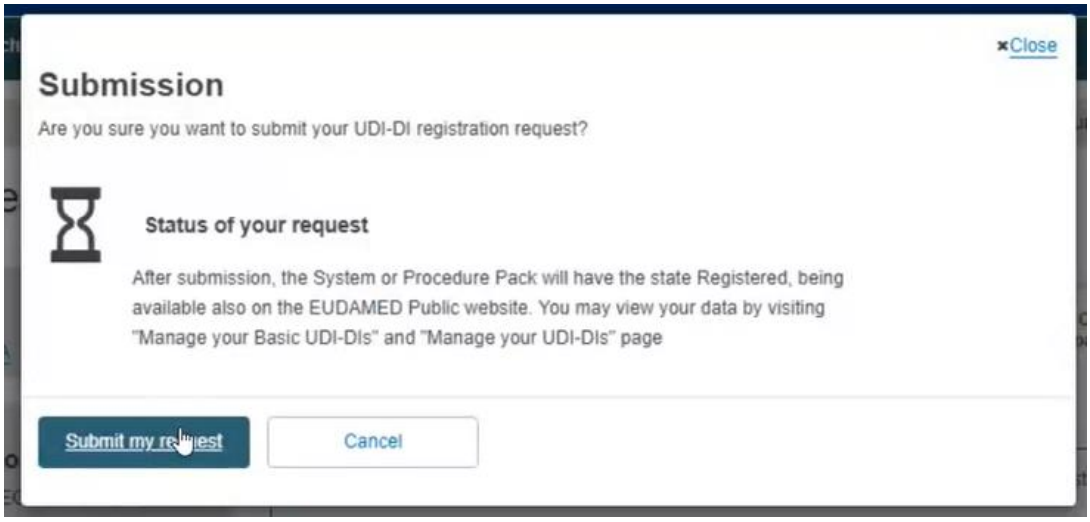
Note: the system calculates the total number of devices according to the quantity per package you provided:



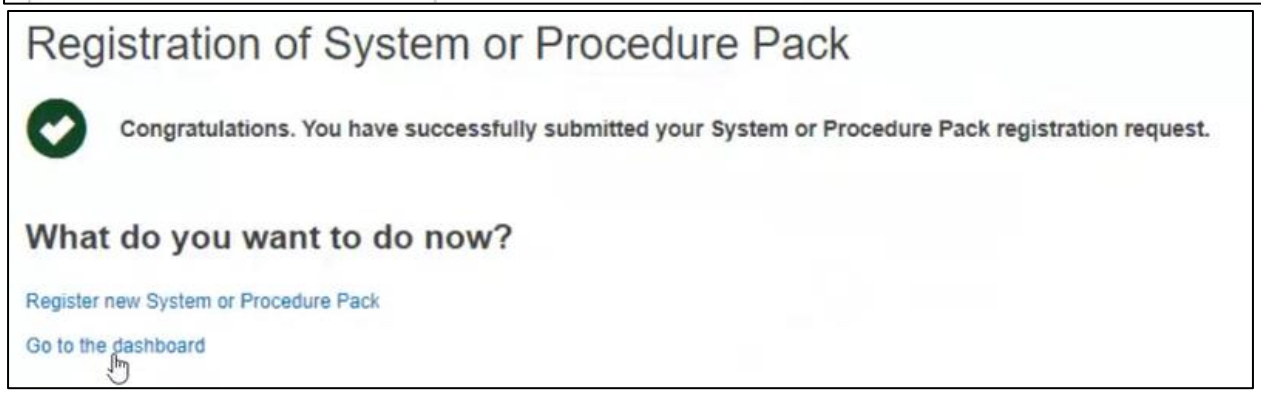
5. If you are ready to submit the registration, click on “Submit”:

You also have the option to preview the information of the registration by clicking on “Preview”.

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



Upon submission, you will see a message that you have successfully submitted a System or Procedure Pack registration request:

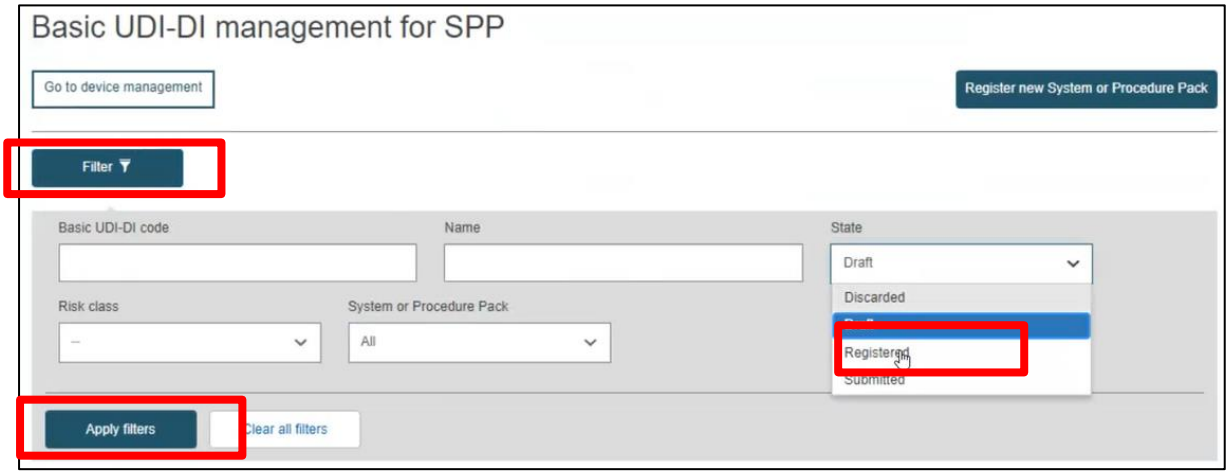


5.2. Registration of UDI-DI for an existing Basic UDI-DI of a System or Procedure Pack

1. On the Dashboard, select “Manage your Basic UDI-DIs”

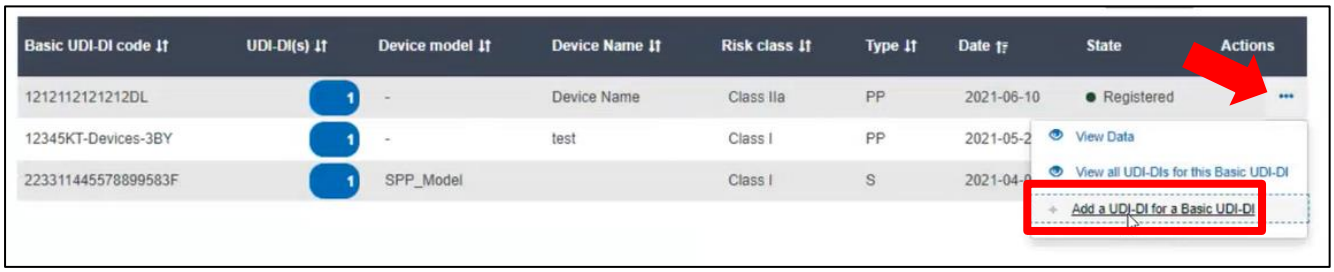
2. Filter the Basic UDI-DIs with state “Registered”.

To do that click on the button “Filter”, then select “Registered” in the “State” box and then click on the button “Apply filter”:



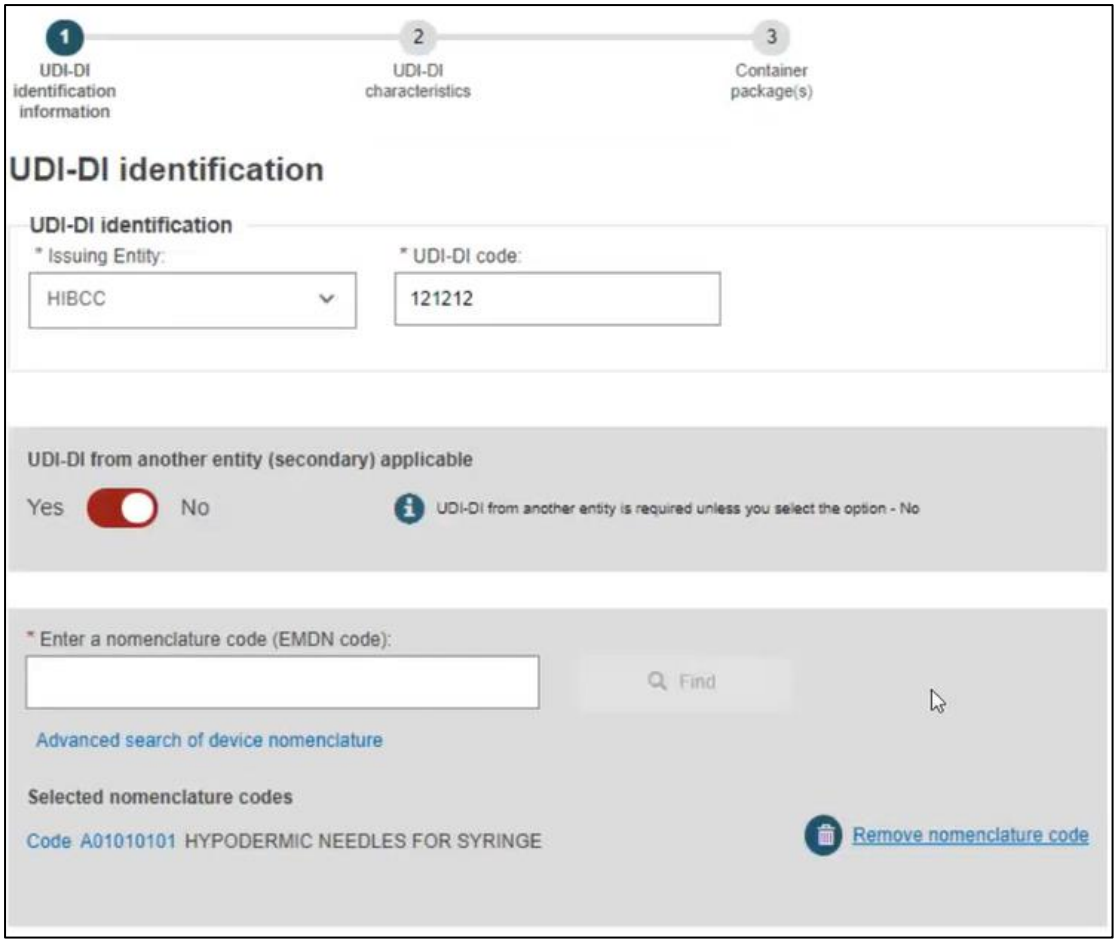
New UDI-DIs can be added only for Basic UDI-DIs in state Registered or Submitted.

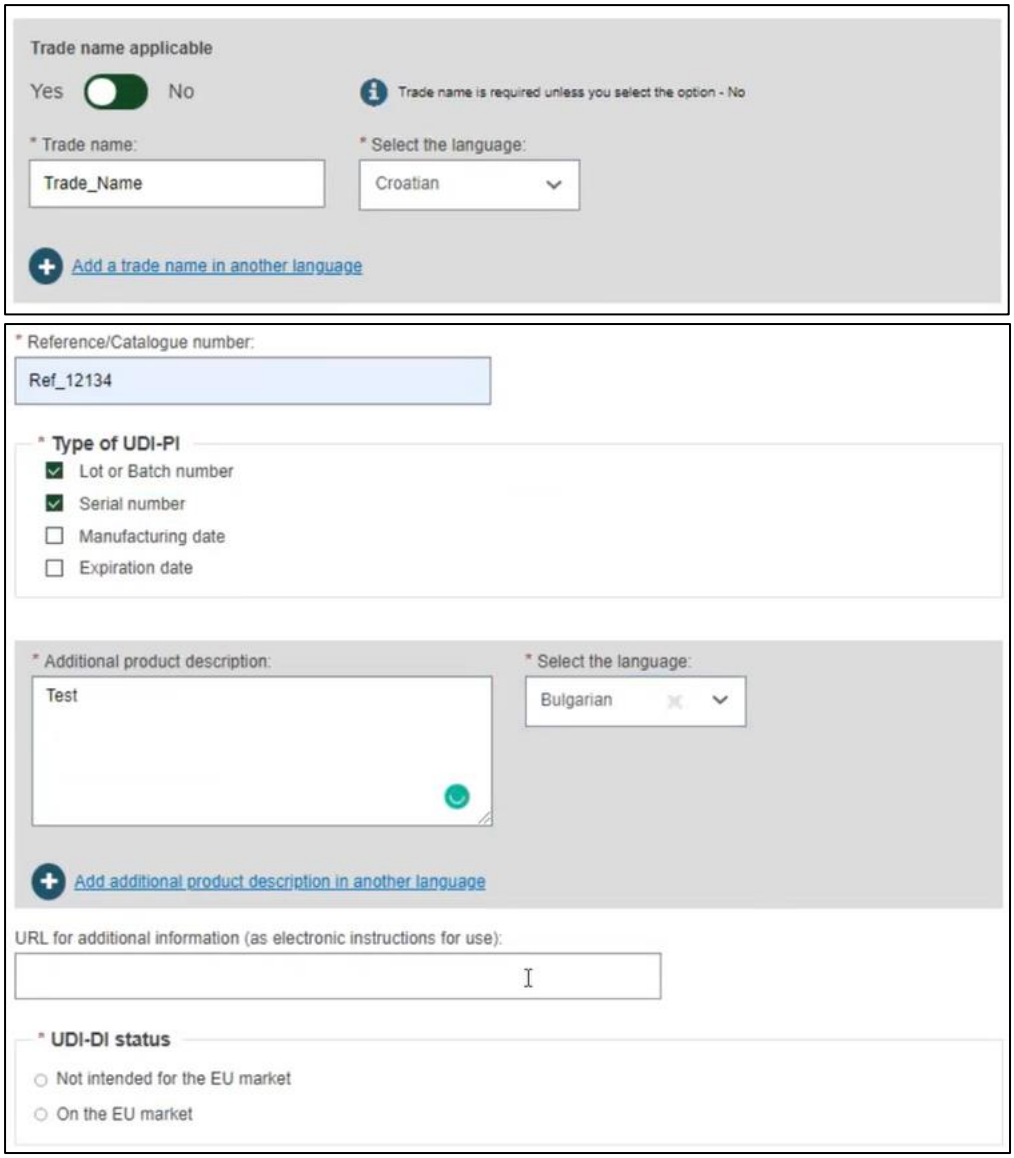
3. Identify the desired Basic UDI-DI for which you would like to add a new UDI-DI and click on the ellipsis symbol to add it:



5.2.1 Step 1: UDI-DI identification information

1. Complete all the fields required in the UDI-DI identification information tab for the registration of a UDI-DI for an existing Basic UDI-DI:

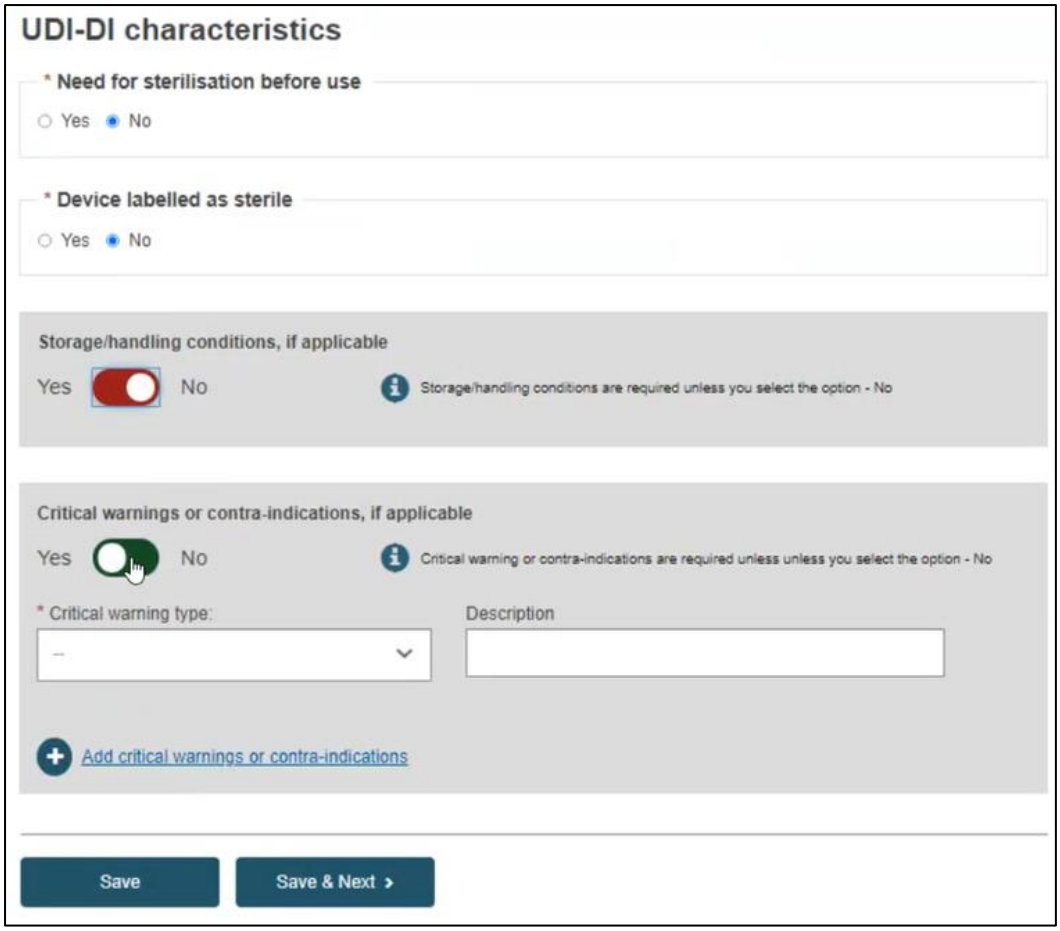

1
UDI-DI identification information
2
UDI-DI characteristics
3
Container package(s)
UDI-DI identification
UDI-DI identification
* Issuing Entity:
HIBCC
* UDI-DI code:
121212
UDI-DI from another entity (secondary) applicable
Yes
No
UDI-DI from another entity is required unless you select the option - 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



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

5.2.2 Step 2: UDI-DI Characteristics

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



2. Click on “Save & Next” to move to the next step (alternatively click on “Save” to save the details you have filled in so far as a draft).

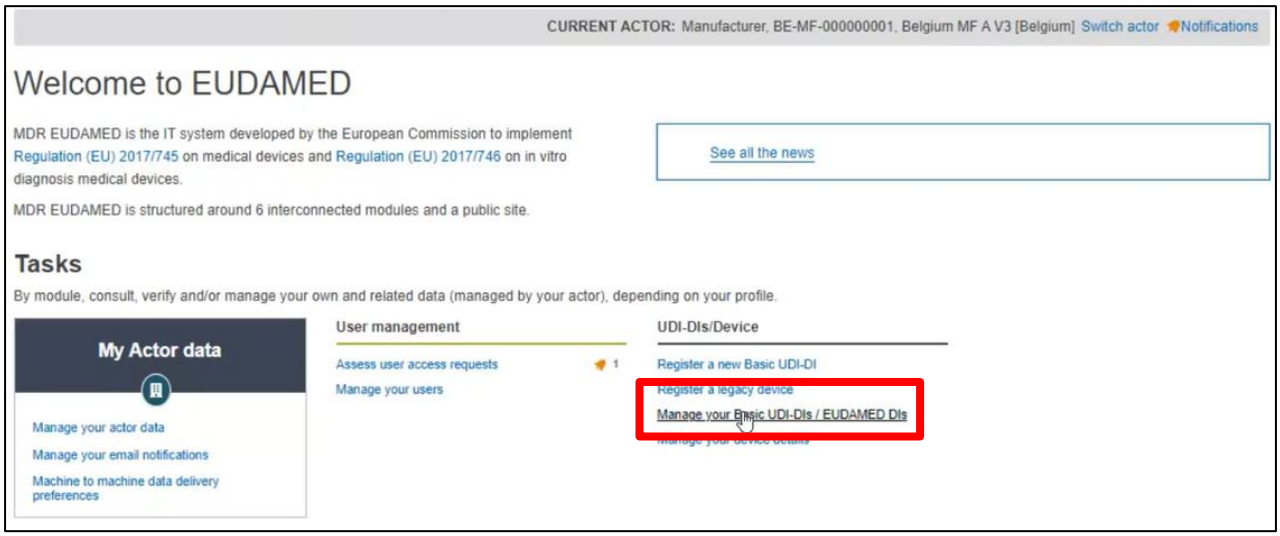
5.2.3 Step 3: Container Package details

To complete this step, please consult Section 5.1.5. of this guide.

6. Manage your own Device Information

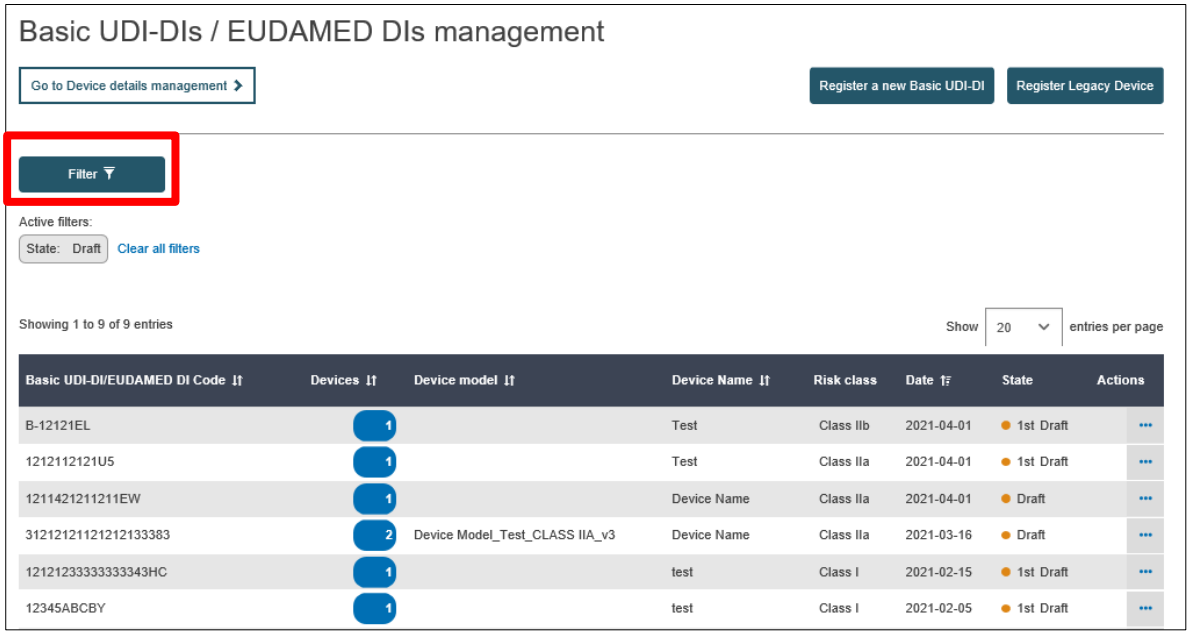
6.1. View own Basic UDI-DI/EUDAMED DIEUDAMED DI Details

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

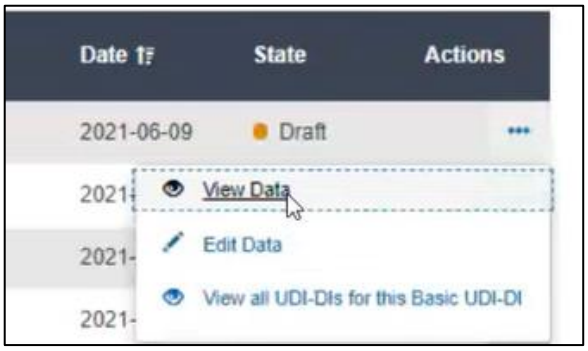


2. You will see a list with all of the Basic UDI-DIs /EUDAMED DIEUDAMED DIs registered to the current actor:

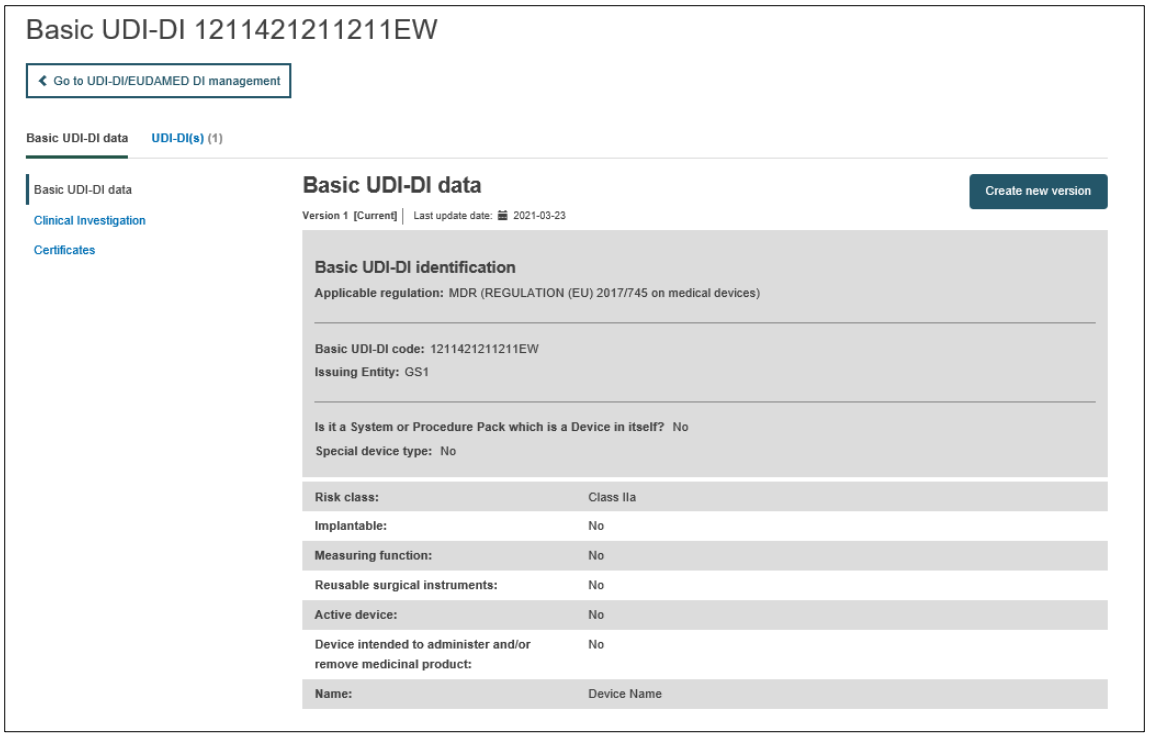
Note: By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in Draft state. In order to retrieve the desired Basic UDI-DIs/EUDAMED DIs, use the filters available:



3. Click on the ellipsis symbol (three dots) on the right of the desired item and then click on “View Data” from the menu:



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



6.1.1 Delete a Draft Basic UDI-DI/EUDAMED DI

After having followed the steps in the previous section 6.1 to view a Draft Basic UDI-DI/EUDAMED DI, you have the option to delete a draft.

1. Once inside the view of the desired draft, click on “Delete”:

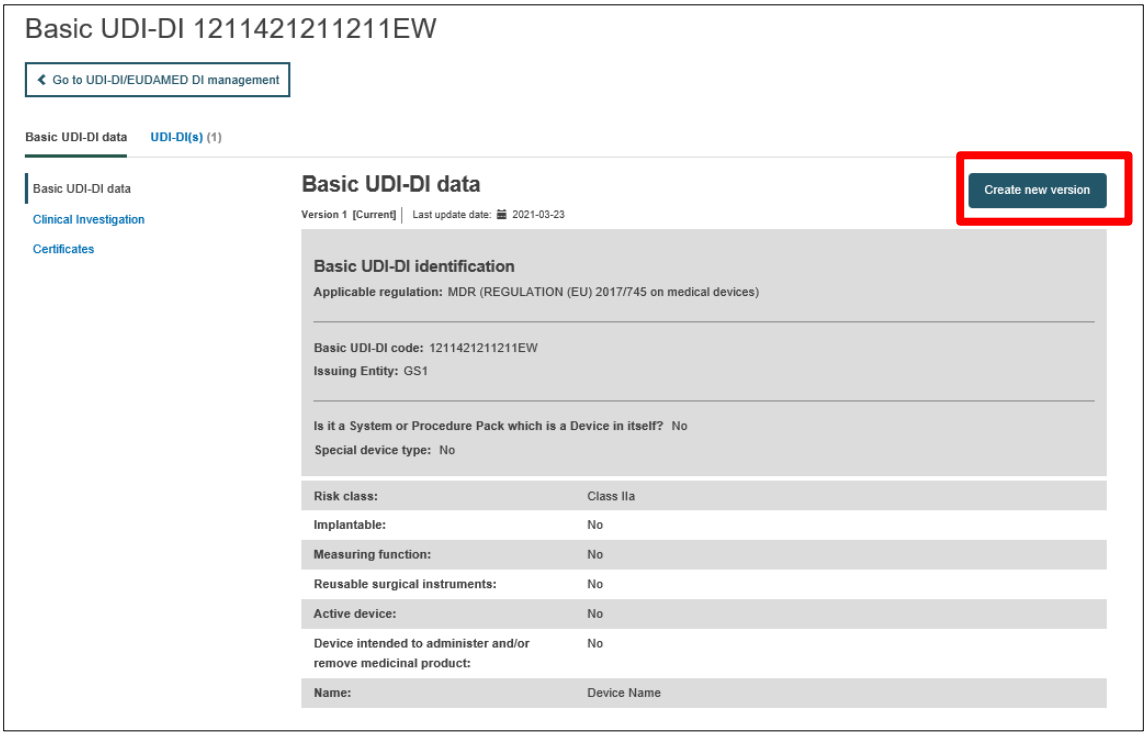
2. The system will prompt you to confirm your intention to delete the draft in a pop-up window. If certain, click on “Yes”:

The system will revert you to the latest registered information for this Basic UDI-DI.

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

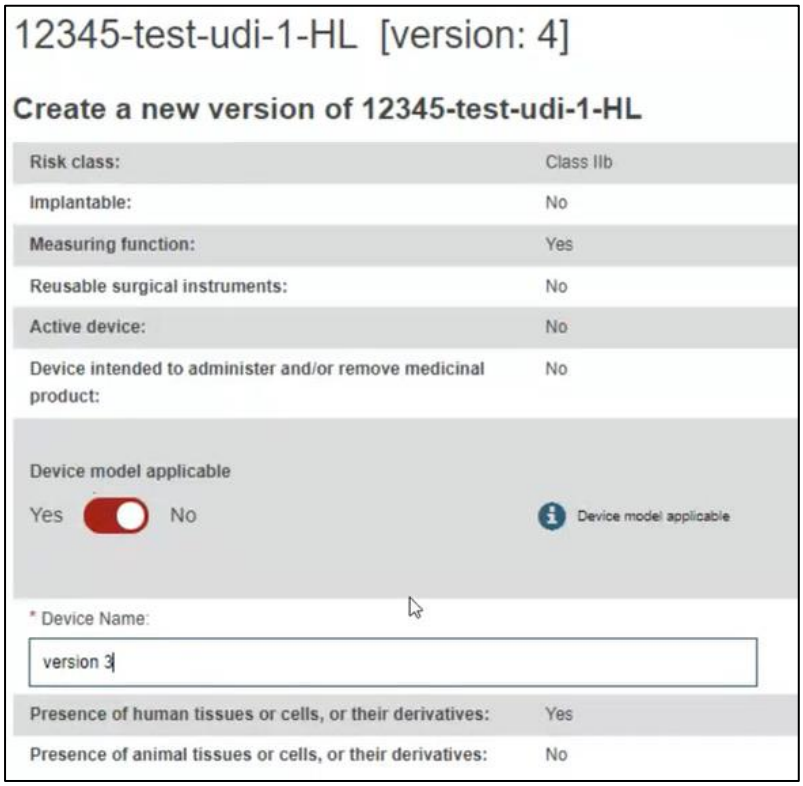
1. Follow the steps in section 6.1 to view a Basic UDI-DI/EUDAMED DI.

2. Once inside the view mode for the desired Basic UDI-DI, click on “Create new version”, on the top right corner:



3. Update the desired details.

Note: only some details can be updated depending on the actor's specifics, such as device model and device name:



4. To finish the action you have two options:

a. Click on "Save" to save the updated details without submitting the new version. This option saves the update as "Draft" and allows you to go back and edit/delete if you are uncertain about the update.

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

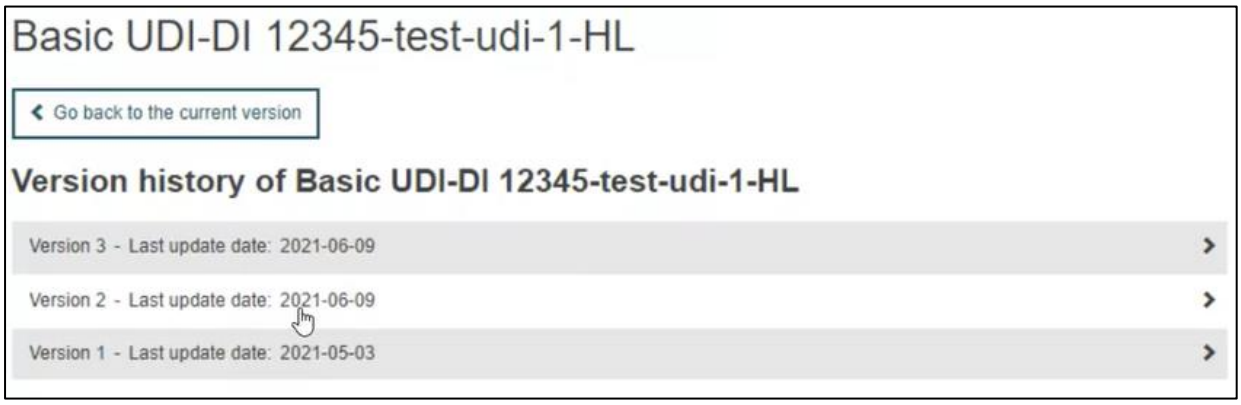
Alternatively, you can press "Cancel" to cancel the update.

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

1. Follow the steps in section 6.1 to view a Basic UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired Basic UDI-DI, click on "See version history" on the top of the table:

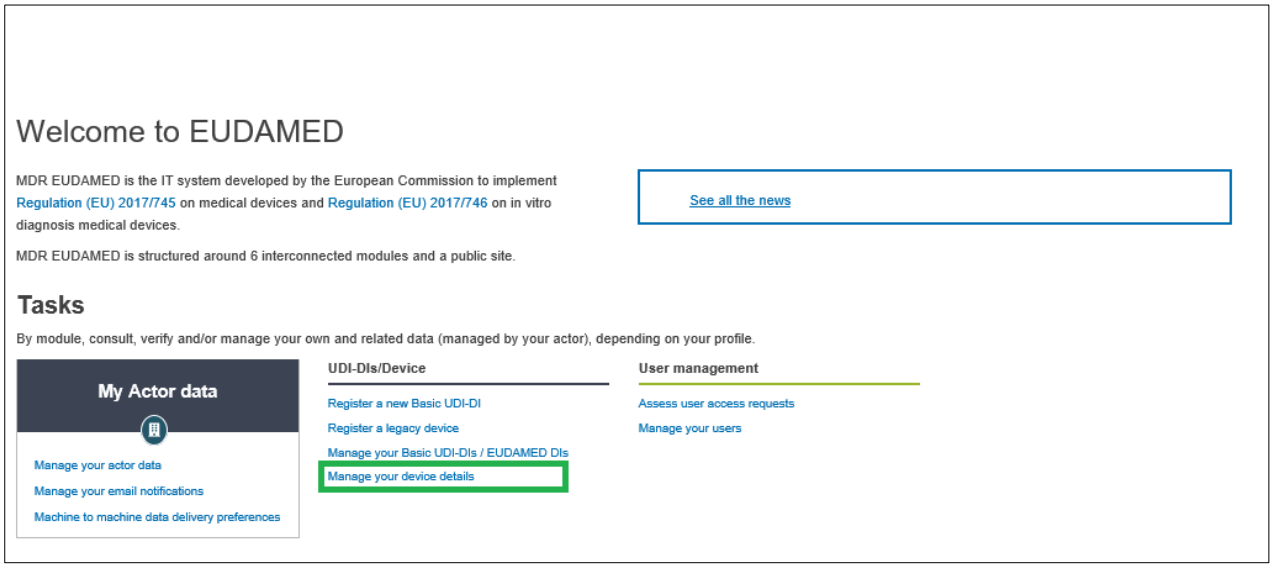
3. View the list of versions for the desired Basic UDI-DI and click on the desired version to view its details:



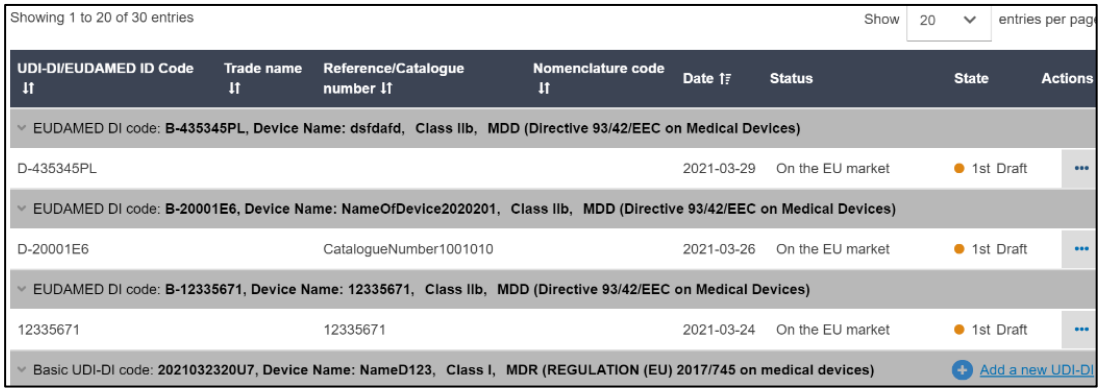
4. Inside the summary of a version, note that you can browse through the different versions via the browsing function on the top right corner:

6.2. View own UDI-DI/EUDAMED DI Details

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

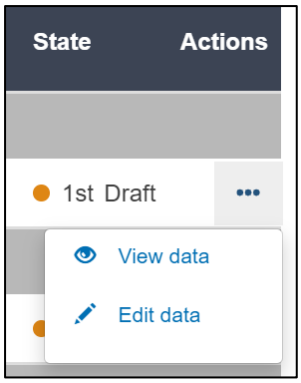


2. You will see a list with all of the devices registered to you:

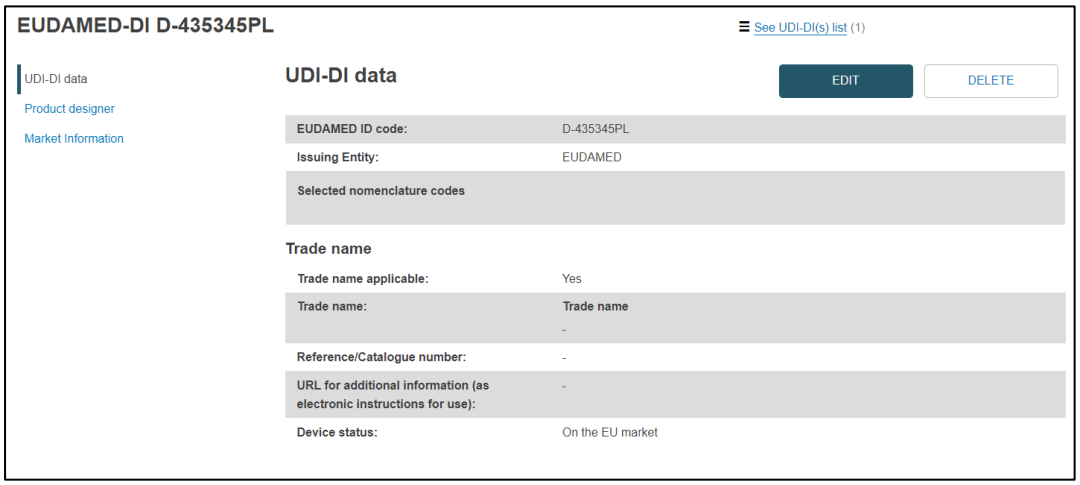


Note: By default, the system lists the devices in “Draft” state. In order to retrieve the desired Devices, use the filters available by clicking on “Filter”:

3. On the right-hand side of each device there is an ellipsis symbol (three dots); click on it and then click “View data” from the menu:



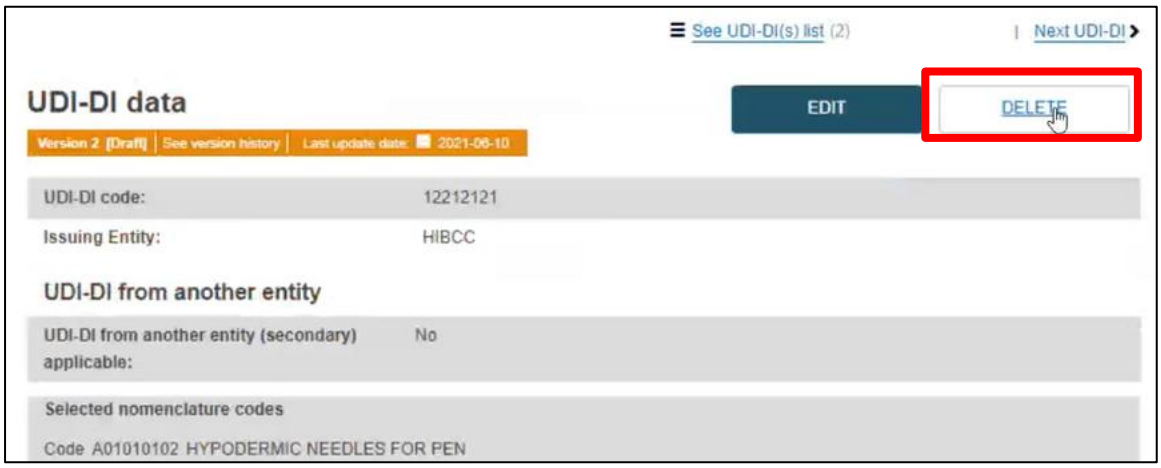
4. You will see a summary of the details concerning your device:



6.2.1 Delete a Draft UDI-DI/EUDAMED DI

1. Follow the steps in Section 6.2. to view a Draft UDI-DI.

2. Once inside the summary for the desired Draft UDI-DI, simply click on “Delete”, on the top right corner:

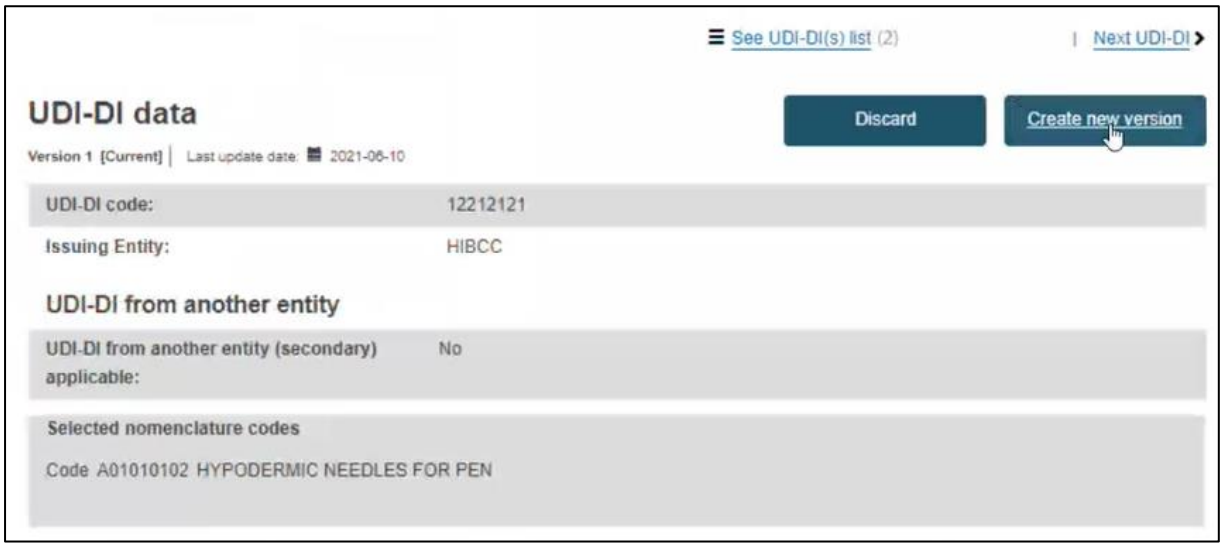


3. A pop-up message will prompt you to confirm the delete action:

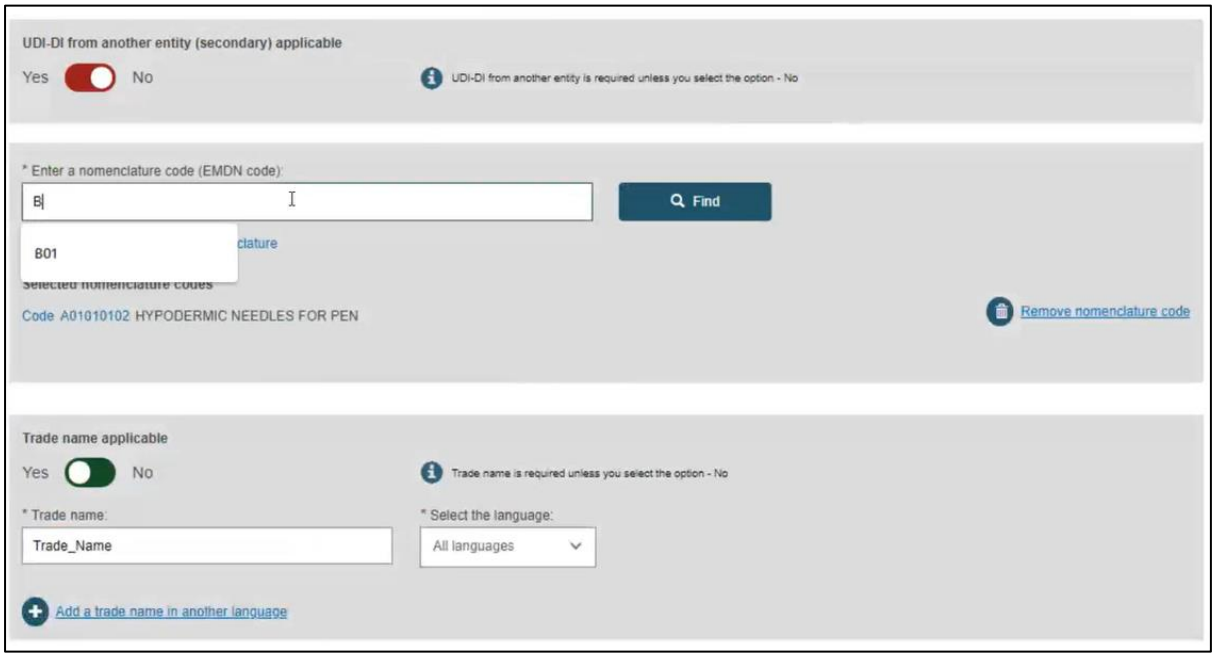
6.2.2 Update (Create a new version) for UDI-DI/EUDAMED DI

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired UDI-DI, click on “Create new version”, on the top right corner:



3. Update the desired details, for example:



Note: only some details can be updated depending on the actor’s specifics.

4. To finish the action you have two options:

a. “Save” to save the updated details without submitting the new version.

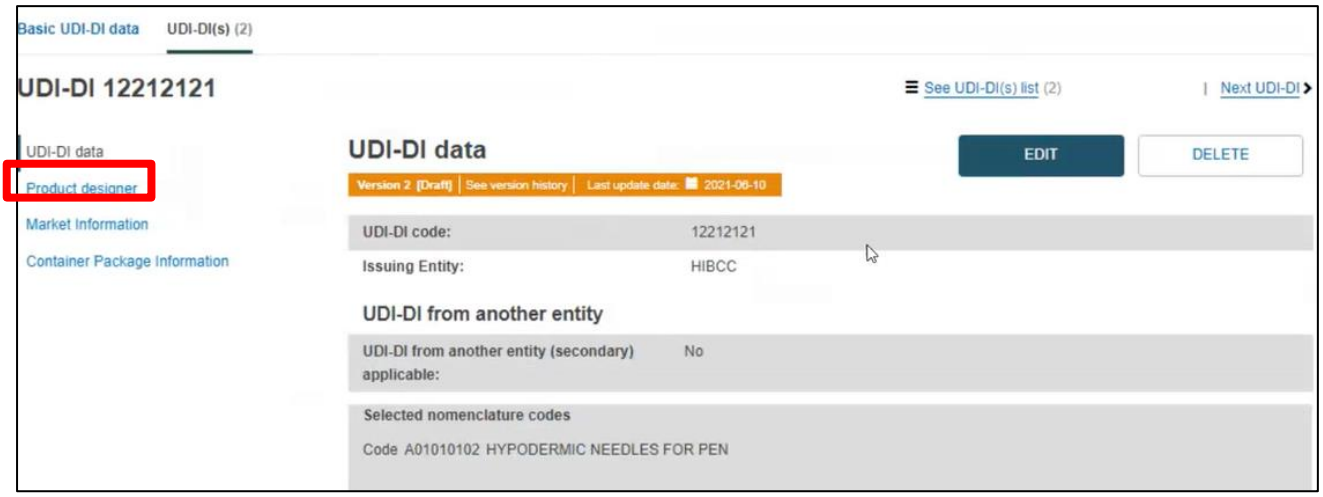
b. “Submit new version”, if you wish to finalise the update.

6.2.3 Update (Create new version) for Product Designer

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

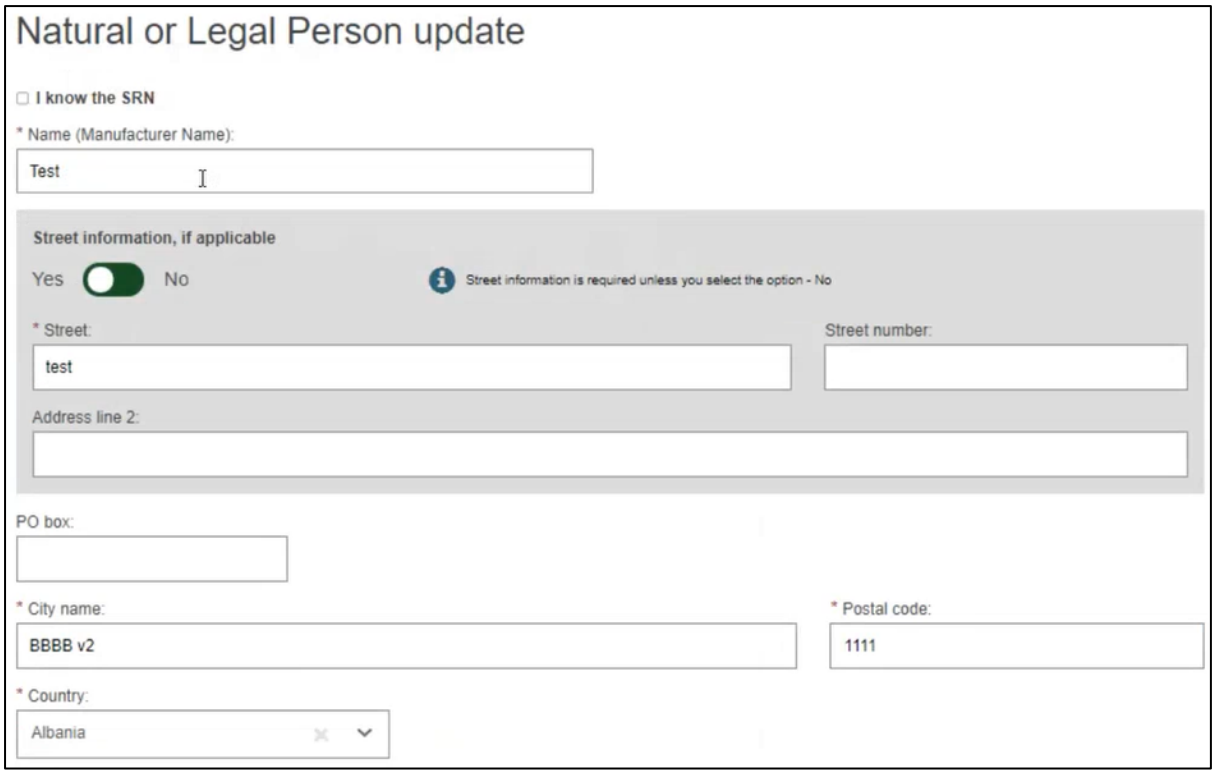
1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired UDI-DI, click on “Product Designer” from the list on the left (or scroll down to the Product Designer section):



3. Click on the “Update” button of the Product Designer section:

4. Update the fields under Product Designer:



5. Click on “Submit” at the bottom of the screen to finalise the update.

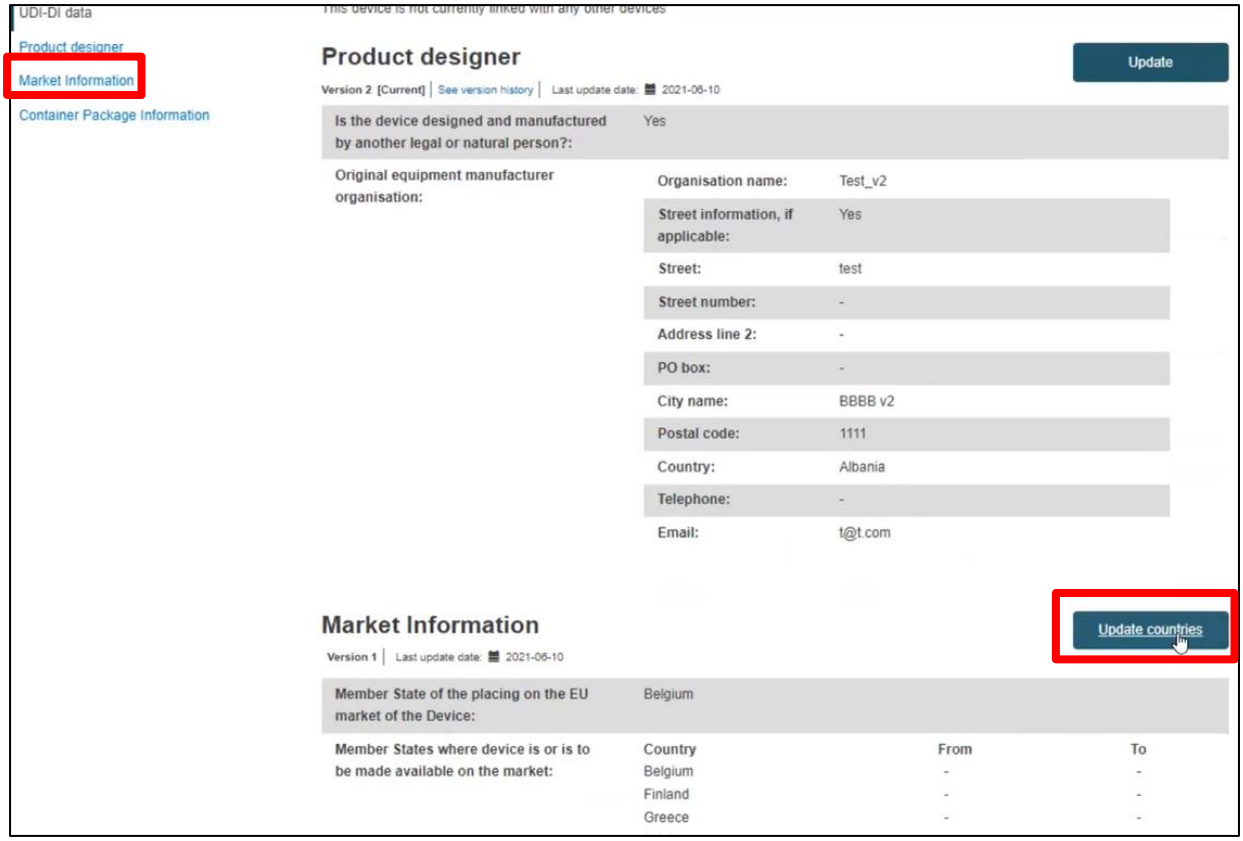
You will be able to see the new version created for the “Product Designer” information.

6.2.4 Update (Create new version) for Market Information

The Market information can be updated independently of the rest of the data in a device UDI-DI.

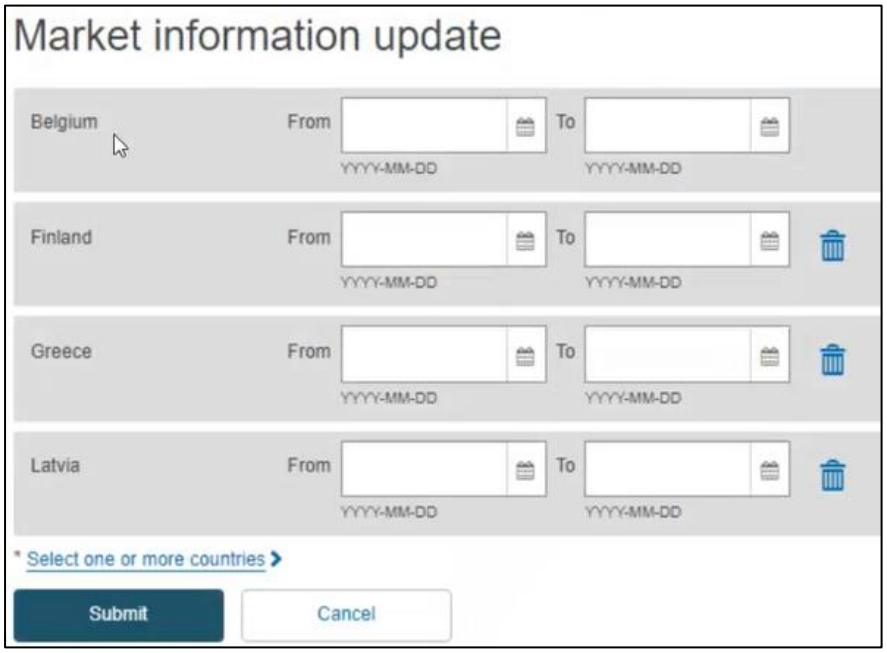
1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired UDI-DI, click on “Market information” from the list on the left (or scroll down to the Market information section):



3. Click on “Update countries”.

4. Update the relevant fields under “Market information”:



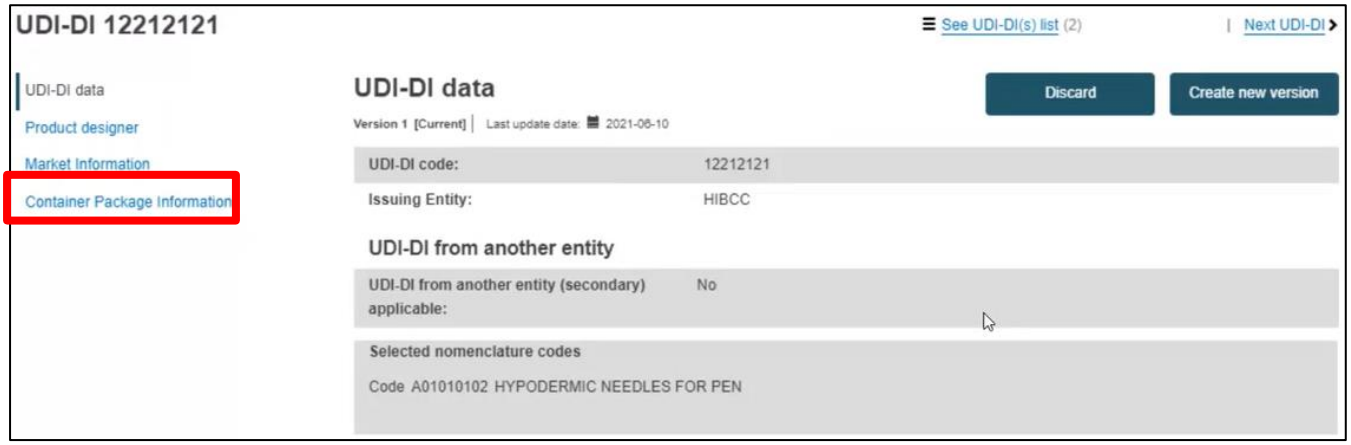
5. Click on “Submit” to finalise the update. You will be able to see the updated version of Market information:

6.2.5 Update (Create new version) for Container Packages

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

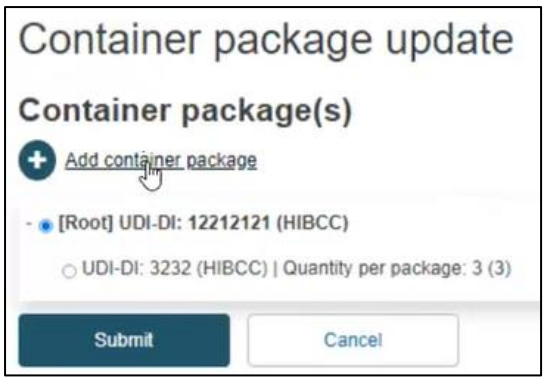
1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):

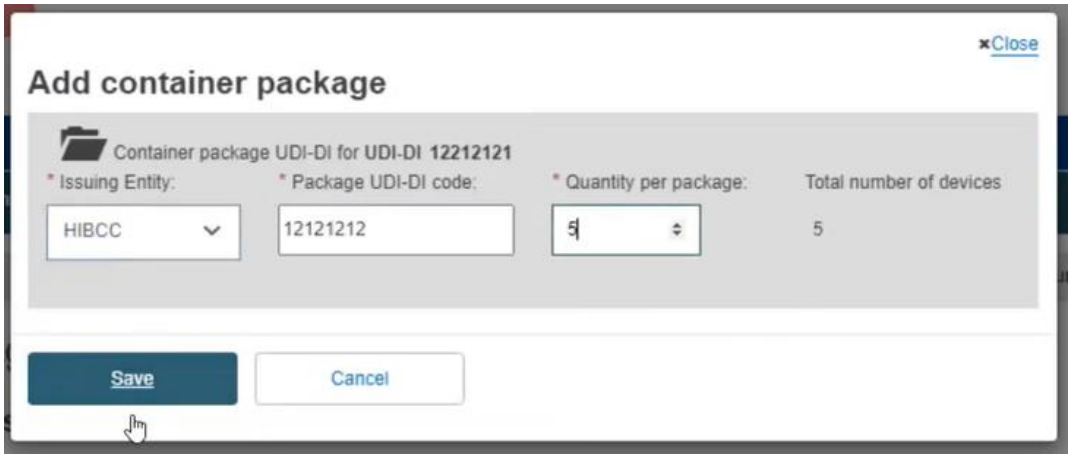


3. Click on “Create new version” in the Container Package section:

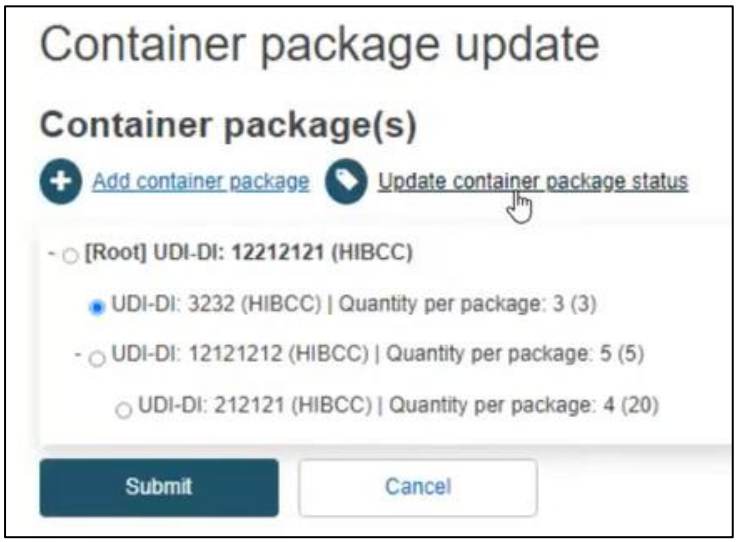
4. Click on “Add container package” to add new information about the packaging format of the device:



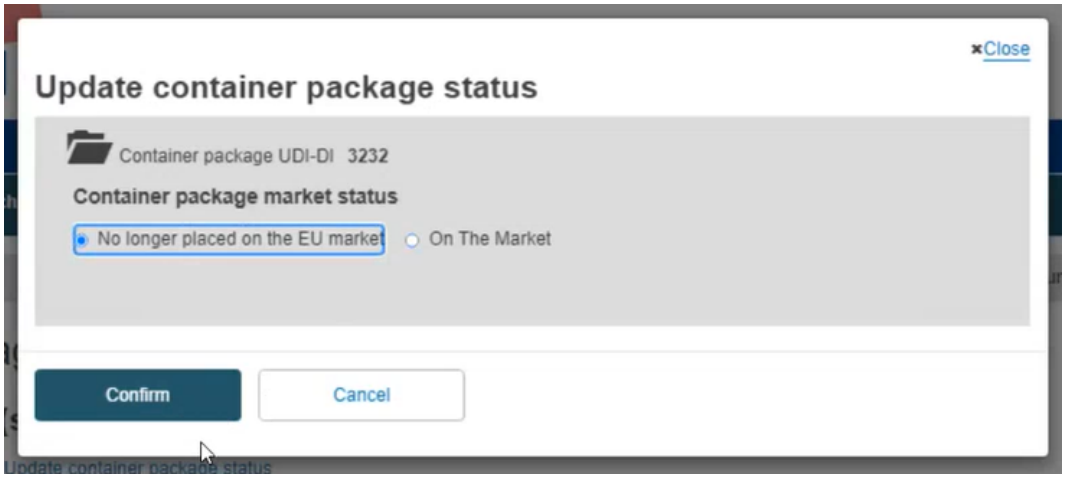
5. Insert the package details in the pop-up window and click on “Save”:



5. Once you add new package details, you also have the option to update the container package status:



6. Update the package market status if needed and click on “Confirm”:



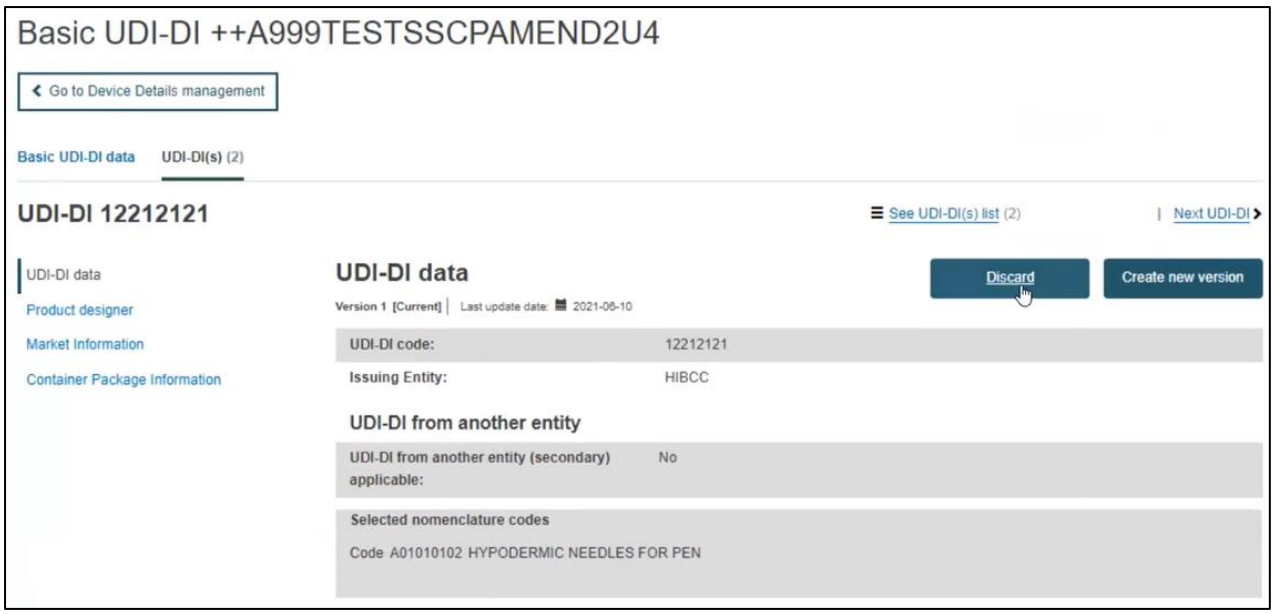
7. Click on “Submit” to finalise the container package update:

6.2.6 Discard registered UDI-DIs/EUDAMED DIs

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

1. Follow the steps in section 6.2 to view a registered UDI-DI/EUDAMED DI.

2. Once inside the summary of the desired UDI-DI, click on “Discard”, on the top right corner:



3. The system will prompt you to confirm your wish to permanently discard the registered UDI-DI. Click on “Yes” to finalise the action:

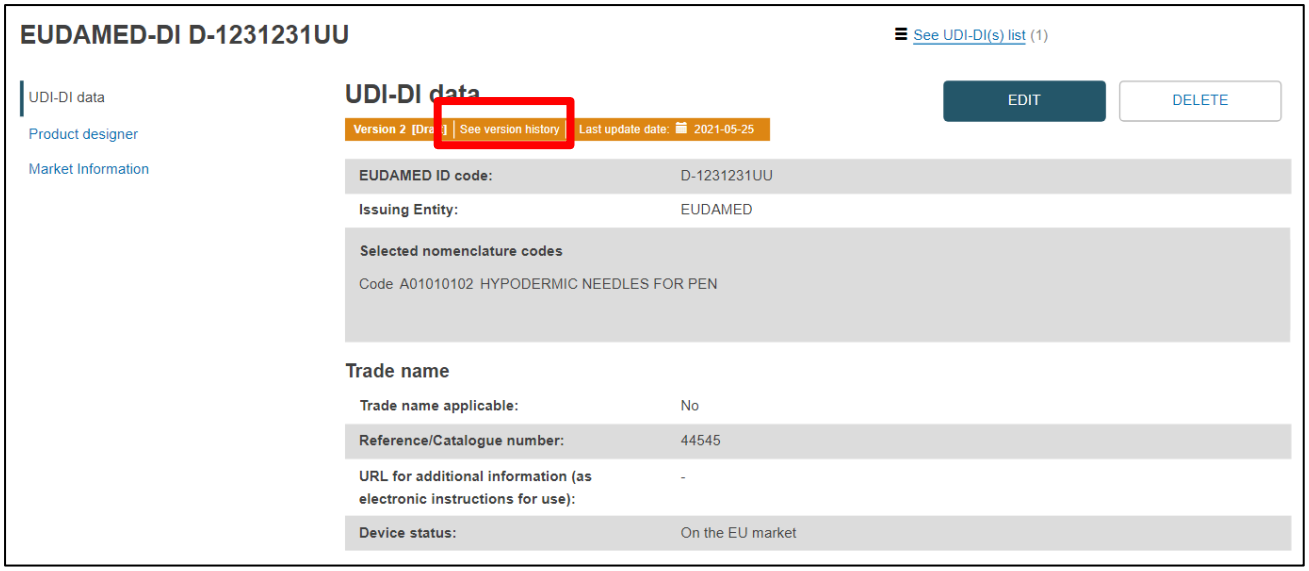
The UDI-DI will be discarded and thus no longer visible on the public EUDAMED platform.

Attention: if the UDI-DI is the only one remaining in this Basic UDI-DI category, performing the “discard” action will also discard the Basic UDI-DI. The system will inform you accordingly:

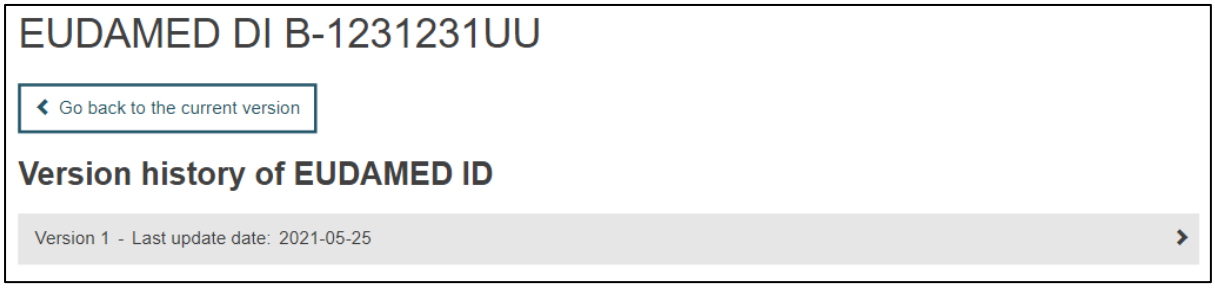
6.2.7 View historical versions of UDI-DI/EUDAMED ID and associated entities

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED ID.

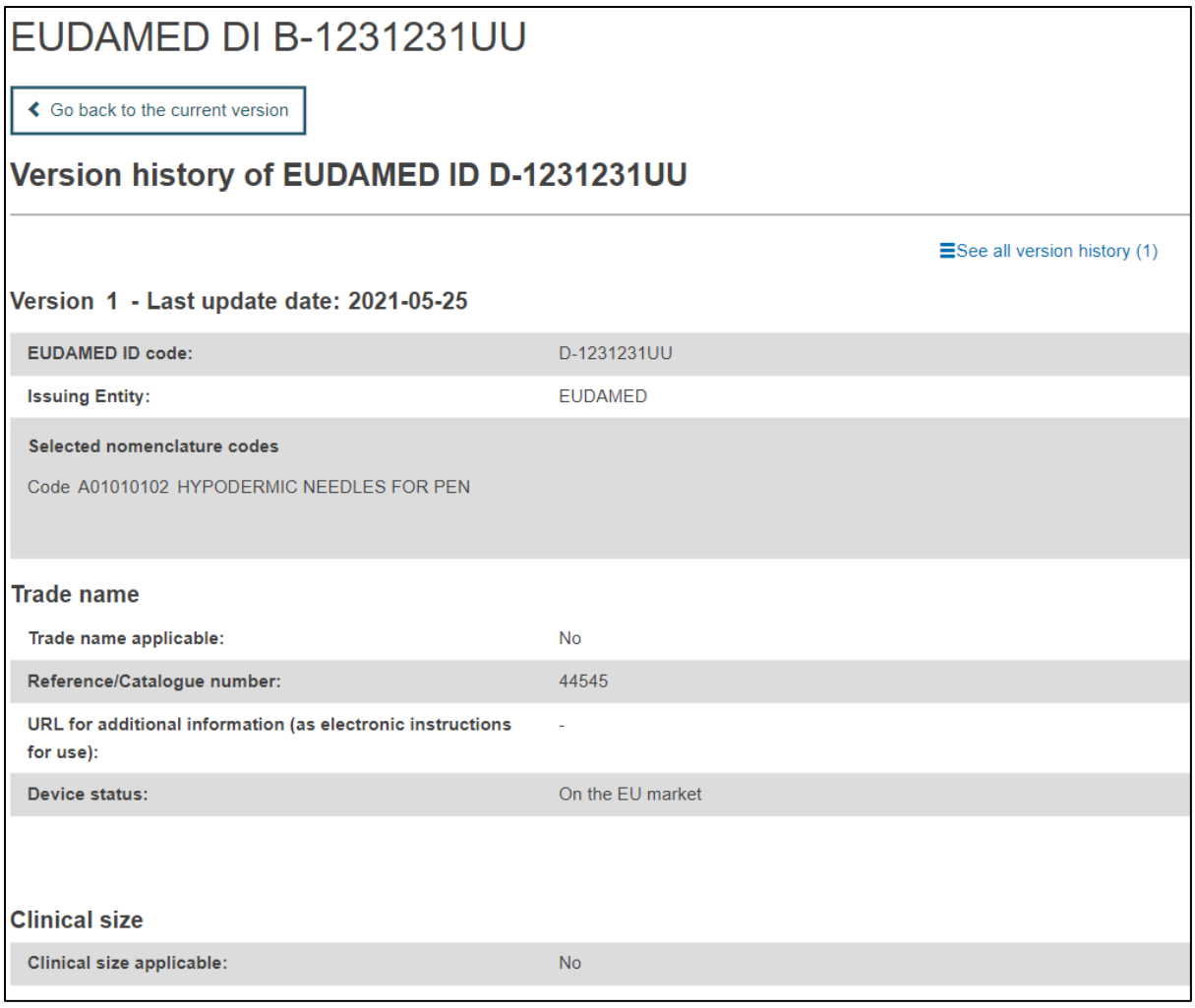
2. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:



3. You will see a list of all previously created versions (in the example below, there is only one version available):



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

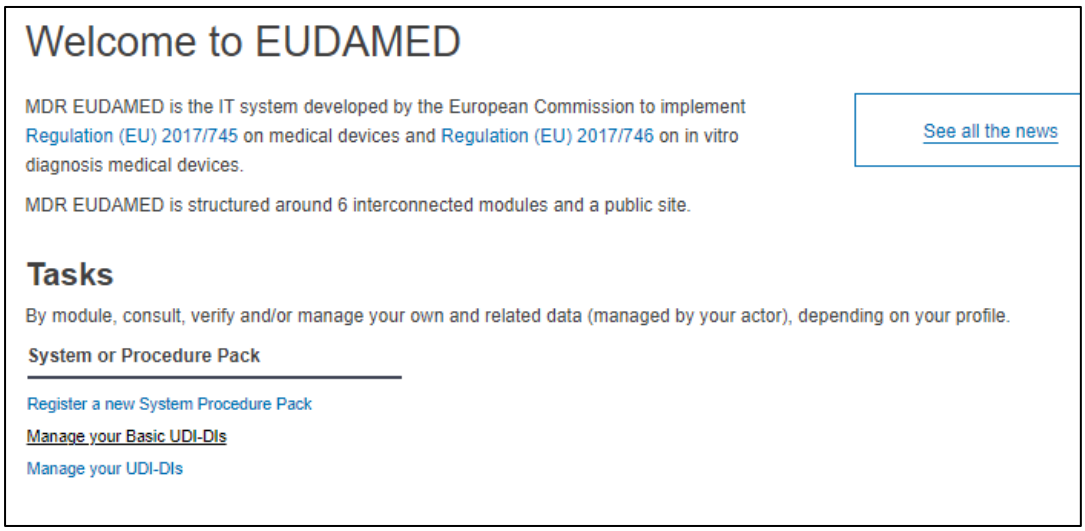


You can return to the version history list, by clicking on “See all version history” on the top right corner.

7. Manage your own System or Procedure Pack information

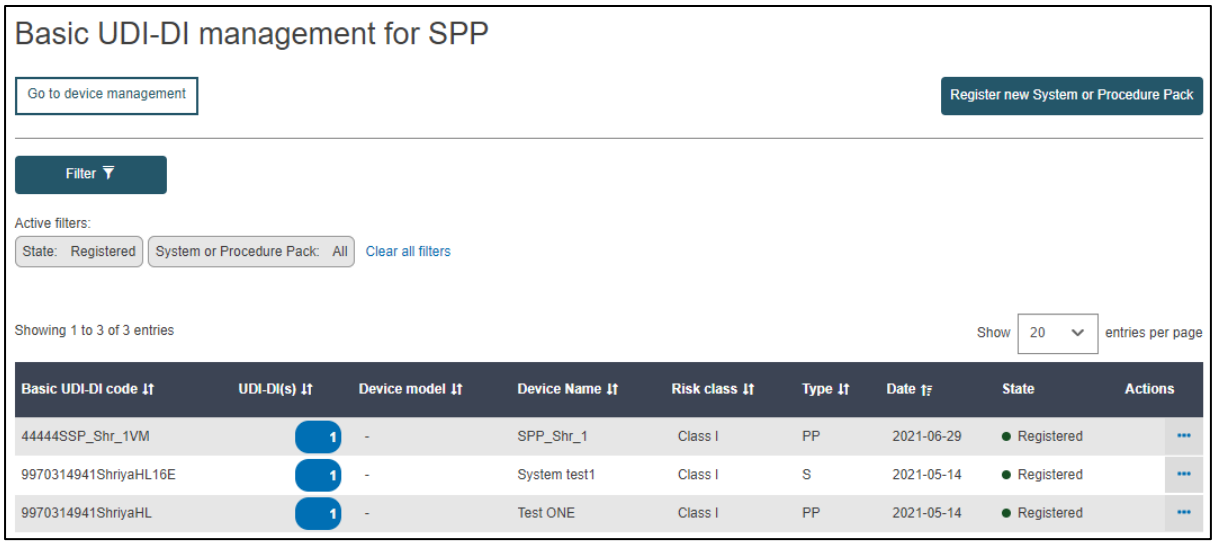
7.1. View own Basic UDI-DI details

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

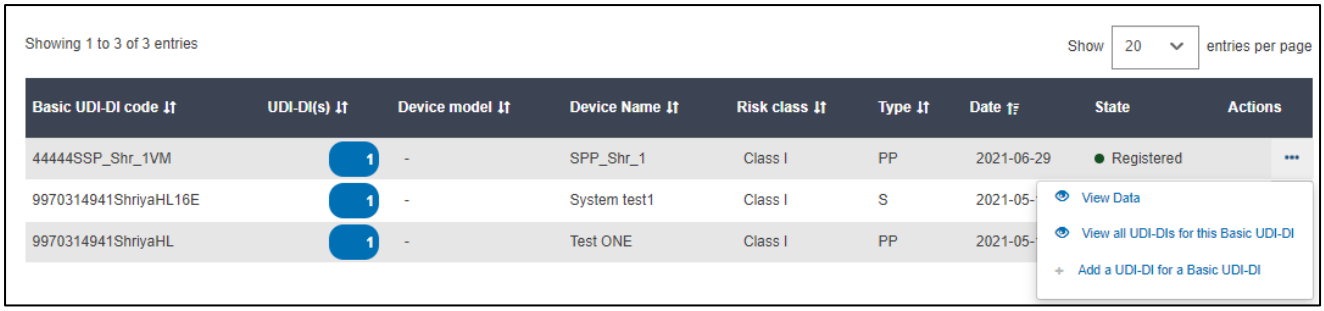


Note: By default, the system displays the System or Procedure Packs in state “Draft”.

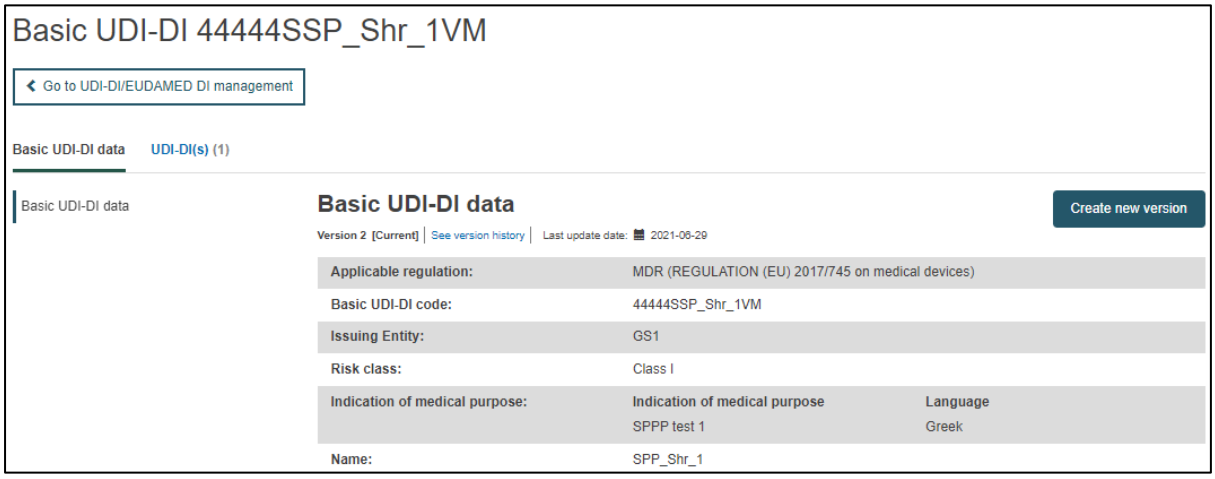
2. In order to retrieve the desired SPP, use the filters available by clicking on the “Filter” button and selecting the desired parameters:



3. On the right-hand side of each item there is an ellipsis symbol (three dots); click on it and then click on “View data” from the menu:

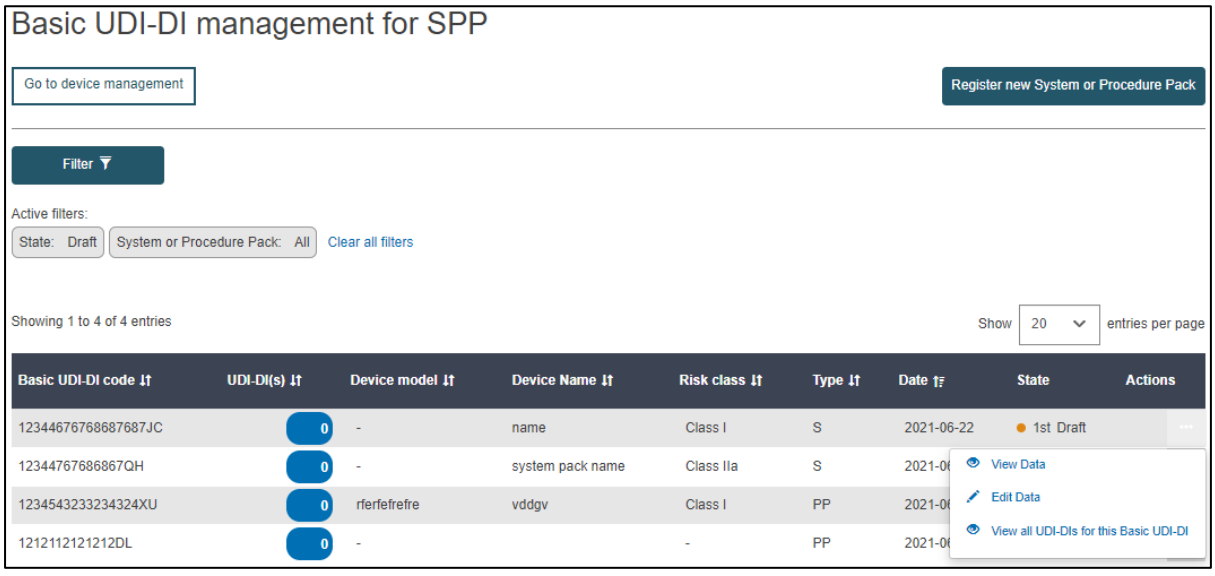


4. You will see a summary of the details concerning your system or procedure pack:

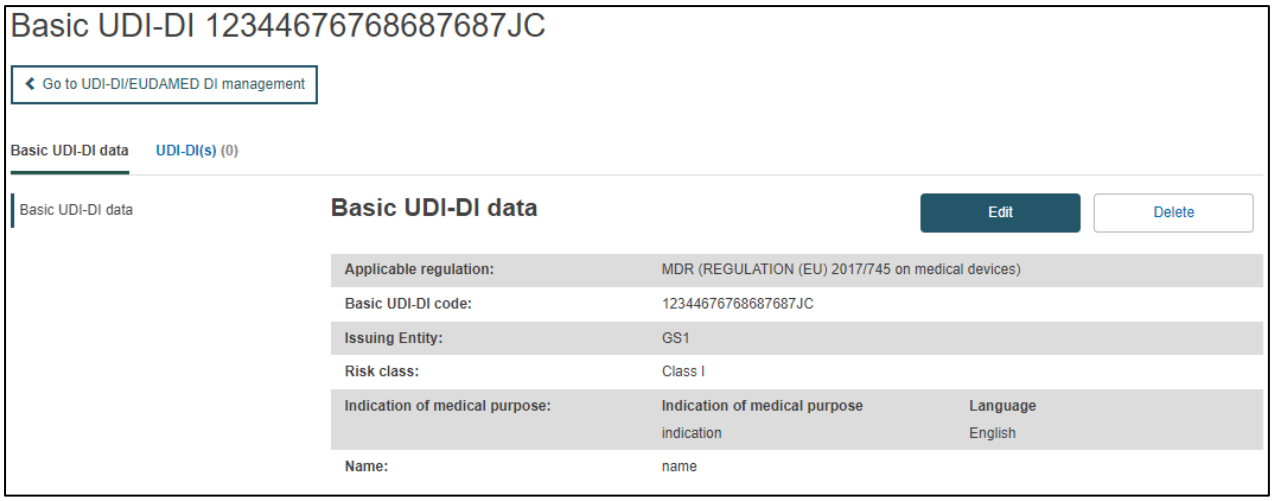


7.1.1 Delete a Draft Basic UDI-DI

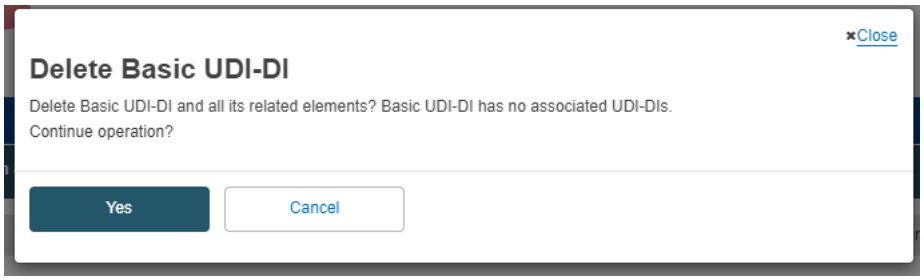
1. Follow the steps in Section 7.1 to view a Draft Basic UDI-DI:



2. Once inside the summary for the desired Draft Basic UDI-DI, click on “Delete”, on the top right corner:



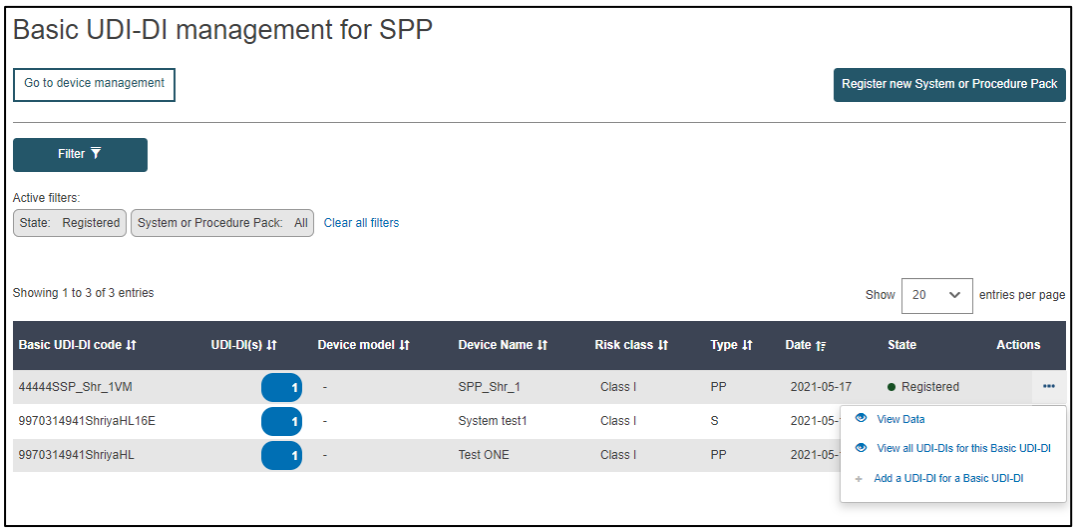
3. The system will prompt you to confirm your intention to delete the draft in a pop-up window. If certain, click on “Yes”:



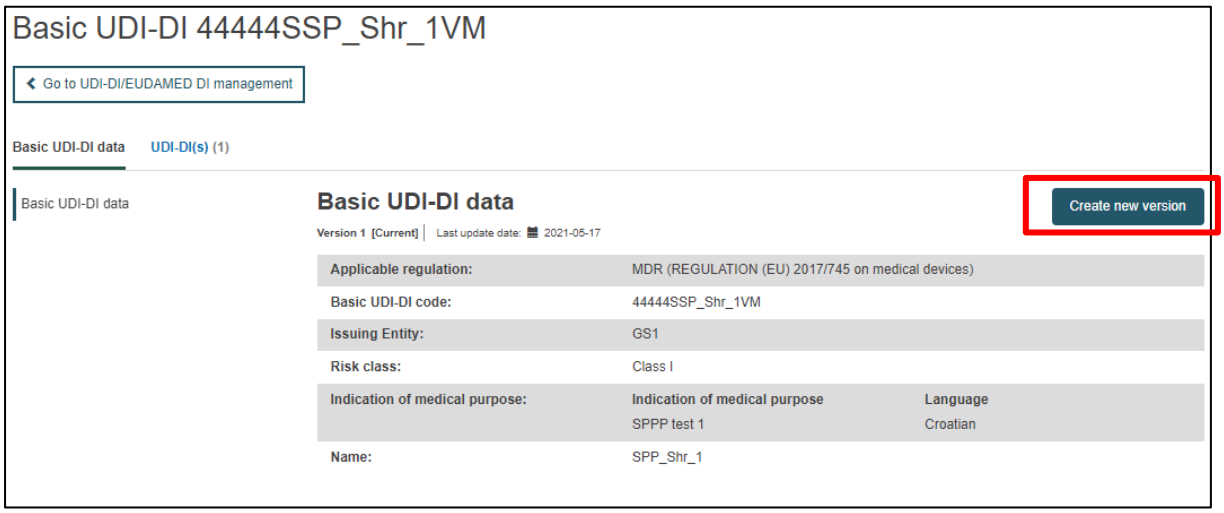
The system will revert you to the latest registered information for this Basic UDI-DI.

7.1.2 Update (Create a new version) for Basic UDI-DI

1. Follow the steps in Section 7.1 to view a Basic UDI-DI:

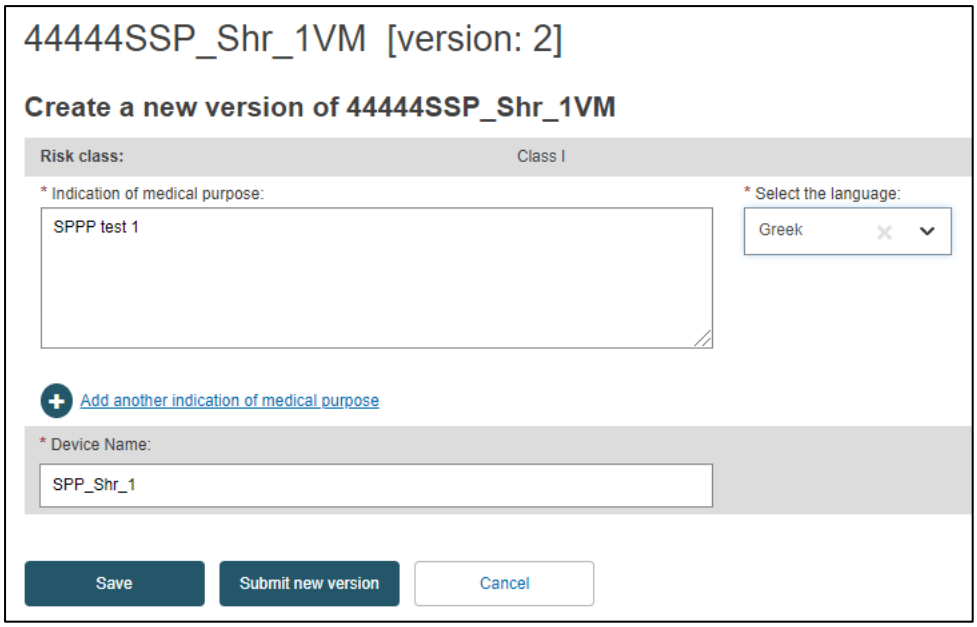


2. Once inside the summary for the desired Basic UDI-DI, click on “Create new version” on the top right corner:



3. Update the desired details.

Note: only some details can be updated depending on the actor’s specifics:



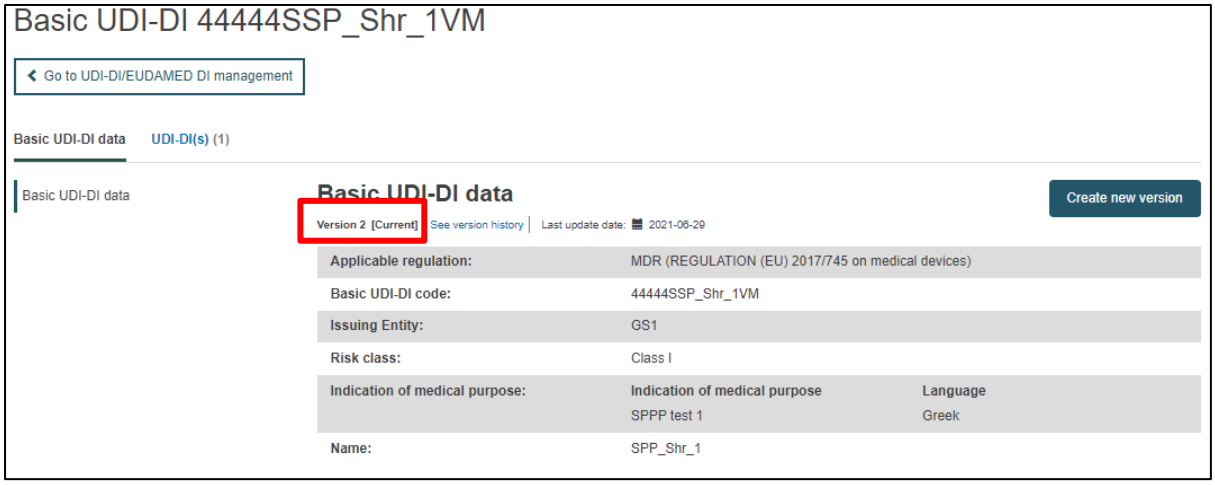
4. To finish the action you have two options:

a. Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are uncertain about the update.

b. Click on “Submit new version”, if you are certain about the update and wish to finalise it.

Alternatively, you can click on “Cancel” to cancel the update.

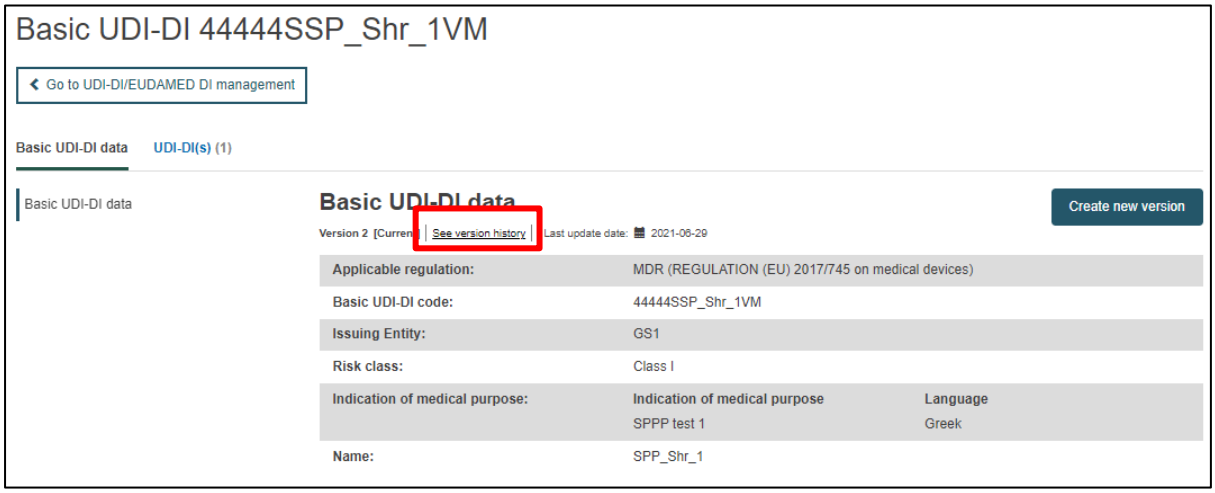
5. After you have submitted the new version, you can see it has been updated under the Basic UDI-DI details:



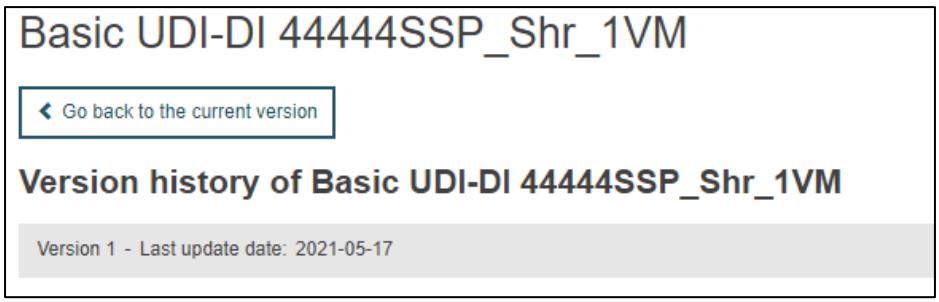
7.1.3 View historical versions for Basic UDI-DI

1. Follow the steps in Section 7.1 to view a Basic UDI-DI.

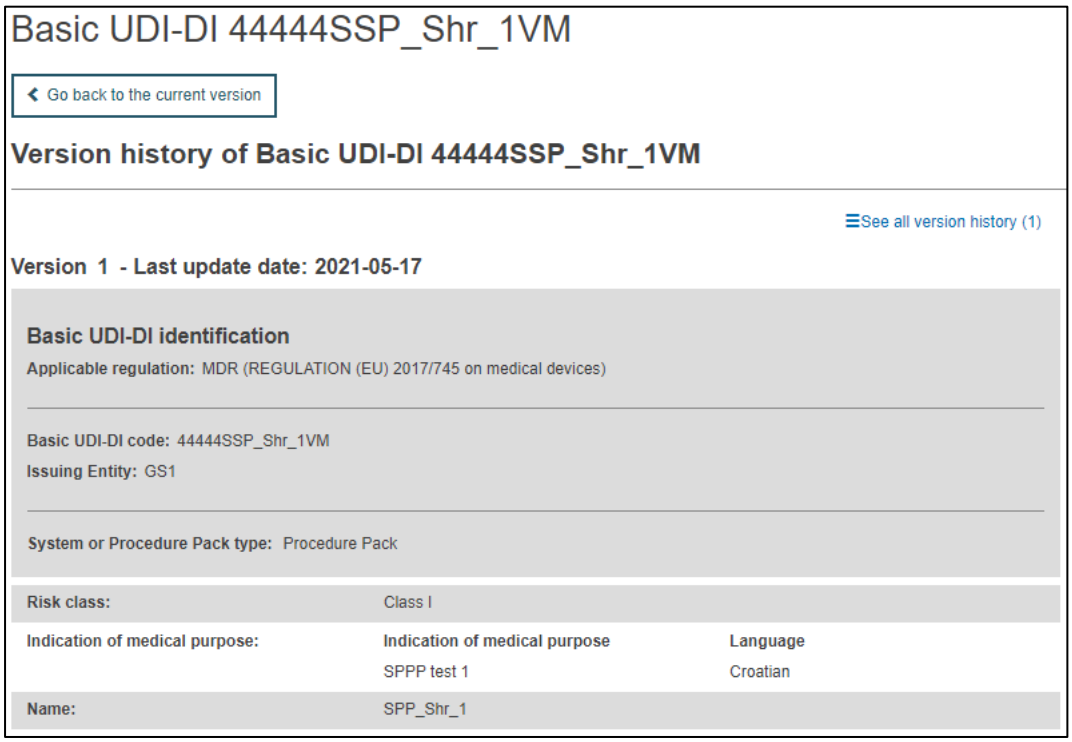
2. Once inside the summary for the desired Basic UDI-DI, click on “See version history” at the top of the table:



3. View the list of versions for the desired Basic UDI-DI and click on the desired version to view its details (in the example below, there is only one older version):

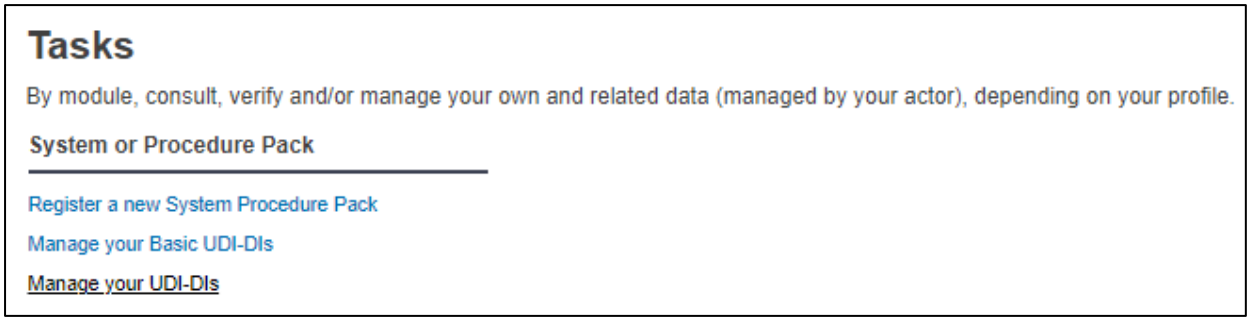


4. Once inside a historical version, you can return to the versions list by clicking on “See all version history” on the top right corner:

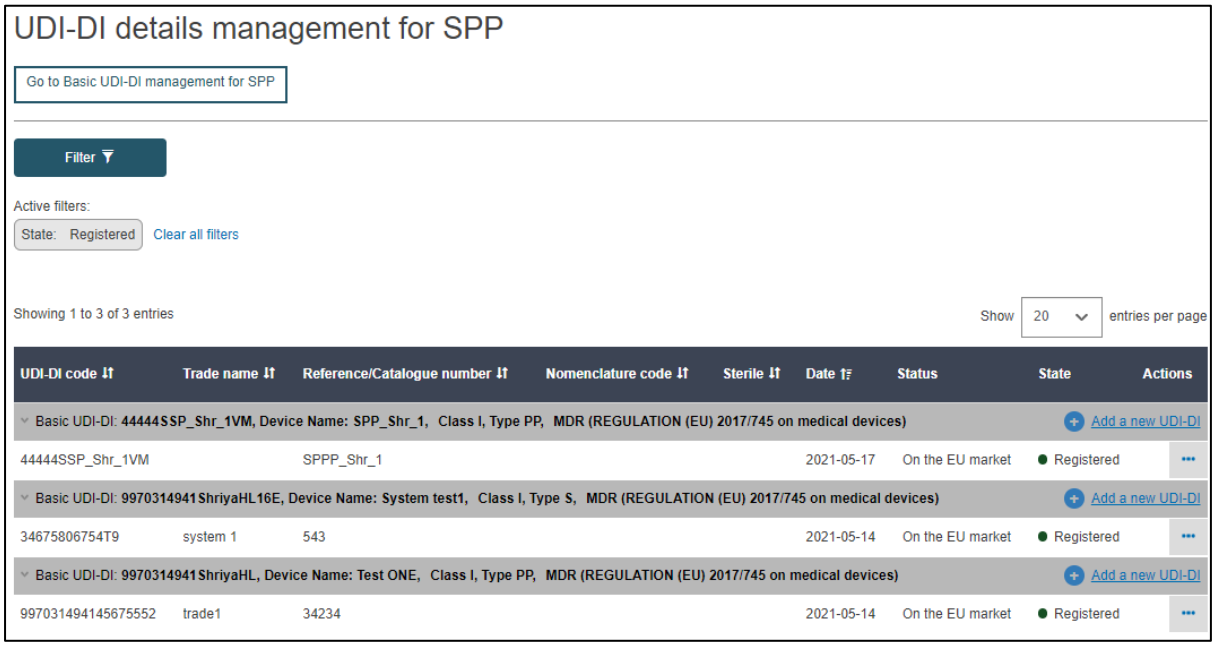


7.2. View own UDI-DI details

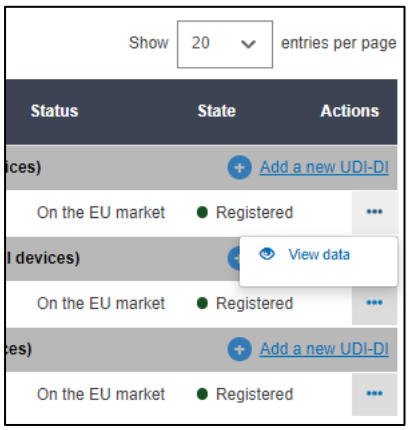
1. On the EUDAMED dashboard, click on “Manage your UDI-DIs” to see a list of all your UDI-DIs for SPPs:



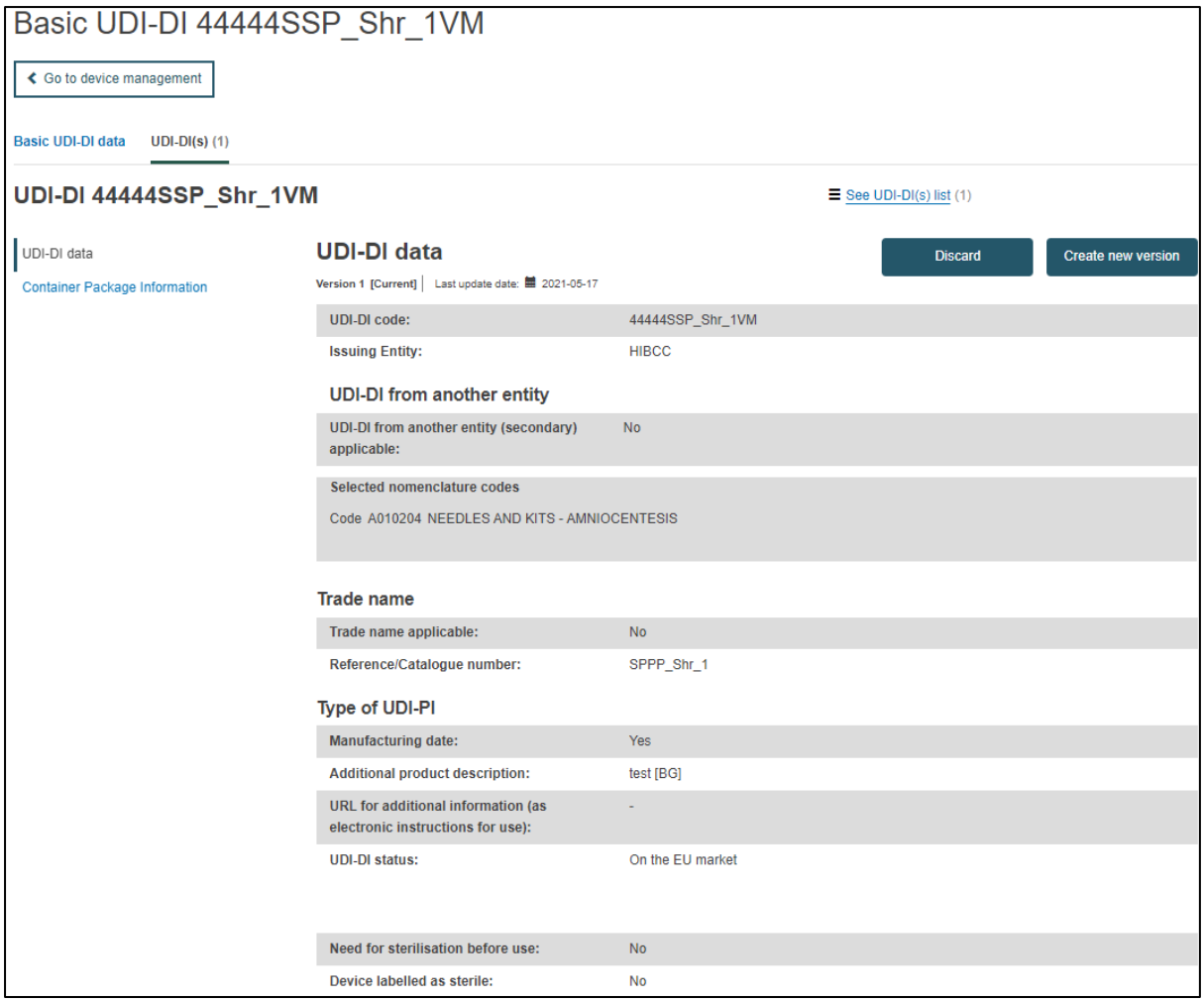
2. In order to retrieve the desired UDI-DI, use the filters available by clicking on the blue “Filter” button and selecting the desired parameters:



3. On the right-hand side of each item, there is an ellipsis symbol (three dots); click on it and then click on “View data” from the menu:



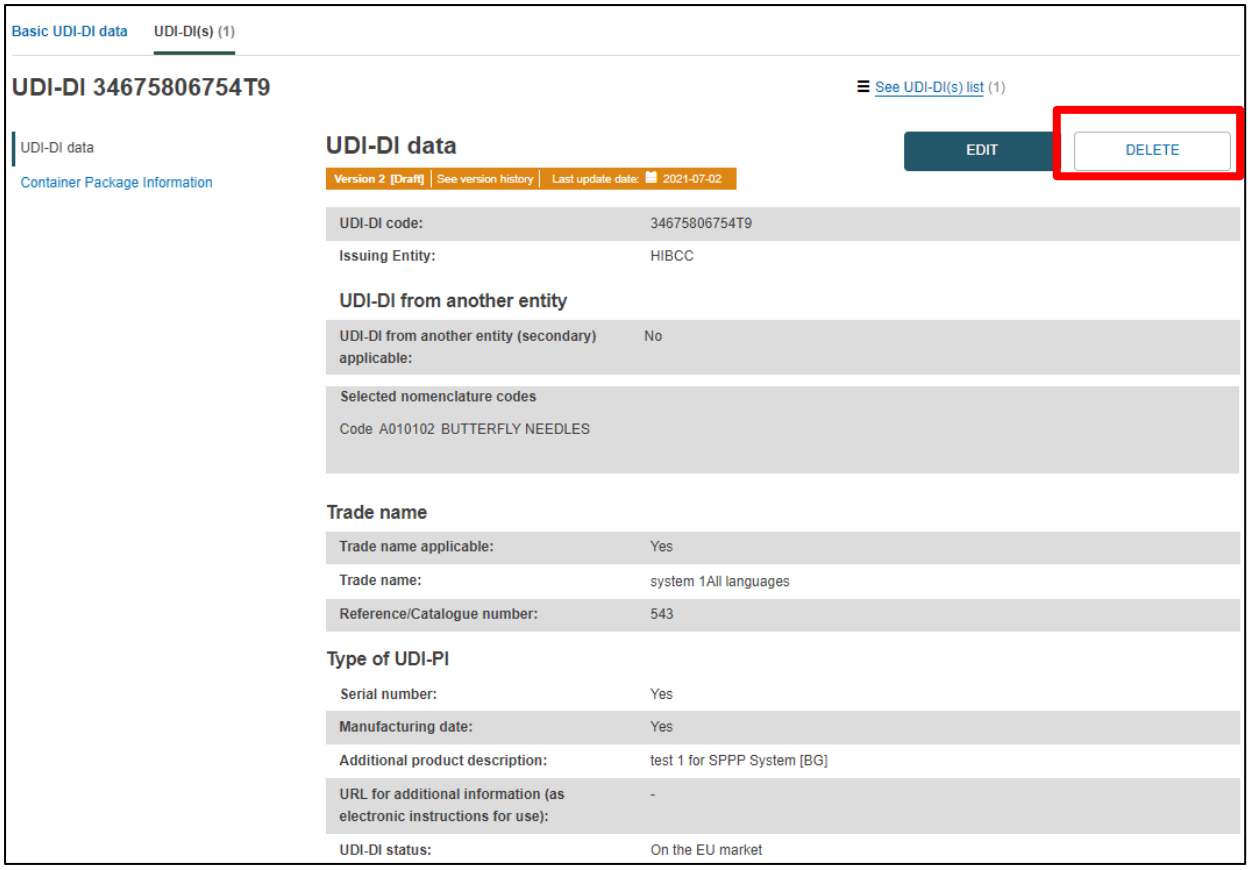
4. You will see a summary of the details concerning your chosen system or procedure pack UDI-DI:



7.2.1 Delete a Draft UDI-DI

1. Follow the steps in Section 7.2 to view a Draft UDI-DI.

2. Once inside the summary of the desired Draft UDI-DI, click on “Delete” on the top right corner:

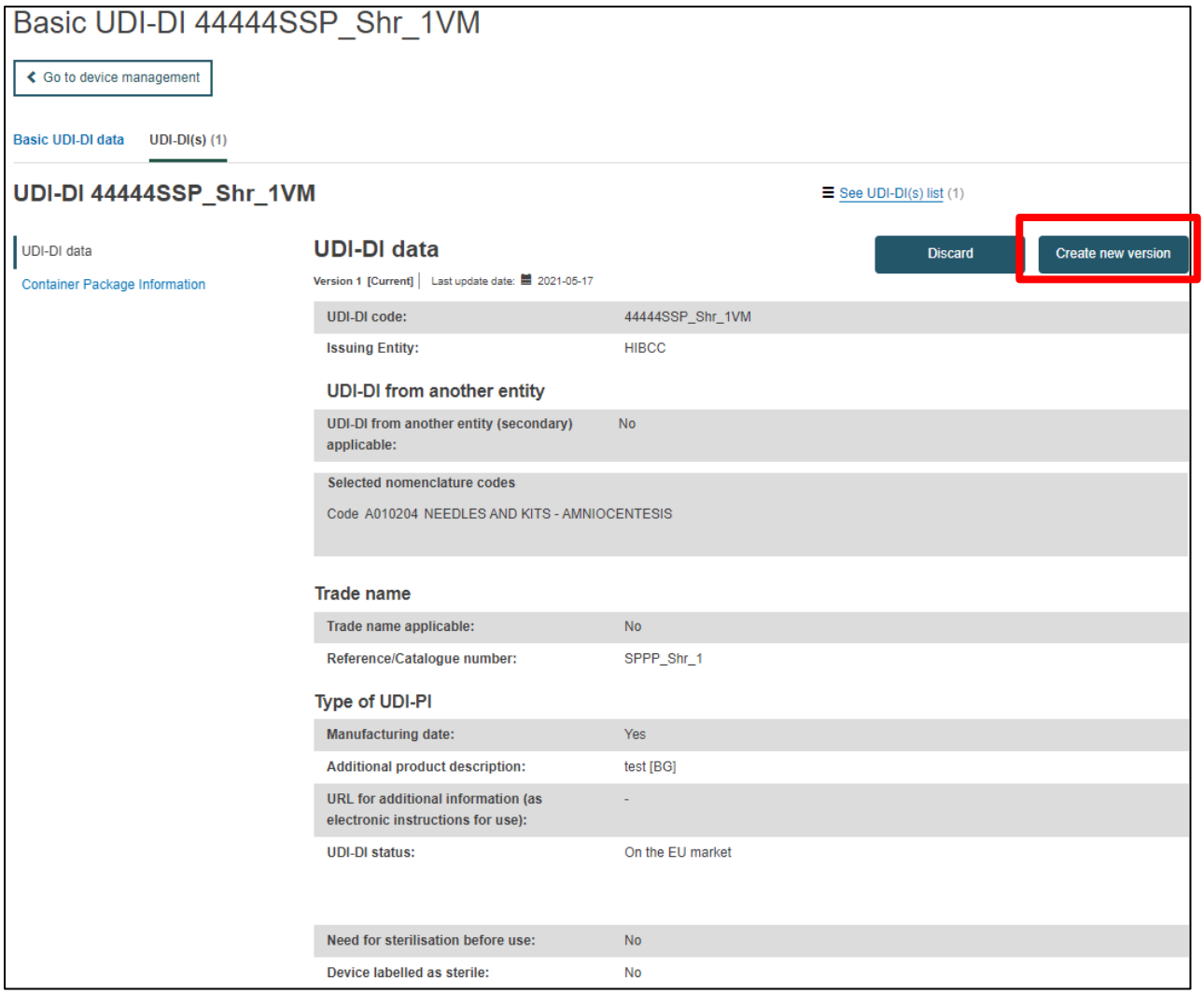


3. A pop-up message will prompt you to confirm the action by clicking on “Yes”:

7.2.2 Update (Create a new version) for UDI-DI

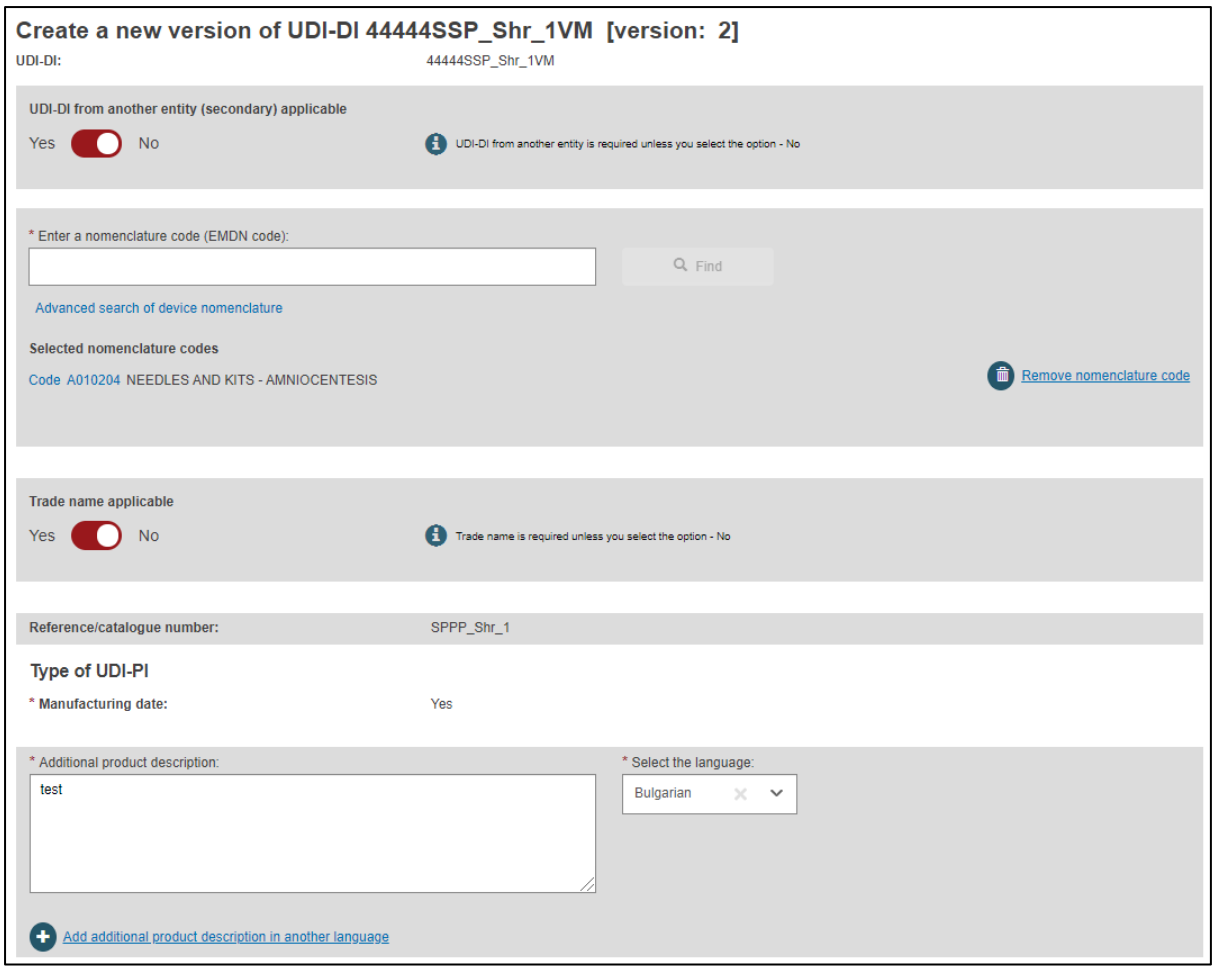
1. Follow the steps in Section 7.2 to view a UDI-DI.

2. Once inside the summary for the desired UDI-DI, click on “Create new version” on the top right corner:



3. Update the desired details.

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

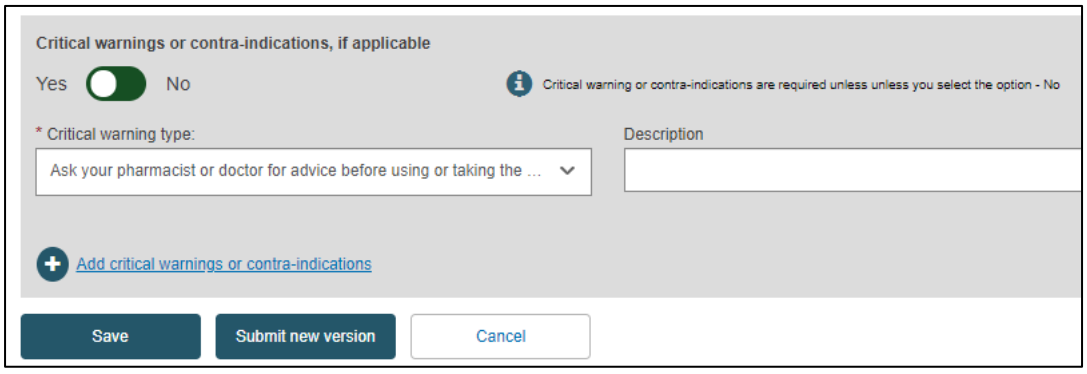


4. To finish the action you have two options:

a. Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are uncertain about the update.

b. Click on “Submit new version”, if you are certain about the update and wish to finalise it.

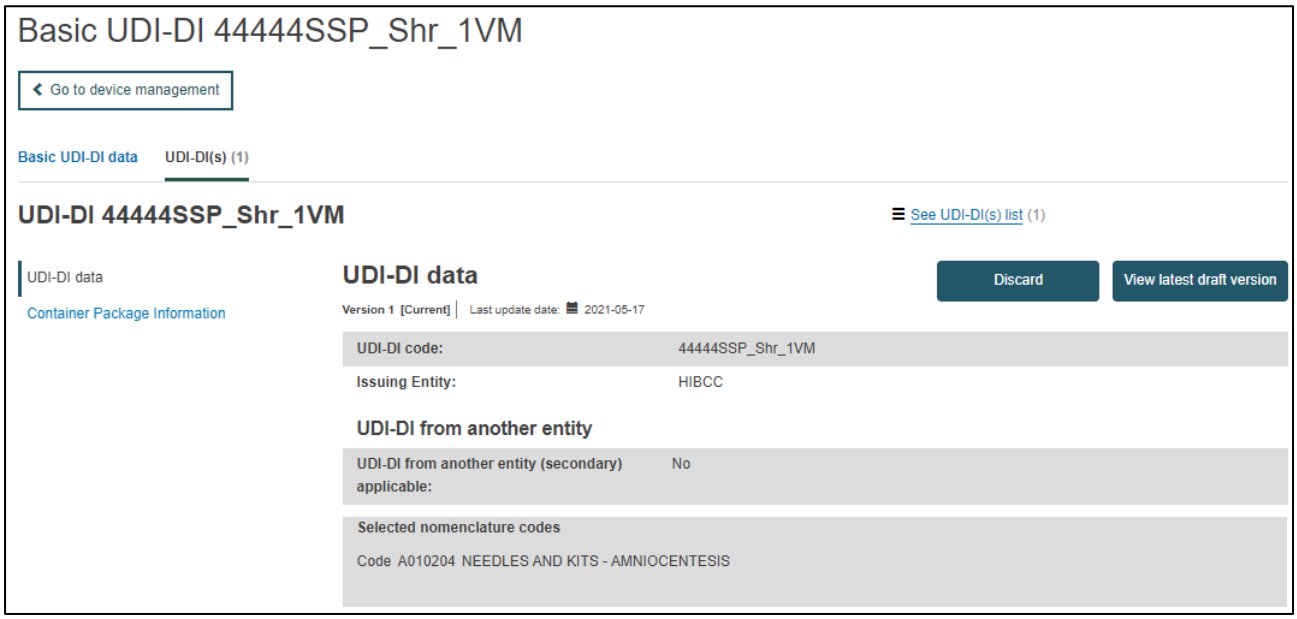
Alternatively, you can press “Cancel” to cancel the update.



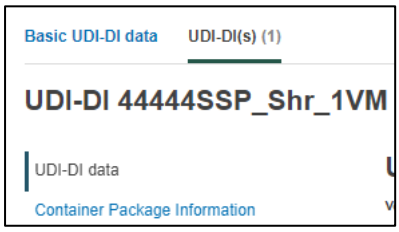
7.2.3 Update (Create new version) for Container Packages

The Container Packages information can be updated independently of the rest of the data in a SPP UDI-DI.

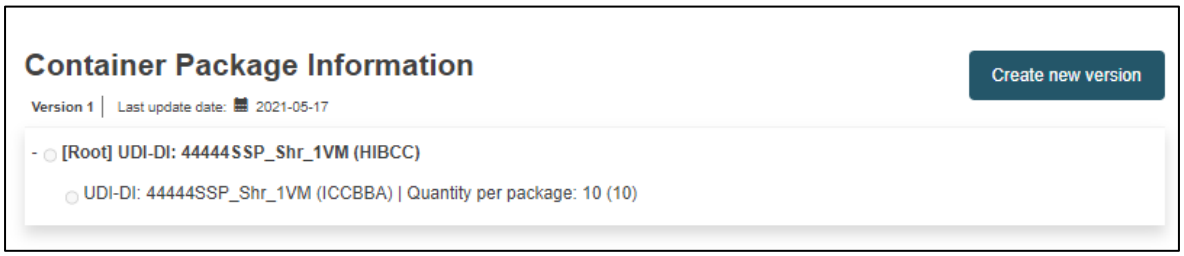
1. Follow the steps in section 7.2 to view a specific UDI-DI:



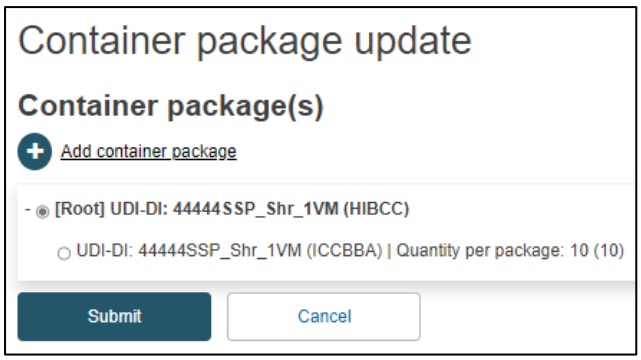
2. Once inside the summary of the desired UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):



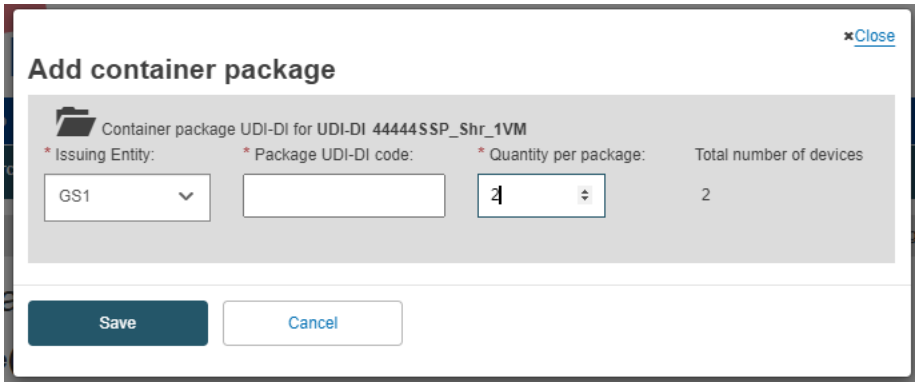
3. Click on “Create new version” in the Container Package section:



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

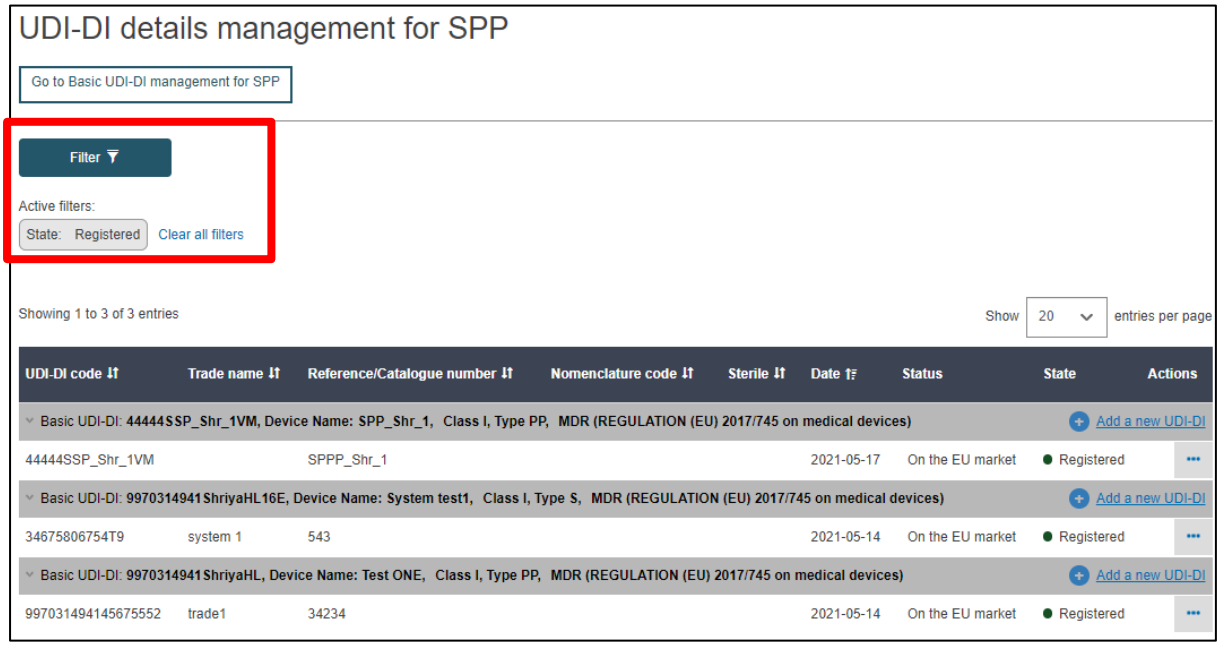


5. Insert the package details in the pop-up window and click on “Save”:

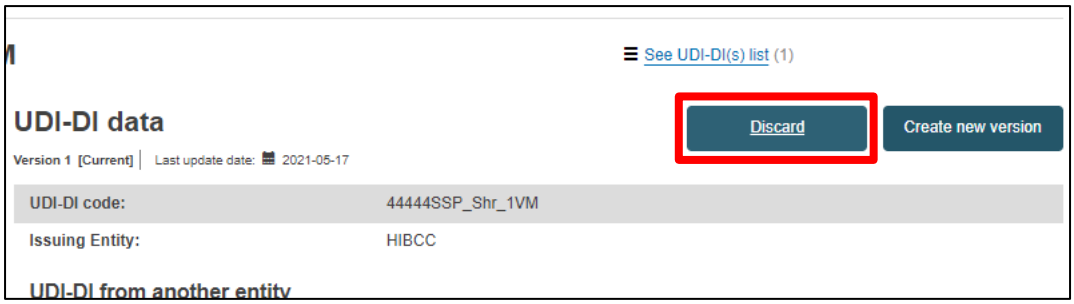


7.2.4 Discard Registered UDI-DIs

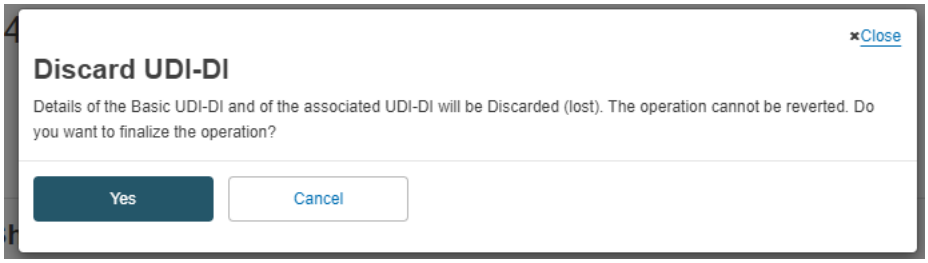
1. Follow the steps in Section 7.2 to view a desired Registered UDI-DI:



2. Once inside the summary of the desired UDI-DI, click on “Discard”, on the top right corner:



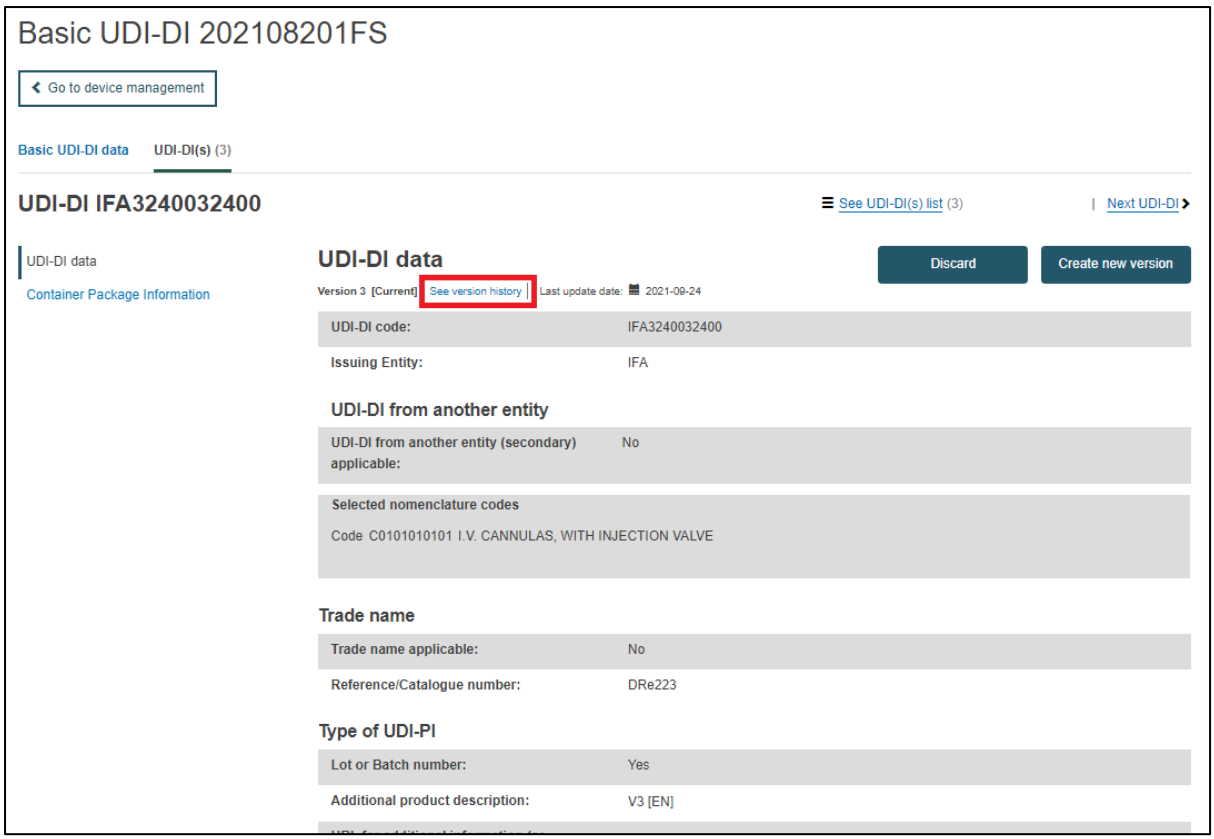
3. The system will prompt you to confirm your wish to permanently discard the registered UDI-DI. Click on “Yes” to finalise the action:



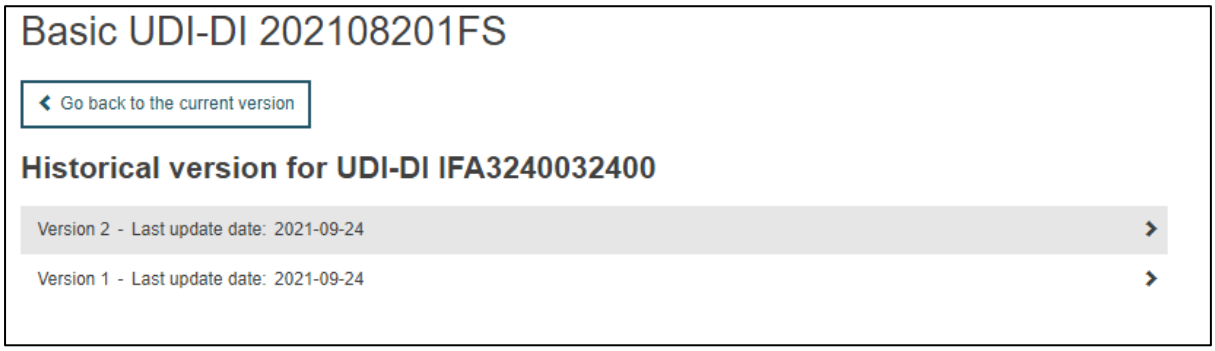
7.2.5 View historical versions for UDI-DI and associated entities

1. Follow the steps in section 7.2 to view a UDI-DI for the SPP.

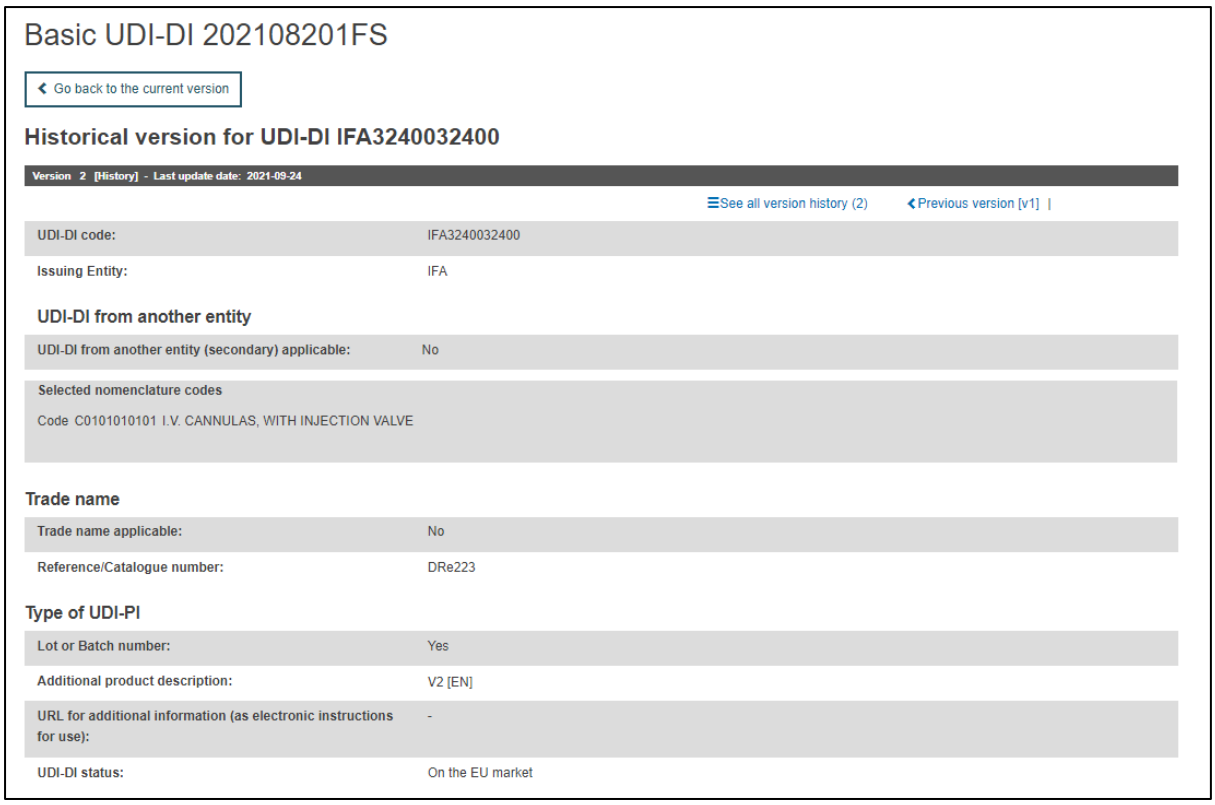
2. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:



3. You will see a list of all previously created versions :



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

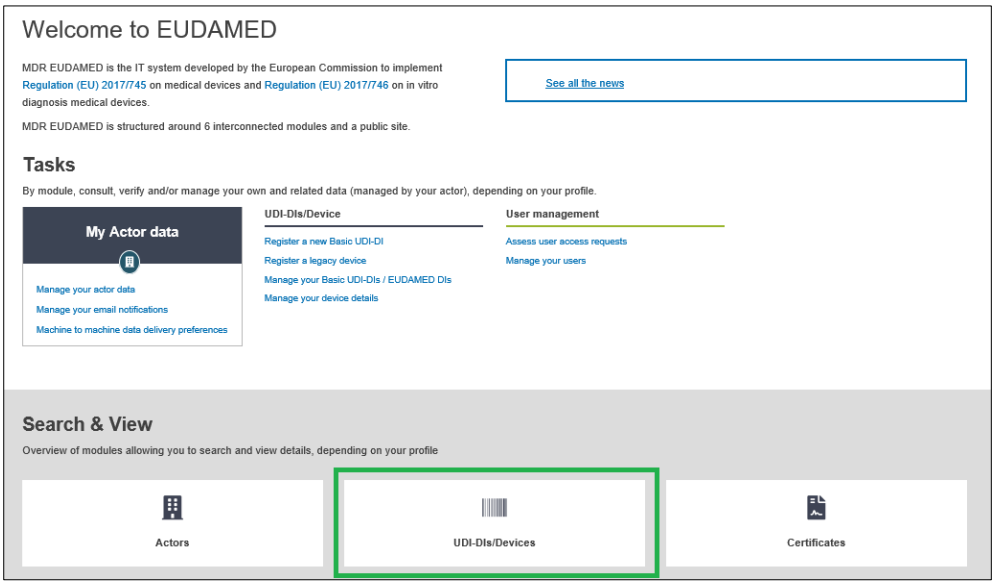


You can return to the version history list, by clicking on “See all version history” on the top right corner.

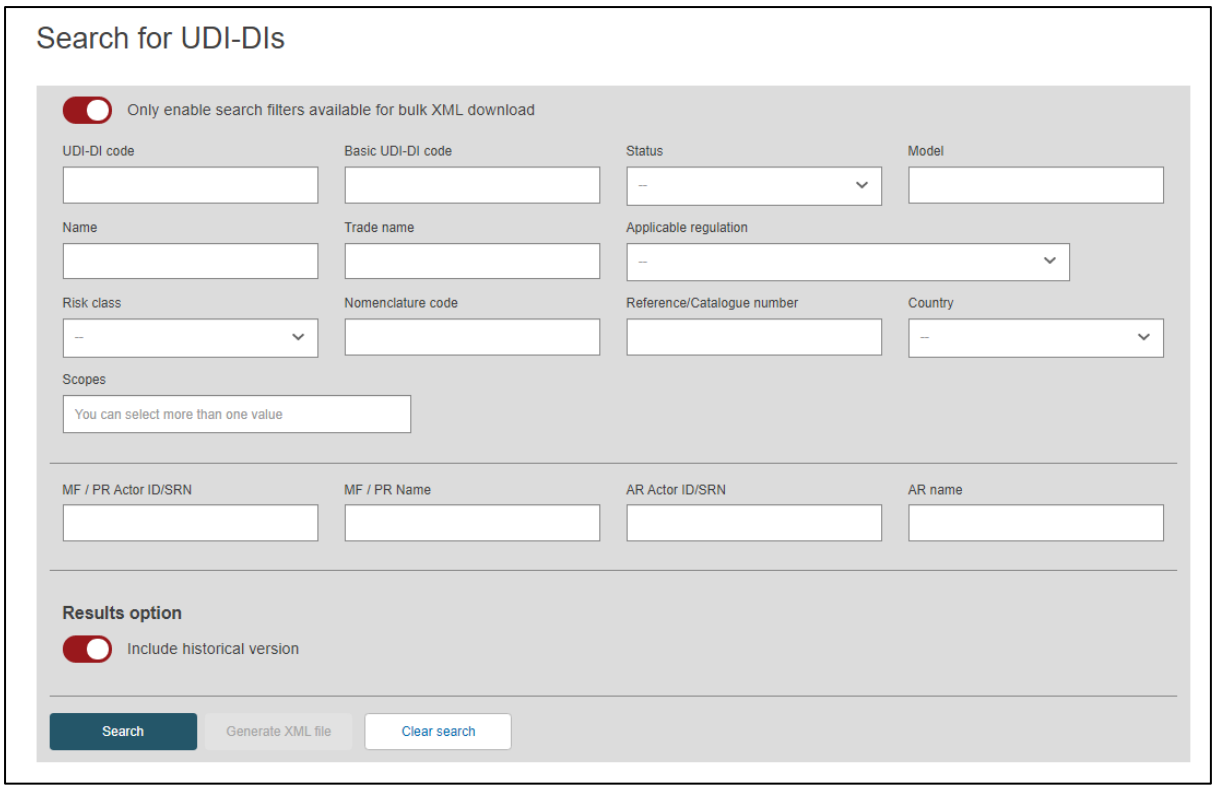
8. Search and View Devices and System or Procedure Packs on the platform

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

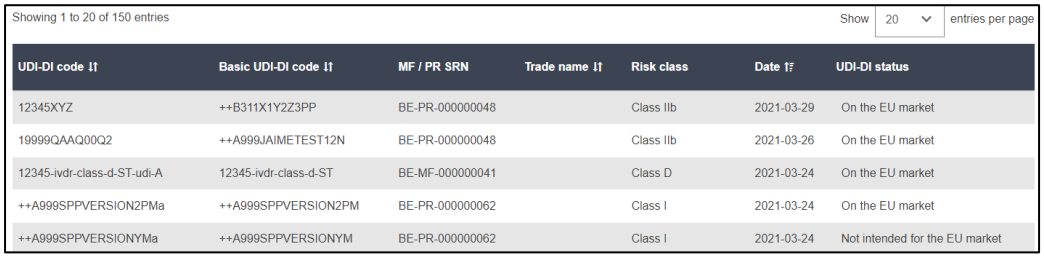
Alternatively, use the option available in the dashboard called ‘Search and View’:



2. EUDAMED will display the filters available for searching in the list of Devices and Systems or Procedure Packs registered in EUDAMED:

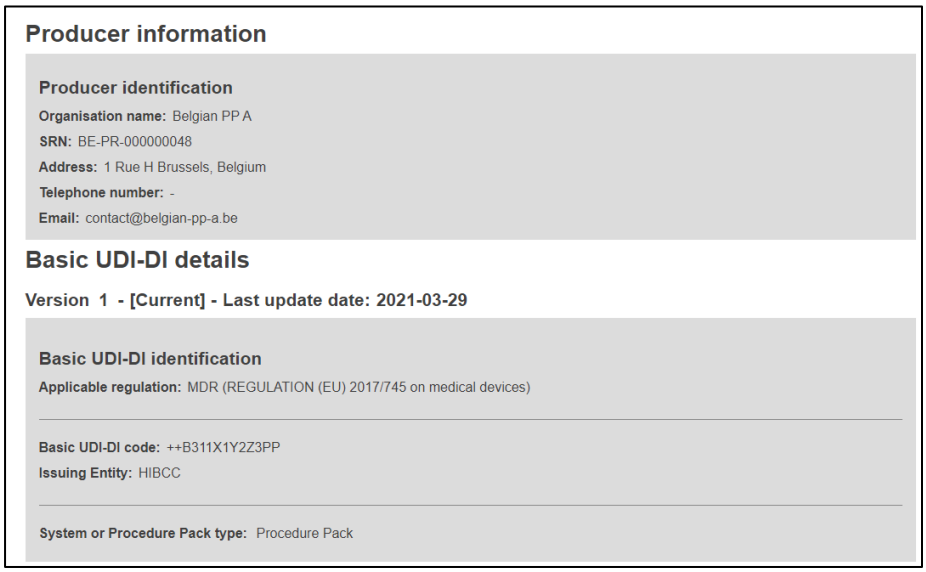


3. Once you are have entered the desired search filters, click on “Search”. A list of Devices (UDI-DIs/EUDAMED IDs) and System or Procedure Packs will appear:



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

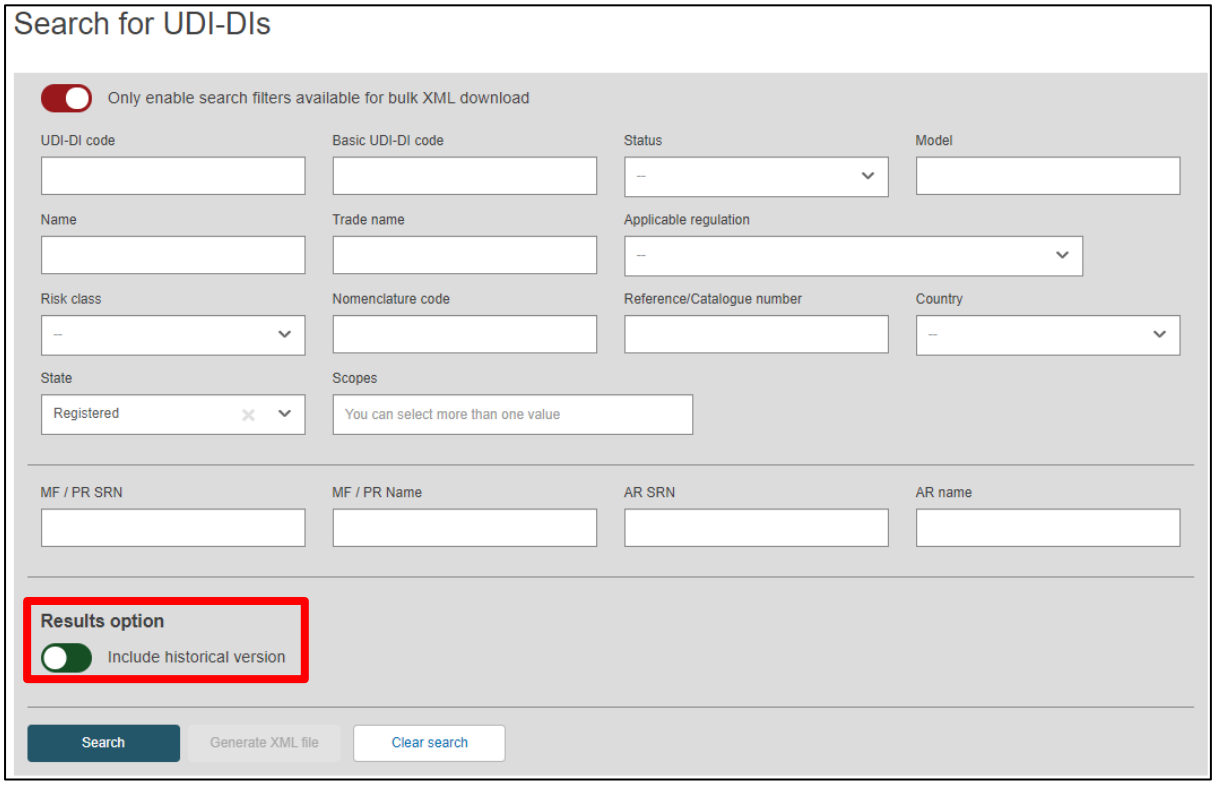
4. Click on the desired UDI-DI/EUDAMED ID to see a summary of the details:



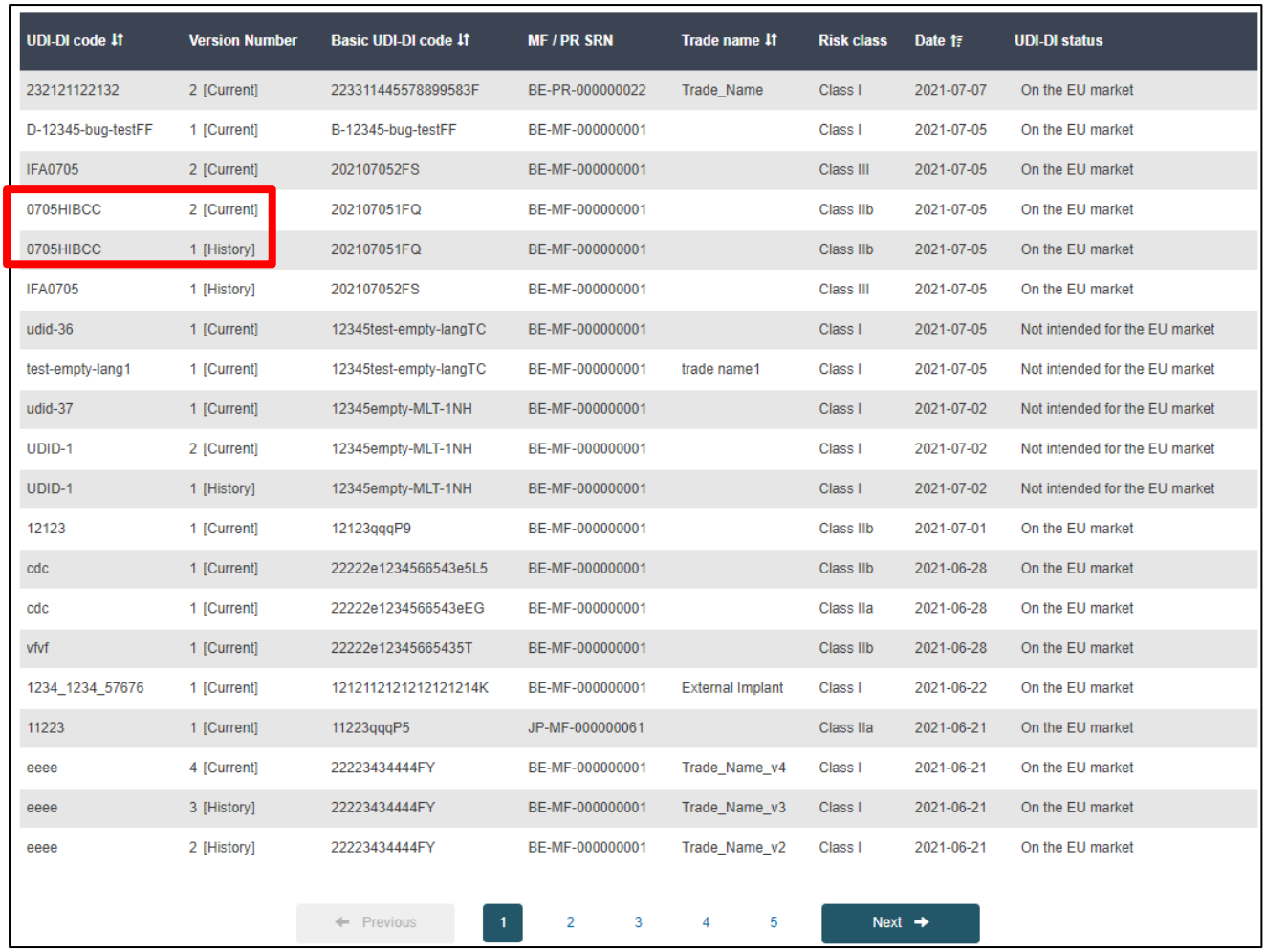
8.1. Search and View historical versions of Devices and System or Procedure Packs

1. Follow the steps in Section 8 to search and view a device or SPP.

2. Inside the search page, fill in the desired parameters for your search, activate the result option to include historical versions and click on “Search”:



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



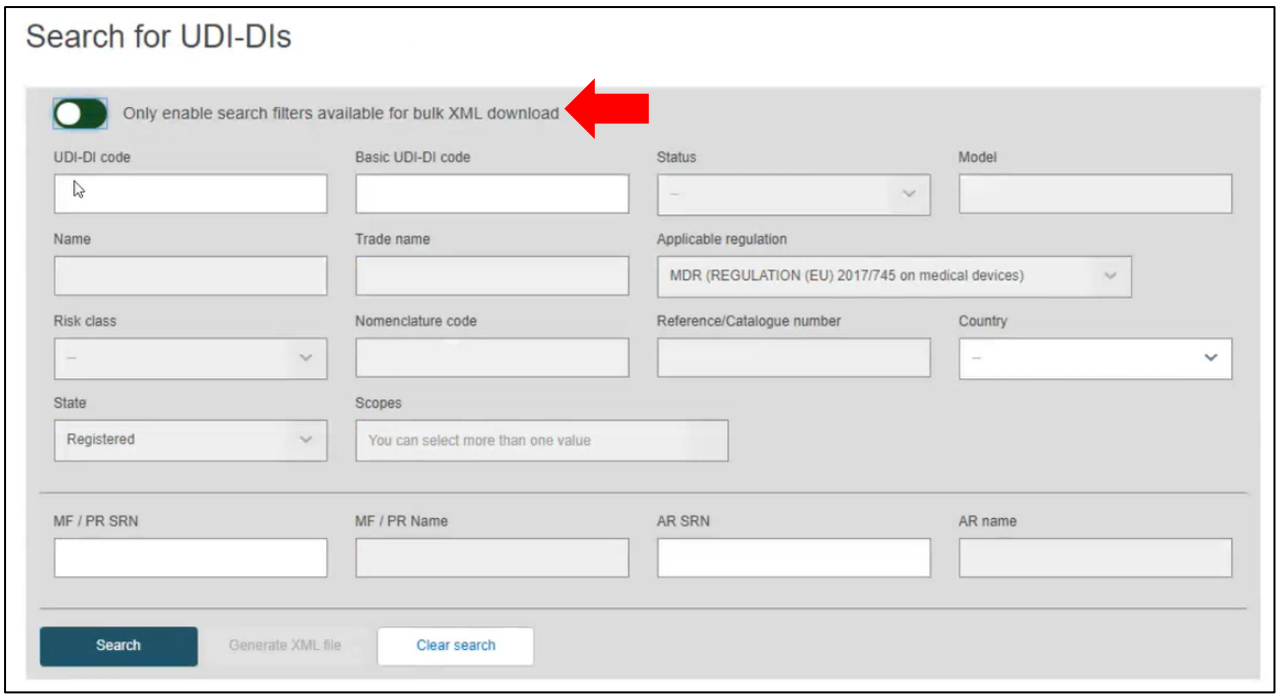
UDI-DI code	Version Number	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
232121122132	2 [Current]	223311445578899583F	BE-PR-000000022	Trade_Name	Class I	2021-07-07	On the EU market
D-12345-bug-testFF	1 [Current]	B-12345-bug-testFF	BE-MF-000000001		Class I	2021-07-05	On the EU market
IFA0705	2 [Current]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
0705HIBCC	2 [Current]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
0705HIBCC	1 [History]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
IFA0705	1 [History]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
udid-36	1 [Current]	12345test-empty-langTC	BE-MF-000000001		Class I	2021-07-05	Not intended for the EU market
test-empty-lang1	1 [Current]	12345test-empty-langTC	BE-MF-000000001	trade name1	Class I	2021-07-05	Not intended for the EU market
udid-37	1 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	2 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	1 [History]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
12123	1 [Current]	12123qqqP9	BE-MF-000000001		Class IIb	2021-07-01	On the EU market
cdc	1 [Current]	22222e1234566543e5L5	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
cdc	1 [Current]	22222e1234566543eEG	BE-MF-000000001		Class IIa	2021-06-28	On the EU market
vfvf	1 [Current]	22222e12345665435T	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
1234_1234_57676	1 [Current]	1212112121212121214K	BE-MF-000000001	External Implant	Class I	2021-06-22	On the EU market
11223	1 [Current]	11223qqqP5	JP-MF-000000061		Class IIa	2021-06-21	On the EU market
eeee	4 [Current]	22223434444FY	BE-MF-000000001	Trade_Name_v4	Class I	2021-06-21	On the EU market
eeee	3 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v3	Class I	2021-06-21	On the EU market
eeee	2 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v2	Class I	2021-06-21	On the EU market

8.2. Download Devices and System or Procedure Packs in a structure format

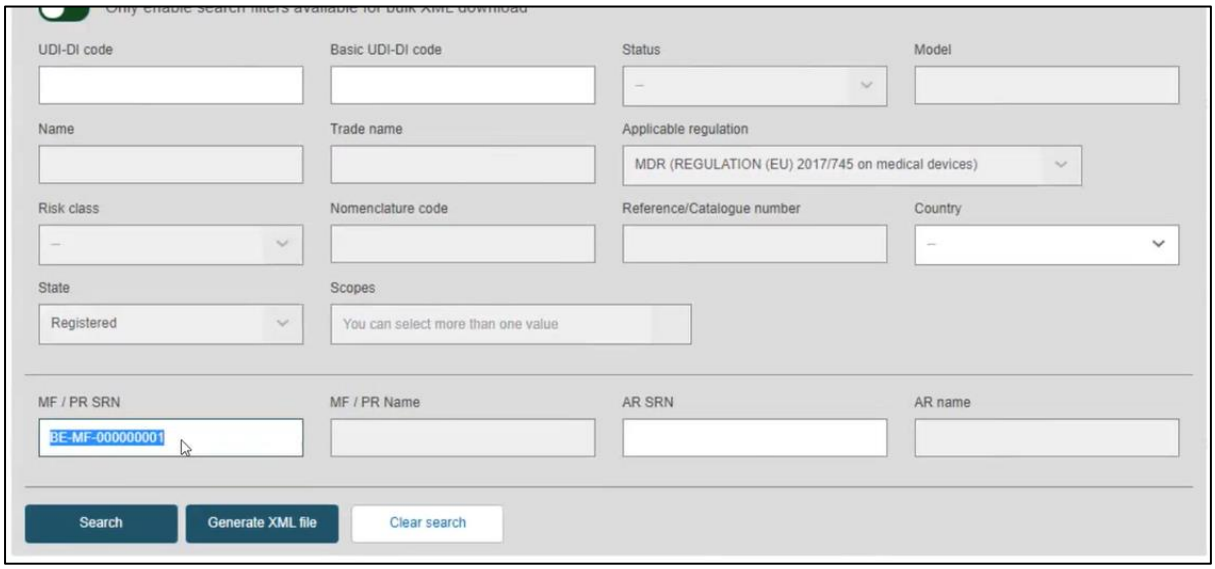
Note: You can only download your own device or system/procedure pack in a structured format.

1. Follow the steps in section 8 to search and view a device or system or procedure pack.

2. On the search parameters screen, enable the top filter to enable only the search criteria that can be downloaded in an XML format, and enter your search criteria:



3. Complete the search criteria you wish to enter, and click on “Search”, to generate results:

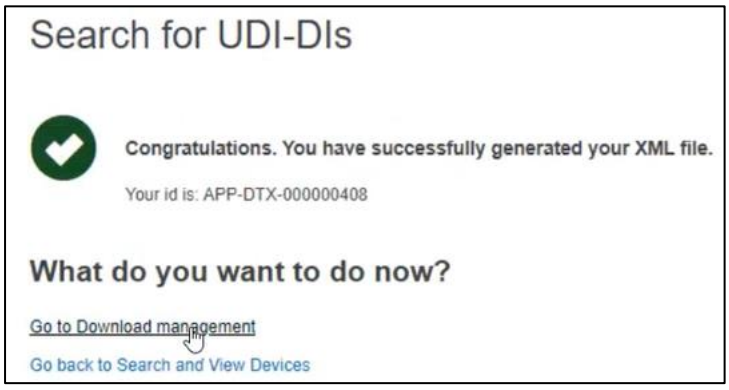


4. Click on “Generate XML file”:

Note: only what is shown on the result list will be included in the generated file and not all the results of your search (in cases where these exceed the default number of results on one page).

5. A pop-up window will prompt you to confirm your action:

6. The system will inform you that the action has been successful and will prompt you to take further action. Click on “Go to Download Management”:

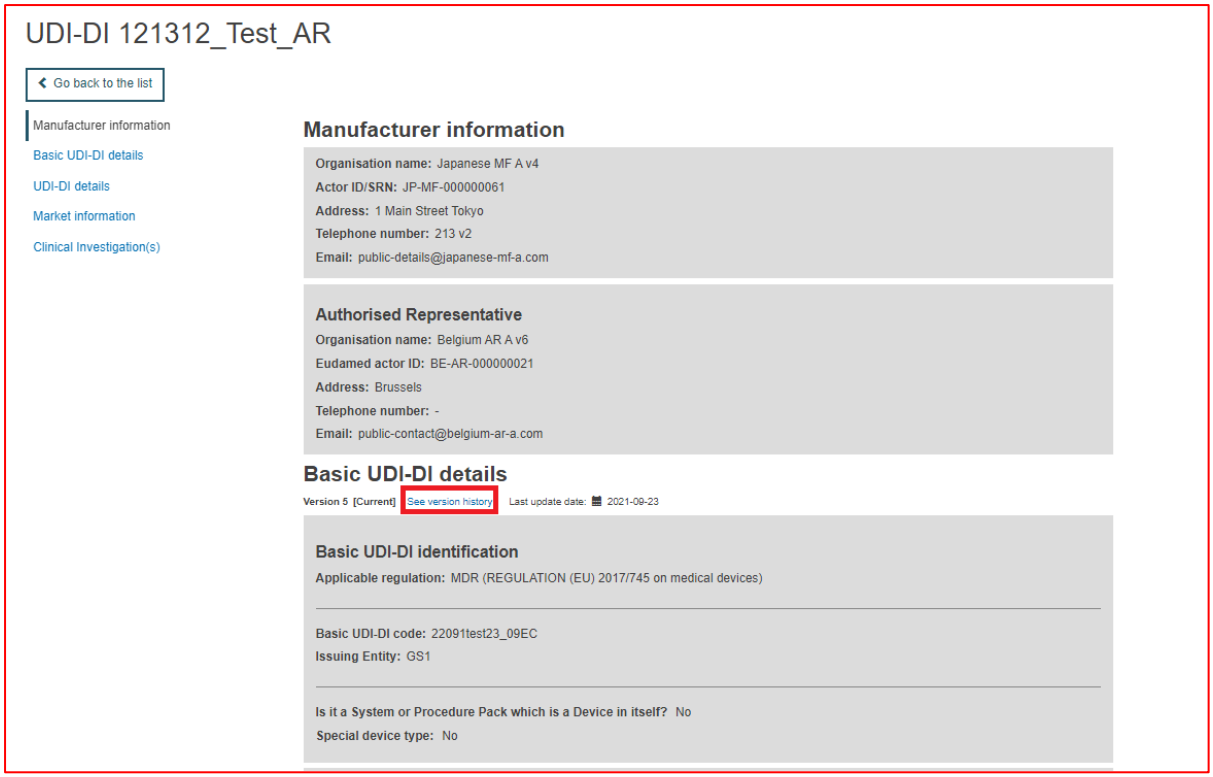


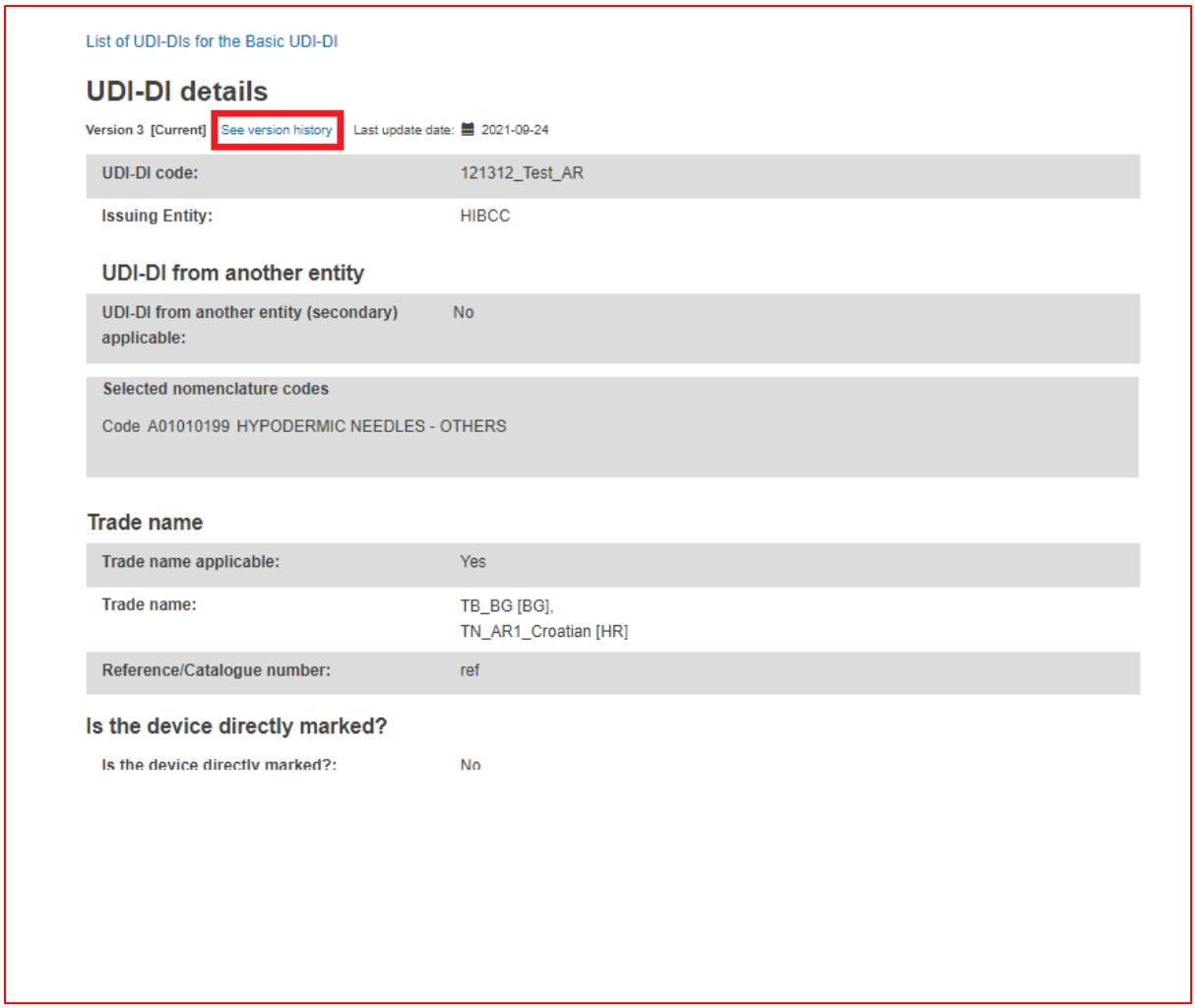
7. The generated XML response file can be downloaded by clicking on it under the “Download” column title:

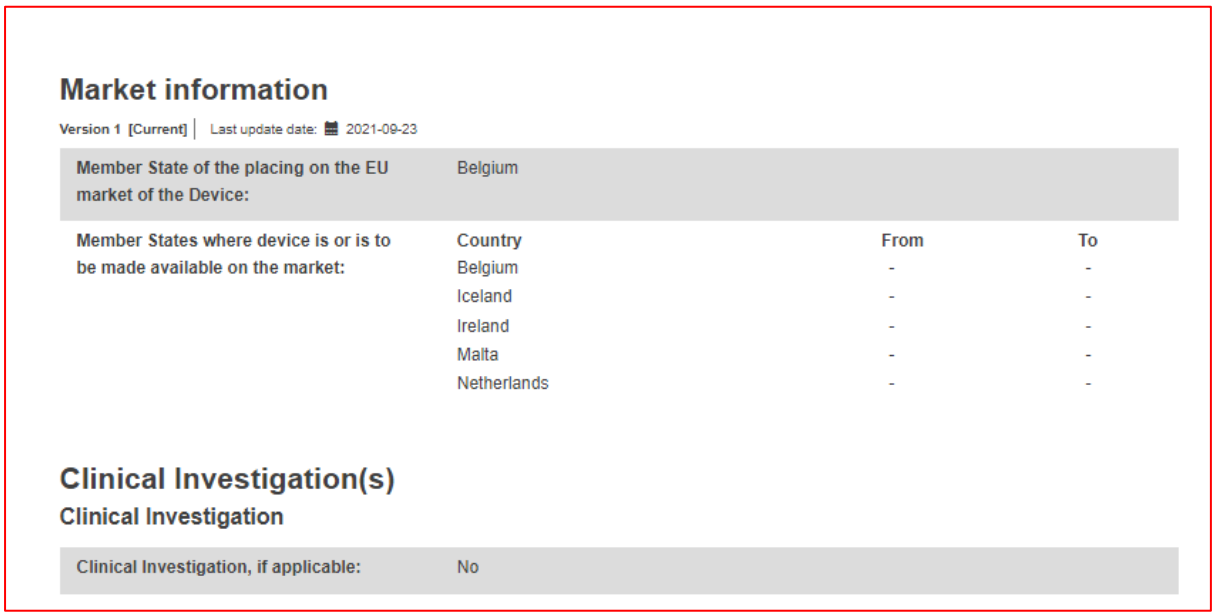
8.3. View historical versions for Basic UDI, UDI-DI and associated entities

1. Follow the steps in section 8.1 to view the details of a Device or SPP.

2. Once inside the summary of the desired UDI-DI, click on “See version history” for the element for which you want preview the version history: Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID , Market Information, Product Designer or Container Package


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


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



Market information

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

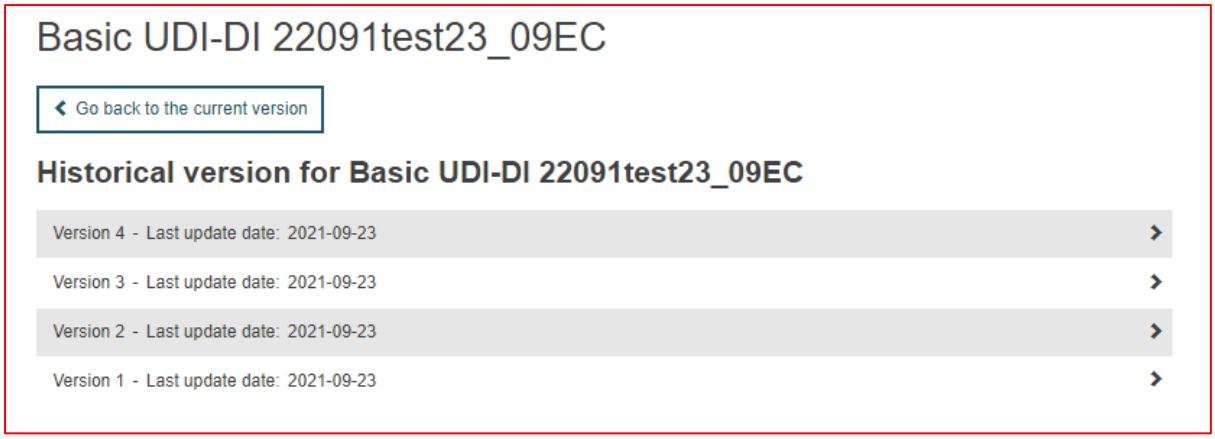
Member State of the placing on the EU market of the Device:	Belgium		
Member States where device is or is to be made available on the market:	**Country**	**From**	**To**
	Belgium	-	-
	Iceland	-	-
	Ireland	-	-
	Malta	-	-
	Netherlands	-	-

Clinical Investigation(s)

Clinical Investigation

Clinical Investigation, if applicable:	No

3.You will see a list of all previously created versions for the selected entity (we will continue the example presenting the version history of the Basic UDI-DI):



Basic UDI-DI 22091test23_09EC

Go back to the current version

Historical version for Basic UDI-DI 22091test23_09EC

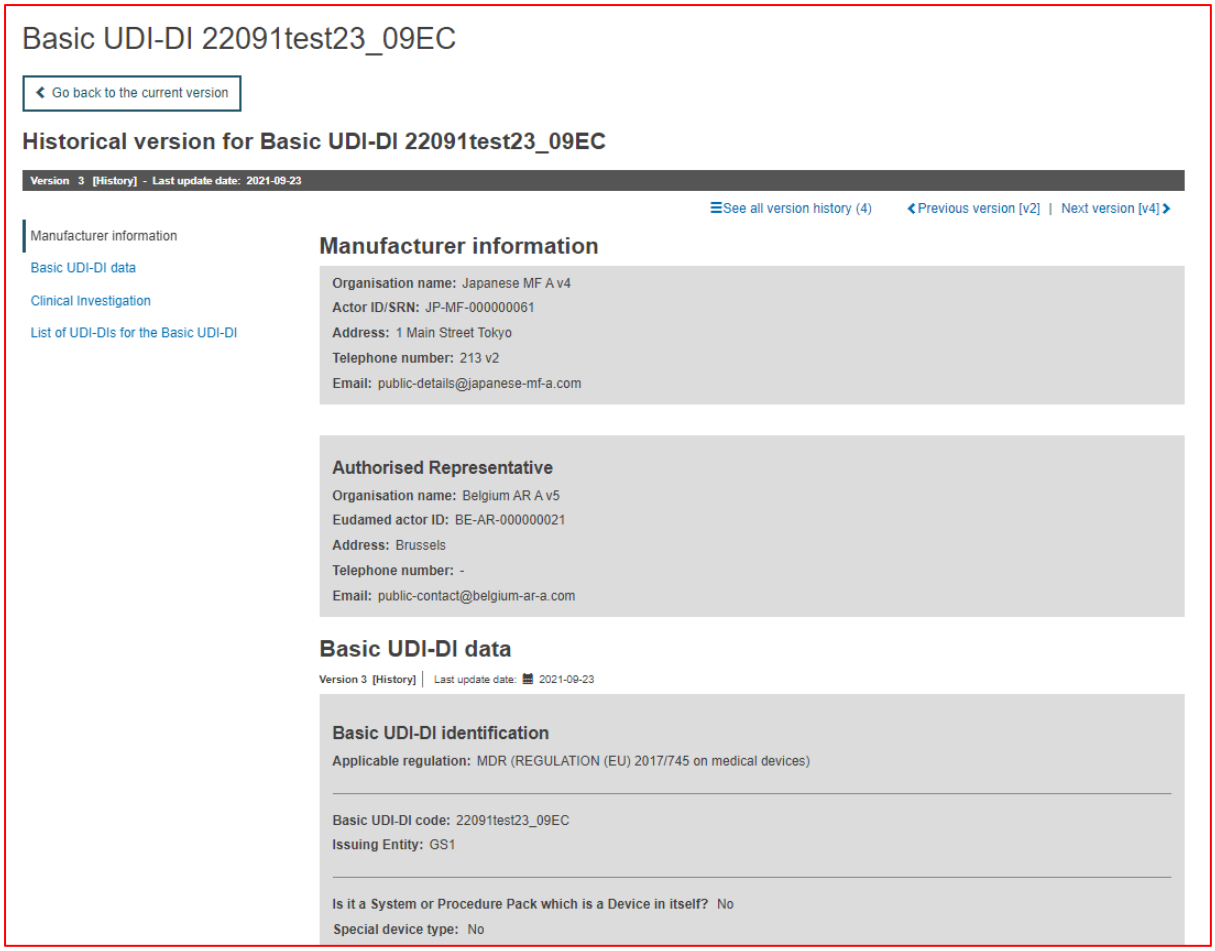
Version 4 - Last update date: 2021-09-23 >

Version 3 - Last update date: 2021-09-23 >

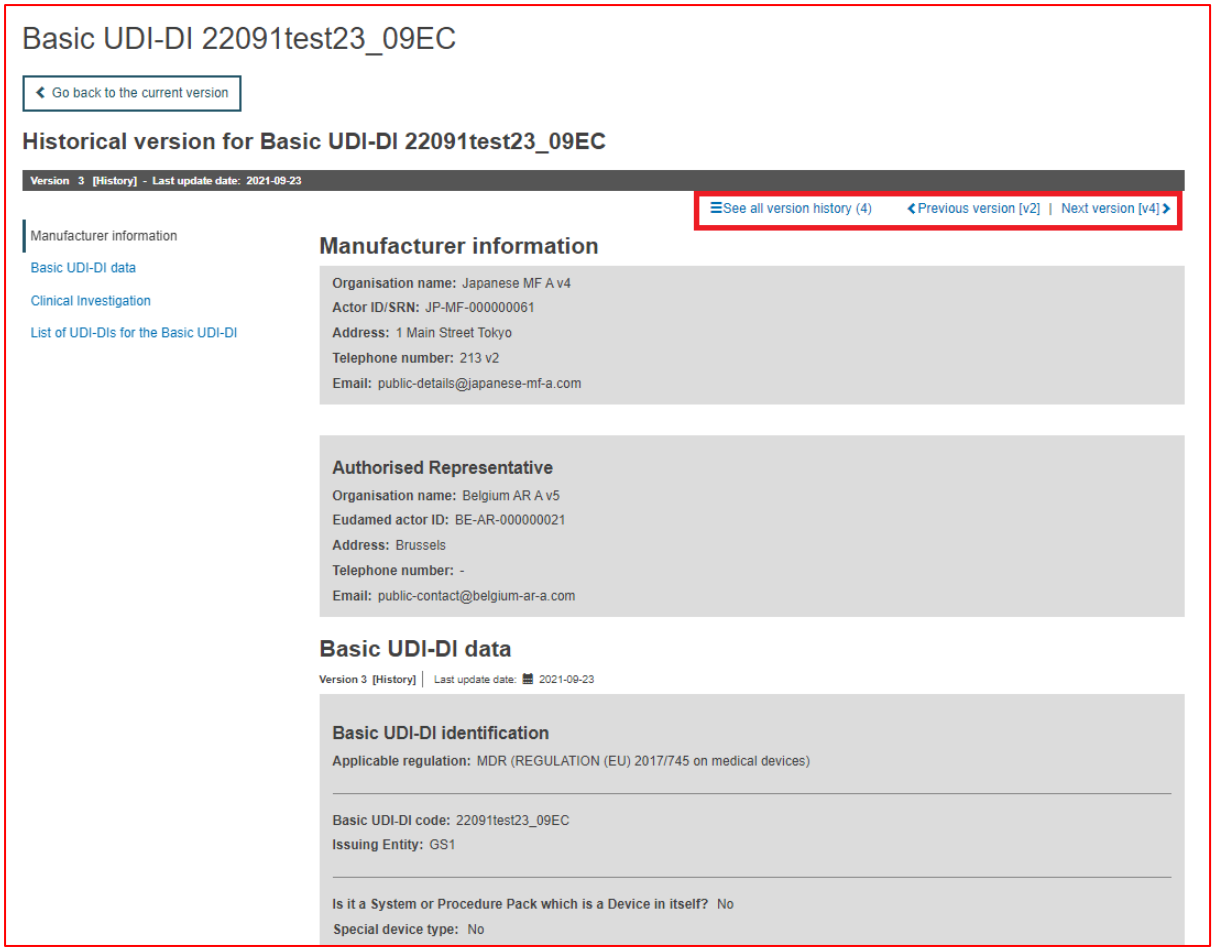
Version 2 - Last update date: 2021-09-23 >

Version 1 - Last update date: 2021-09-23 >

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



5.Inside the summary of a version, note that you can browse through the different versions via the browsing function on the top right corner:


Basic UDI-DI 22091test23_09EC
Go back to the current version
Historical version for Basic UDI-DI 22091test23_09EC
Version 3 [History] - Last update date: 2021-09-23
See all version history (4)
Previous version [v2] | Next version [v4]
Manufacturer information
Basic UDI-DI data
Clinical Investigation
List of UDI-DIs for the Basic UDI-DI
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 v5
Eudamed actor ID: BE-AR-000000021
Address: Brussels
Telephone number: -
Email: public-contact@belgium-ar-a.com
Basic UDI-DI data
Version 3 [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

Annex 1 – Device Certificate Information

Current Annex presents the cases in which the Certificate information is required to be provided when registering a Regulation Device and the Certificate type required to be provided based on the properties of the Device.

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

			EU type-examination certificate (Annex X)	EU technical documentation assessment certificate (Annex IX Chapter II)

Color option description

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

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

Annex 2 – Legacy Device Certificate Types

Current Annex presents the Certificate types that can be used when registering a Legacy Device.

Certificate types are depending on the Applicable legislation of the Device.

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