European Commission

UDI Devices - User guide

EUDAMED v2.7
April 2022

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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 guide 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 (SPP).

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 and different 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 which is 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 specific medical device.

(PACKAGEUDI-DI) - If applicable, each device may have an additional, higher-level UDI-DI assigned to its higher package. Package UDI-DIs identify each package format, 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). In some cases, legacy devices shall be registered in EUDAMED without a Basic UDI-DI and without a UDI-DI.

A Legacy Device must 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). A legacy device has to be registered in the 'UDI/Device module' of EUDAMED, which allows EUDAMED to process it similarly to a Regulation Device.

EUDAMED DI - The EUDAMED DI is equivalent to the Basic UDI-DI. It can either be fully 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 is equivalent to the UDI-DI. In case a UDI-DI has not been assigned yet, the EUDAMED ID will always be automatically and fully generated by EUDAMED from the EUDAMED DI.

2. Getting started

What I need to access EUDAMED:

1. EU Login (ECAS) account

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

2. User profile registration in EUDAMED

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

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"; this profile can create and delete draft records in the Device module, or
- A "Confirmer"; this profile may also submit and discard records in the Device module

If you have already registered as a user in EUDAMED before the release of this version, in order to create and submit records you must request a profile upgrade in the Device module from "Viewer" 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. Finally, do bear in mind that any question or field marked with a red asterisk is mandatory and cannot be left blank.

3. Registering Regulation Devices

Click on the following link to arrive to EUDAMED:

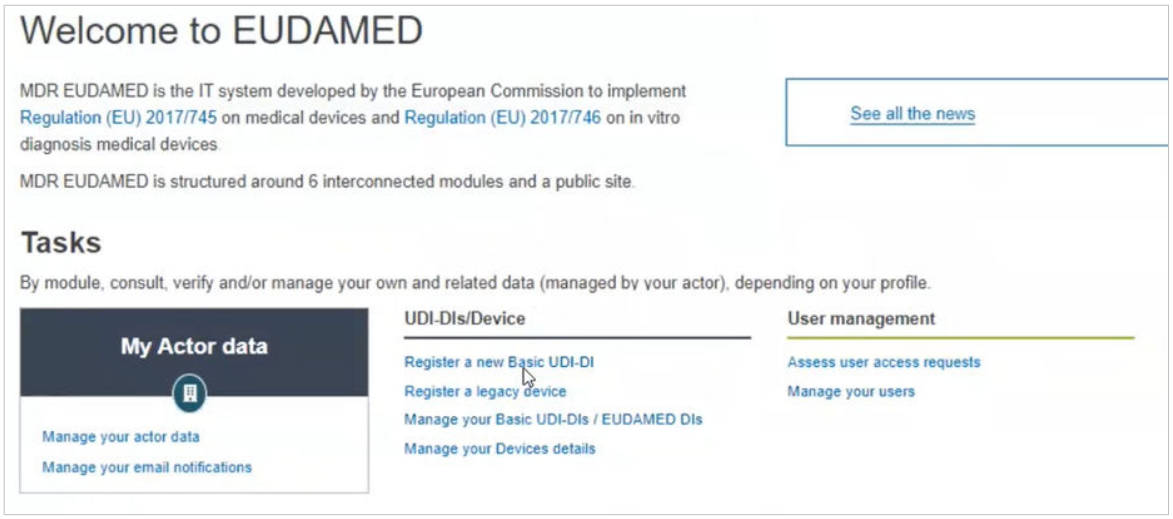
https://webgate.ec.europa.eu/eudamed/

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

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

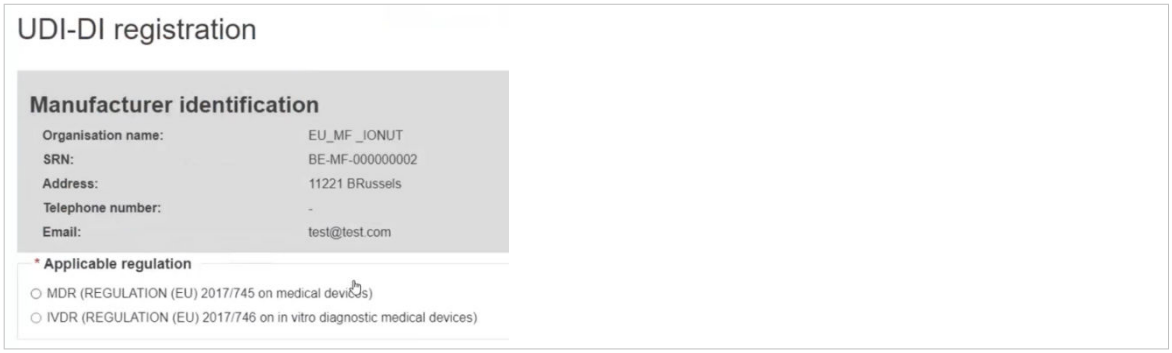
3.1.1. Step 1: Basic UDI-DI identification information

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



2. On the next page, enter the Basic UDI-DI information for your device. Select the applicable legislation for your Basic UDI-DI, from the two options provided:

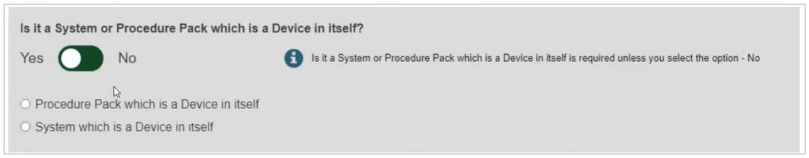
> **NOTE**
> In this guide demonstration, we assume that you have selected MDR (Regulation (EU) 2017/745). Based on the legislation you choose, the characteristics of the Device to be entered will vary.



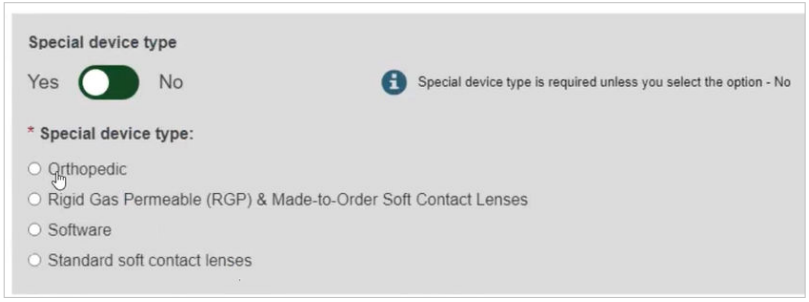
Depending on the regulation that you have selected an additional question appears at the bottom of the page:

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

In this example for the MDR regulation, answer the question by clicking on “Yes” or “No”:



If you select “No”, please choose the right information under the appearing section “Special Device type”:



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

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

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

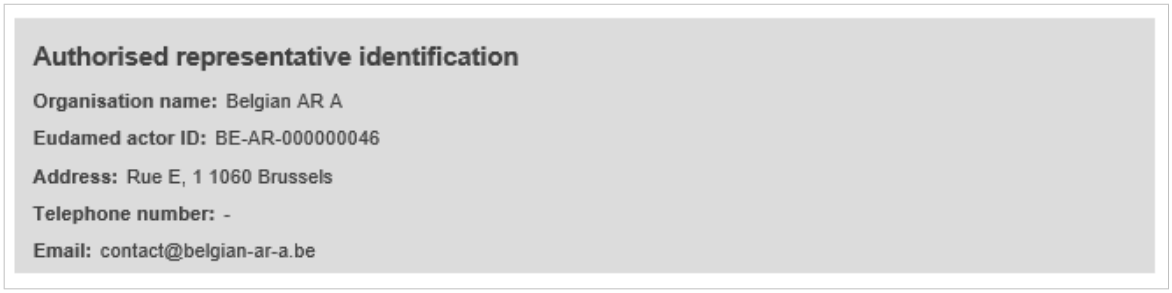
IMPORTANT
EUDAMED will validate the Basic UDI-DI code you insert based on the specific format provided by each Issuing Entity. Please make sure that you provide the correct code.

Basic UDI-DI **duplicates** (two identical entries) cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be asked to provide another code.

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

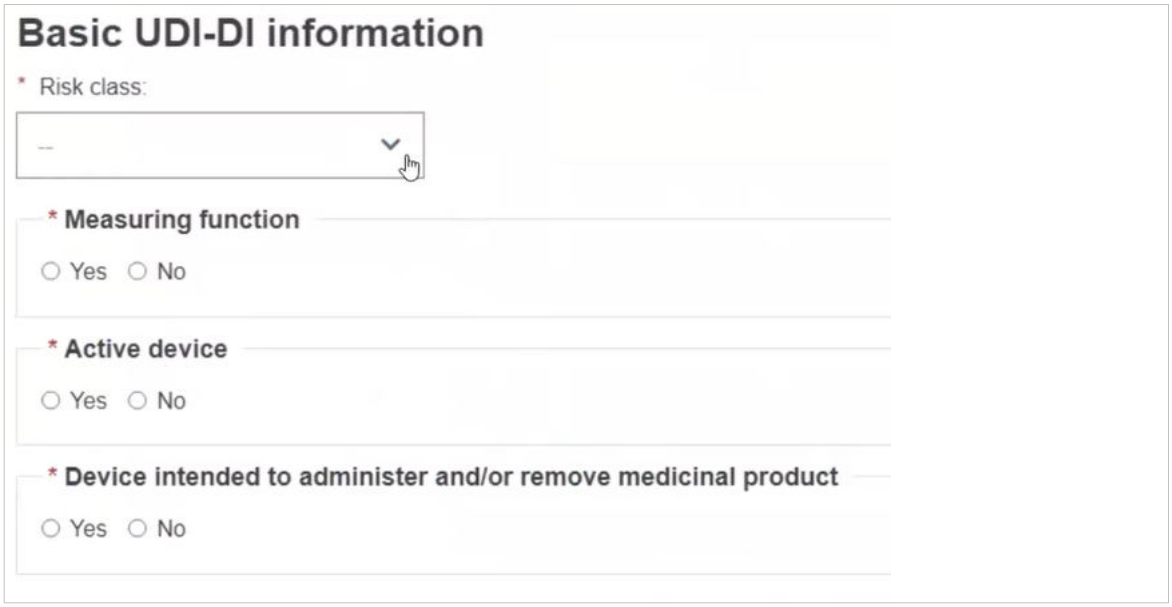
NOTE
The authorised representative and the manufacturer must have an active Mandate in order to assign the authorised representative for the device.

If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically chosen as shown below:

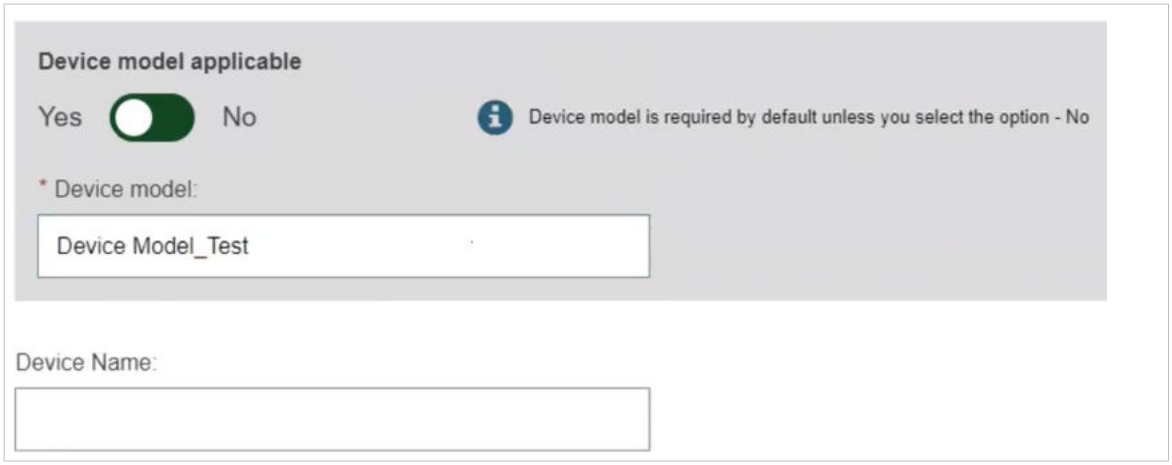


5. On the next page, you must choose a Risk Class and select “Yes” or “No” for each option that follows.

NOTE
These options change depending on your previous choices and the applicable legislation of the device:



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



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

3.1.2. Step 2: Certificate information

1. Select the certificate type and enter some or all of the Notified Body name(s) or number(s).

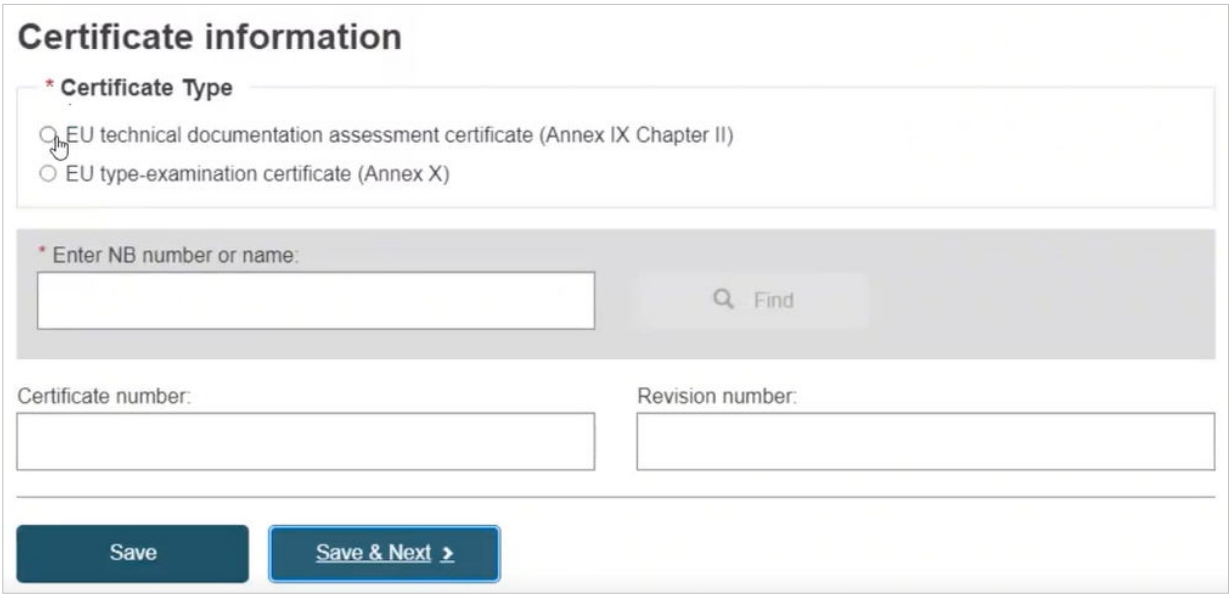
2. Click on “Find” and choose the correct Notified Body from the new window.

3. If you wish, enter the certificate number and revision number and click on “Save” or “Save & Next”.

NOTE
You must provide Certificate Information for Basic UDI-DIs which need confirmation from the Notified Body for the information 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 needed for the Device and the type of certificate that should be given in each case apart.

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



3.1.3. Step 3: UDI-DI identification information

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

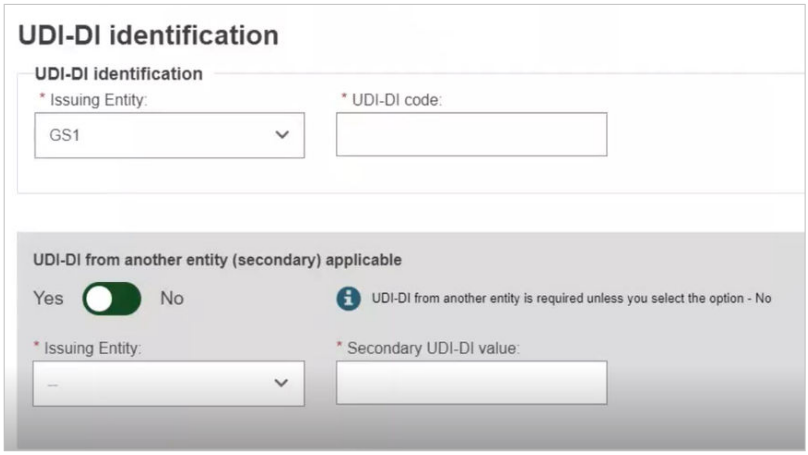
IMPORTANT
The UDI-DI code you enter must be unique in EUDAMED. If it already exists in EUDAMED for the selected IssuingEntity, you will be asked to provide another.

Exception: 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 will be created between the two devices (the Regulation and the Legacy Device).

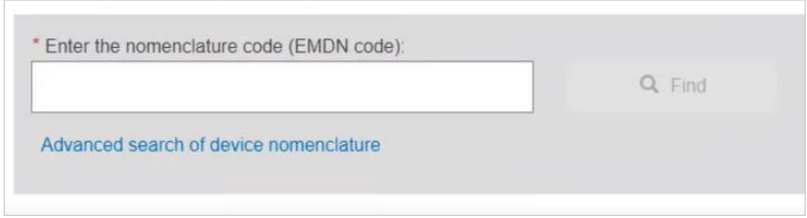
NOTE
In case of GS1 Issuing Entity, the UDI-DI code you enter must have 14 characters.

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



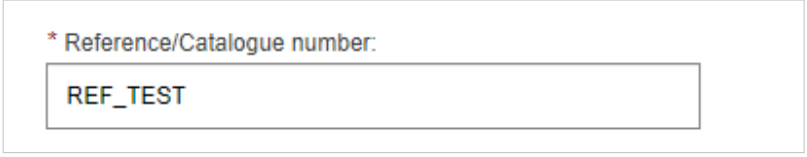
3. Enter the EMDN code and click on “Find”, and select the correct one from the list:

NOTE
EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multi-level, 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.



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

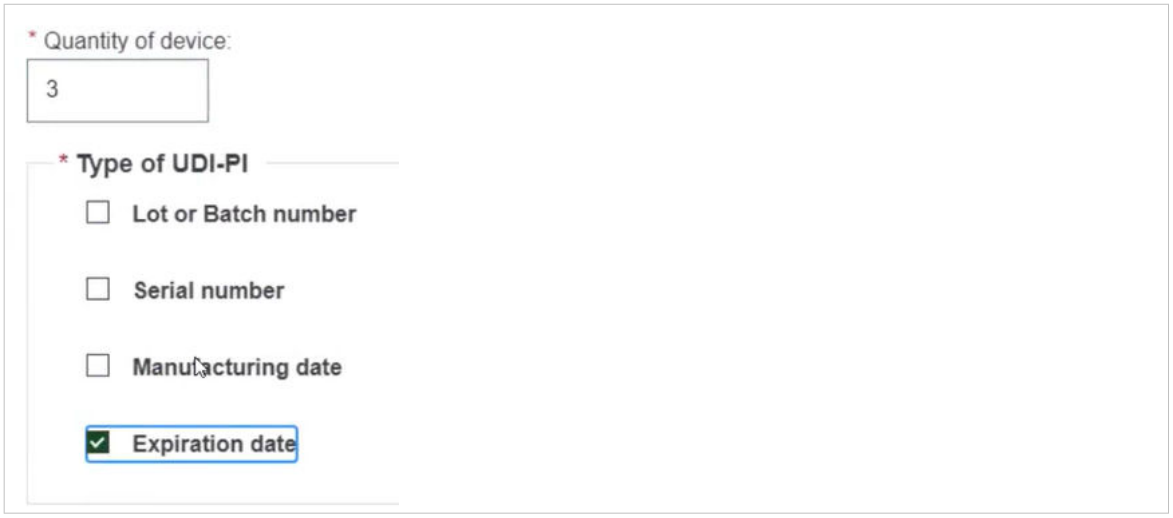
5. Enter the Reference number (as found on the device label):



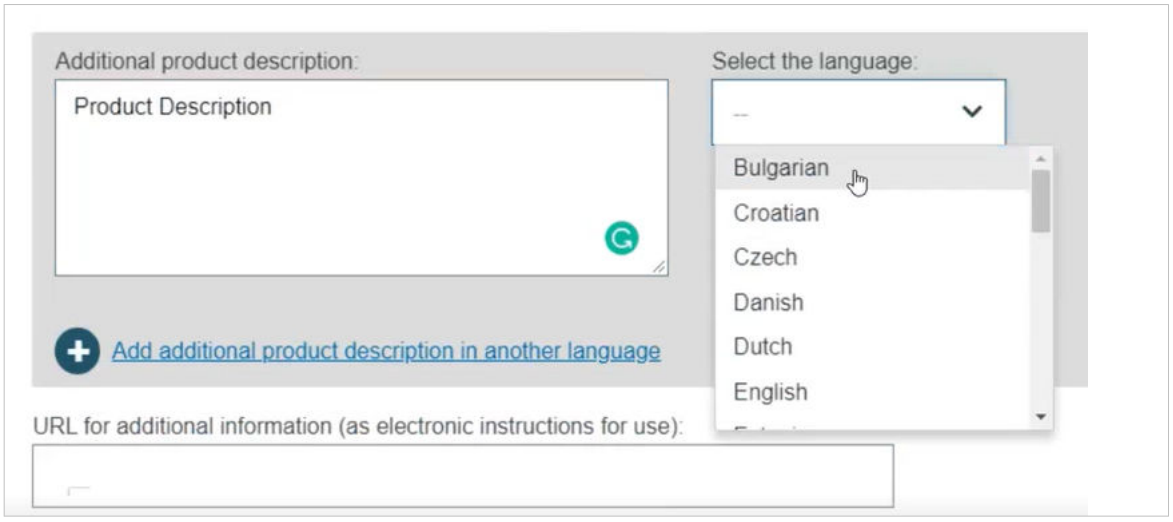
6. Enter details on whether the device is directly marked or not and specify the identifier (Direct Marking DI or Unit of Use DI):
   - If the device is directly marked, the Direct marking DI is required. This can be same as the UDI-DI or can be another UDI-DI.
   - If the device is not directly marked and the base quantity of the device is greater than one, you should enter the Unit of Use DI. 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 be entered 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. Enter 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 way 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 (link) if you have one for additional information online:



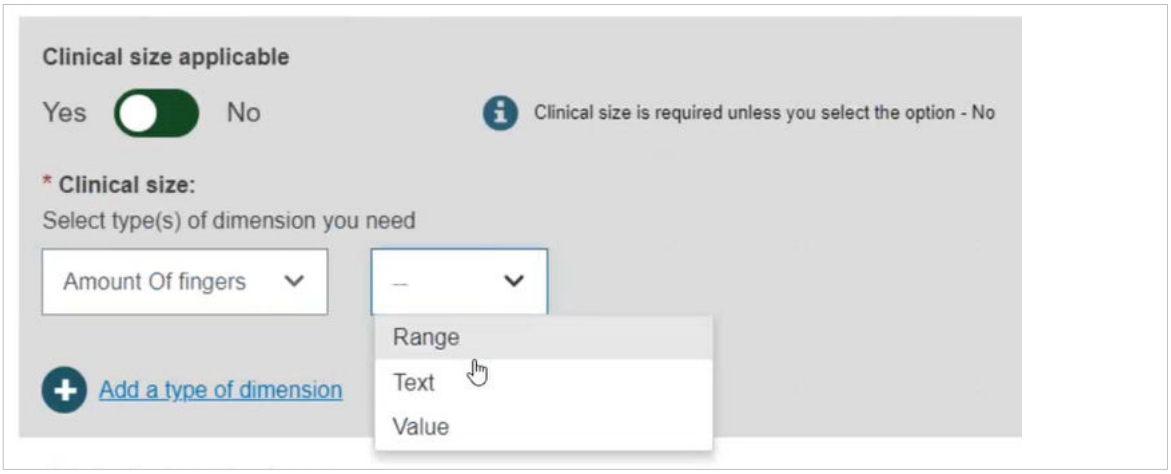
9. Select whether it is on the EU market or not and click on “Save” or “Save & Next”:

3.1.4. Step 4: UDI-DI Characteristics

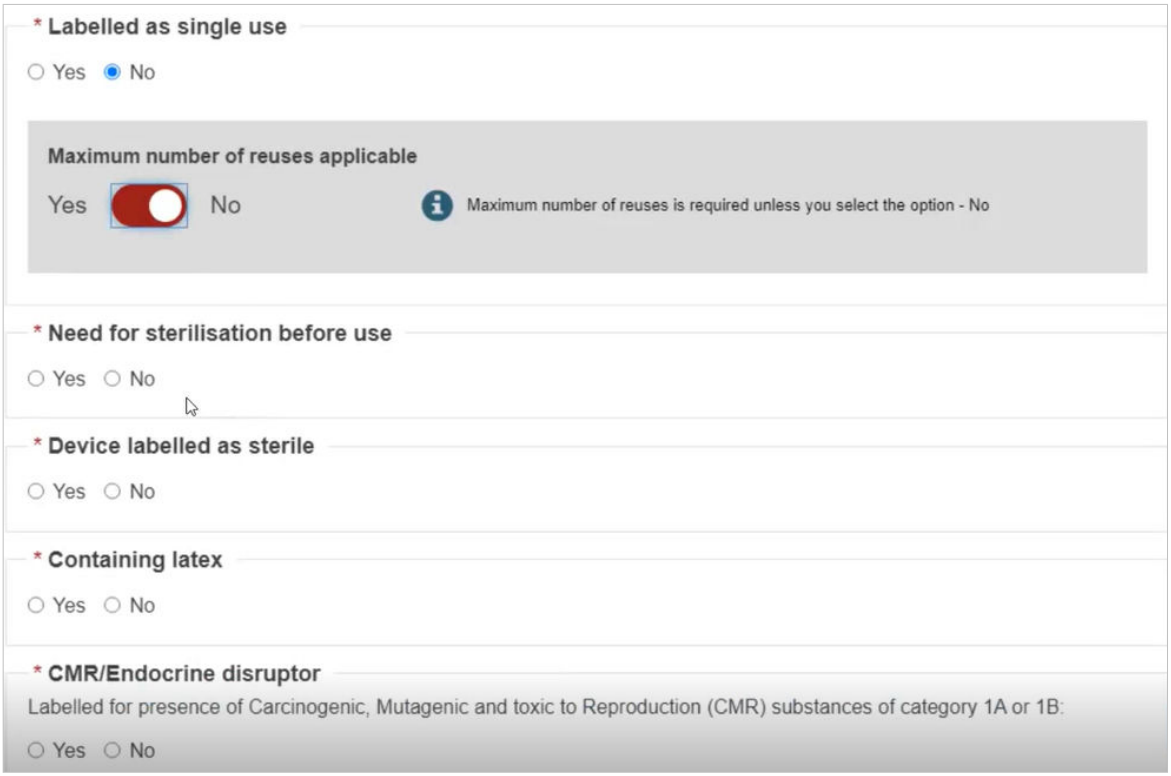
1. Select if the clinical size applies to the UDI-DI and choose the correct values in the drop-down lists below:

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

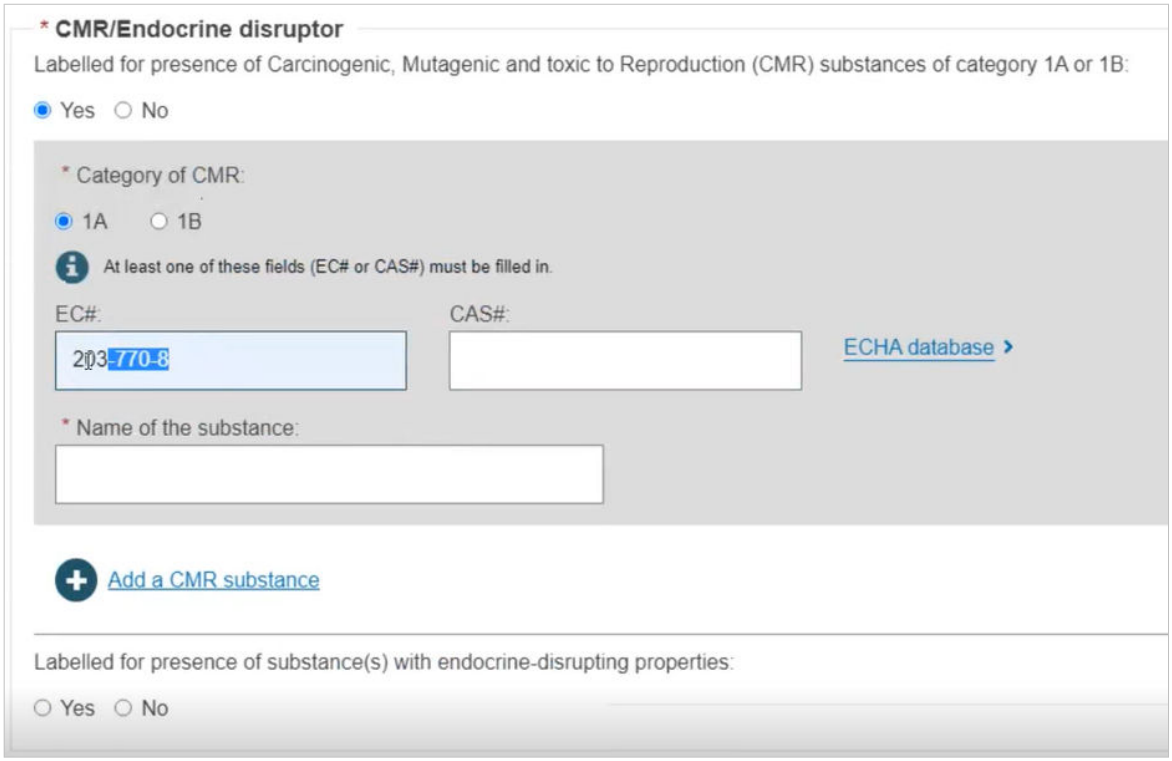
In case both the Clinical size and Measure unit have the option ‘Other’, the description for the two fields needs to be given in the same languages.



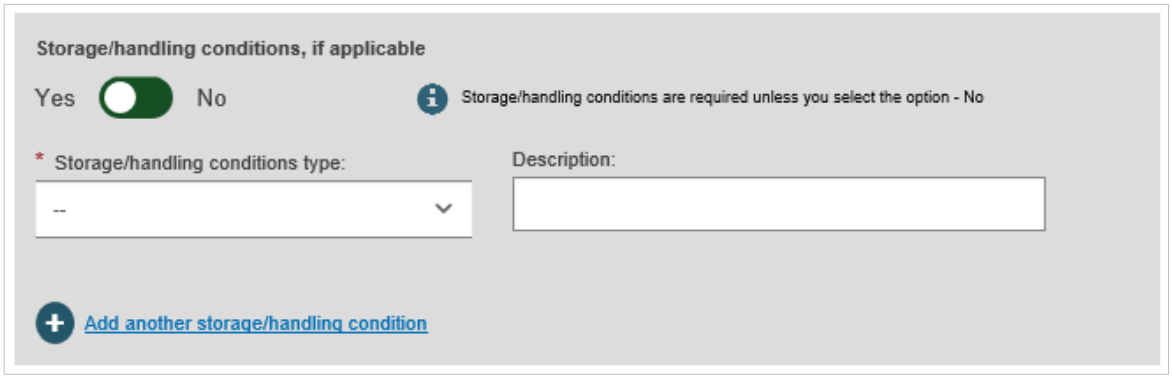
2. Select “Yes” or “No” for each of the options below:



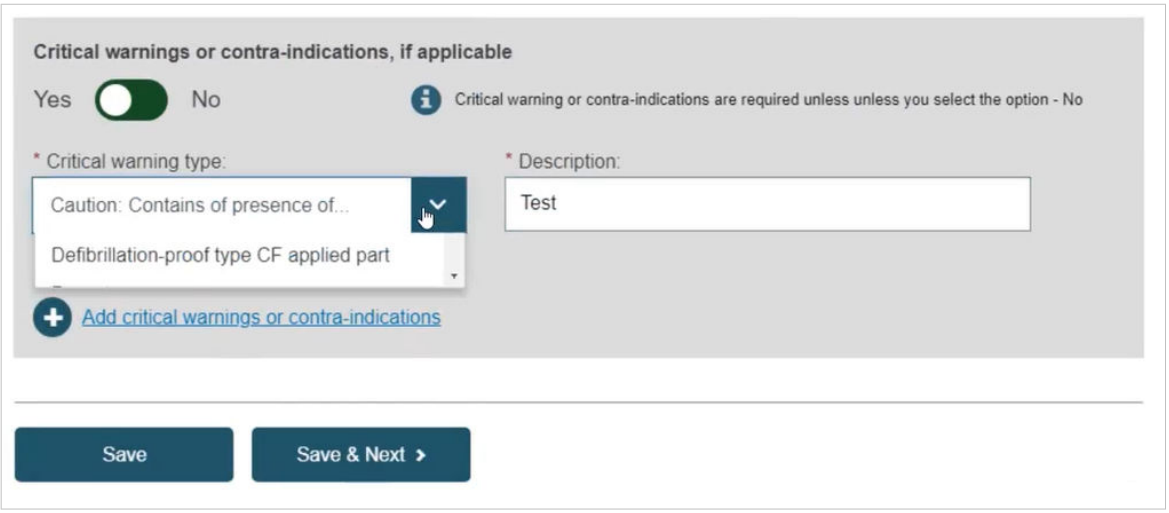
3. Enter the CMR/Endocrine disruptor substances. Select the correct option to indicate if the device is labelled with an indication of the presence of substances. When registering CMR or Endocrine substances you have the option to provide the EC# or CAS#. If you do provide them, only the Name of substance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



4. Select “Yes” or “No” for the Storage/handling conditions, if applicable; choose the correct information from the list and type a description:

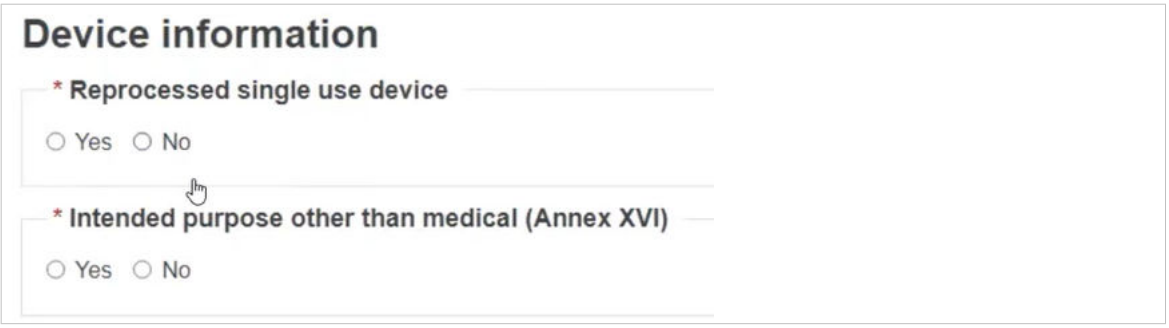


5. Do the same for Critical warnings or contra-indications, and click “Save” or “Save & Next”:

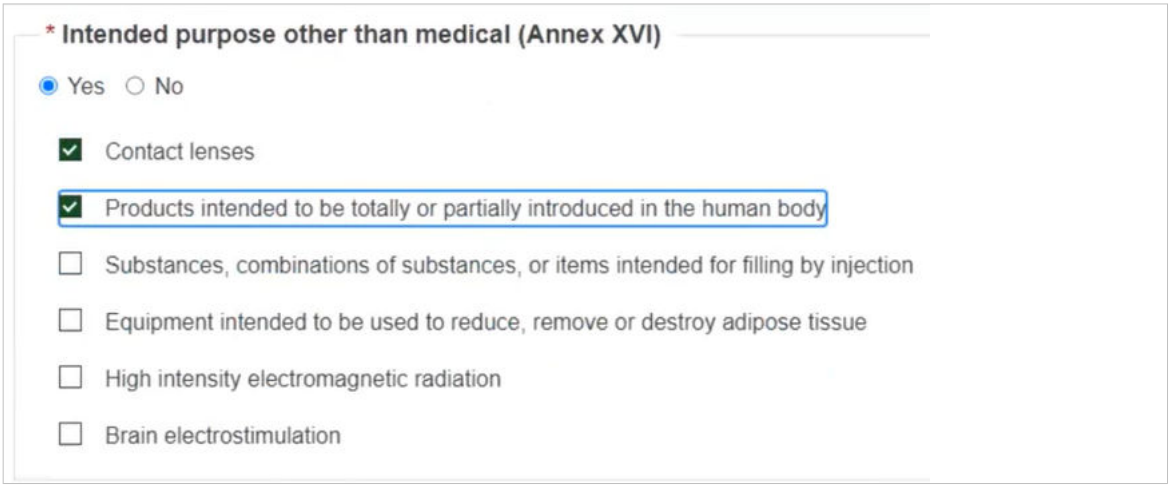


3.1.5. Step 5: Device Information

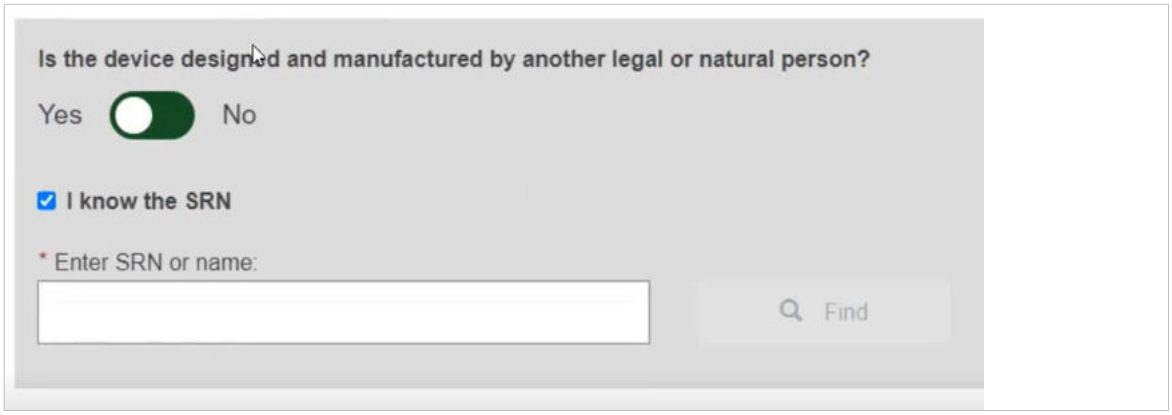
1. Select “Yes” or “No” for the first device information options:



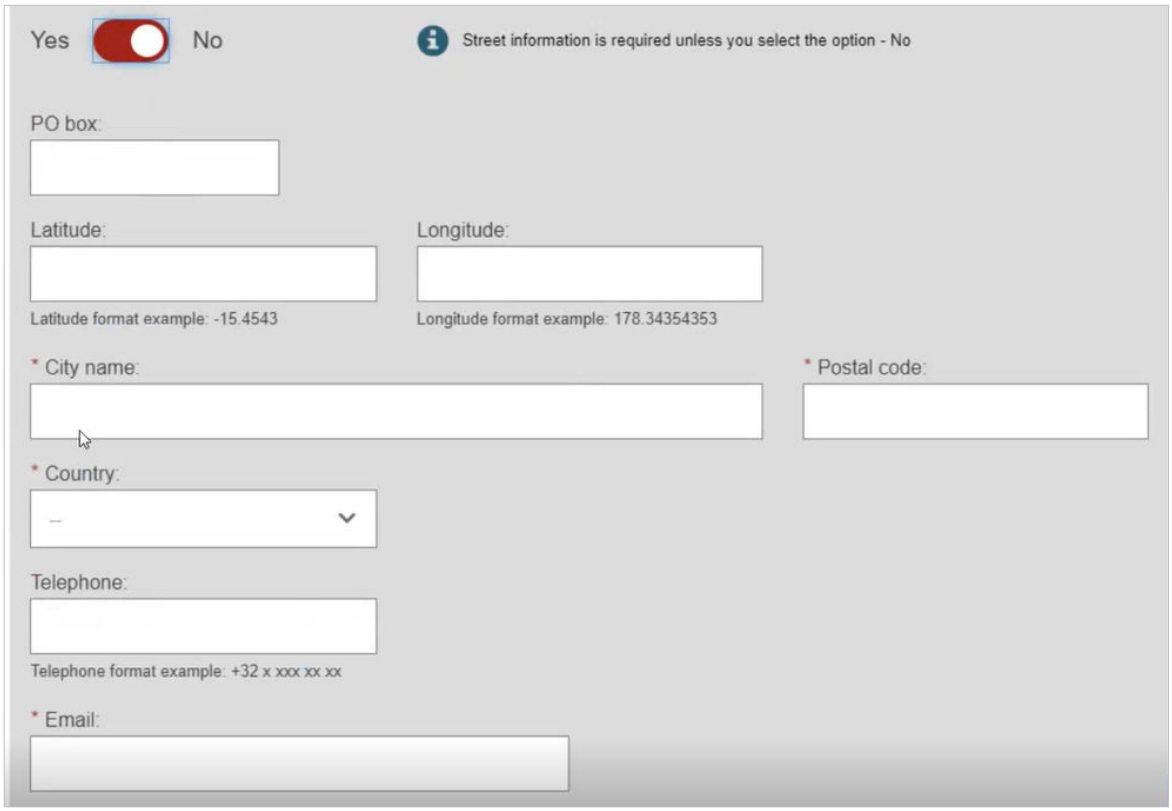
2. If you select “Yes” for the Intended purpose other than medical (Annex XVI), options will appear. Select the correct purposes:



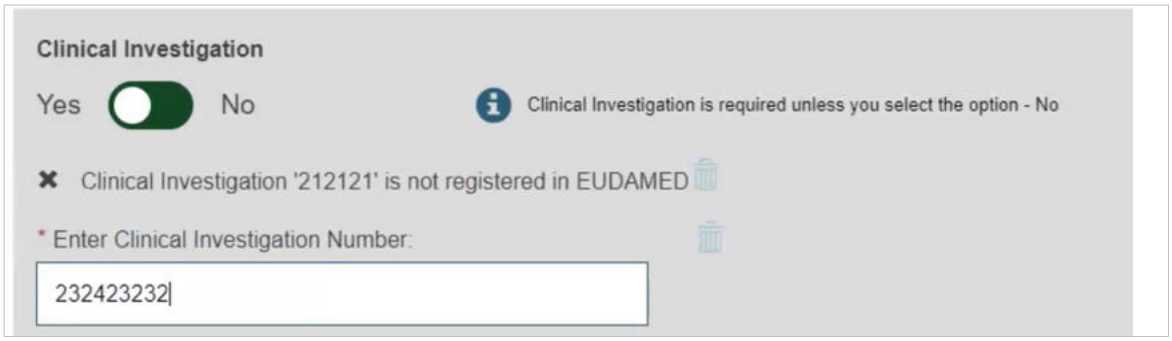
3. Select “Yes” or “No” if the device was designed by another legal or natural person. If you know the SRN, enter below:



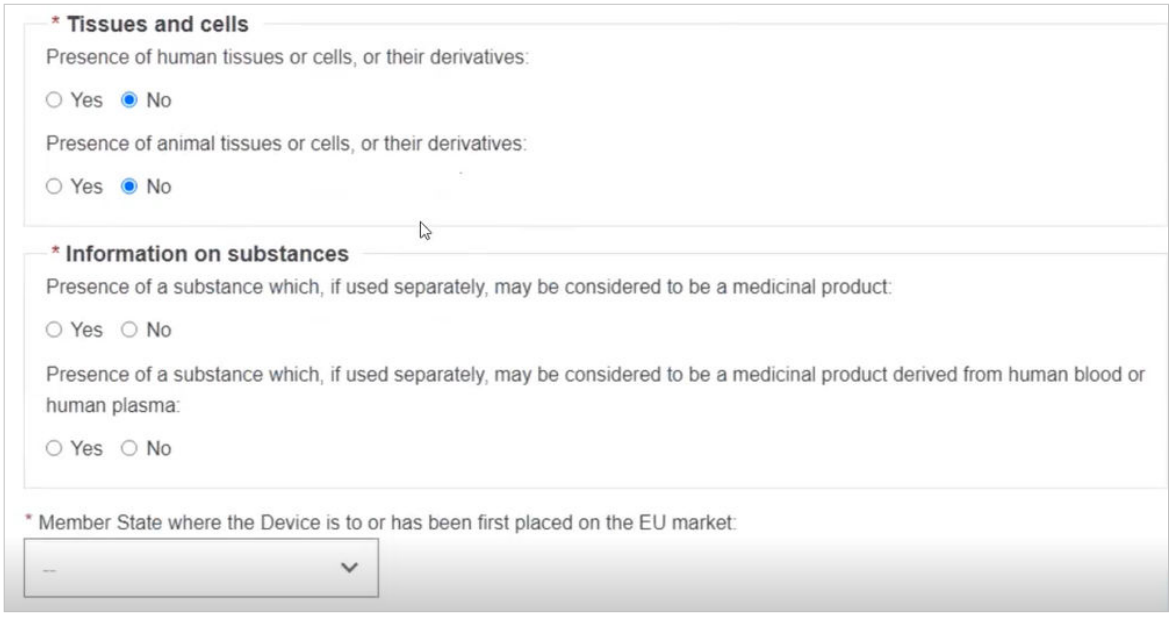
4. If you do not know the SRN, uncheck the box and complete the required fields:



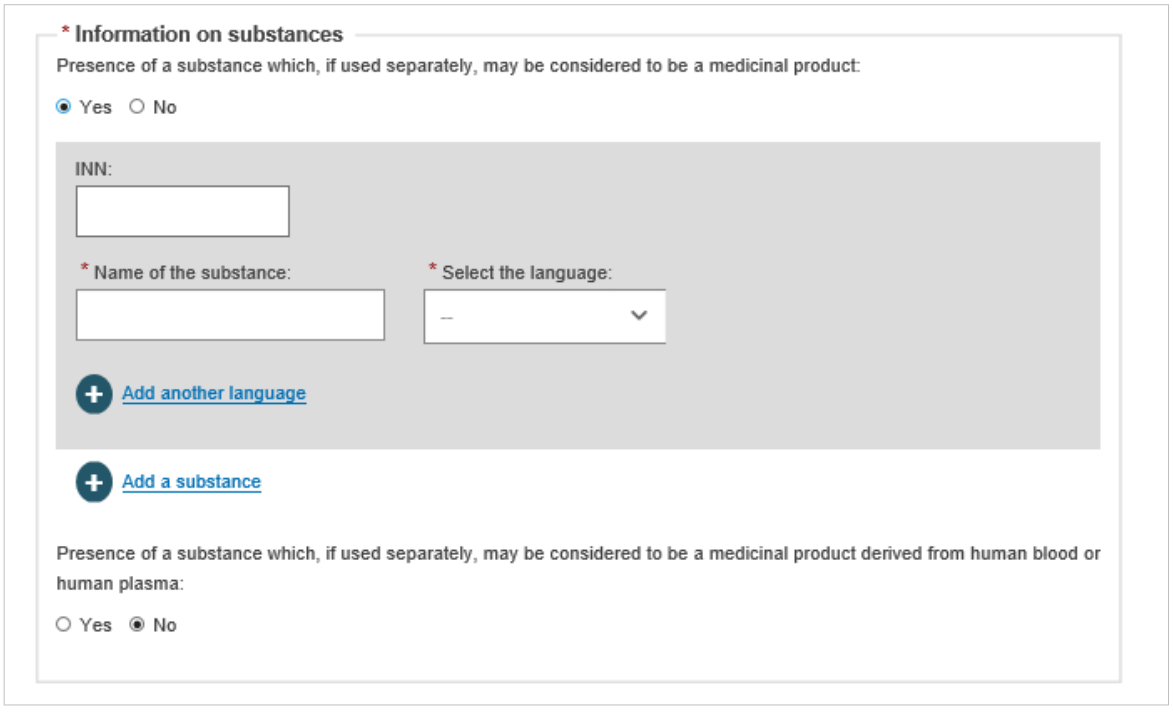
5. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI:



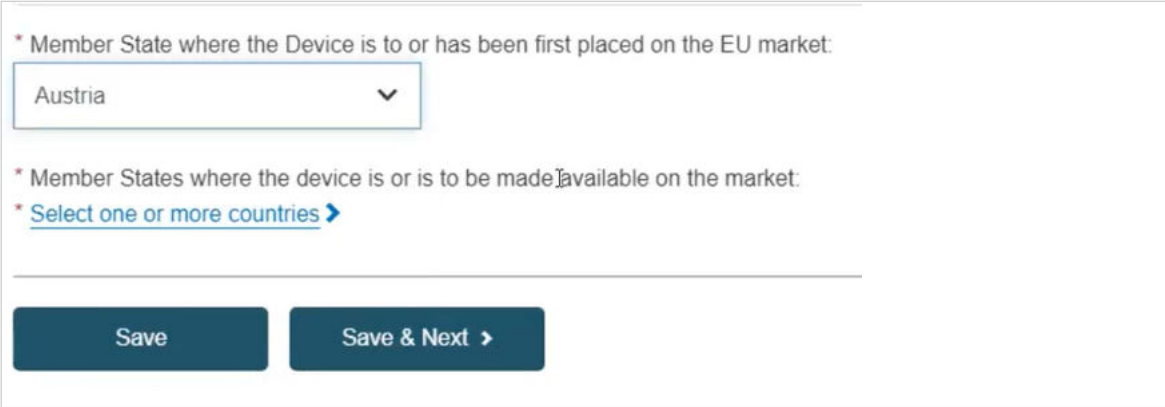
6. Select “Yes” or “No” to complete information on tissues and cells, and information on substances:



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. Choose a Member State from the drop-down list where the device was or will be placed on the EU market, and click “Save” or “Save & Next”:



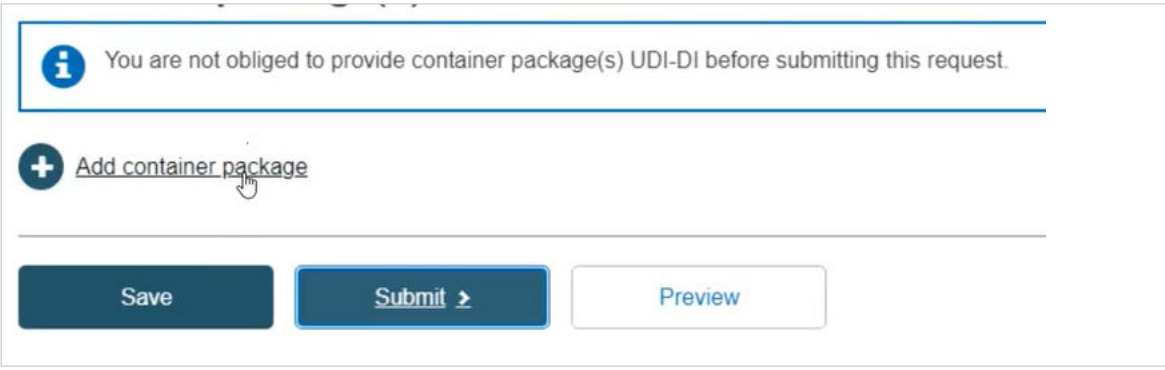
NOTE
This field may be optional or required, based on your previous answers for the device (Basic UDI-DI and UDI-DI). If the device (UDI-DI) has the status “Not intended for EU Market”, this information cannot be provided.

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.

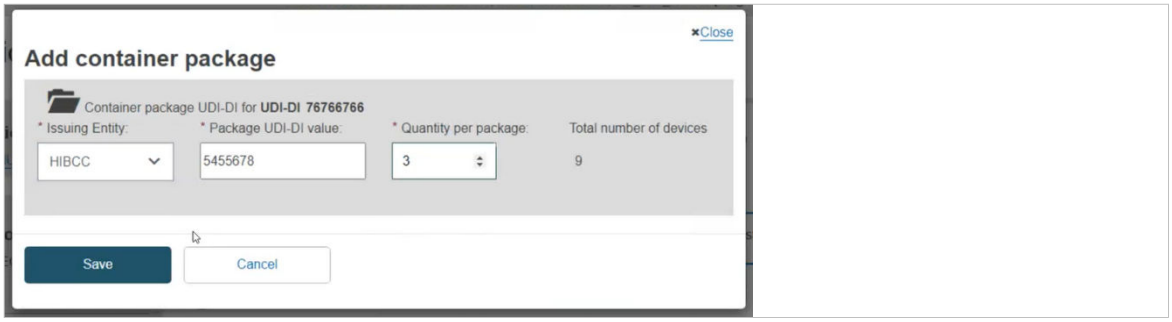
1. Click on “Add container package”:

NOTE
This step is not mandatory in order to submit your registration

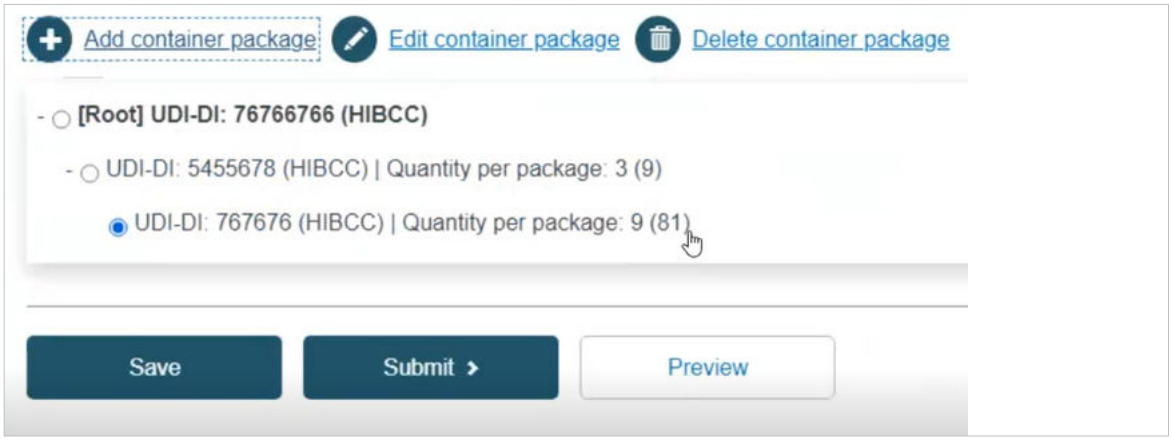


2. Add the Issuing Entity, Package UDI-DI code and the quantity per package, and click on “Save”:

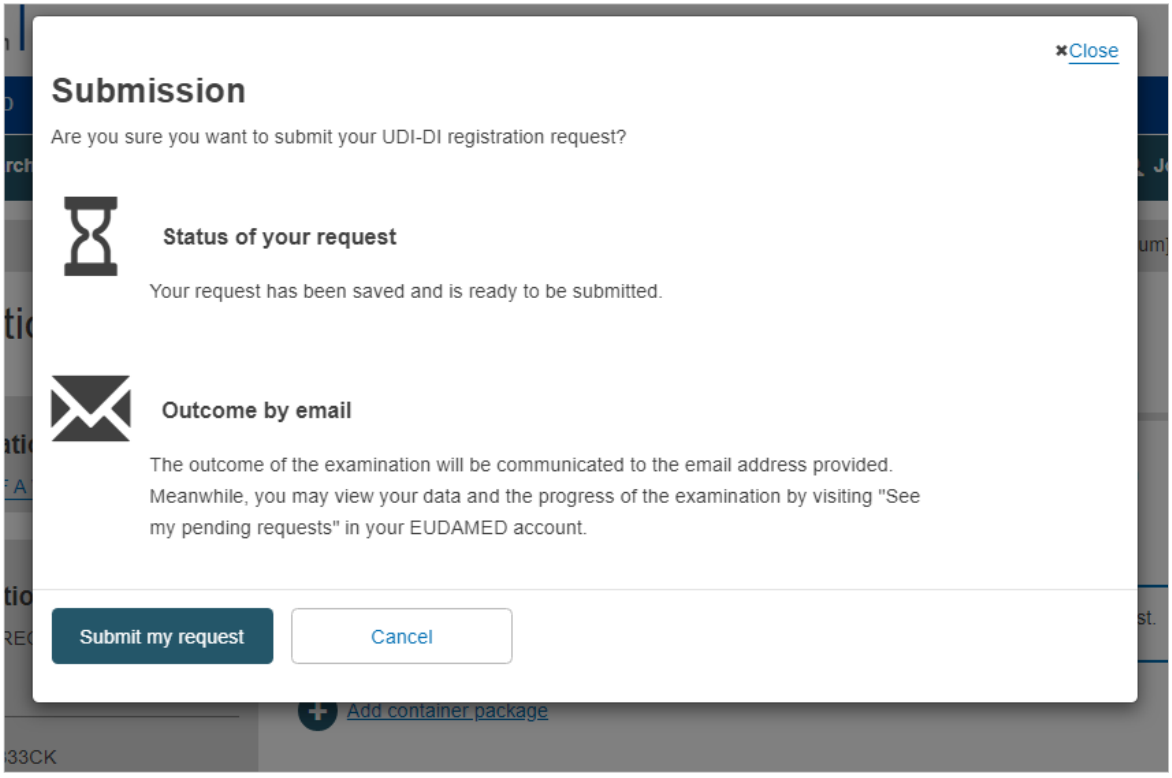
NOTE
The Package UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value.



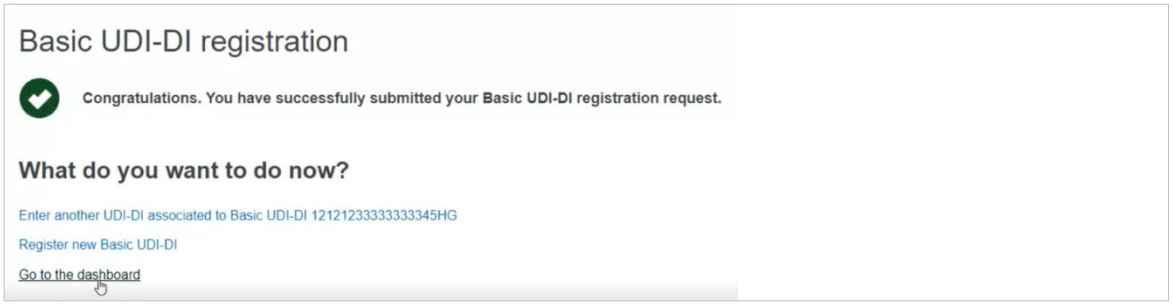
3. Select the generated information and click on “Submit”:



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



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

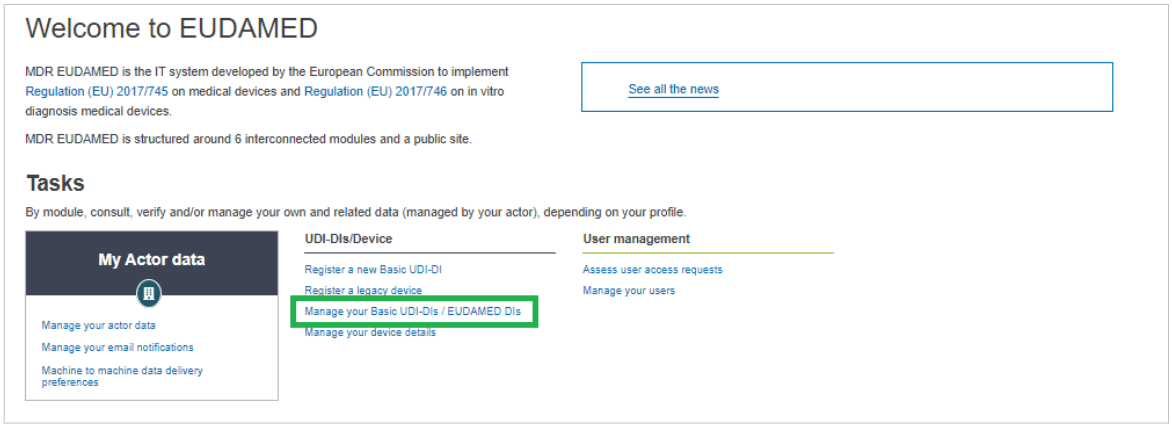


IMPORTANT
After submitting the Device, the state of the Device (Basic UDI-DI and UDI-DI) will be :

- **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

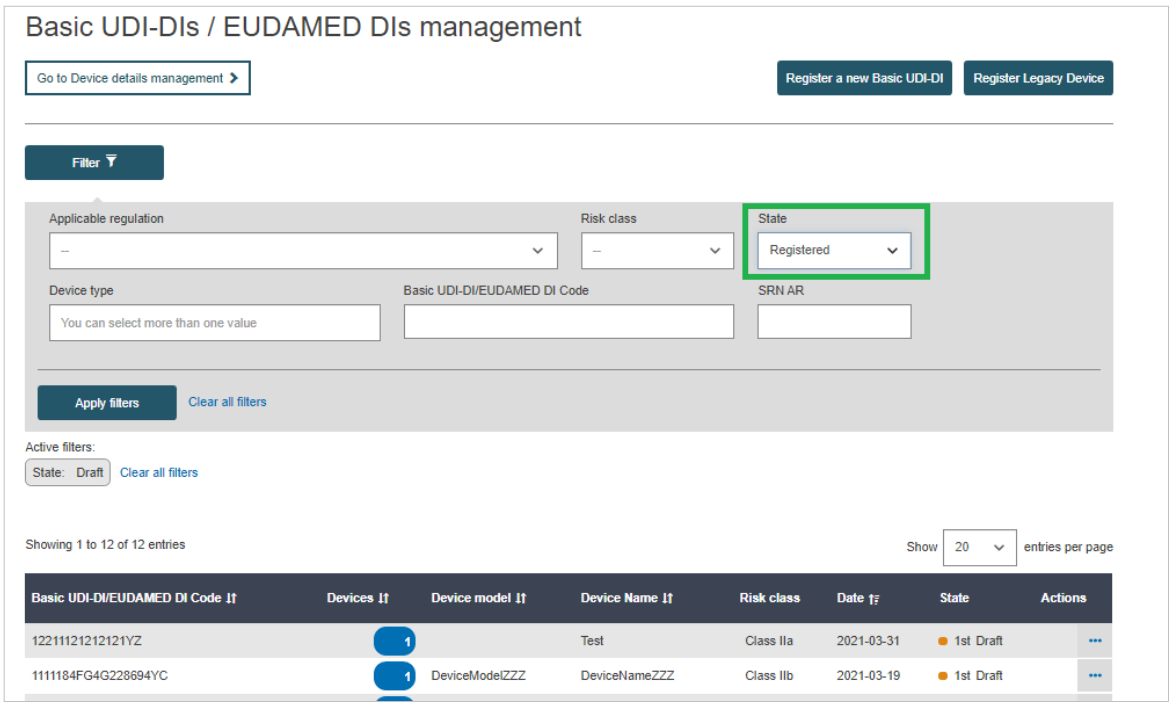
1. On the EUDAMED Dashboard, select “Manage your Basic UDI-DIs/ EUDAMED DIs”:



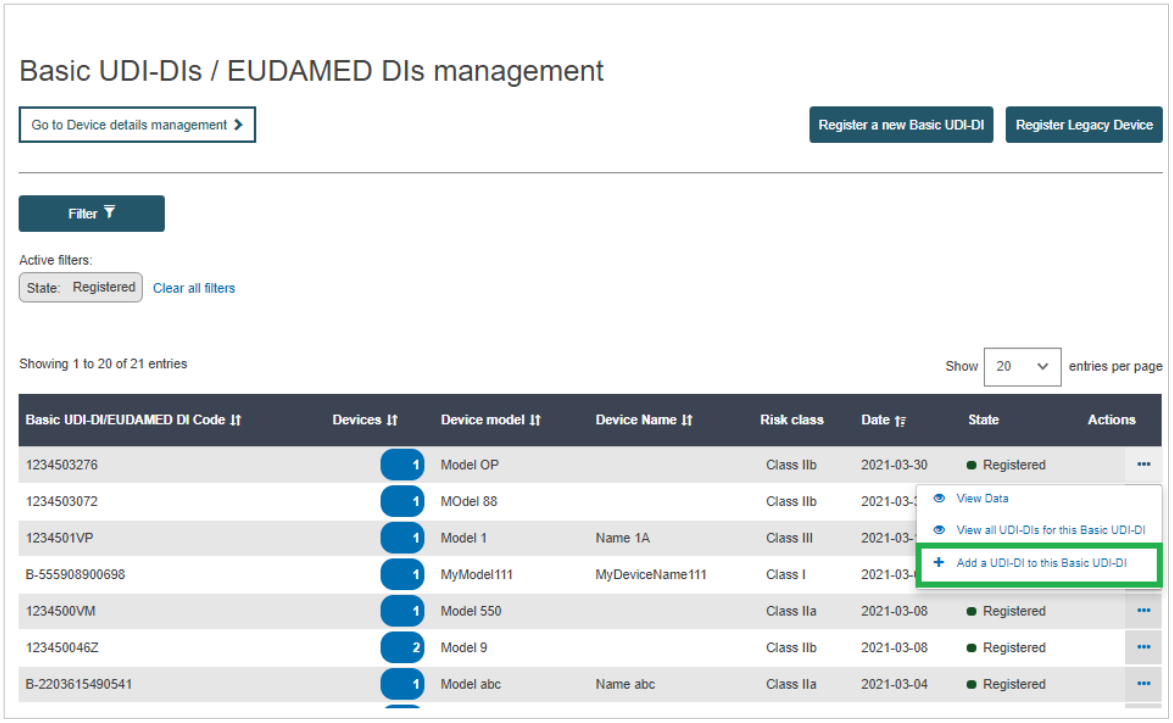
2. Filter the Basic UDI-DIs/ EUDAMED DIs in state Submitted or Registered:

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

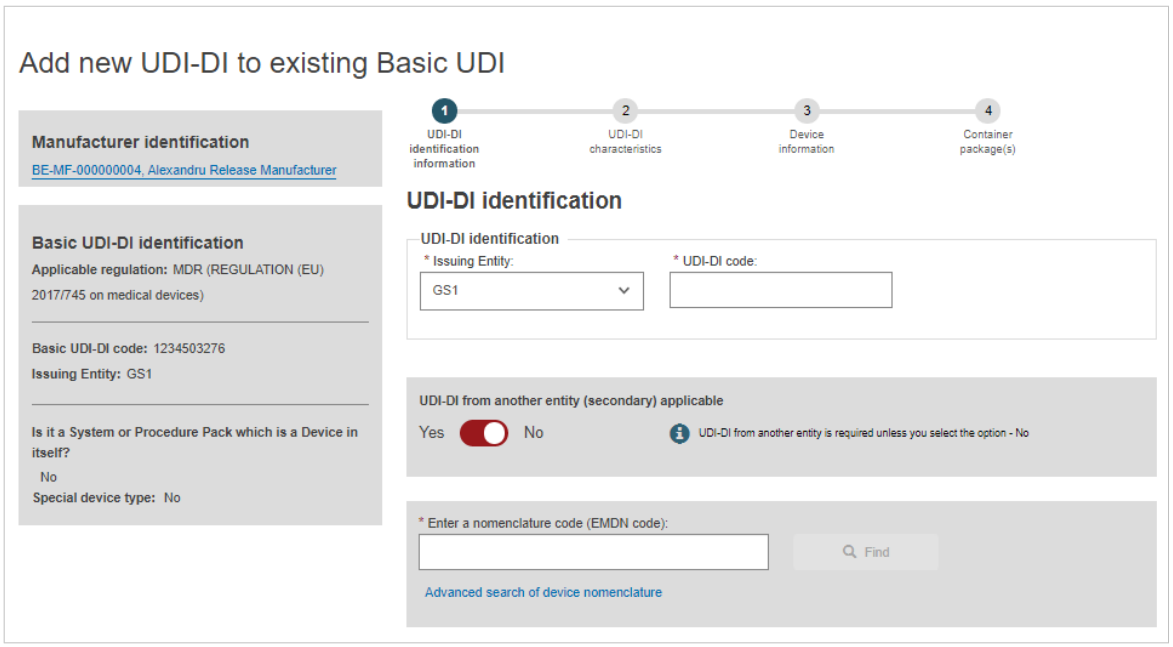
New UDI-DIs can be added only for Basic UDI-DIs that are in state Registered or Submitted.



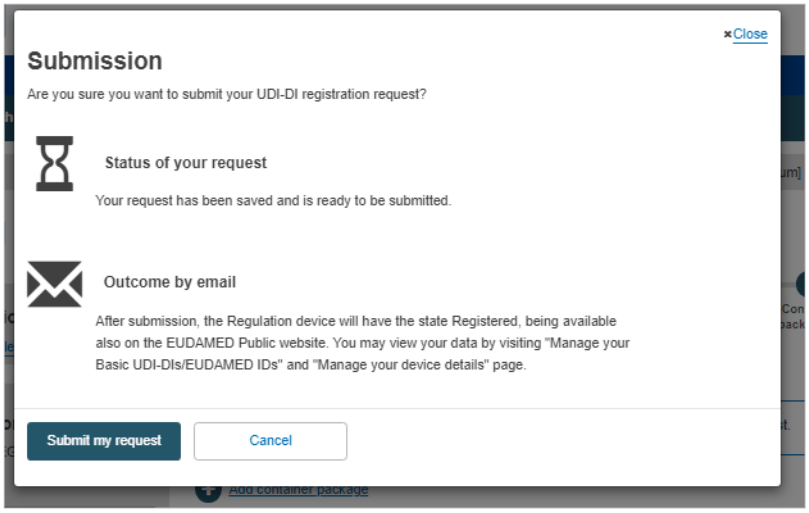
3. From the results, find the Basic UDI-DI for which you would like to add a new UDI-DI. Click on the three dots on the right and click on ‘Add a new UDI-DI to this Basic UDI-DI’:



4. Complete the series of steps required for the registration of a UDI-DI for an existing Basic UDI-DI:



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

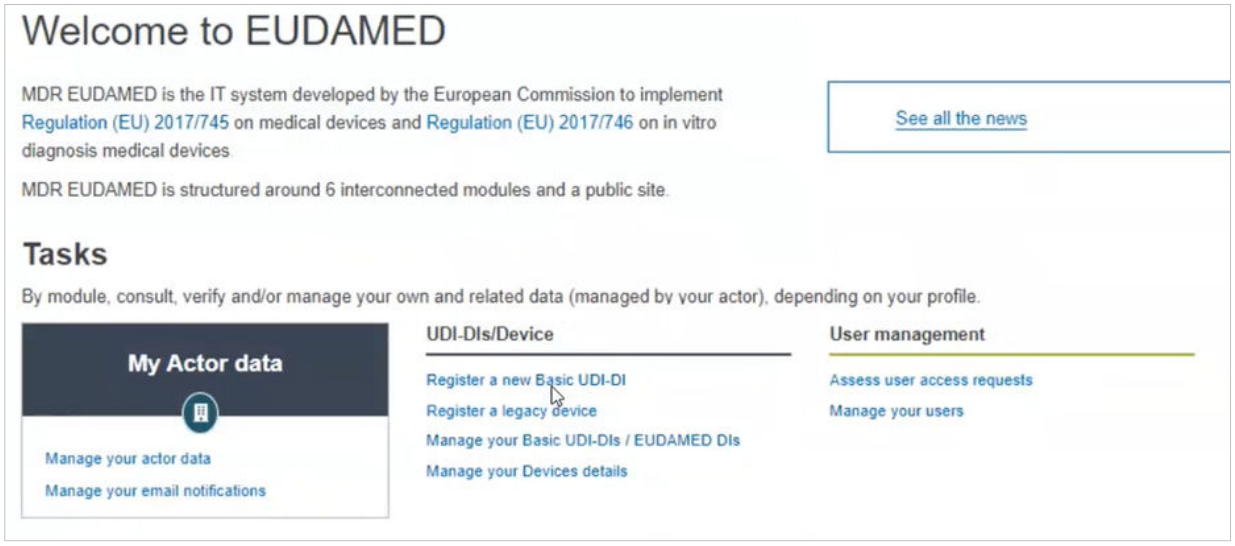


IMPORTANT
After Submitting the UDI-DI, the state of the UDI-DI will be:

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

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

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



4.1. Step 1: EUDAMED DI identification information

1. Select an applicable legislation:

> **NOTE**
> Based on the applicable legislation selected, the characteristics of the Device that you can provide will differ.

> **NOTE**
> For the rest of the procedure in this user guide, we will assume 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.

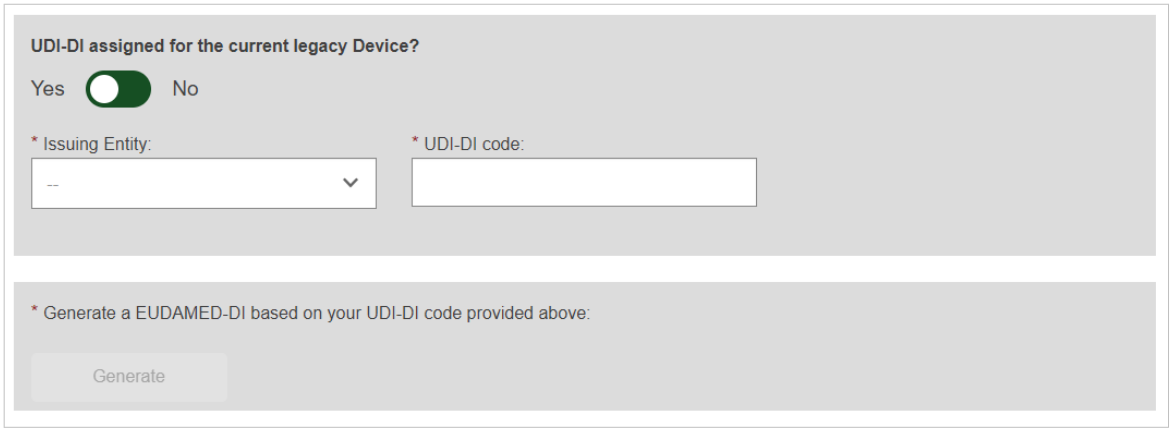
NOTE
If no UDI-DI is available, the EUDAMED DI must be provided.

NOTE
In case of GS1 Issuing Entity, the UDI-DI code you enter must have 14 characters.

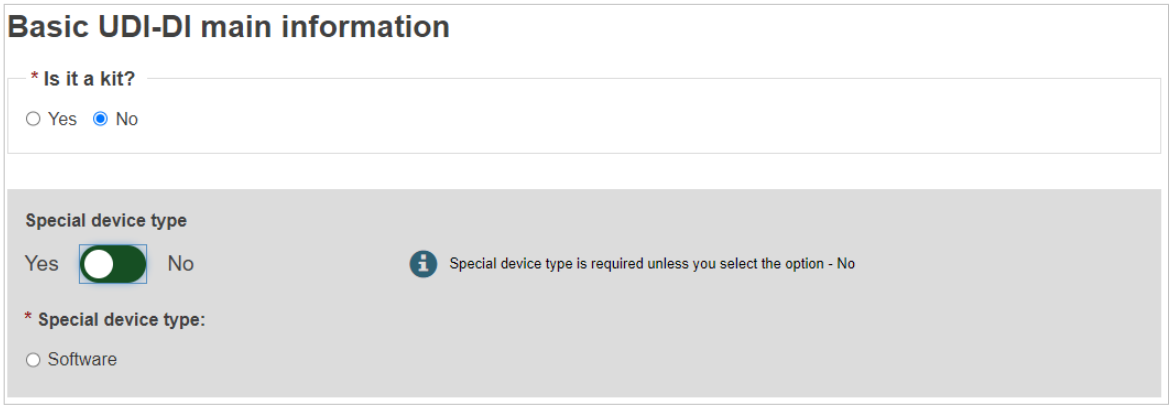
The EUDAMED DI can be generated outside EUDAMED (using the provided algorithm for the generation of EUDAMED DI) or can be generated during the registration process by providing the manufacturer’s device identifier and allowing EUDAMED to generate it.

IMPORTANT
When 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 asked 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 asked to create a link between the two devices (the Regulation and the Legacy Device).



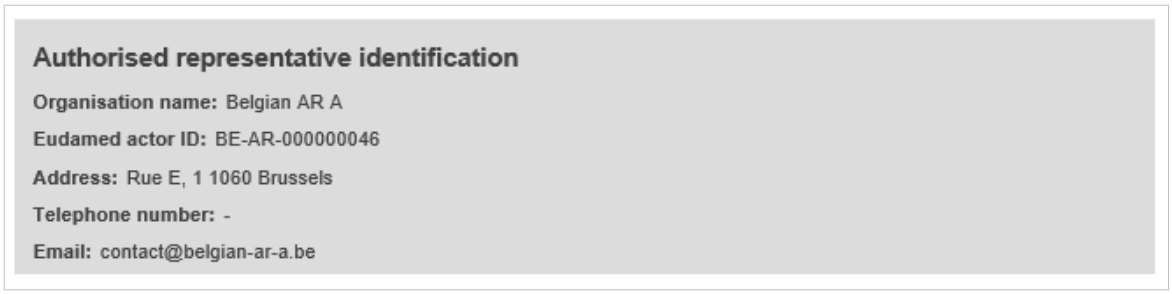
3. Select if it is a kit or not. If you choose “Yes” you can move on to the next step, otherwise fill in the remaining information:



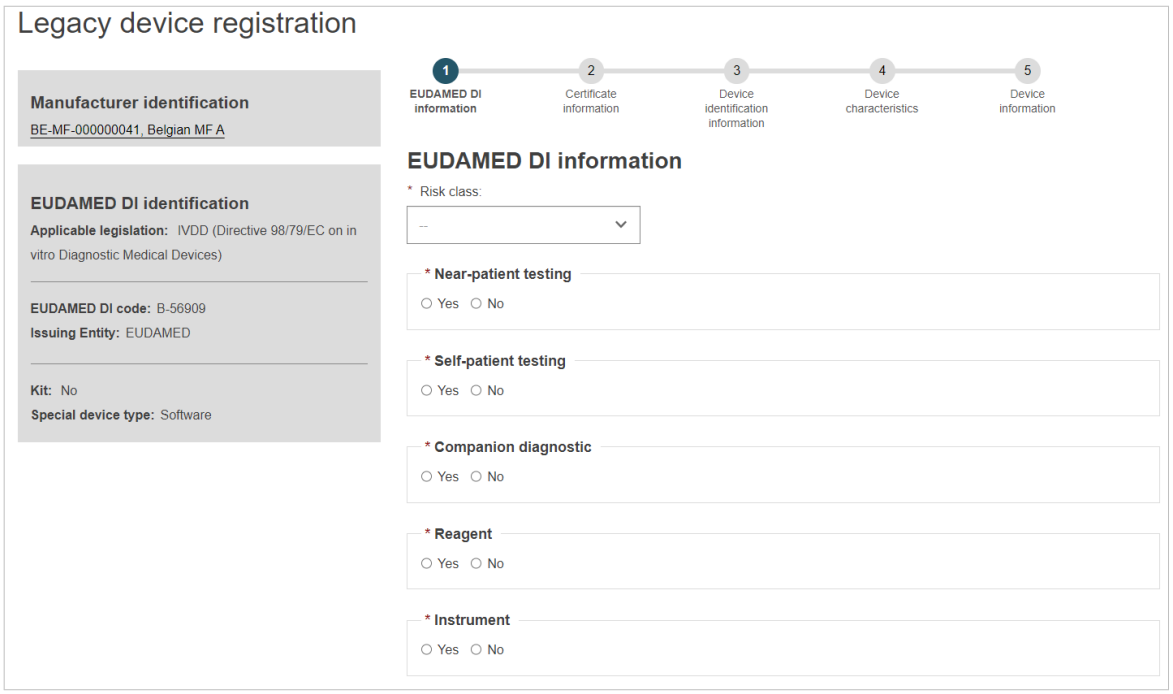
4. Choose the authorised representative for the current device (Basic UDI DI) from the options available (applicable only in case of non-EU manufacturers).

> **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.

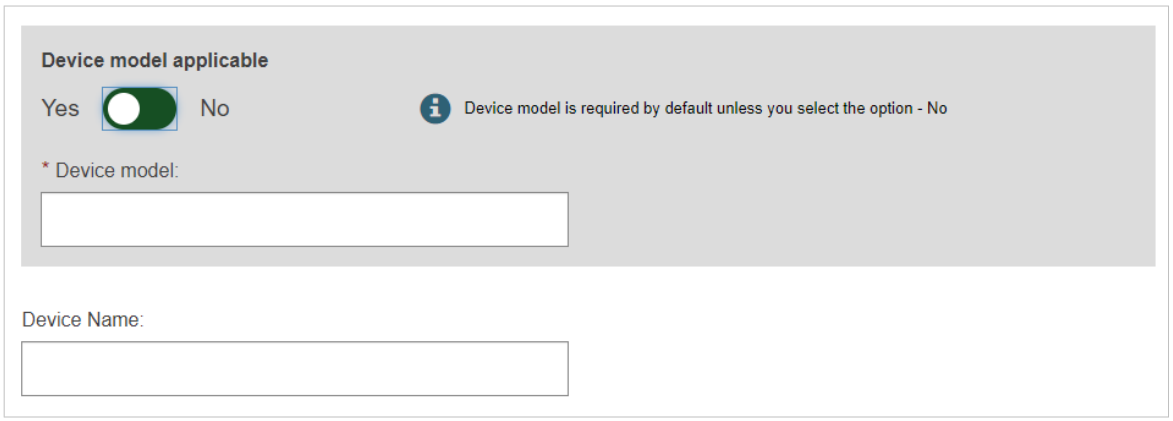
If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically selected as shown below:



5. On the left you will see a summary of the device characteristics.
Choose a “Risk class” from the list and select “Yes” or “No” for each of the options.
Risk Class options depend on the Applicable Legislation of the Device and influence the properties which must be entered 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 draft and complete it later, or on “Save & Next” to save it as a draft and continue with the following steps:

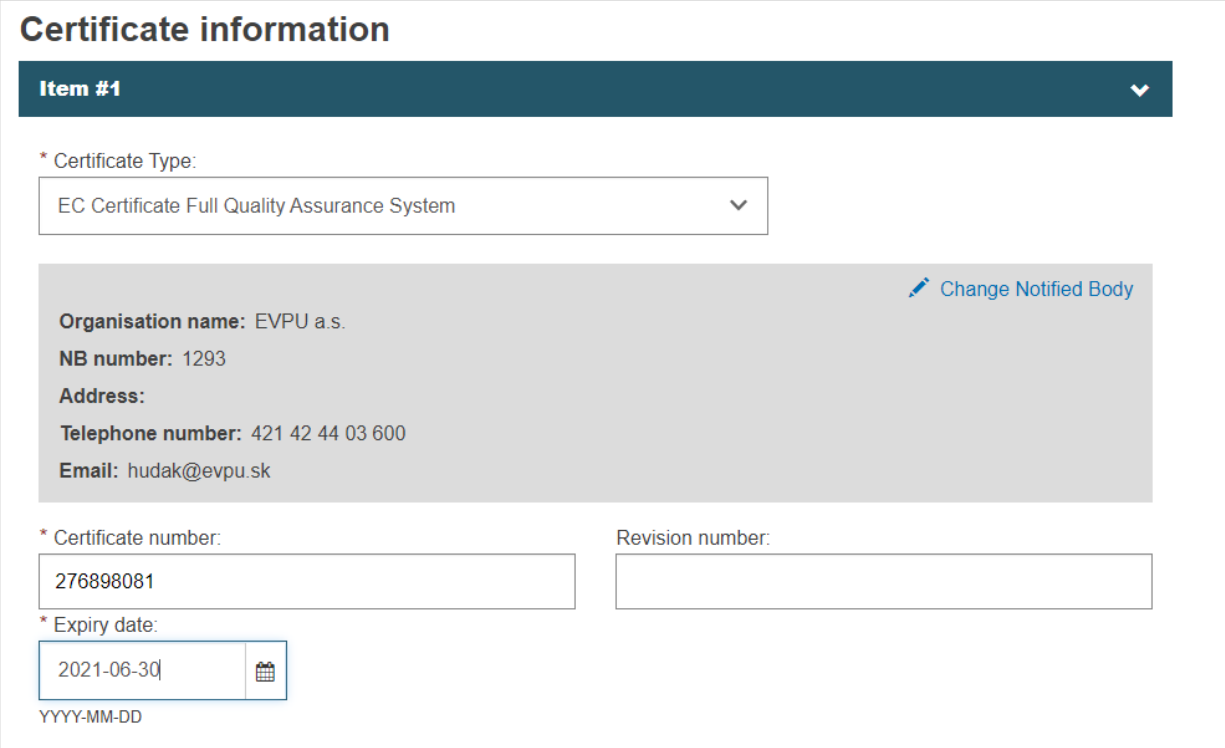
4.2. Step 2: Certificate information

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 can be entered:

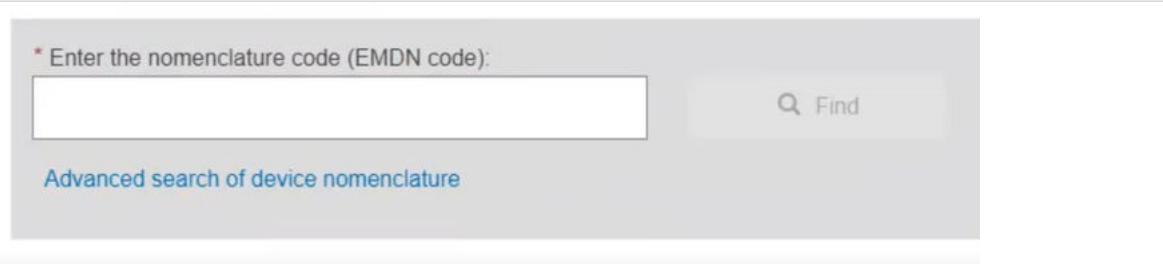


4.3. Step 3: Device identification information

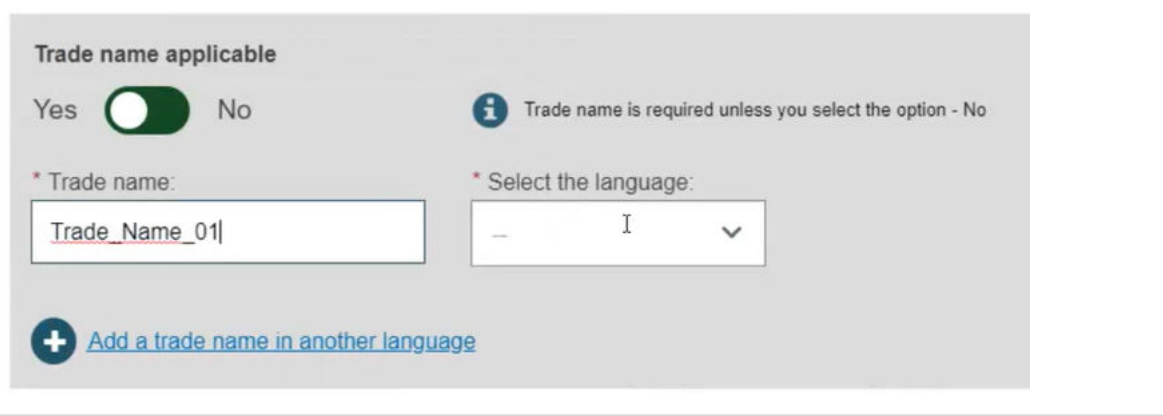
1. EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED ID generated based on the provided/generated EUDAMED DI):

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

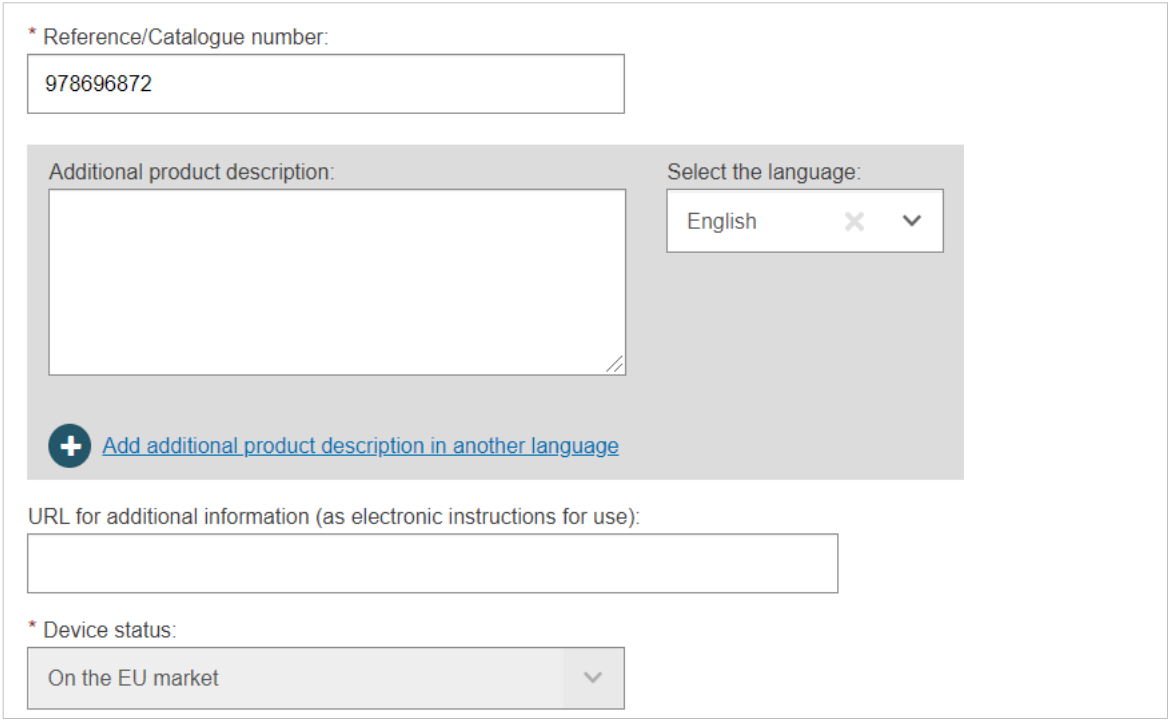
NOTE
EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.



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:

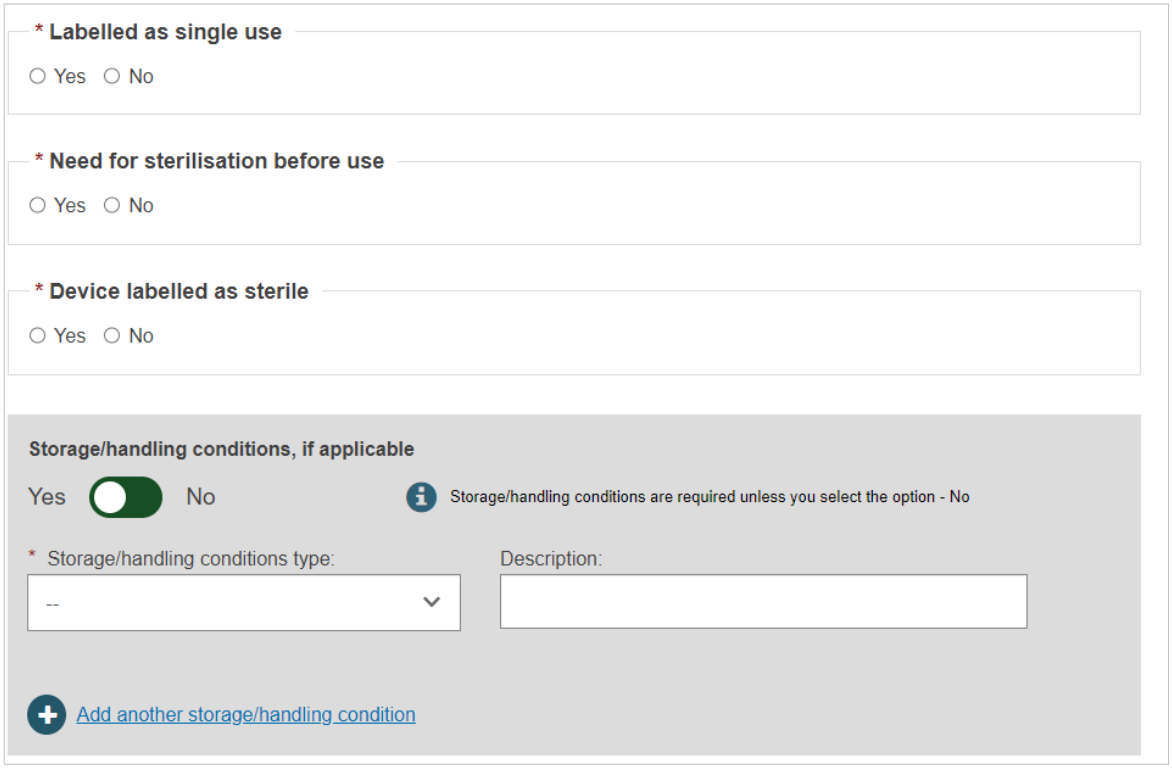


5. EUDAMED will display the status of the Device.

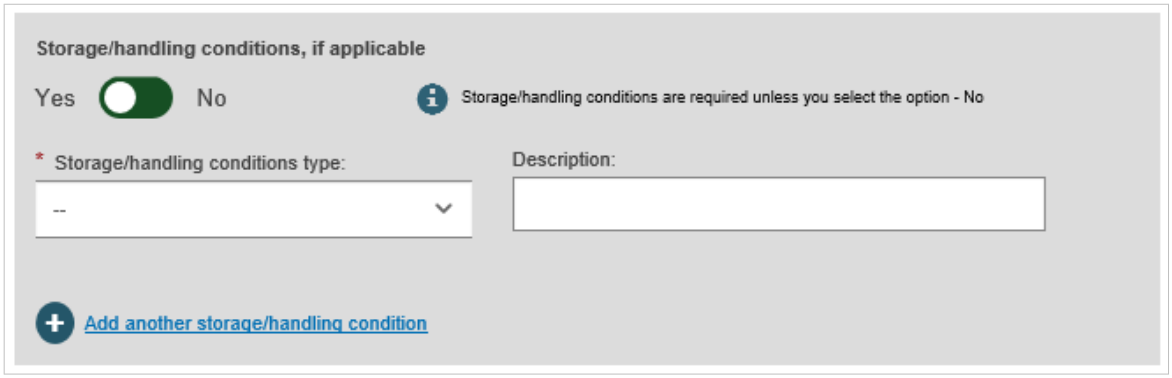
NOTE
In the case of Legacy Devices, the initial status of the Device is considered to be ‘On the market’. If the device is ‘No longer on the market’, an update of the status can be performed on the Device (UDI-DI/EUDAMED ID):

4.4. Step 4: Device Characteristics

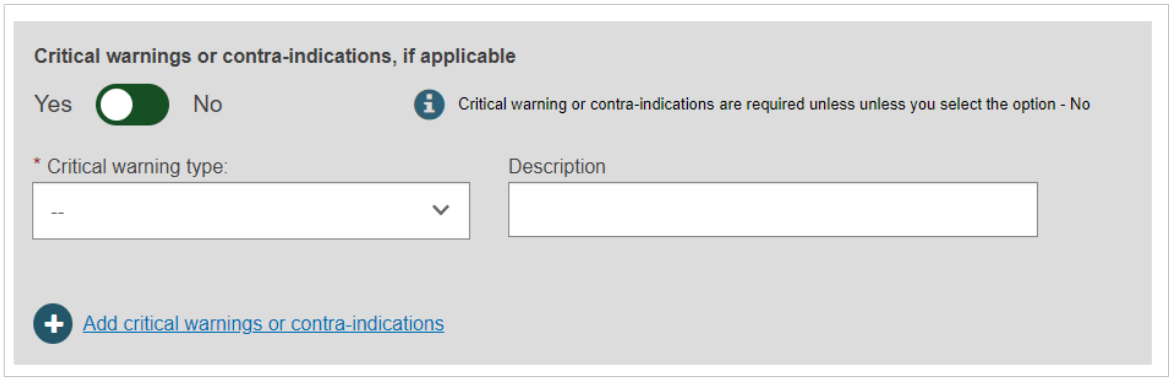
1. Select “Yes” or “No” for the first three options, then select “Yes” or “No” whether if Storage/handling conditions are applicable:



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

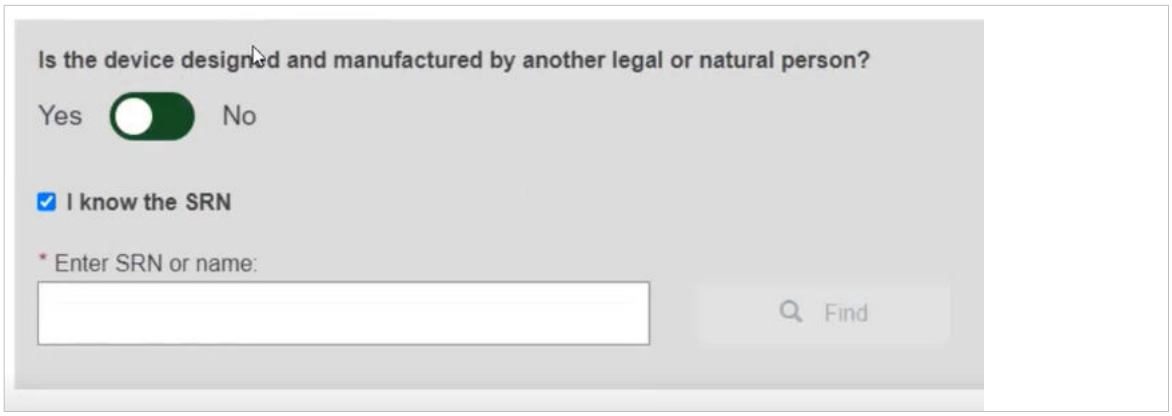


3. Select “Yes” or “No” for Critical warnings or contra-indications and if “Yes”, enter the type and description. After completing, click on “Save” or “Save & Next”:

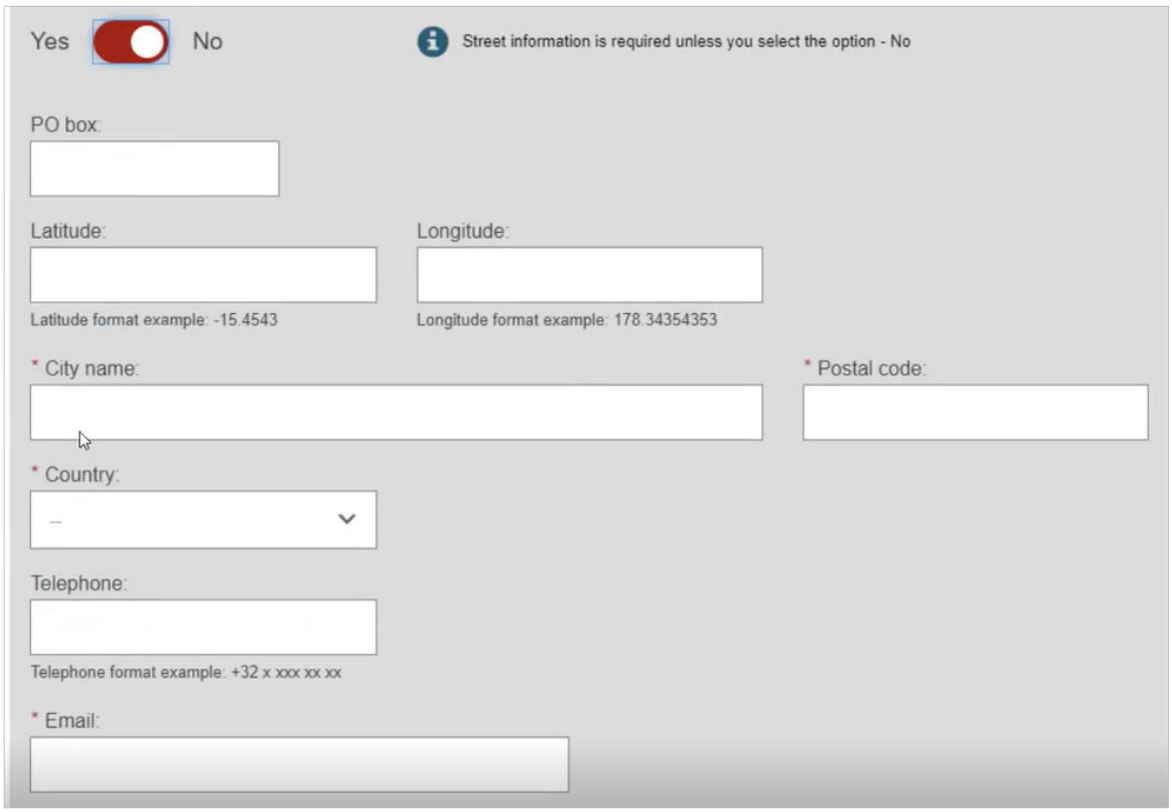


4.5. Step 5: Device Information

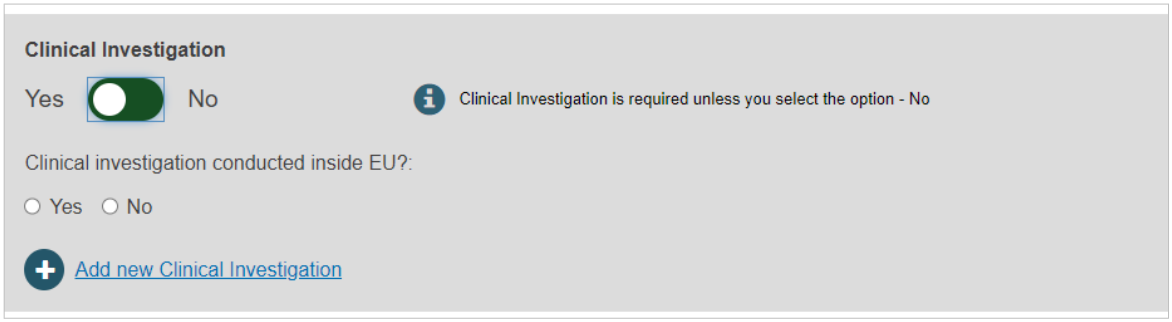
1. Select “Yes” or “No” if the device was designed by another legal or natural person, and enter the SRN number if you know it:



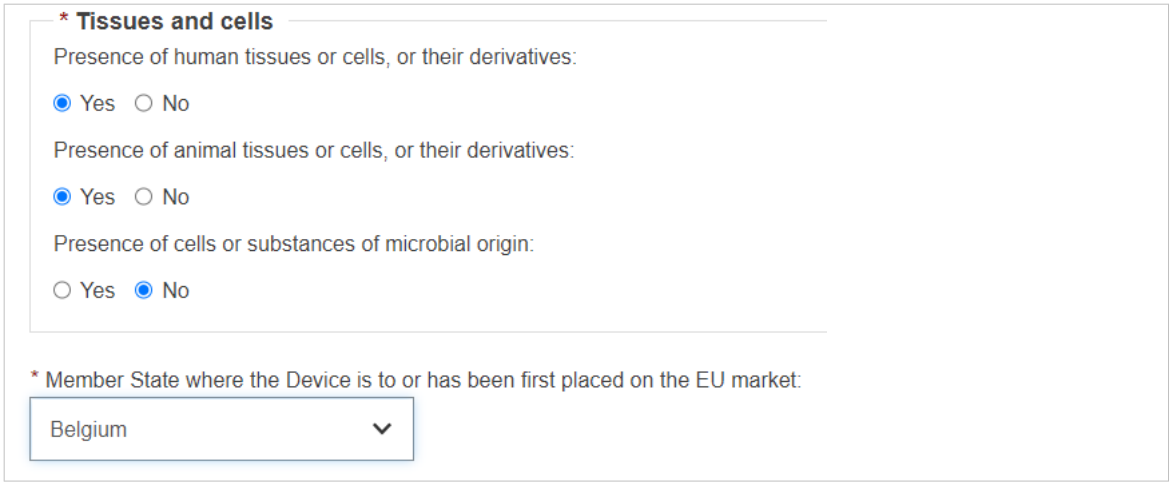
If you select “No”, enter the information manually, fill in all the fields with a red asterisk (the rest are optional):



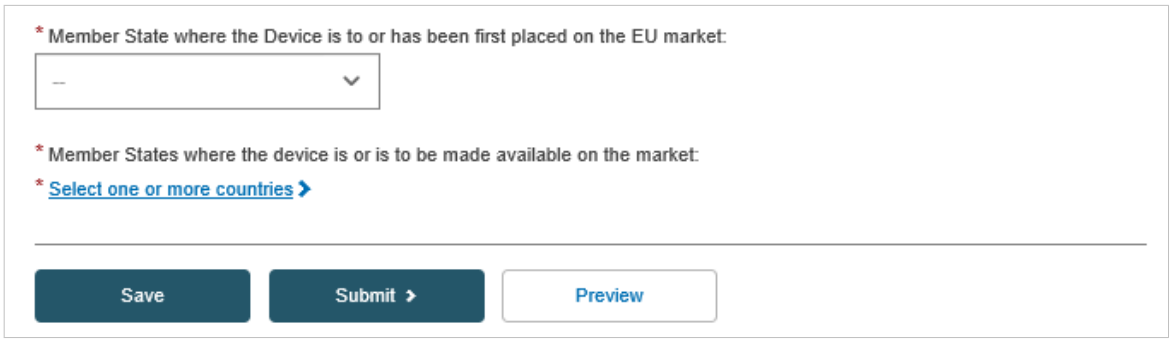
2. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI/EUDAMED ID:



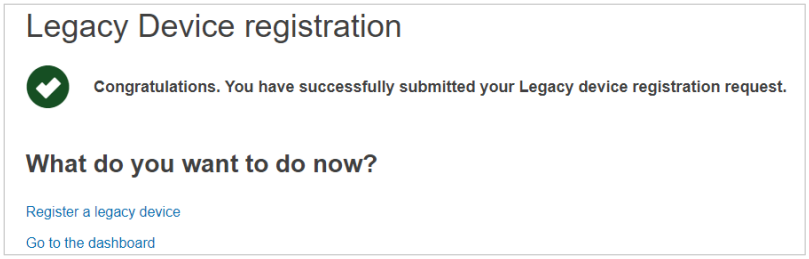
3. Select “Yes” or “No” for the three following options on Tissues and cells:



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



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

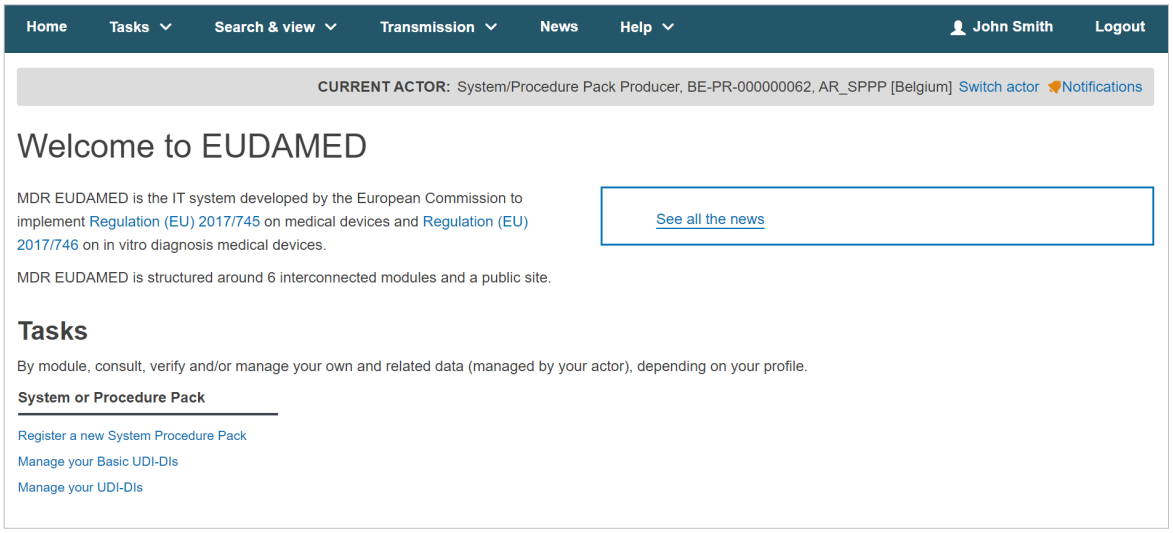


5. Registering System or Procedure Packs

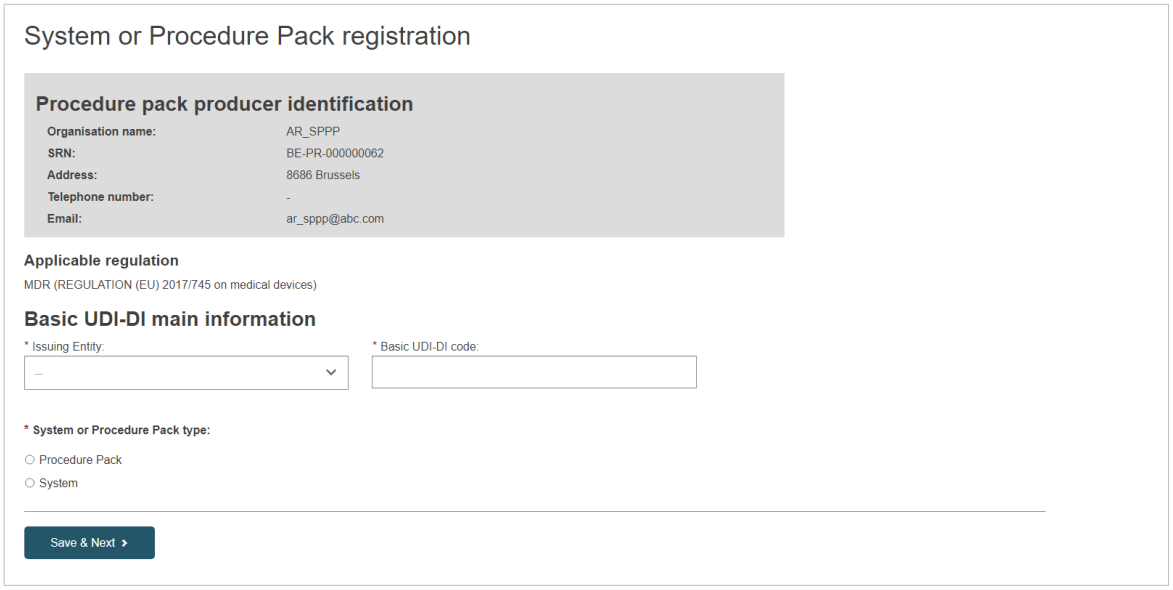
5.1. Registration of Basic UDI-DI together with the first UDI-DI for a System or Procedure Packs

5.1.1. Step 1: Basic UDI-DI main information

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



2. On the next page, register the Basic UDI-DI main information for your system or procedure pack, meaning the Basic UDI-DI Issuing entity and code.



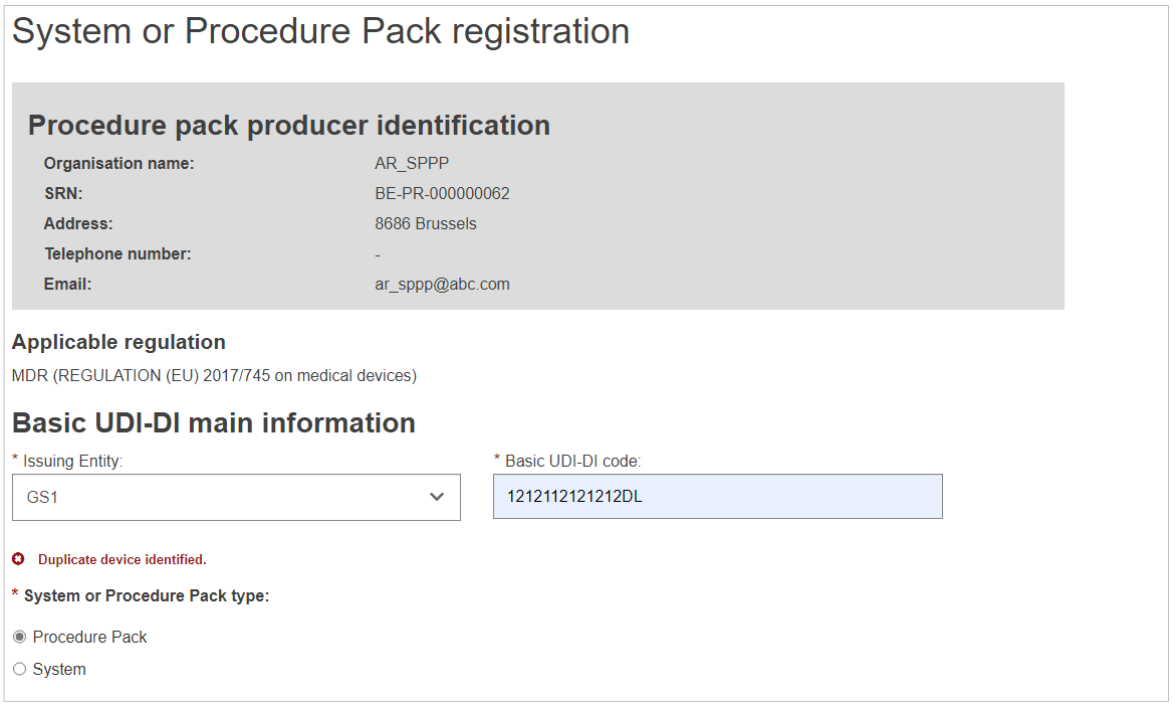
NOTE

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

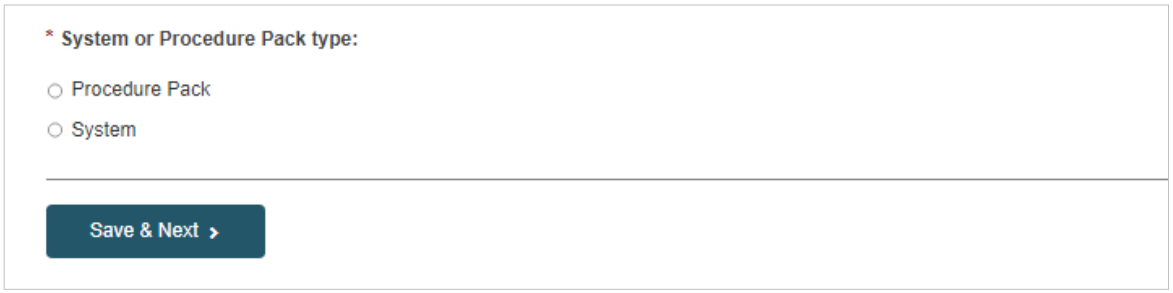
IMPORTANT

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

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 asked to provide another value:

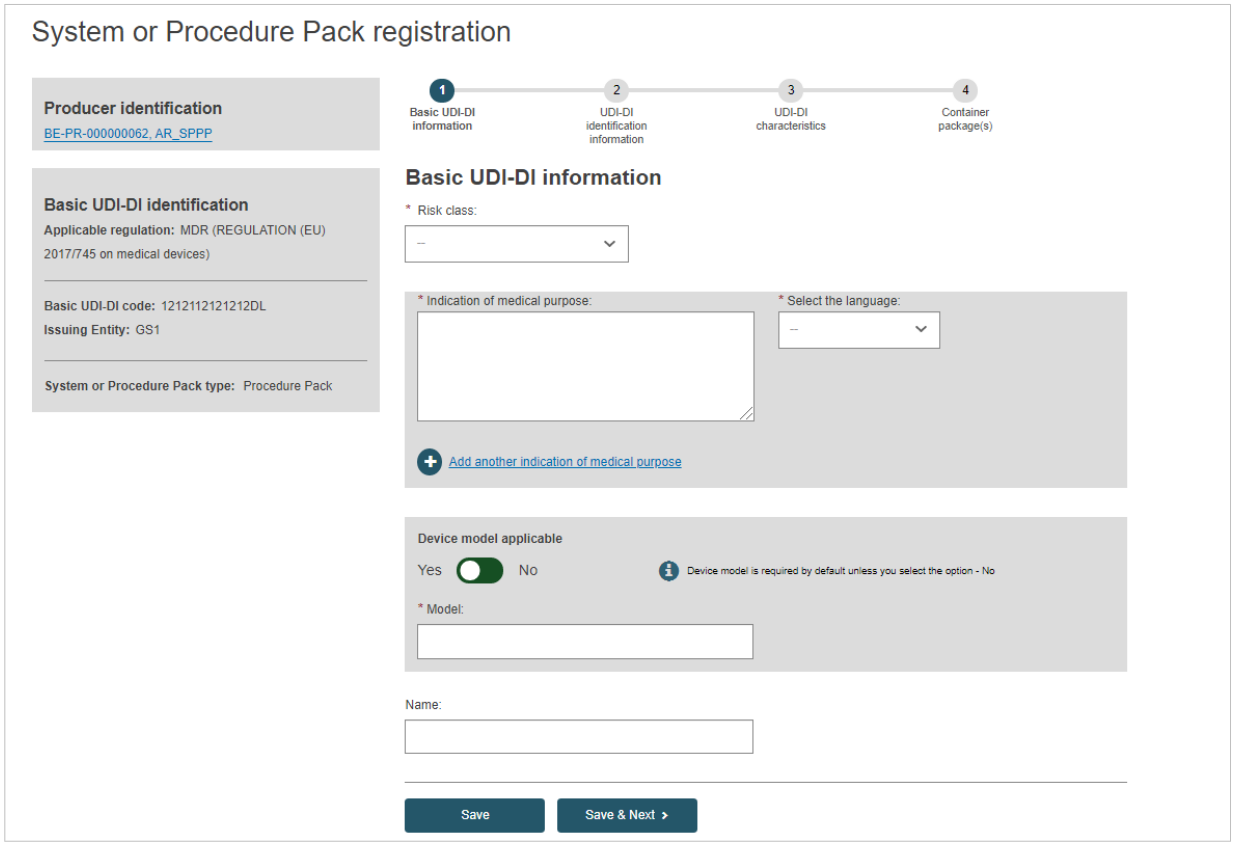


3. Choose if you are registering a system or procedure pack and click on “Save & Next” to save your registration as a draft and move on to the next steps:

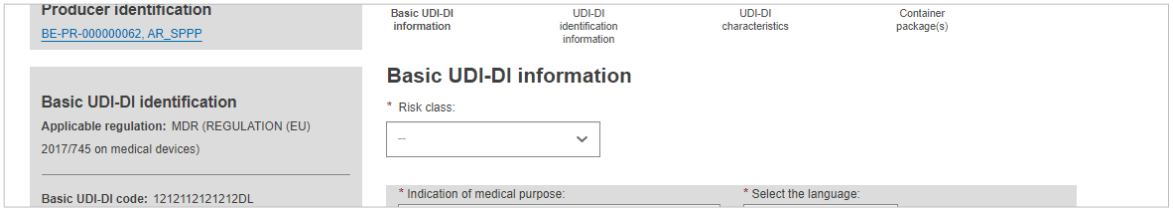


5.1.2. Step 2: Basic UDI-DI information

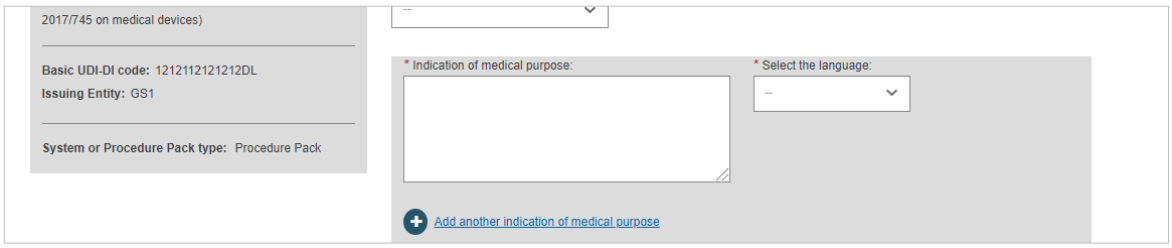
On the next page, enter the Basic UDI-DI information:



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

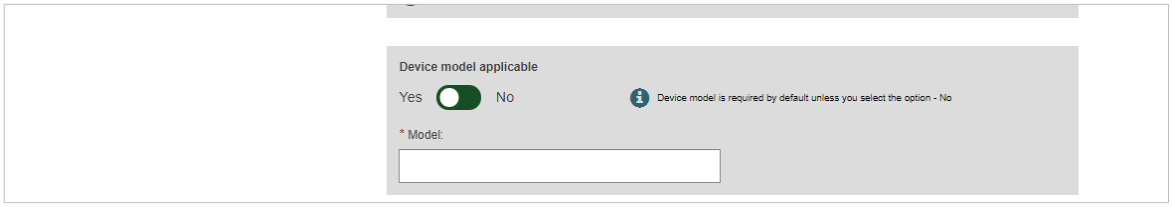


2. Fill in the indication of medical purpose, and choose its corresponding language.

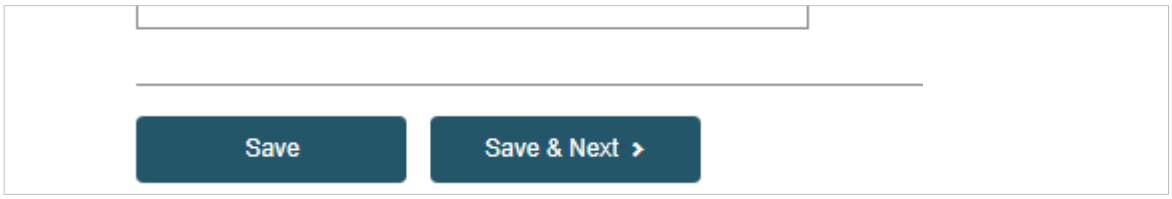


You can choose to add the indication in several languages, in which case you have to click on “Add another indication of medical purpose” and select its language from the drop-down list.

3. Select “Yes” or “No” if a device model is applicable. If you selected “Yes”, it is mandatory to provide the ‘Device model’ and the ‘Device name’ is optional. If you select “No”, providing the ‘Device name’ becomes mandatory.

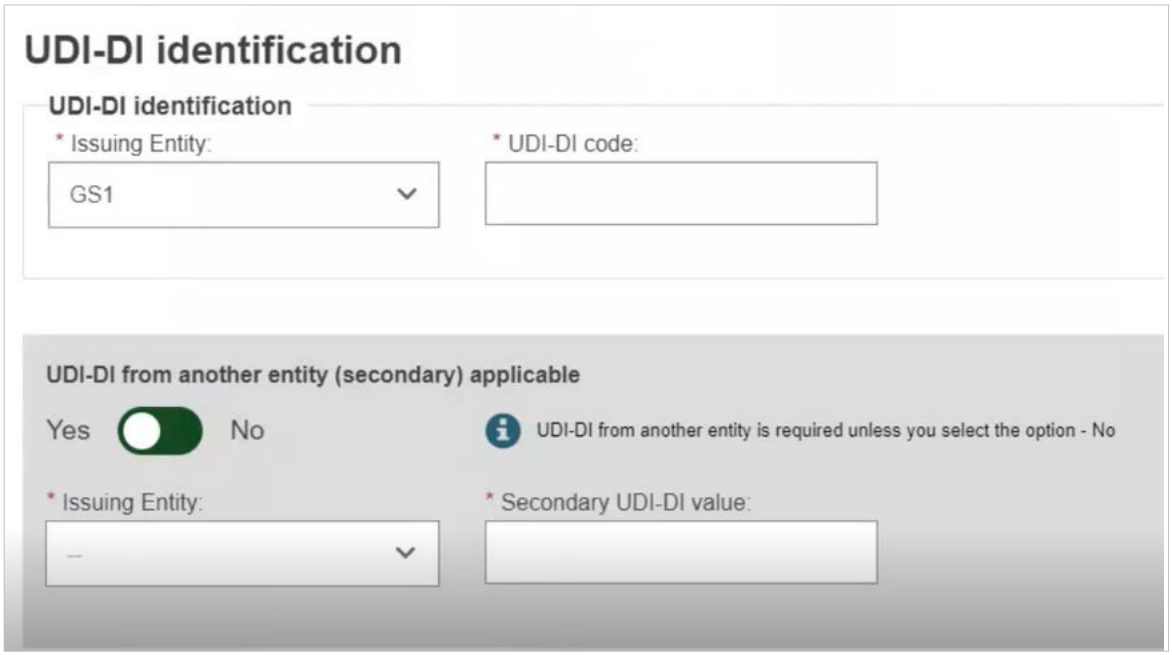


4. Click on “Save” to save your registration as a draft and come back to it later, or click on “Save & Next” to save it as a draft and continue to the next steps.



5.1.3. Step 3: UDI-DI identification information

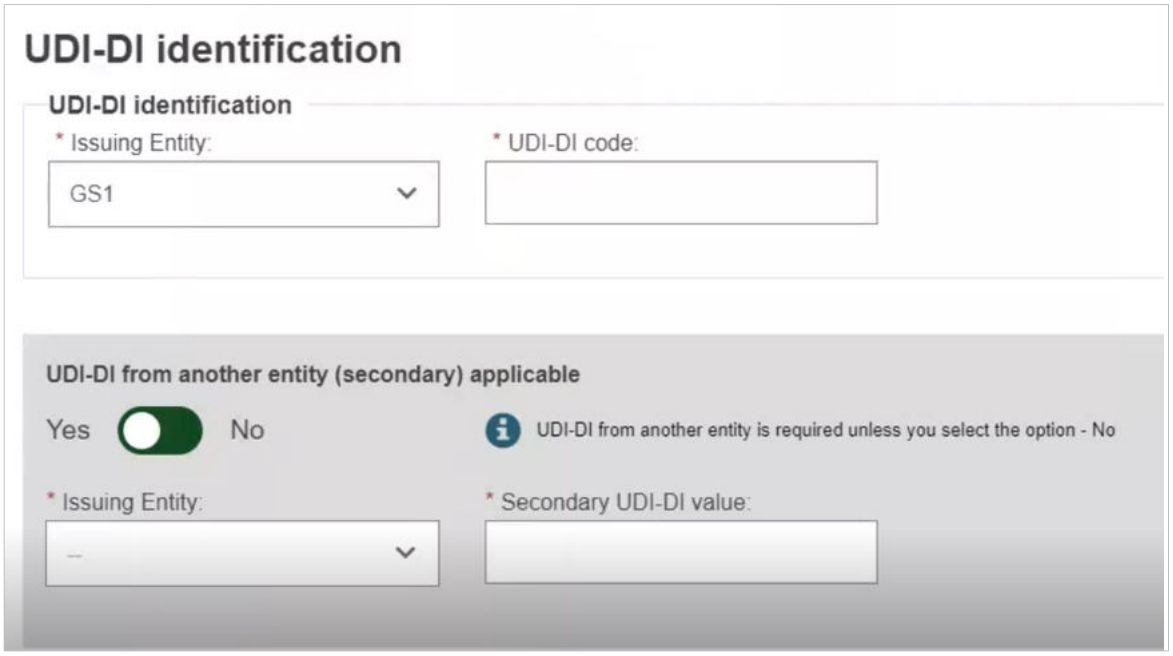
1. Select the “Issuing Entity” from the drop-down list and enter the UDI-DI code:



IMPORTANT
The 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 codeyou enter must have 14 characters.

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



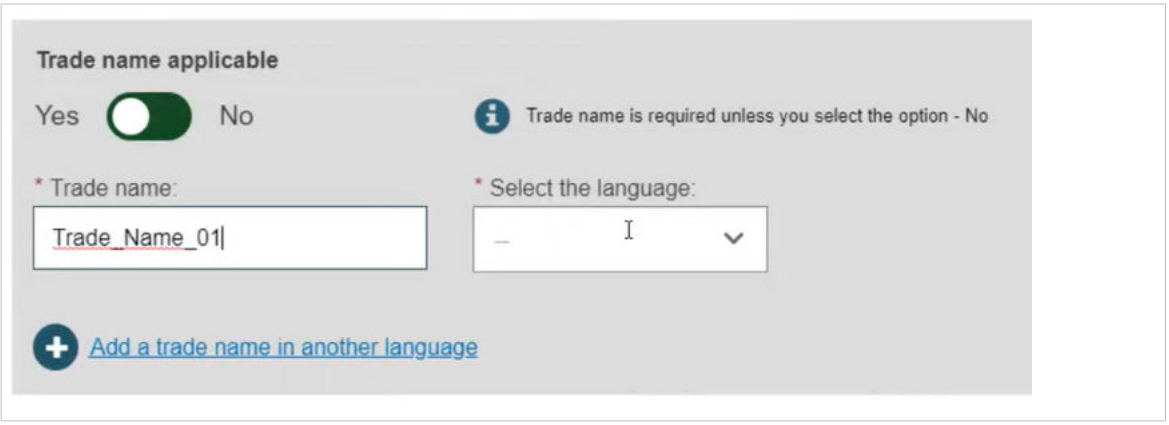
3. Enter the EMDN code (European Medical Device Nomenclature) and click on “Find”:

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.

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

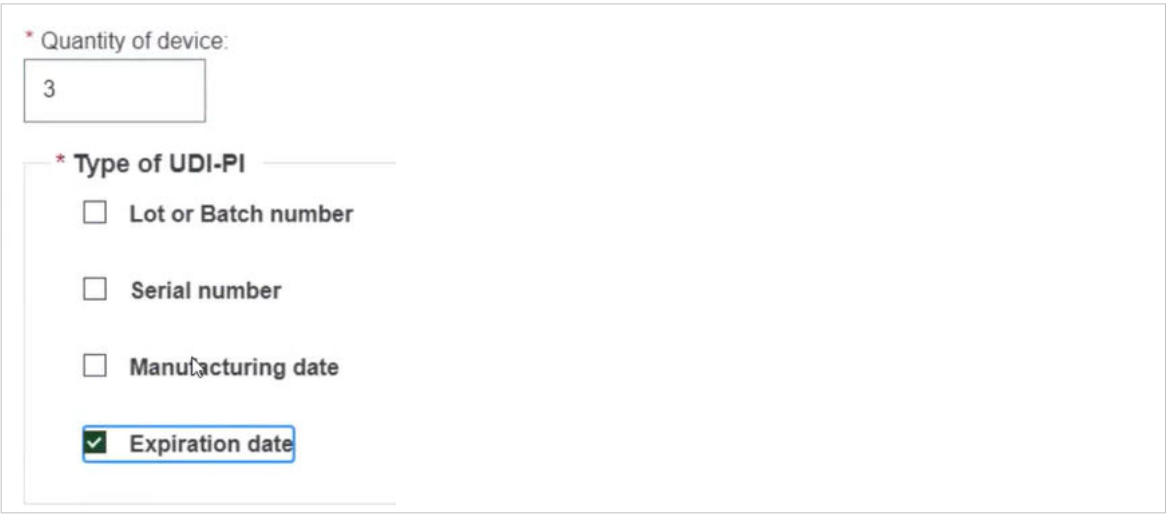
4. If applicable, select “Yes” to enter the trade name and select its language:

You can provide trade names in several languages; just click on “Add a trade name in another language”.

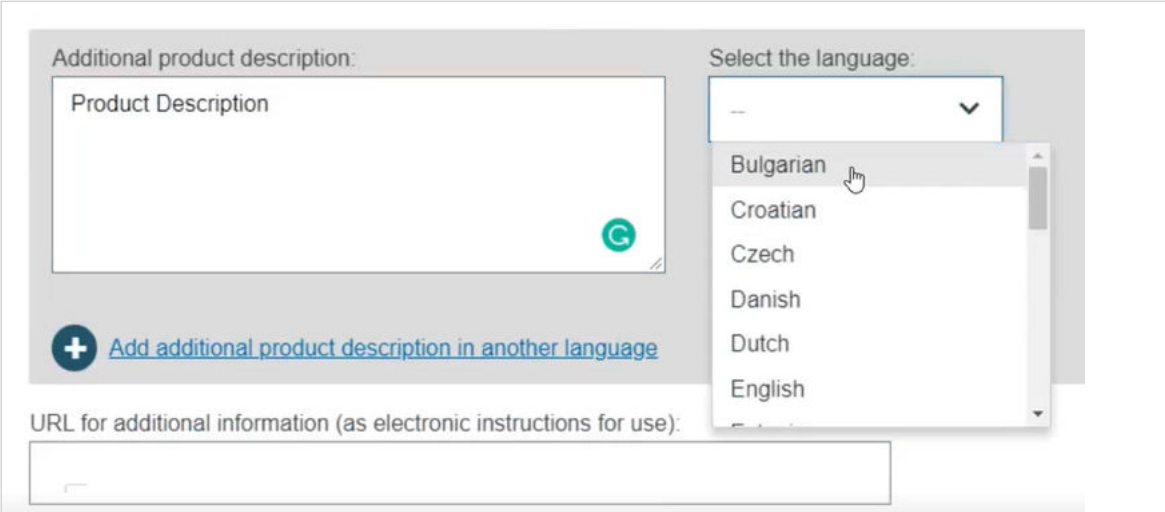


5. Enter the Reference/Catalogue number:

6. Select the type of UDI-PI, which shows the way in which production is controlled. You can select more than one type.



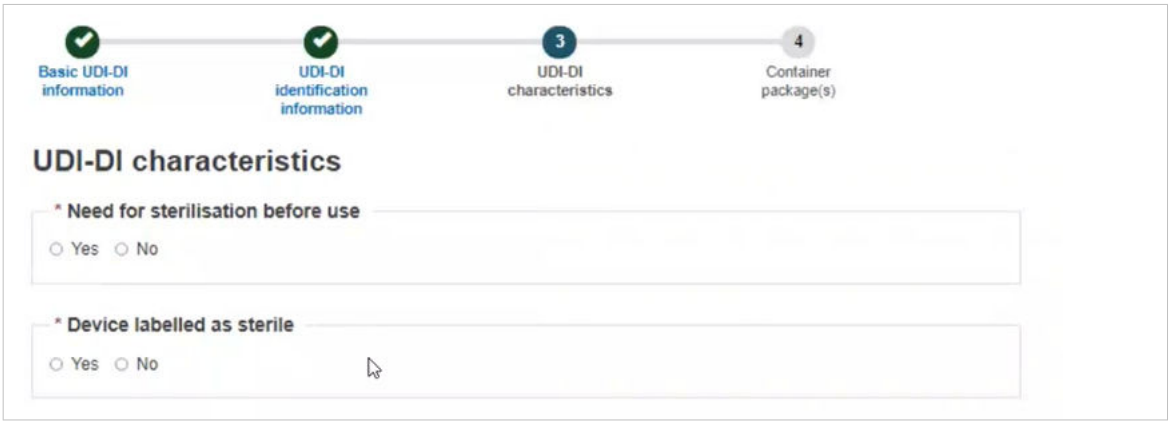
7. Enter any additional information about the system or procedure pack, choose the language of the additional information and enter a URL (link) if you have one for additional information online:



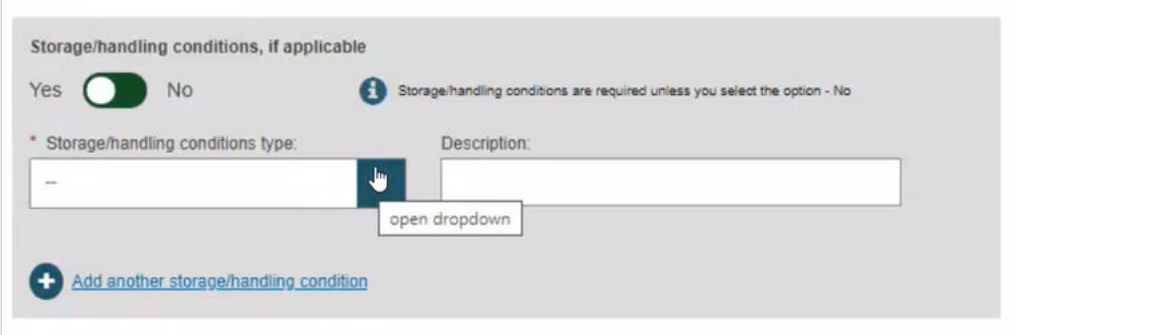
8. Choose if the system or procedure pack is intended for the EU market or not and click on “Save” to save as draft and finish later or “Save & Next” to continue directly to the next steps:

5.1.4. Step 4: UDI-DI Characteristics

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

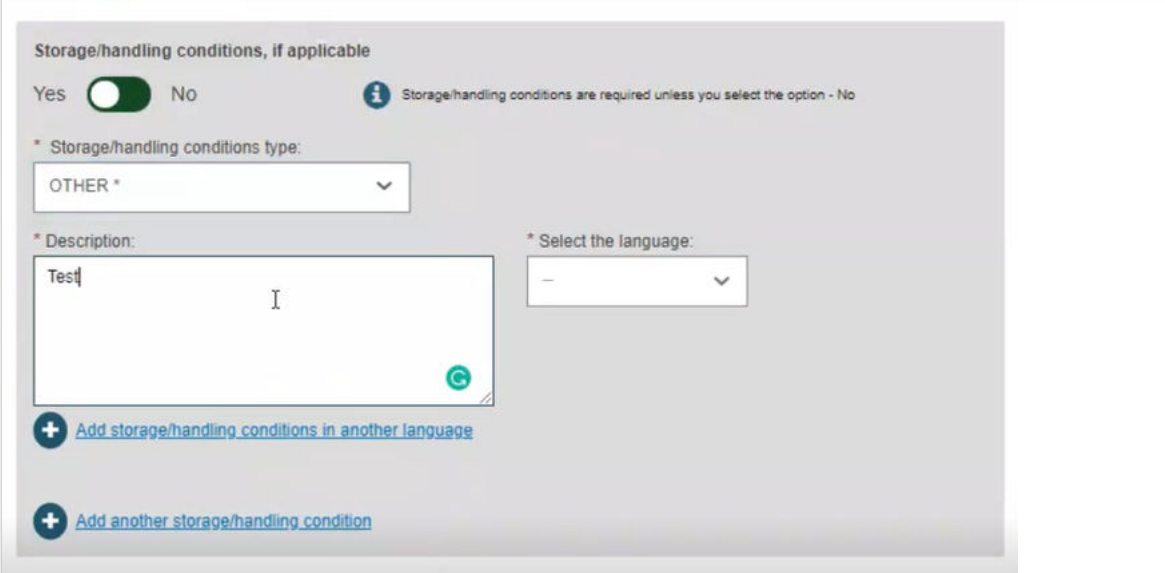


2. Select “Yes” or “No” if storage or handling conditions are applicable:



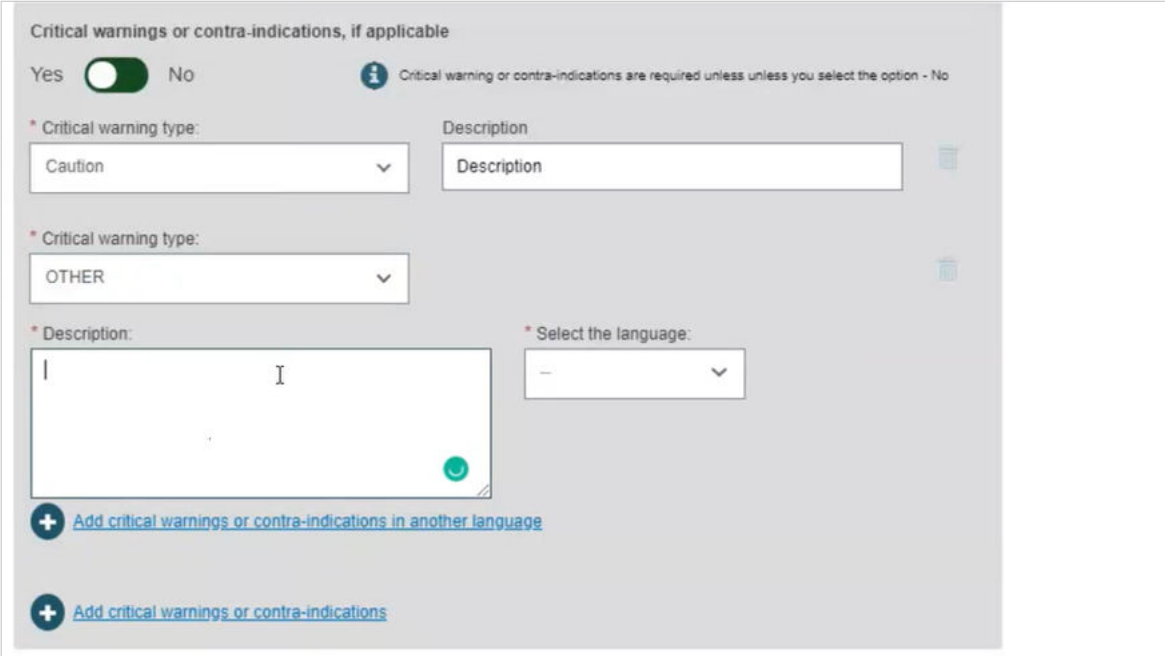
If you choose “Yes”, you have to select the conditions type from a dropdown list. Some of these types need a description, which you can enter in the relevant box. You may add more than one storage and handling conditions types.

NOTE
If you select “Other” from the Storage/Handling conditions type list, you need to provide the description in several languages:

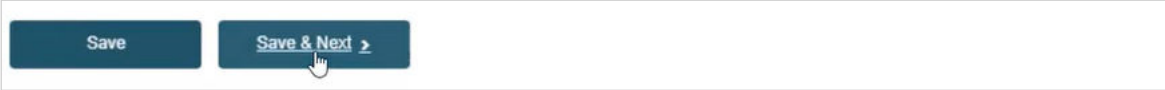


3. Select “Yes” or “No” if any critical warnings or contra-indications are applicable (you can add more than one):

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



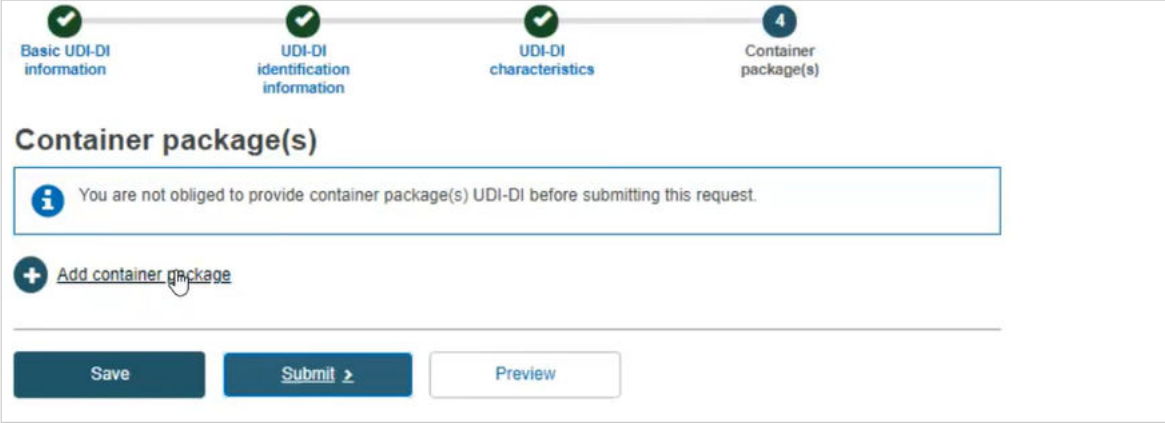
4. Click on “Save” to save draft and finish later or “Save & Next” to move directly to the next step of the process:



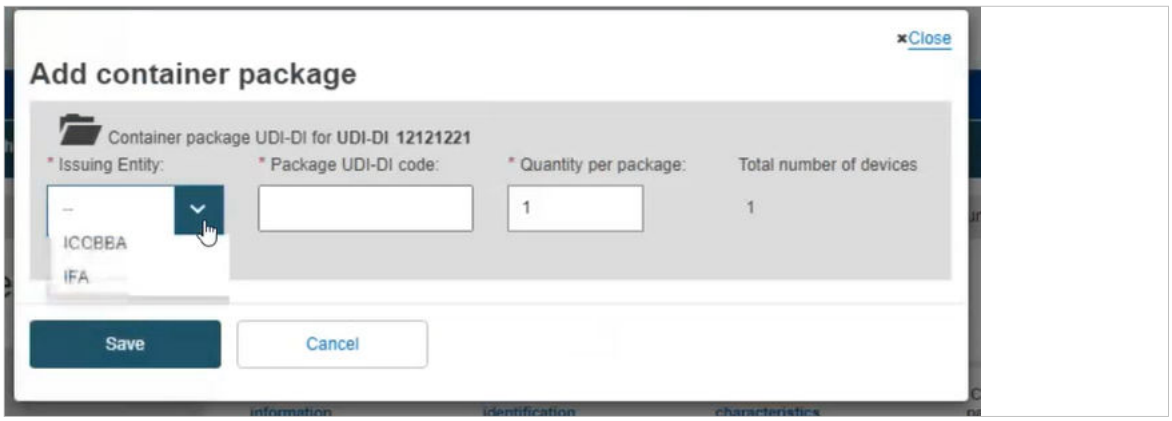
5.1.5. Step 5: Container Package Details

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

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



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

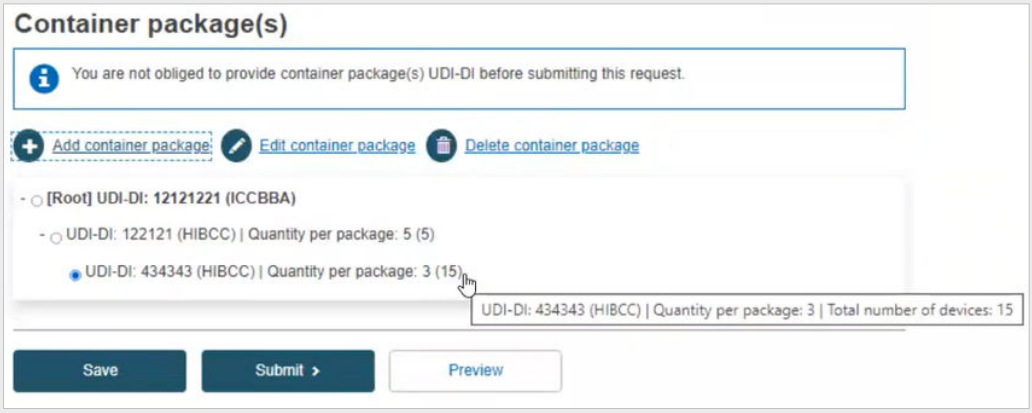


2. From the drop-down list choose the issuing entity.

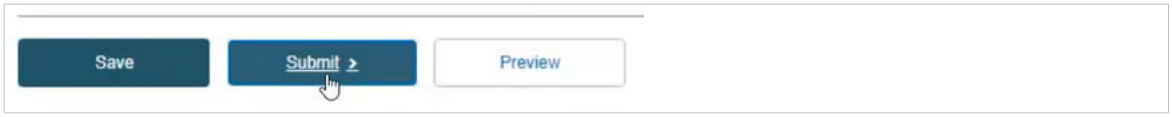
3. Enter the Package UDI-DI code and the quantity per package in the boxes provided.

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 entered.

NOTE
The system calculates the total number of devices according to the quantity per package you entered:

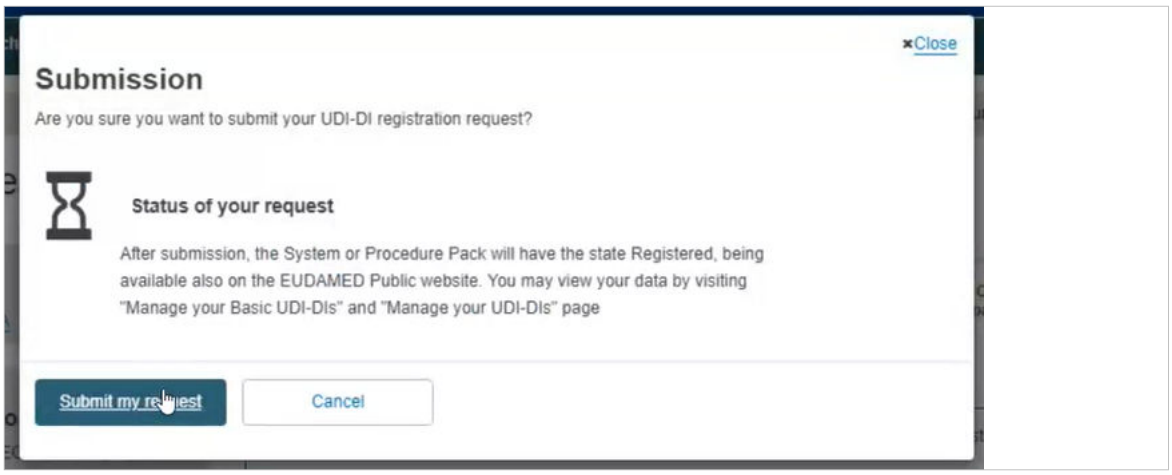


5. If you are ready to submit the registration, click on “Submit”:

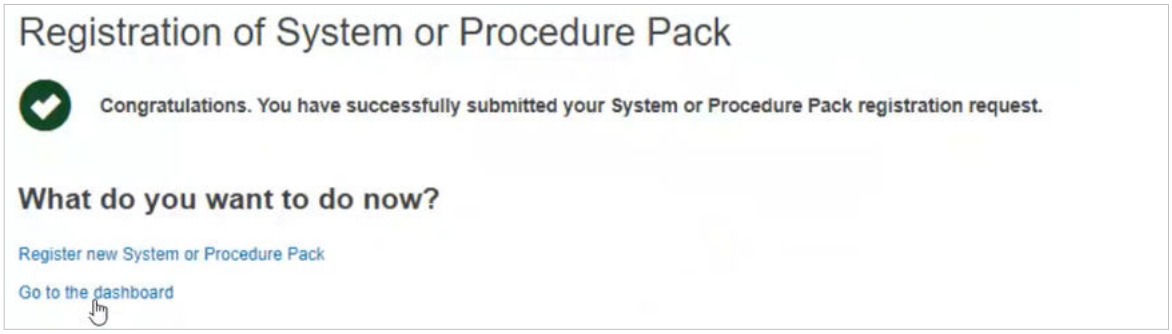


You can also preview the information of the registration by clicking on “Preview”.

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

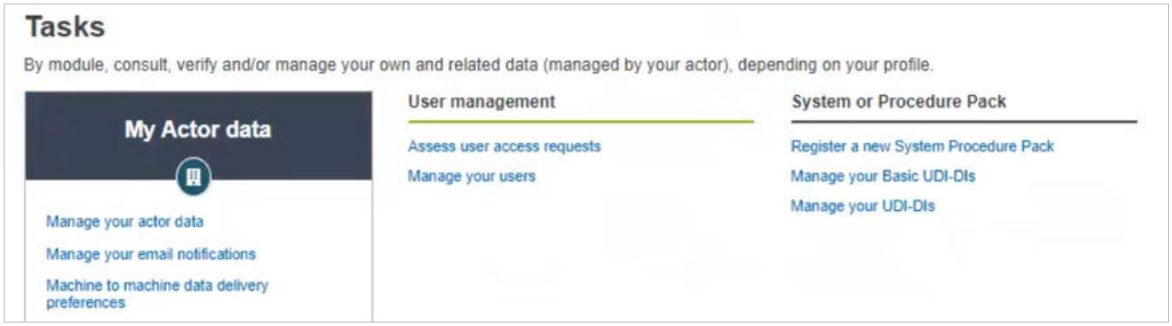


Upon submission, you will see a message that you have successfully submitted a System or Procedure Pack registration request:

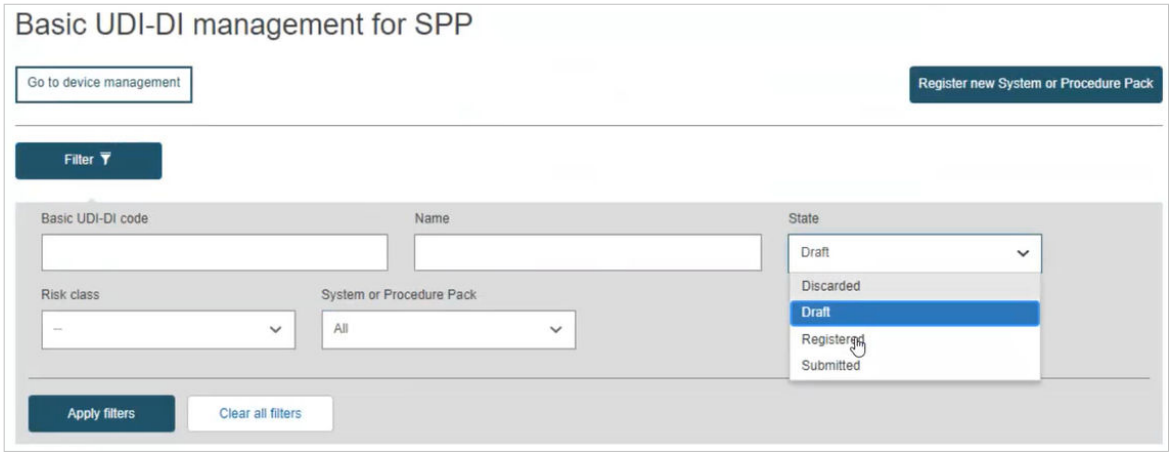


5.2. Registration of UDI-DI for an existing Basic UDI-DI of a System or Procedure Pack

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



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

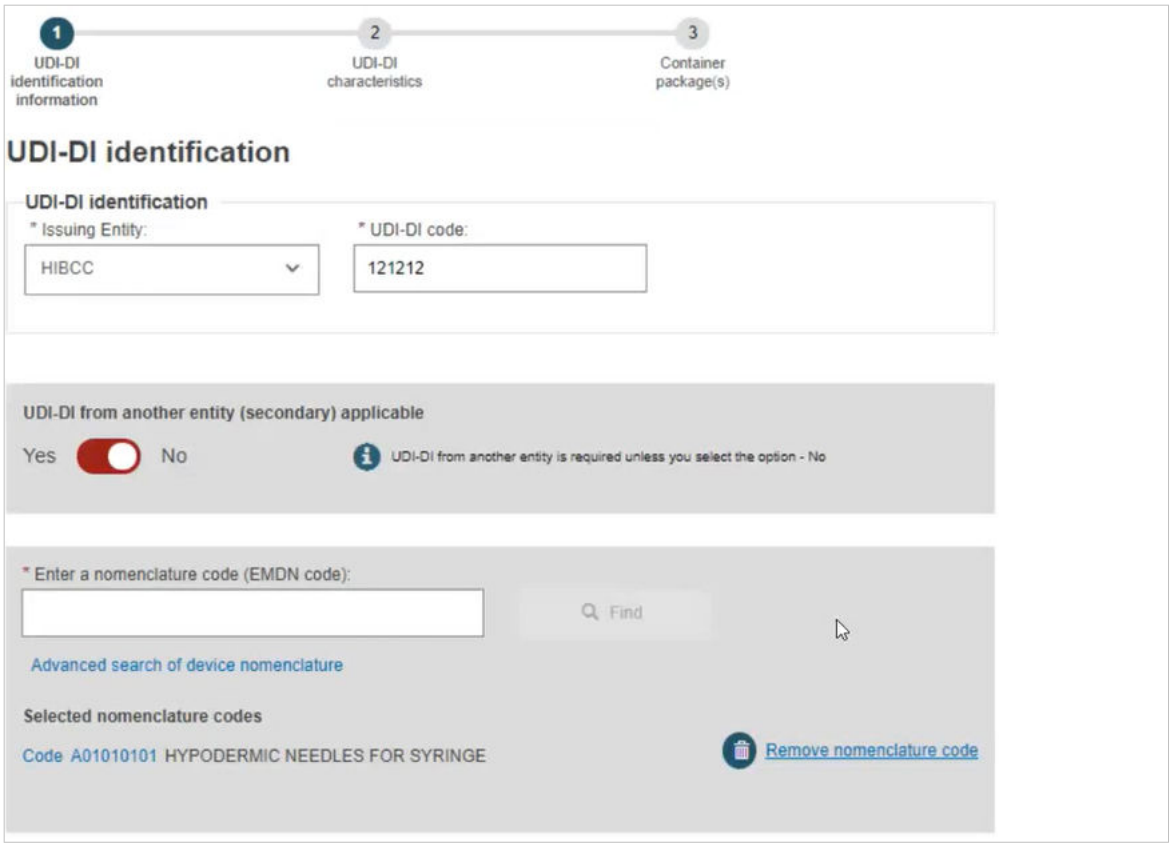


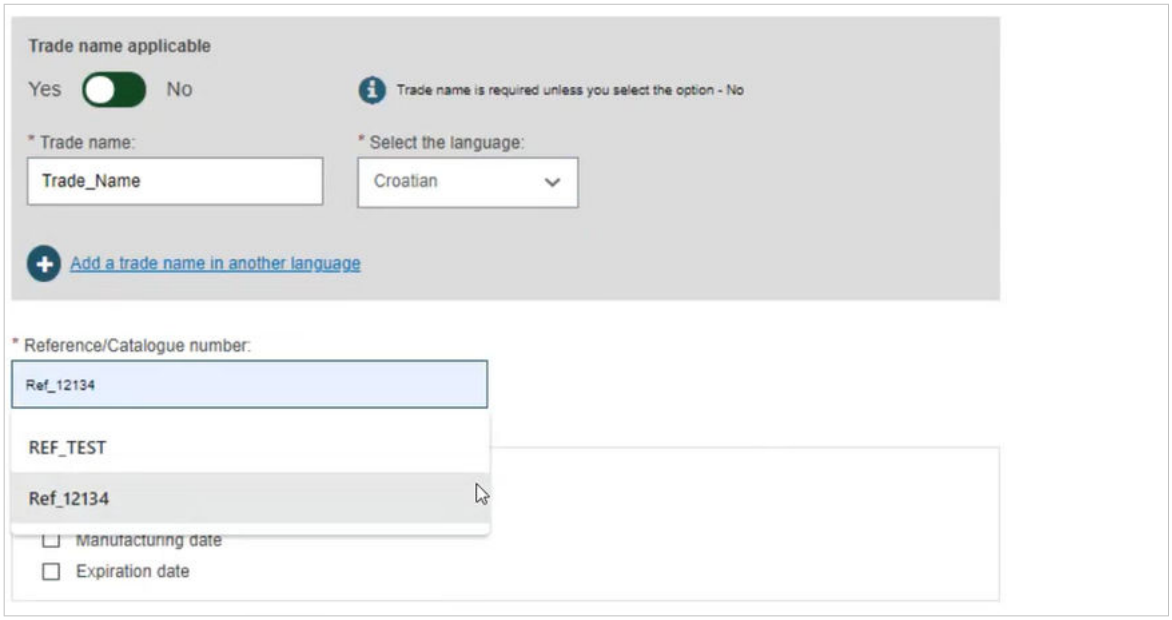
New UDI-DIs can be added only for Basic UDI-DIs in state Registered or Submitted.

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

5.2.1. Step 1: UDI-DI identification information

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

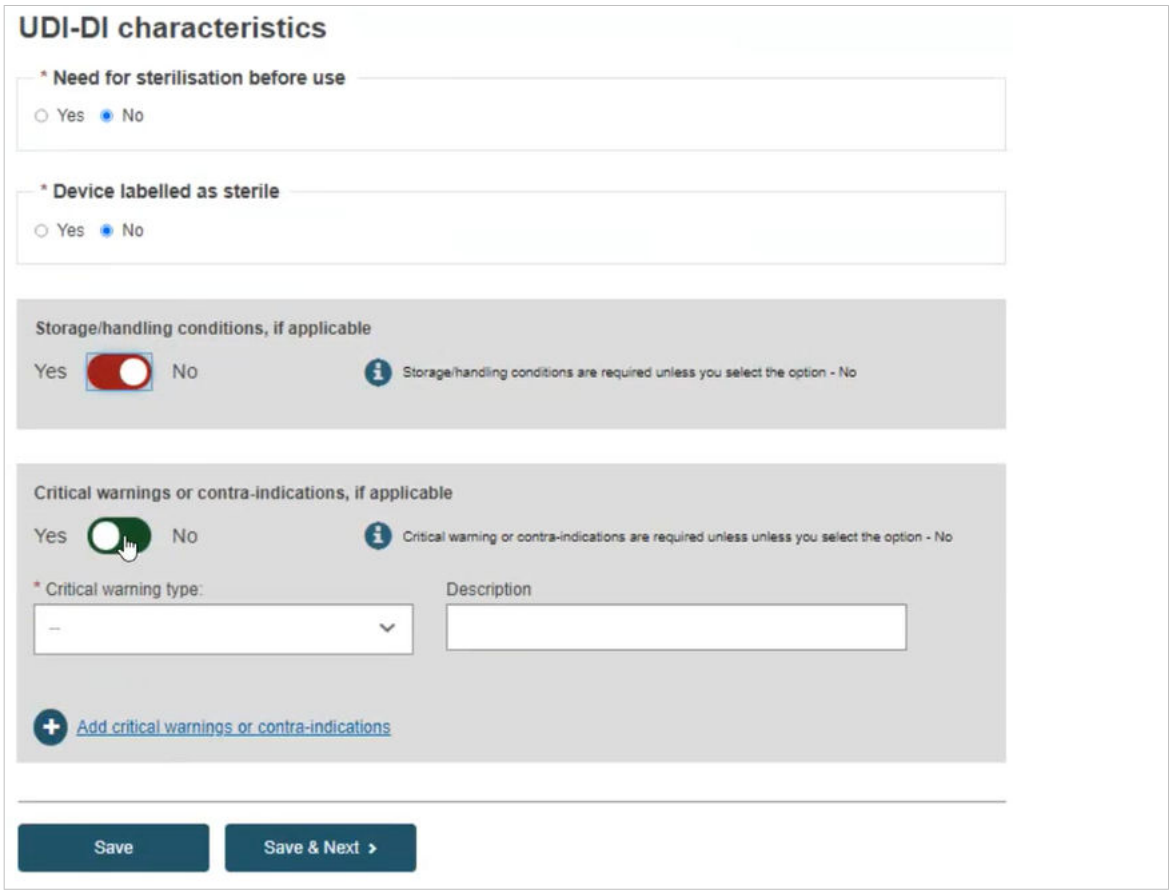




2. Click on “Save & Next” to move to the next step:

5.2.2. Step 2: UDI-DI Characteristics

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



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

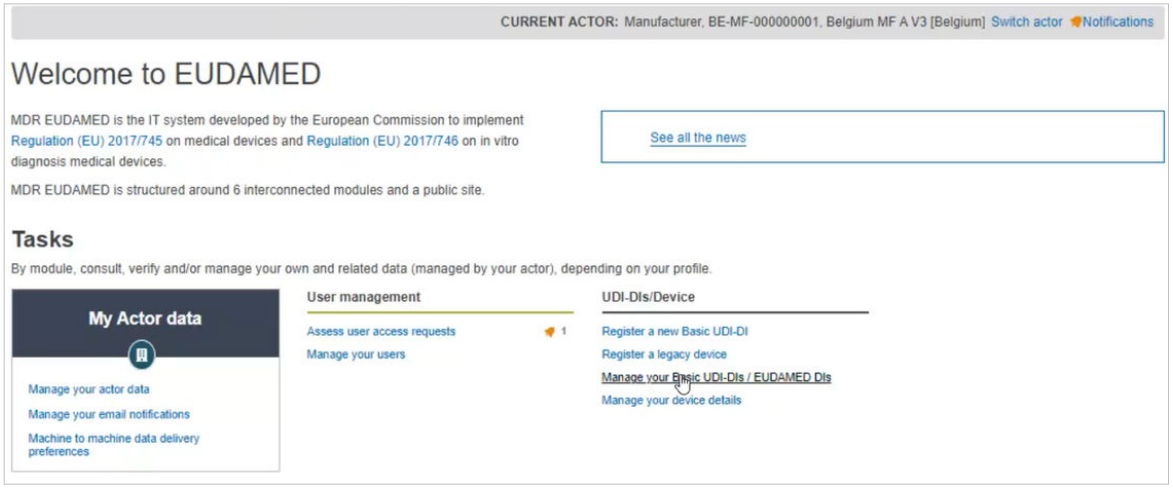
5.2.3. Step 3: Container Package Details

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

6. Manage your own Device Information

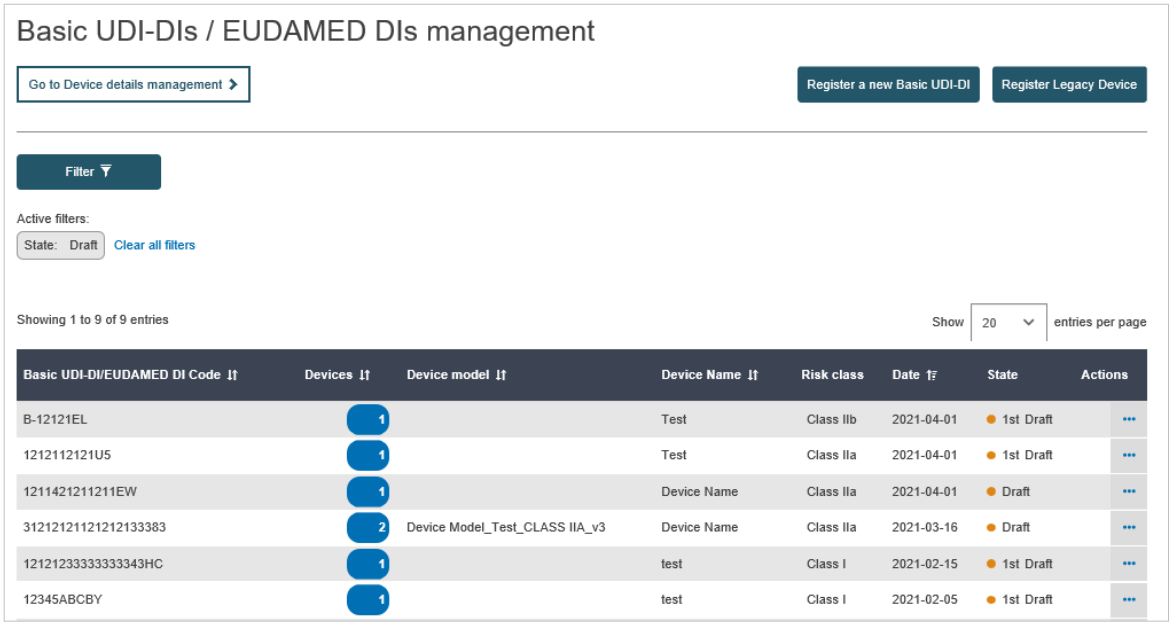
6.1. View own Basic UDI-DI/EUDAMED DI Details

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

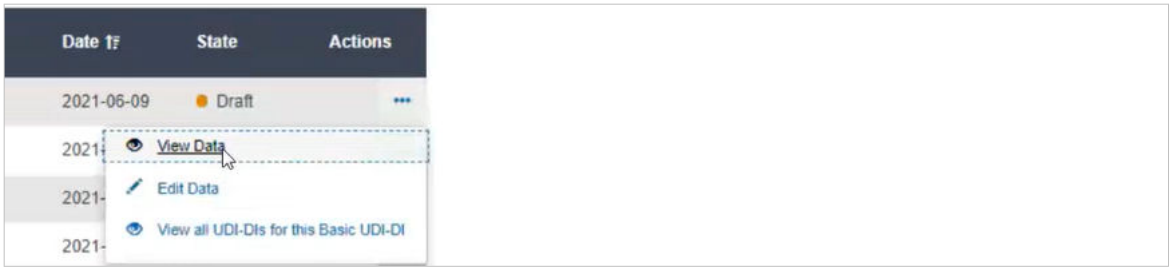


2. You will see a list with all of the Basic UDI-DIs /EUDAMED-DIs registered to the current actor:

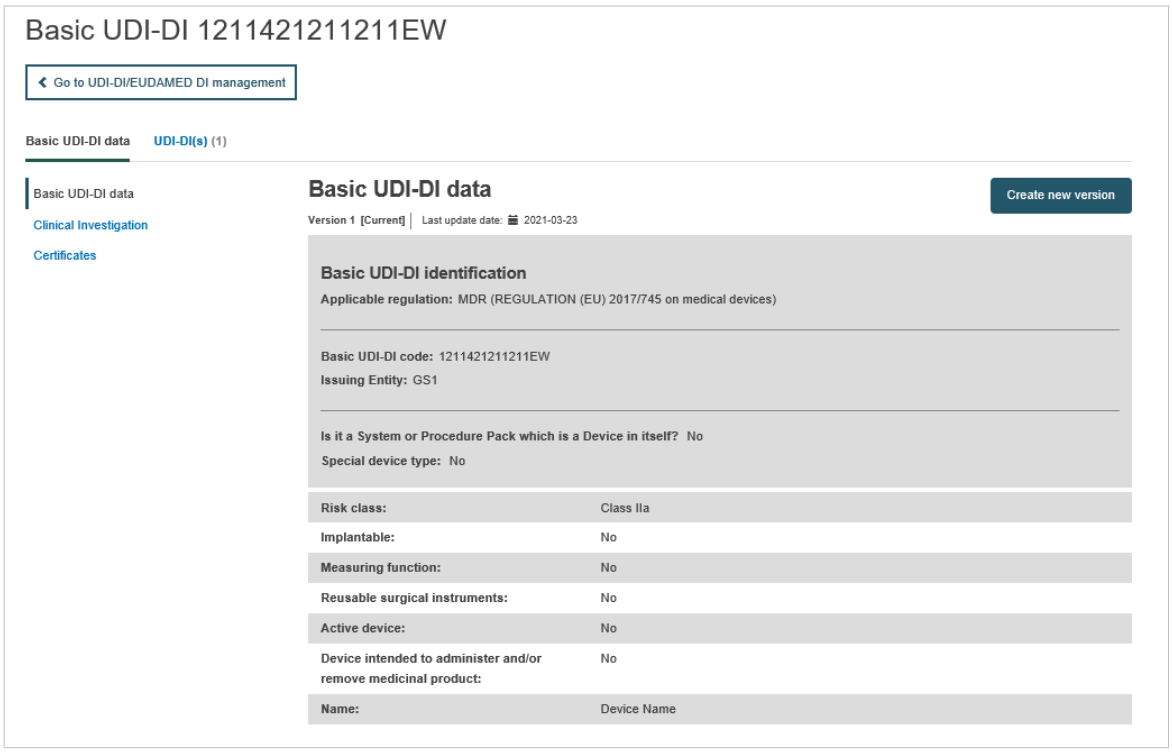
> **NOTE**
> By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in Draft state. In order to retrieve the desired Basic UDI-DIs/EUDAMED DIs, use the filter button.



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



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



6.1.1. Delete a Draft Basic UDI-DI/EUDAMED DI

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

1. When you are inside the summary of the desired draft, click on “Delete”:

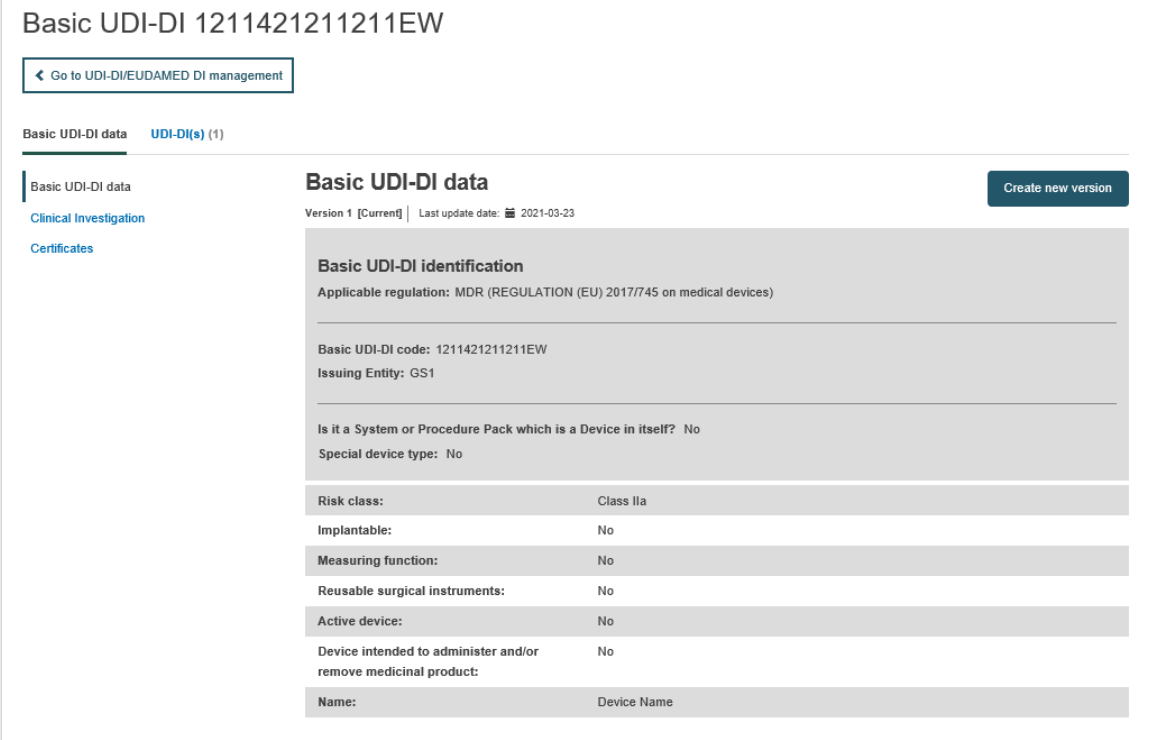
2. The system will ask you to confirm your intention to delete the draft in a pop-up window. If you are sure, click on “Yes”:

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

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

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

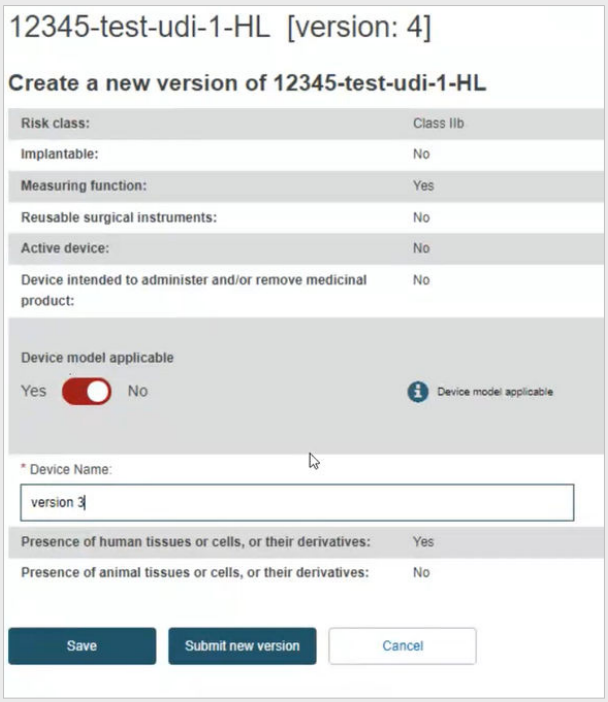
1. Once inside the summary for the desired Basic UDI-DI, click on “Create new version” on the top right corner:



2. Update the desired details:

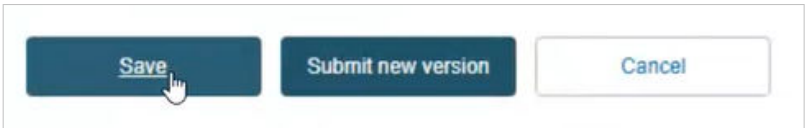
NOTE

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



3. 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.

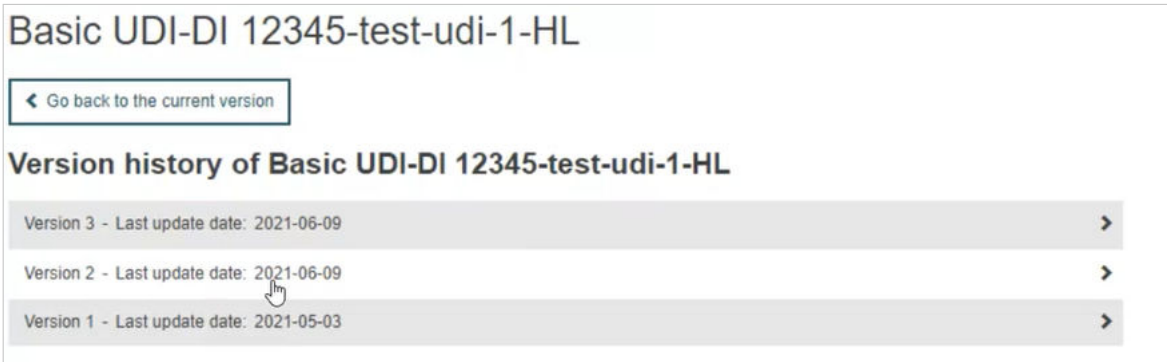


6.1.3. View historical versions for Basic UDI-DI/ EUDAMED DI

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

1. Once inside the summary of the desired Basic UDI-DI, click on “See version history”:

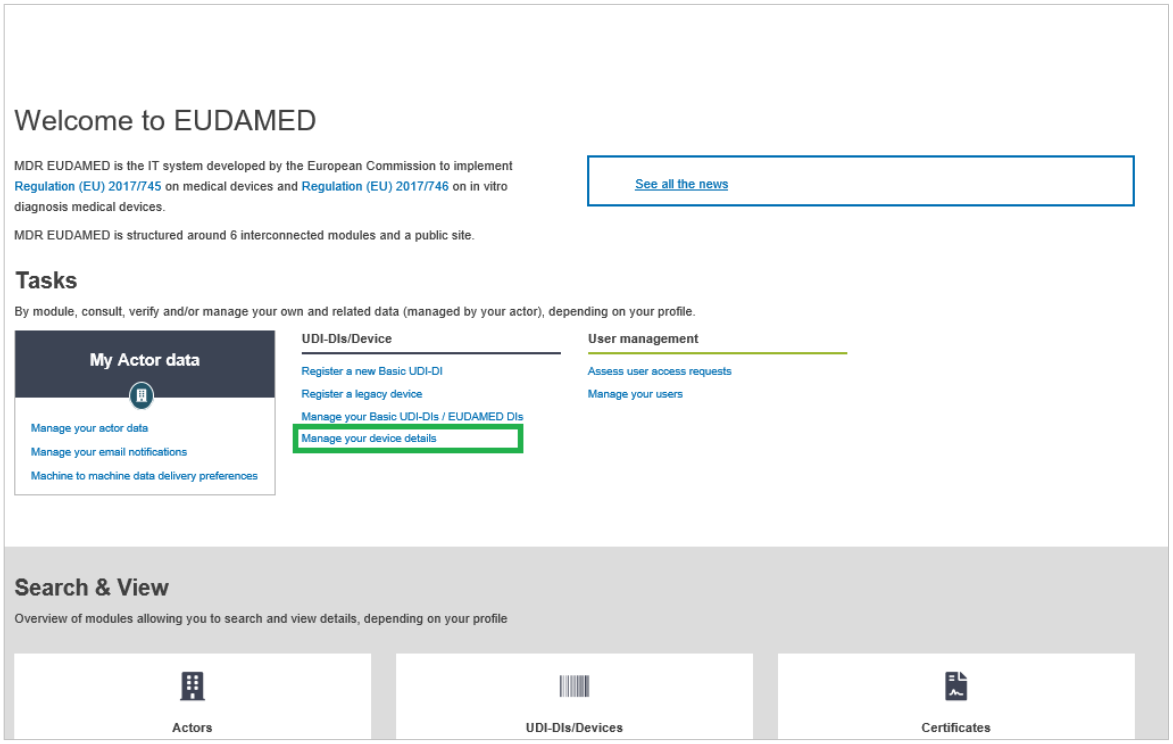
2. View the list of versions for the desired Basic UDI-DI and click on the version you wish to view:



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

6.2. View own UDI-DI/EUDAMED DI Details

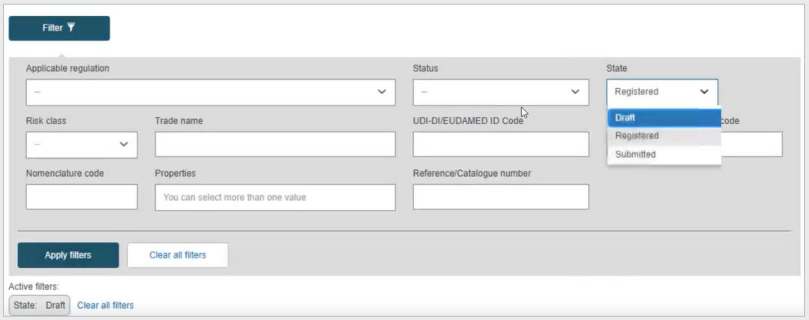
1. On the dashboard of EUDAMED, click on “Manage your Device details”:



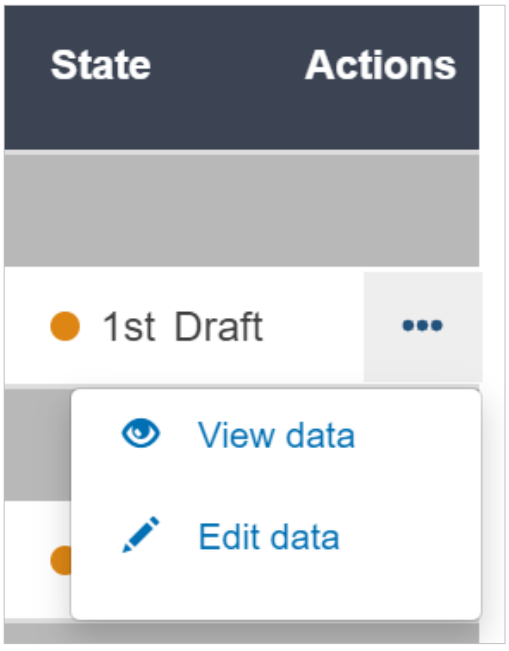
2. You will see a list with all of the devices registered to you:

NOTE

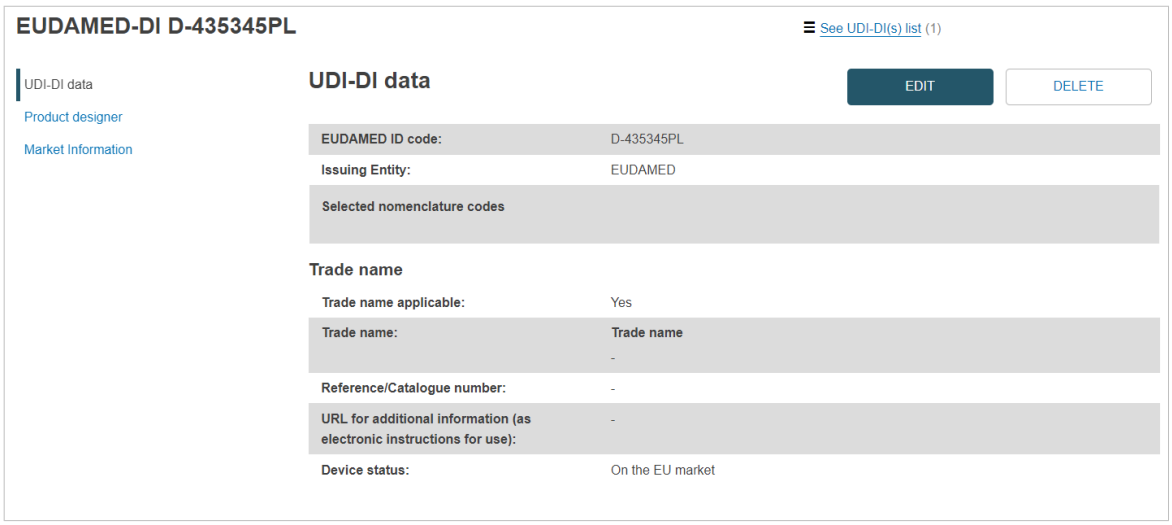
By default, the system lists the devices in “Draft” state. In order to see the desired Devices, use the filters available by clicking on “Filter”:



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:



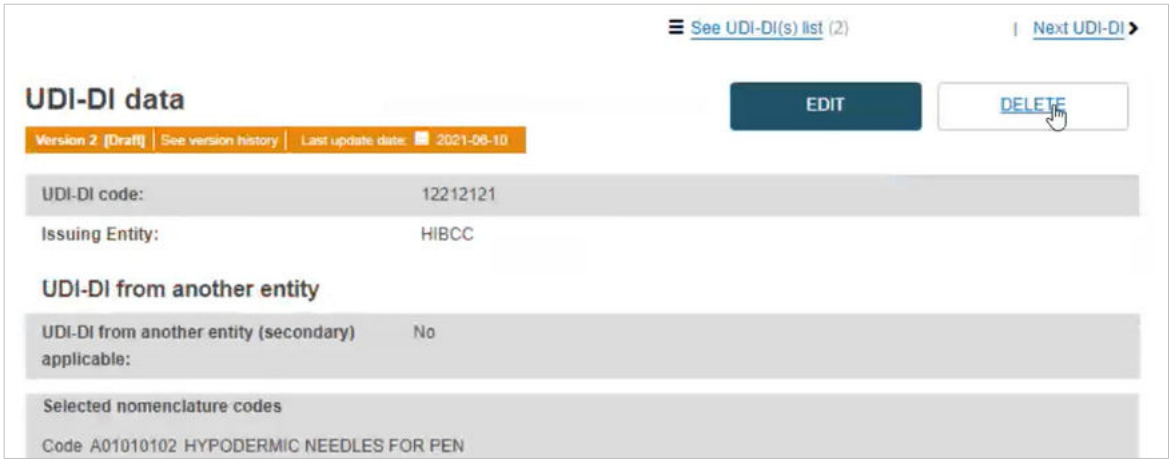
4. You will see a summary of the details of your device:



6.2.1. Delete a draft UDI-DI/EUDAMED-DI

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

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



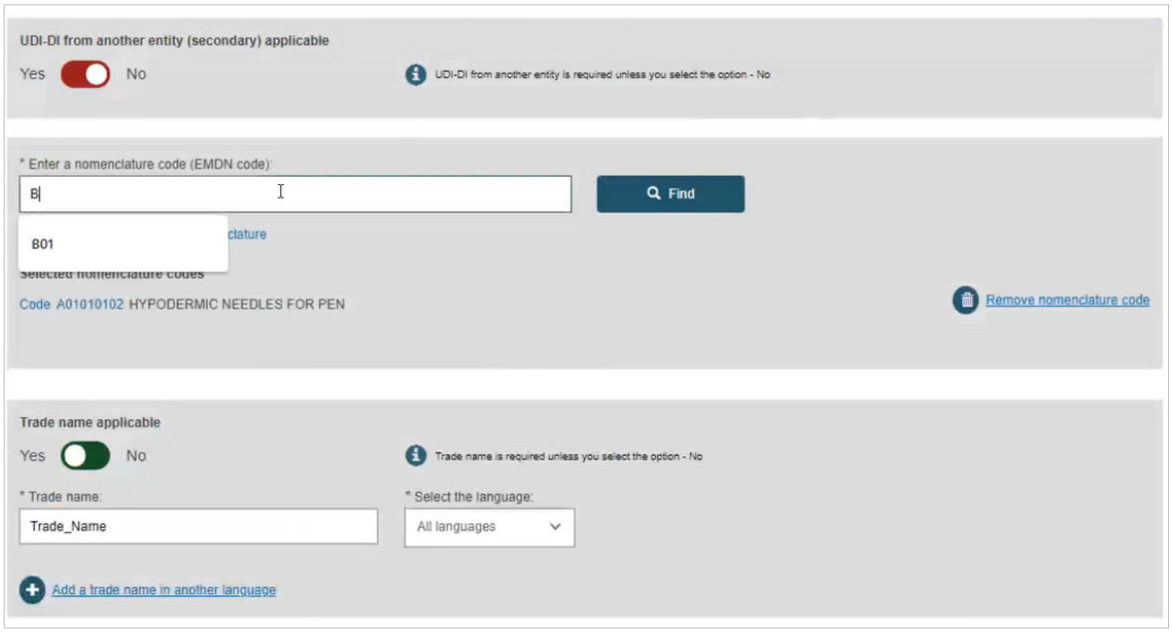
2. A pop-up message will ask you to confirm the delete action:

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

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

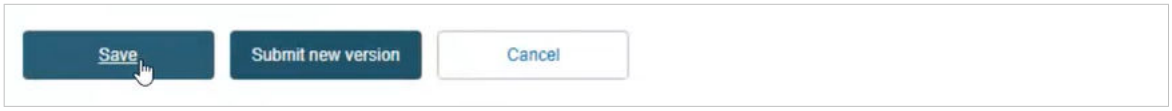
1. Once inside the summary of the desired UDI-DI, click on “Create new version”:

2. Update the desired details, for example:



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

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

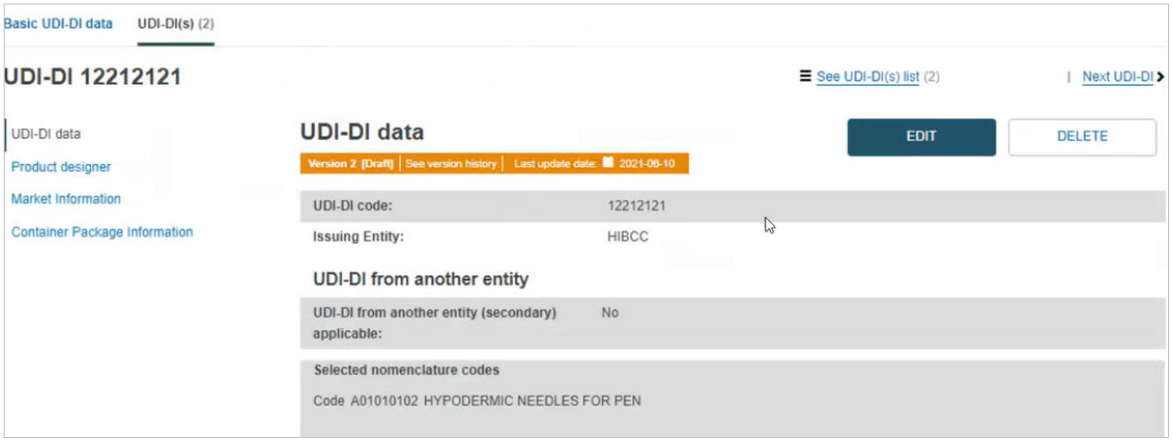


6.2.3. Update (Create new version) for Product Designer

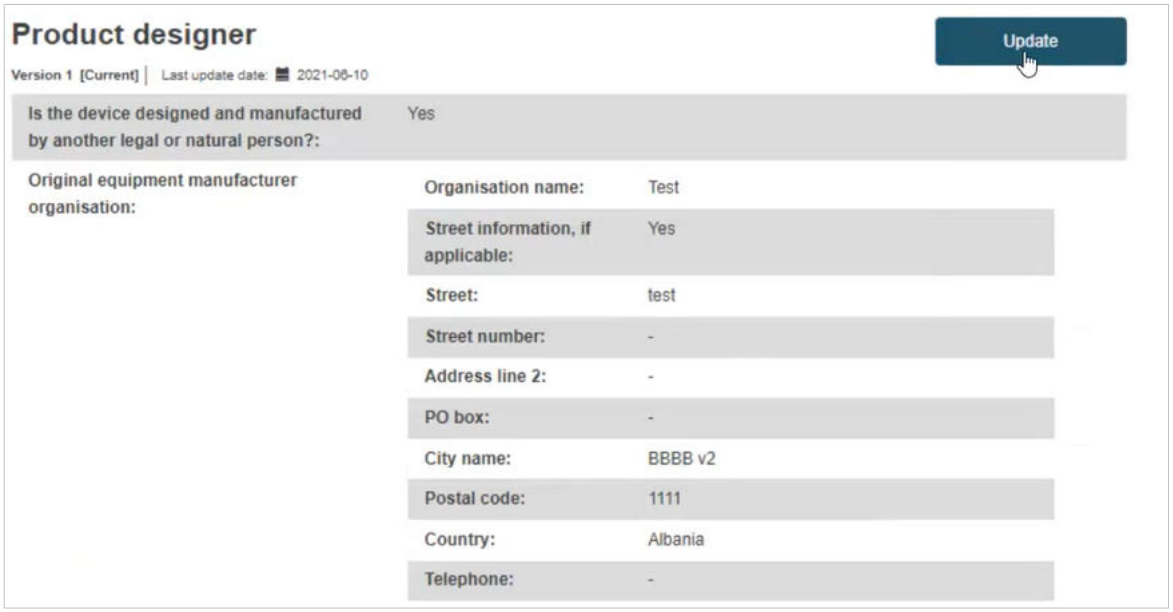
The Product Designer information can be updated independently of the other data in a device UDI-DI.

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

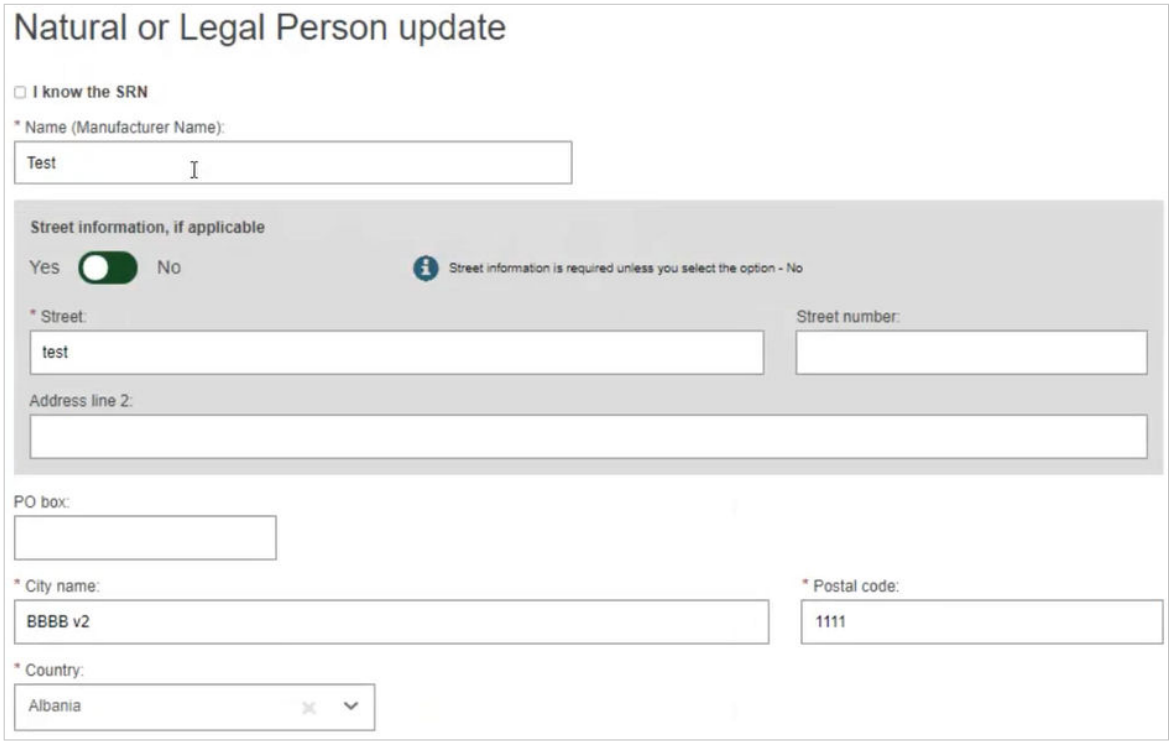
2. Once inside the summary of the desired UDI-DI, click on “Product Designer” from the list on the left (or scroll down to the Product Designer section):



3. Click on “Update”:



4. Update the information under Product Designer:



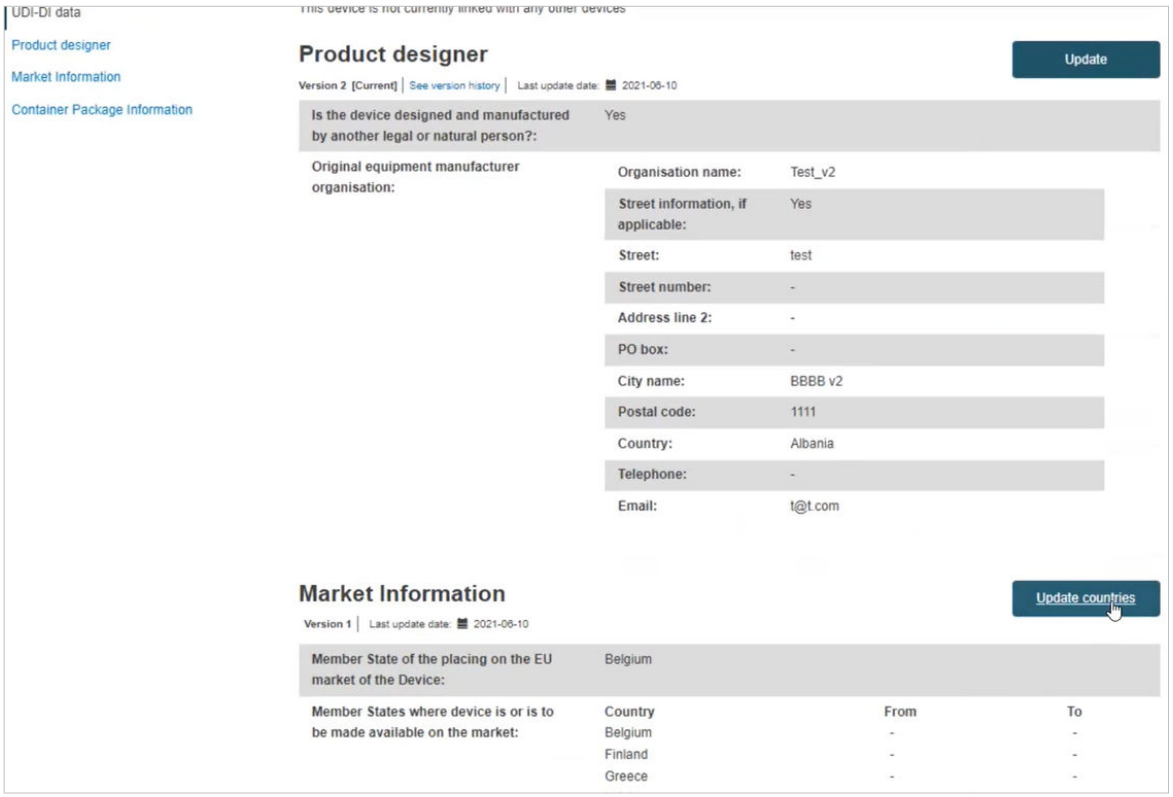
5. Click on “Submit” at the bottom of the screen to finalise the update.
   You will be able to see the new version created for the “Product Designer” information.

6.2.4. Update (Create new version) for Market information

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

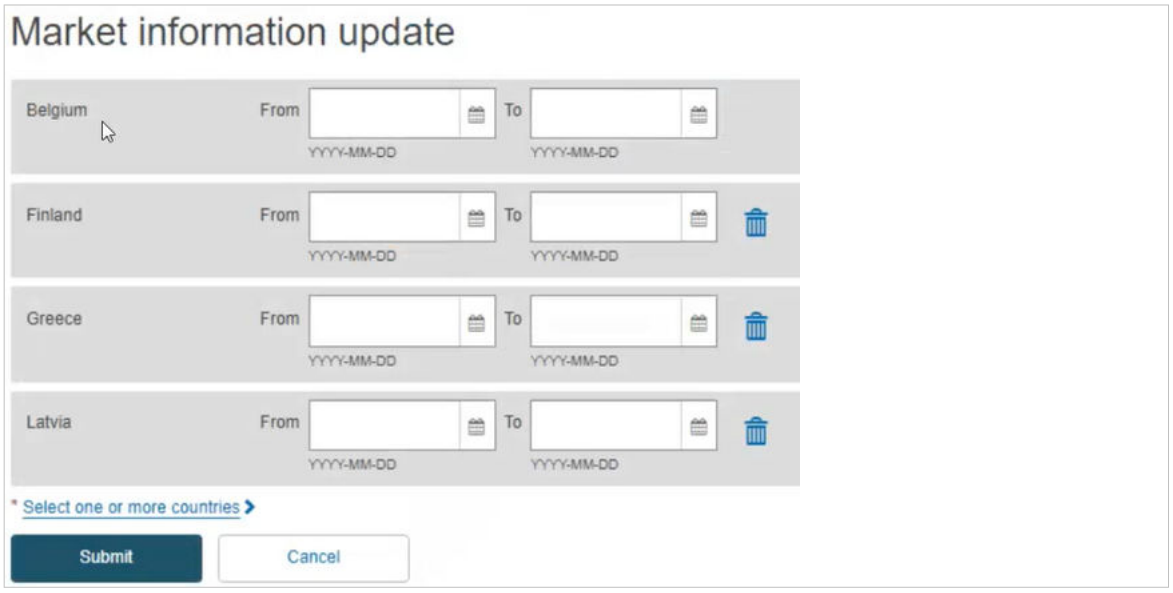
1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

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

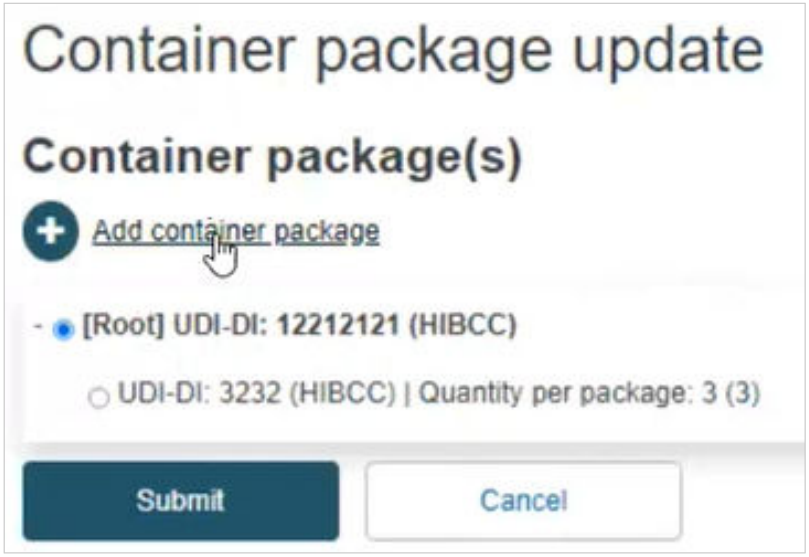
The Container Packages information can be updated independently of the other data in a device UDI-DI.

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

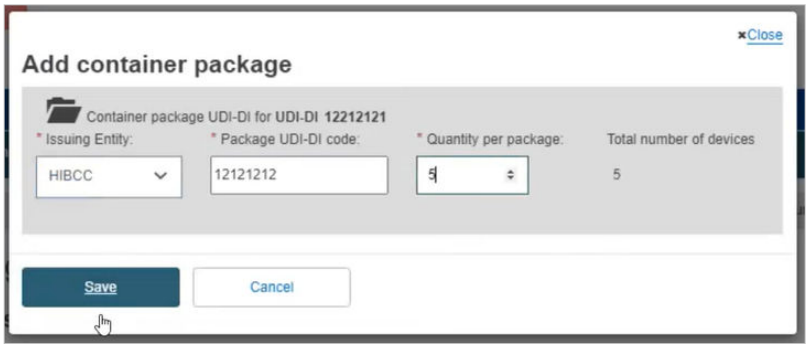
2. Once inside the summary of the desired UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):

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

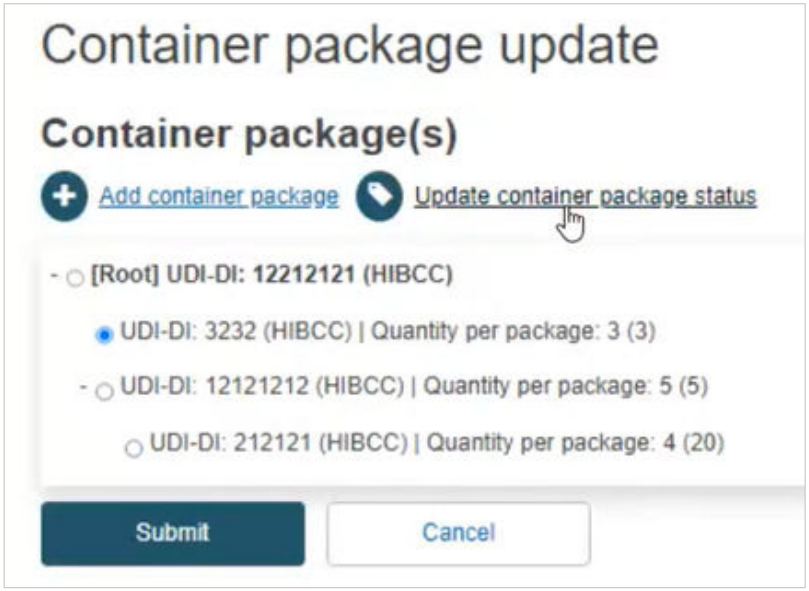
4. Click on “Add container package” to add new information about the packaging format of the device:



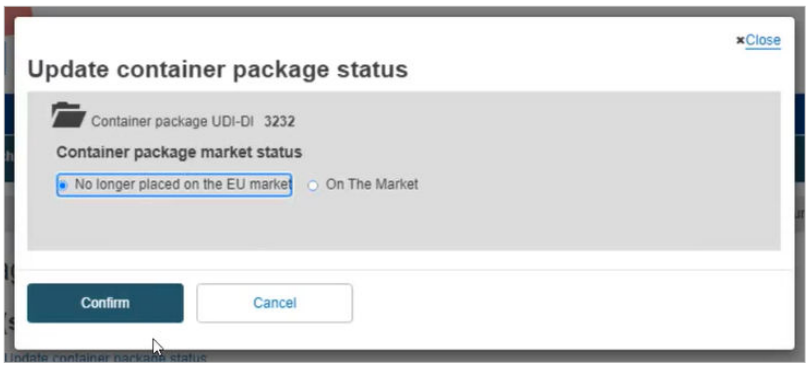
5. Enter the package details in the pop-up window and click on “Save”:



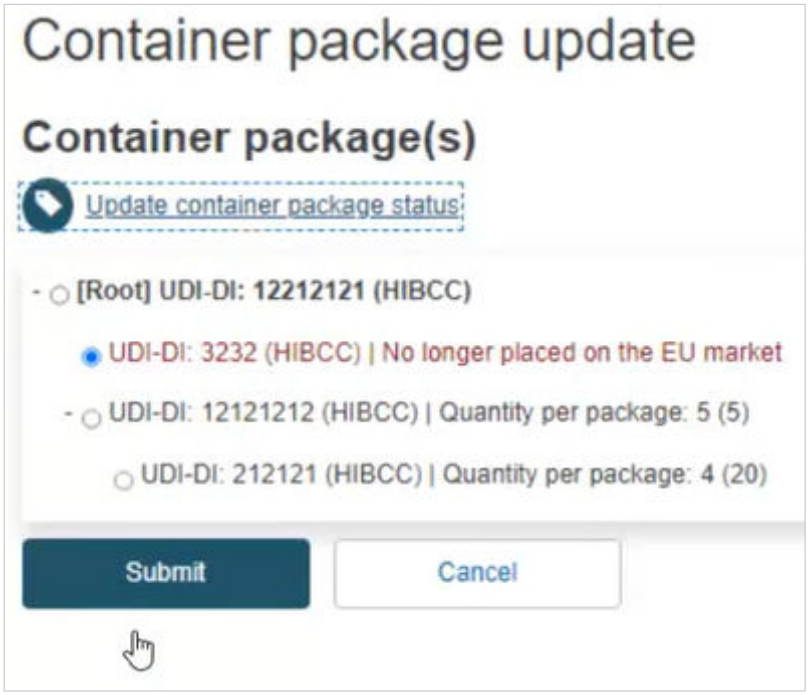
6. Once you add new package details, you can also update the container package status:



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



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

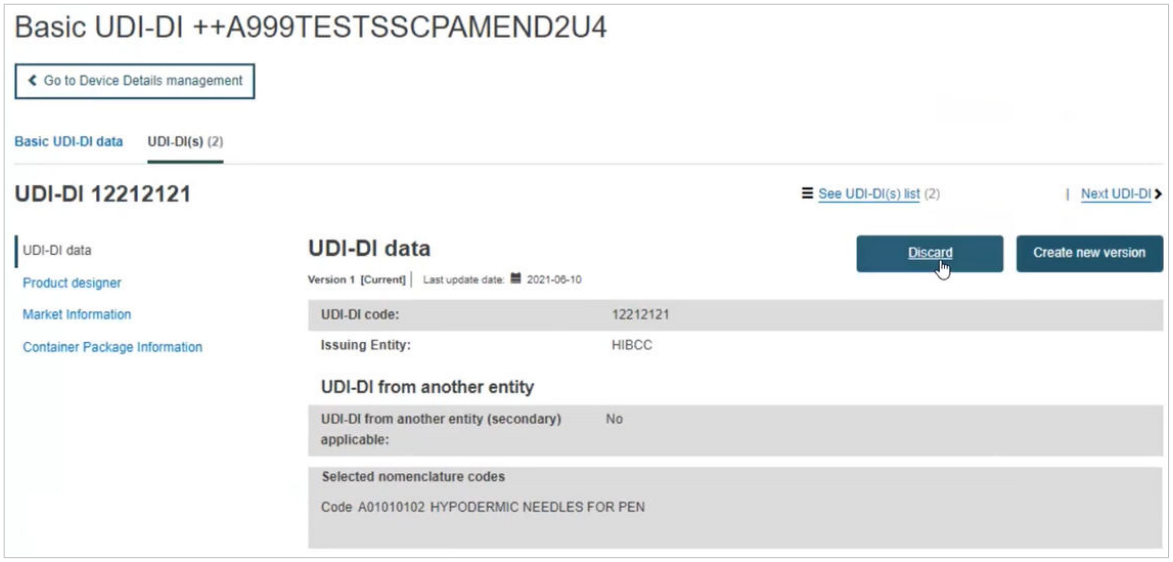


6.2.6. Discard registered UDI-DIs/EUDAMED DIs

You may 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 ask you to confirm your wish to permanently discard (delete) the registered UDI-DI. Click on “Yes” to finalise the action:

The UDI-DI will be discarded and as a result it will no longer be visible on the public EUDAMED platform.

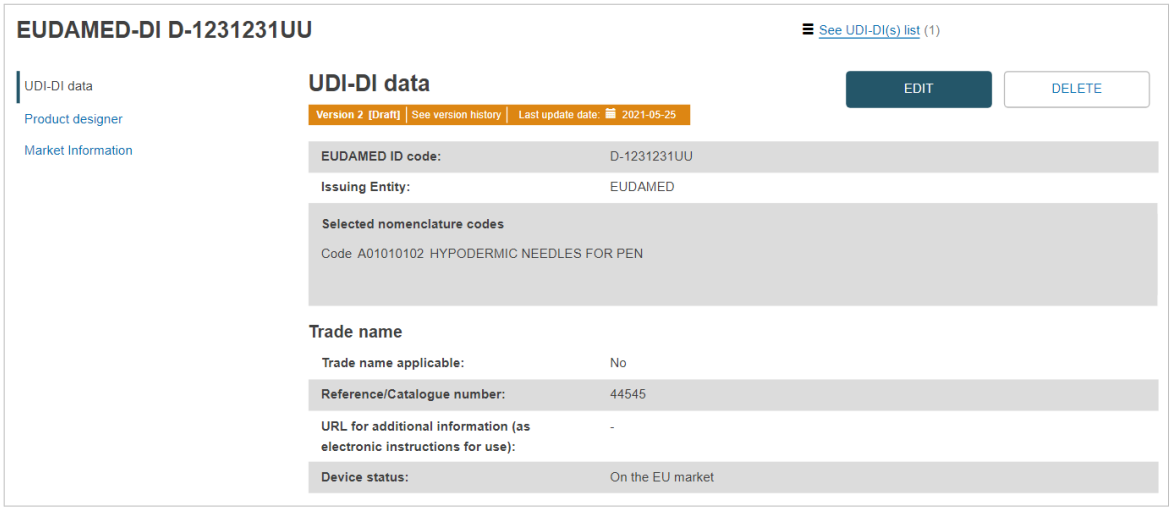
CAUTION

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

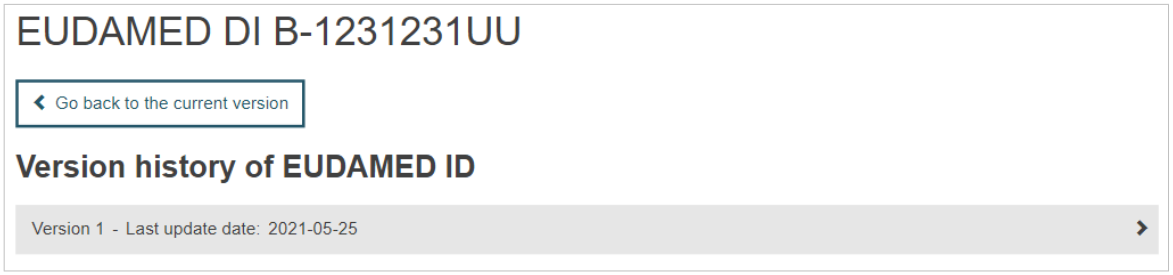
6.2.7. View historical versions of UDI-DI/EUDAMED-DI and associated entities

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

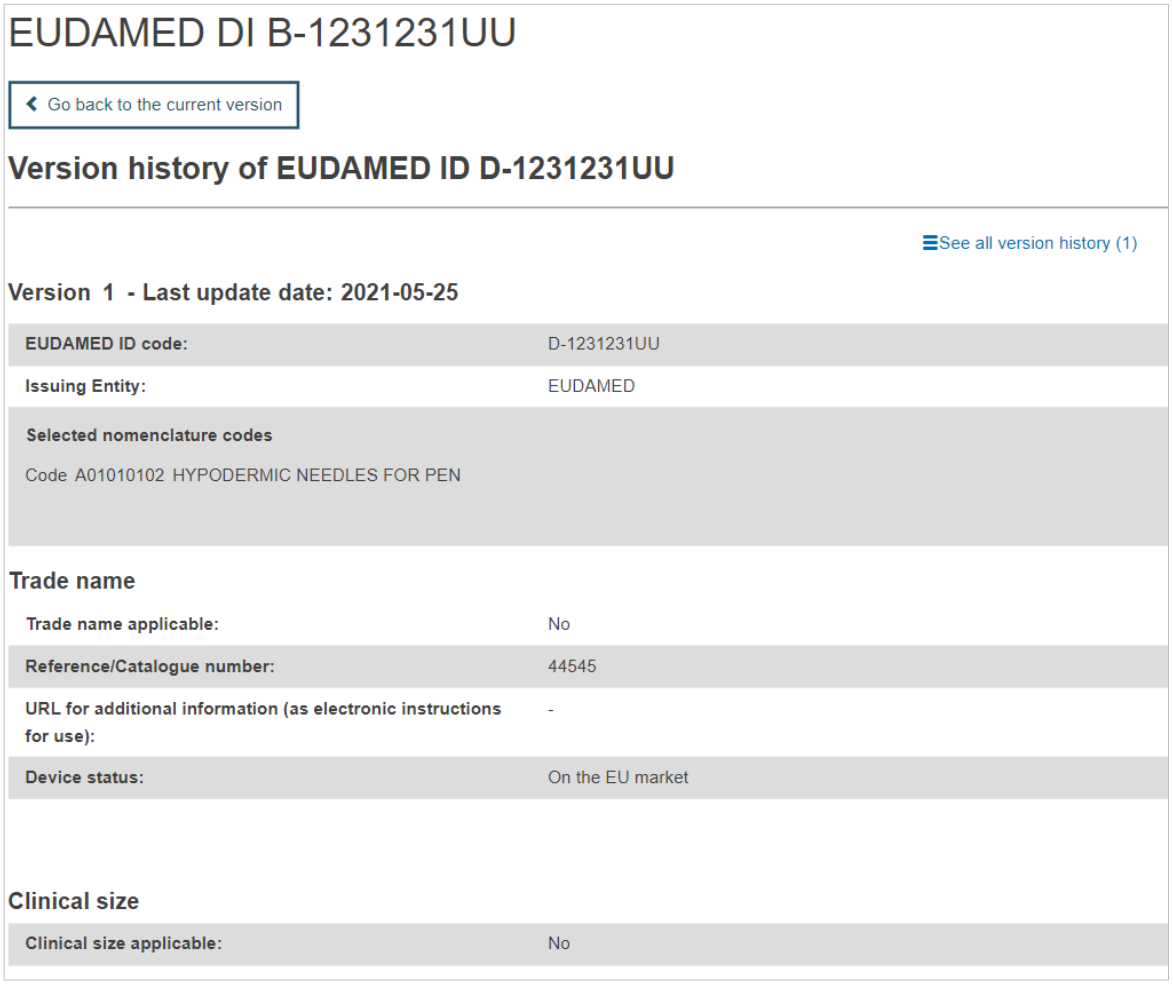
1. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:



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



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

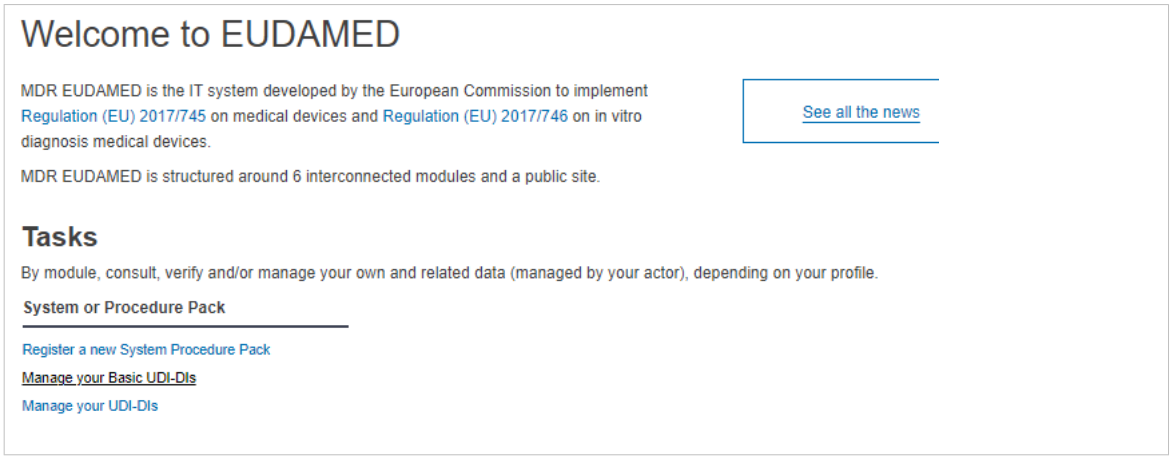


4. You can return to the version history list, by clicking on “See all version history” on the top right corner.

7. Manage your own System or Procedure Pack information

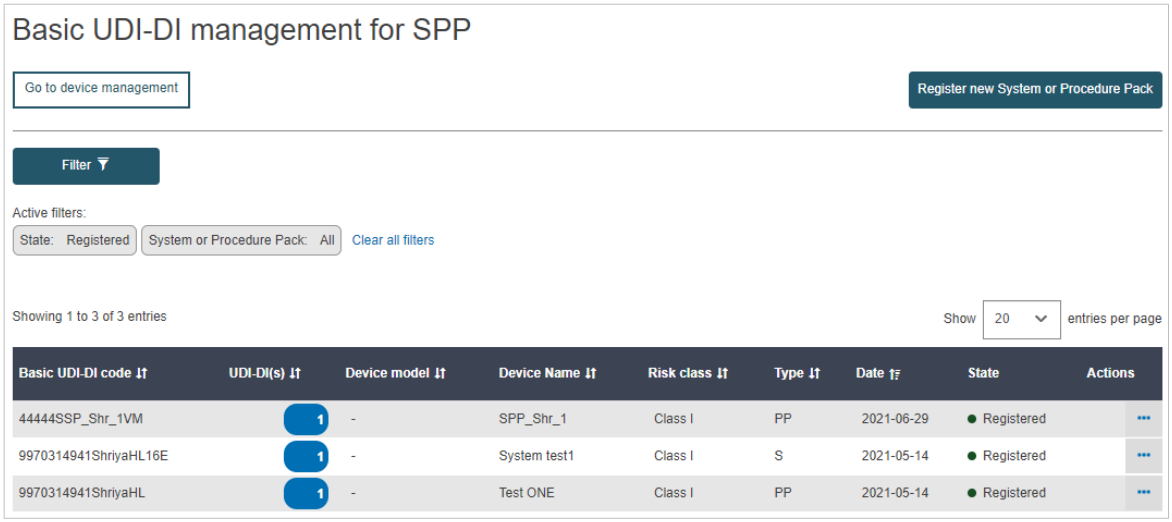
7.1. View own Basic UDI-DI details

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

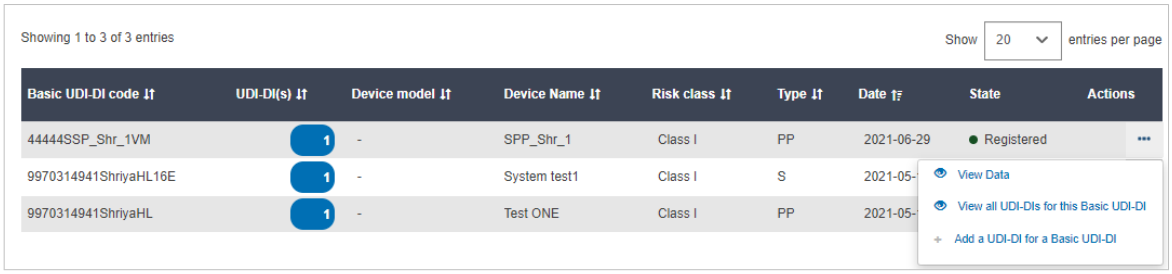


> **NOTE**
> By default, the system displays the System or Procedure Packs in state “Draft”.

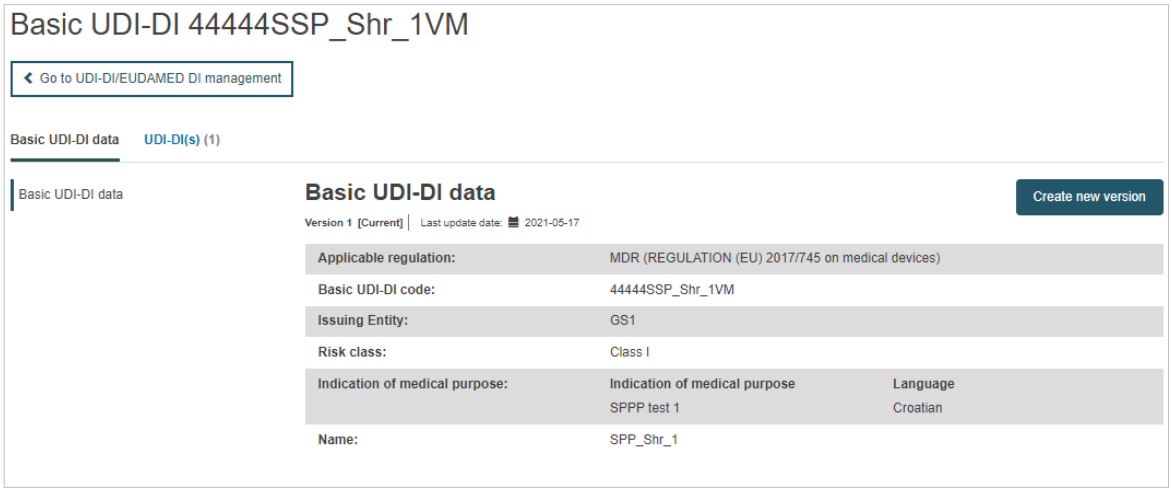
2. In order to see the desired SPP, click on the “Filter” button and choose the correct parameters:



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

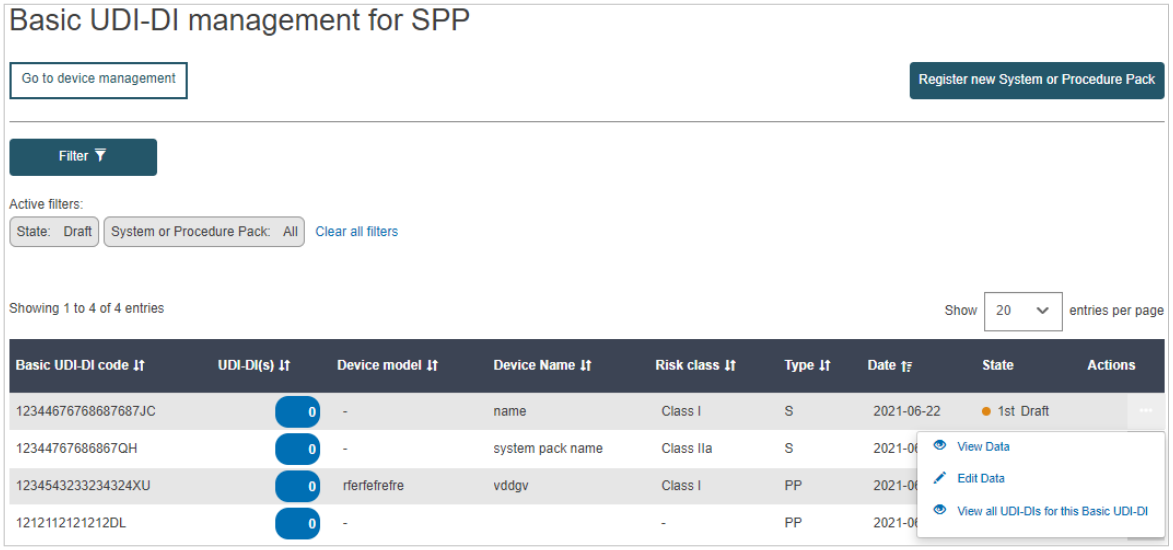


4. You will see a summary of the details concerning your system or procedure pack:

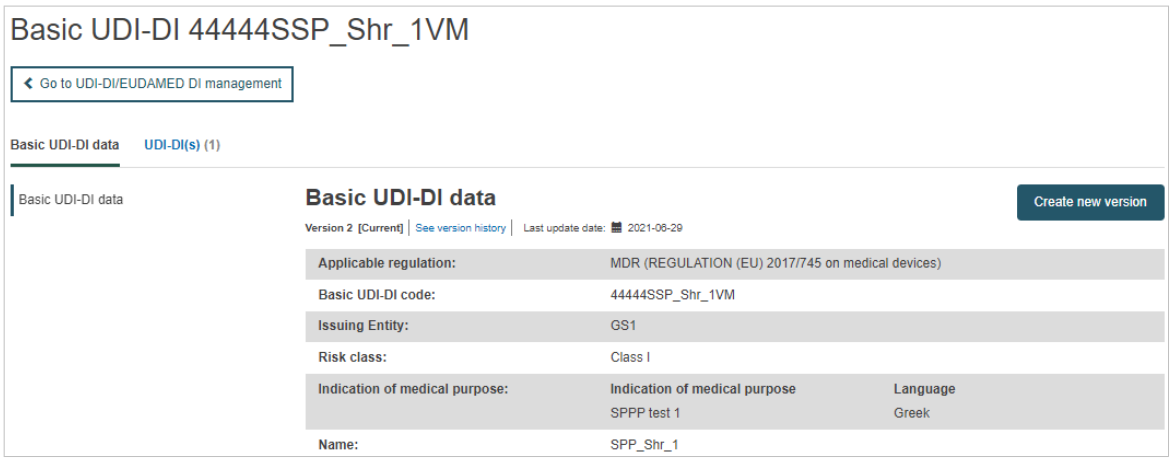


7.1.1. Delete a Draft Basic UDI-DI

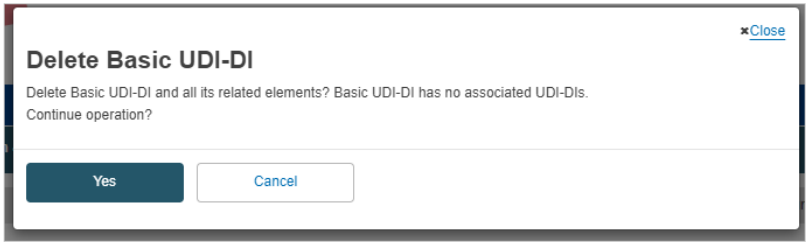
1. Follow the steps in Section 7.1 to view a Draft Basic UDI-DI:



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



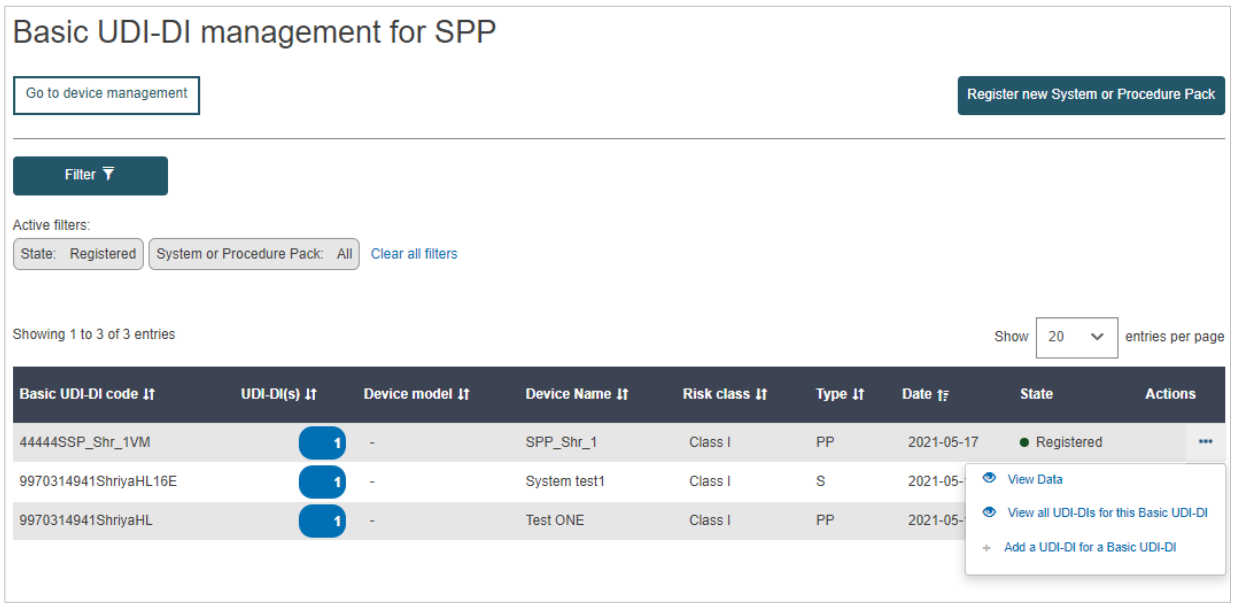
3. The system will ask you to confirm your intention to delete the draft in a pop-up window. If you are sure, click on “Yes”:



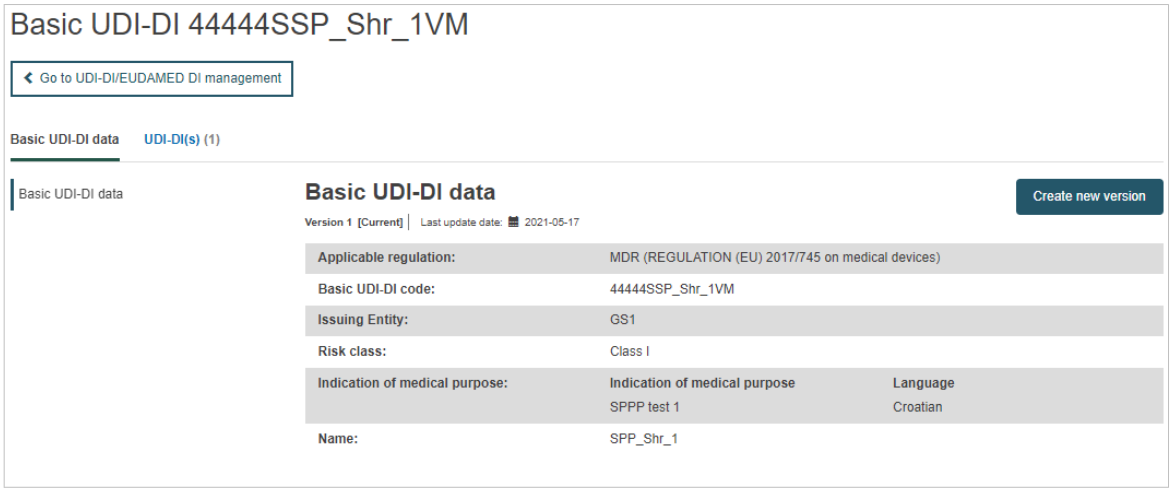
4. The system will redirect you to the latest registered information for this Basic UDI-DI.

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

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

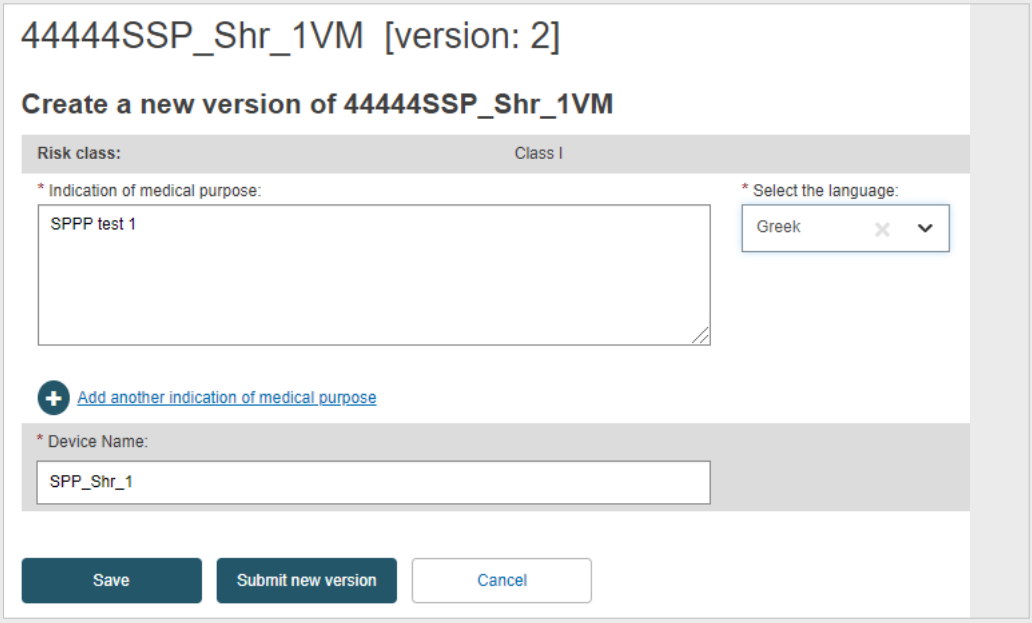


1. Once inside the summary for the relevant Basic UDI-DI, click on “Create new version”:

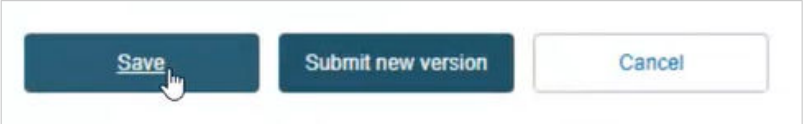


2. Update the desired details.

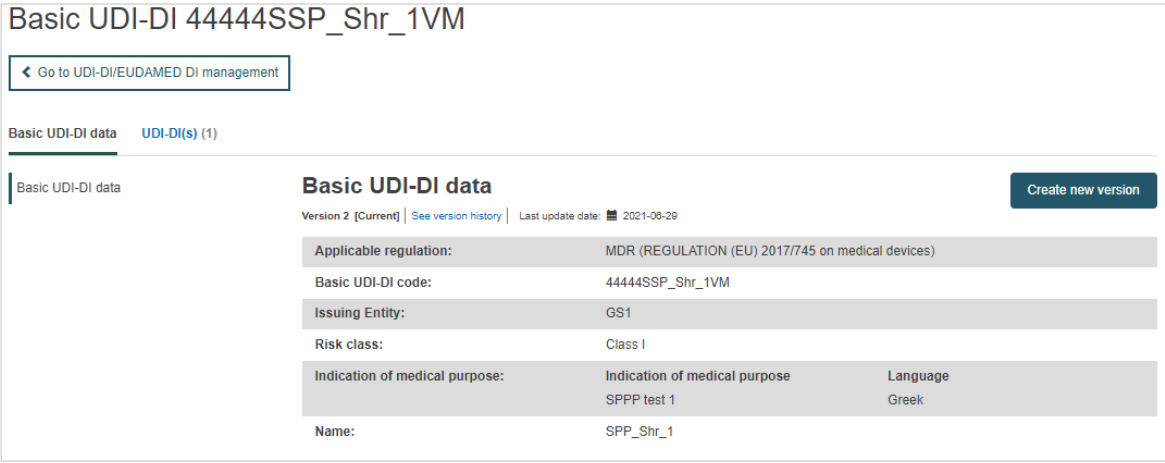
NOTE
Only some details can be updated depending on the actor's specifics:



3. To finish the action you have two options:
   a. Click on "Save" to save the updated details without submitting the new version. 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 yo finalise it.
   Alternatively, you can click on "Cancel" to cancel the update.



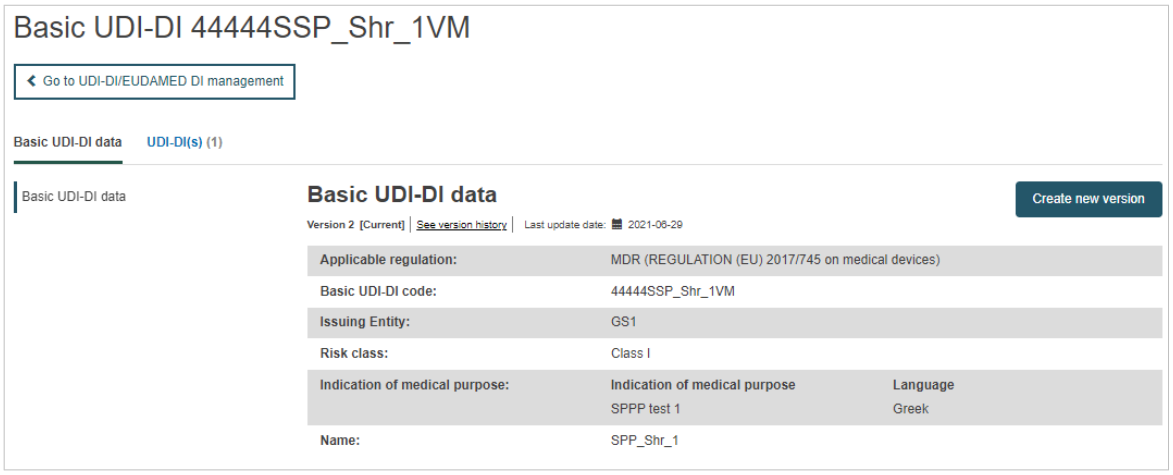
4. After you have submitted the new version, you can see the update under the Basic UDI-DI details:



7.1.3. View historical version for Basic UDI-DI

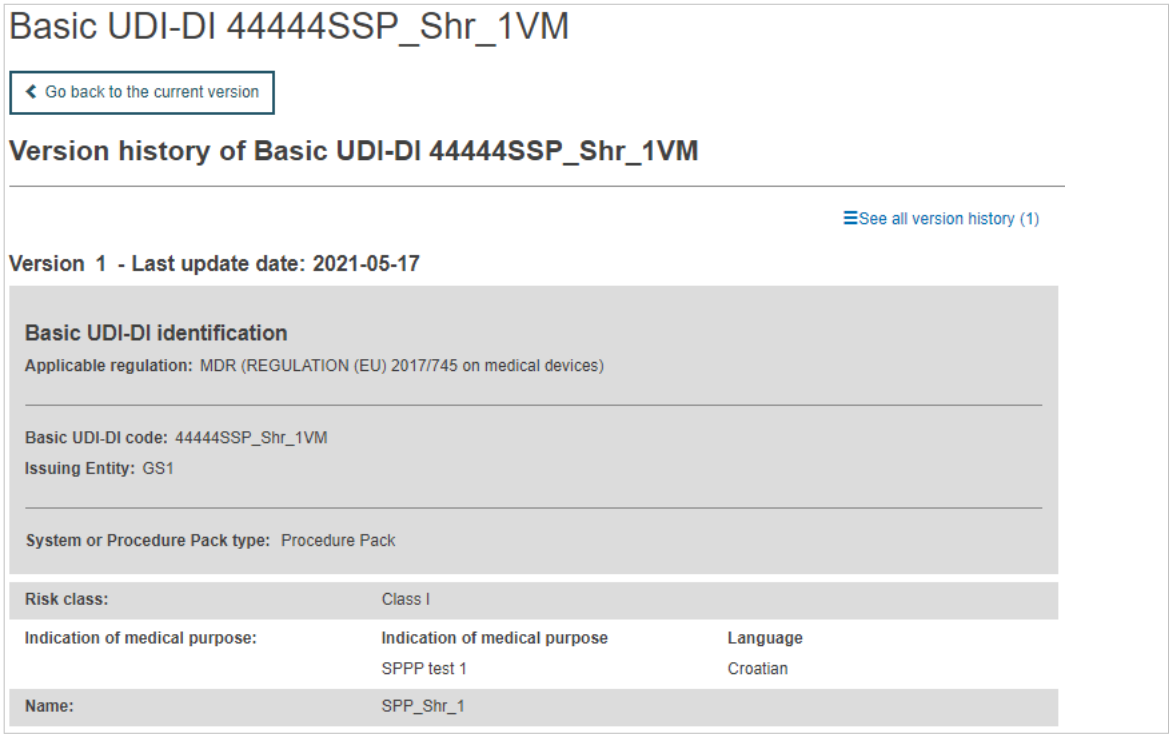
1. Follow the steps in Section 7.1 to view a Basic UDI-DI.

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



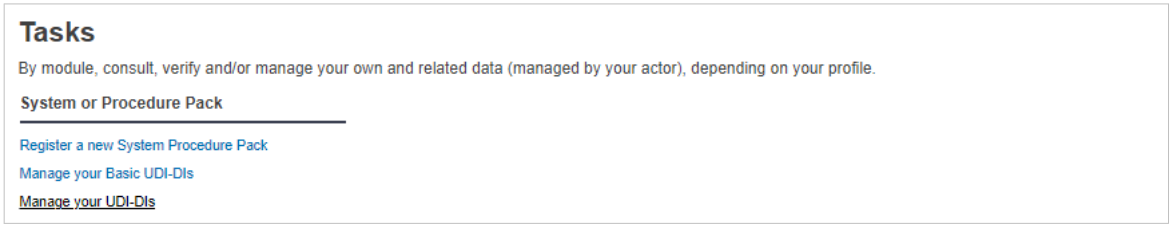
3. View the list of versions for the desired Basic UDI-DI and click on the chosen version to view its details (in the example below, there is only one older version):

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:

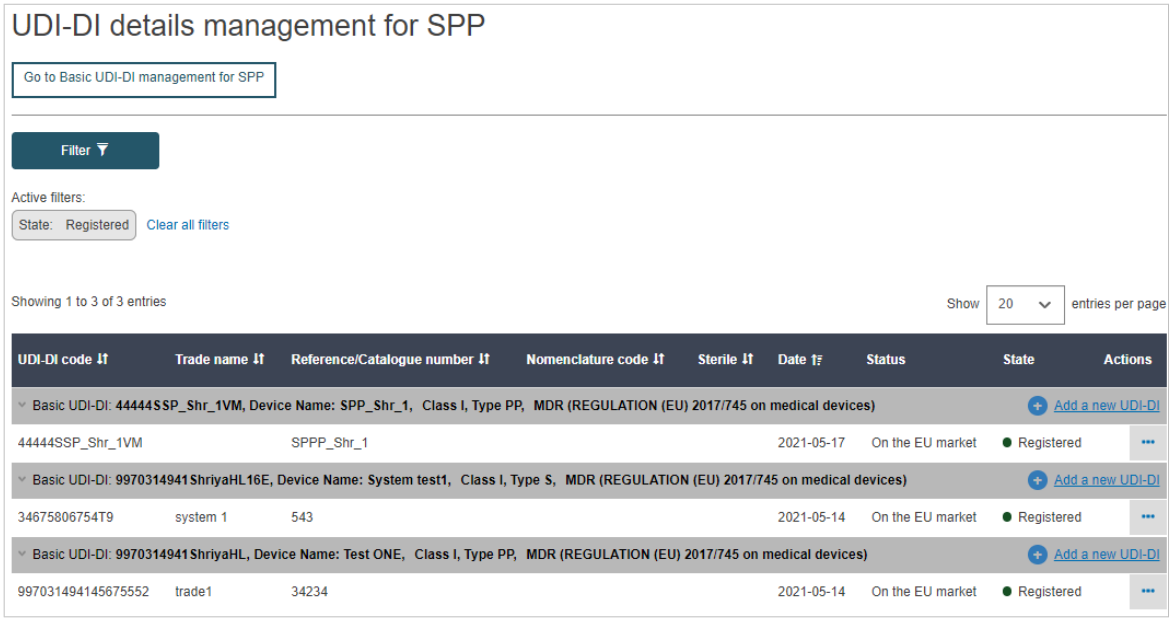


7.2. View own UDI-DI details

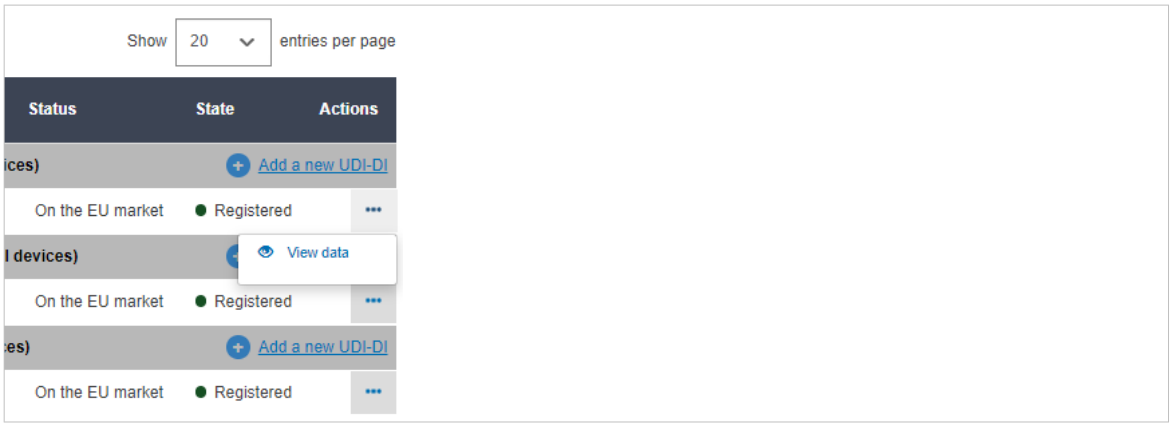
1. On the EUDAMED dashboard, click on “Manage your UDI-DIs” to see a list of all your UDI-DIs for SPPs:



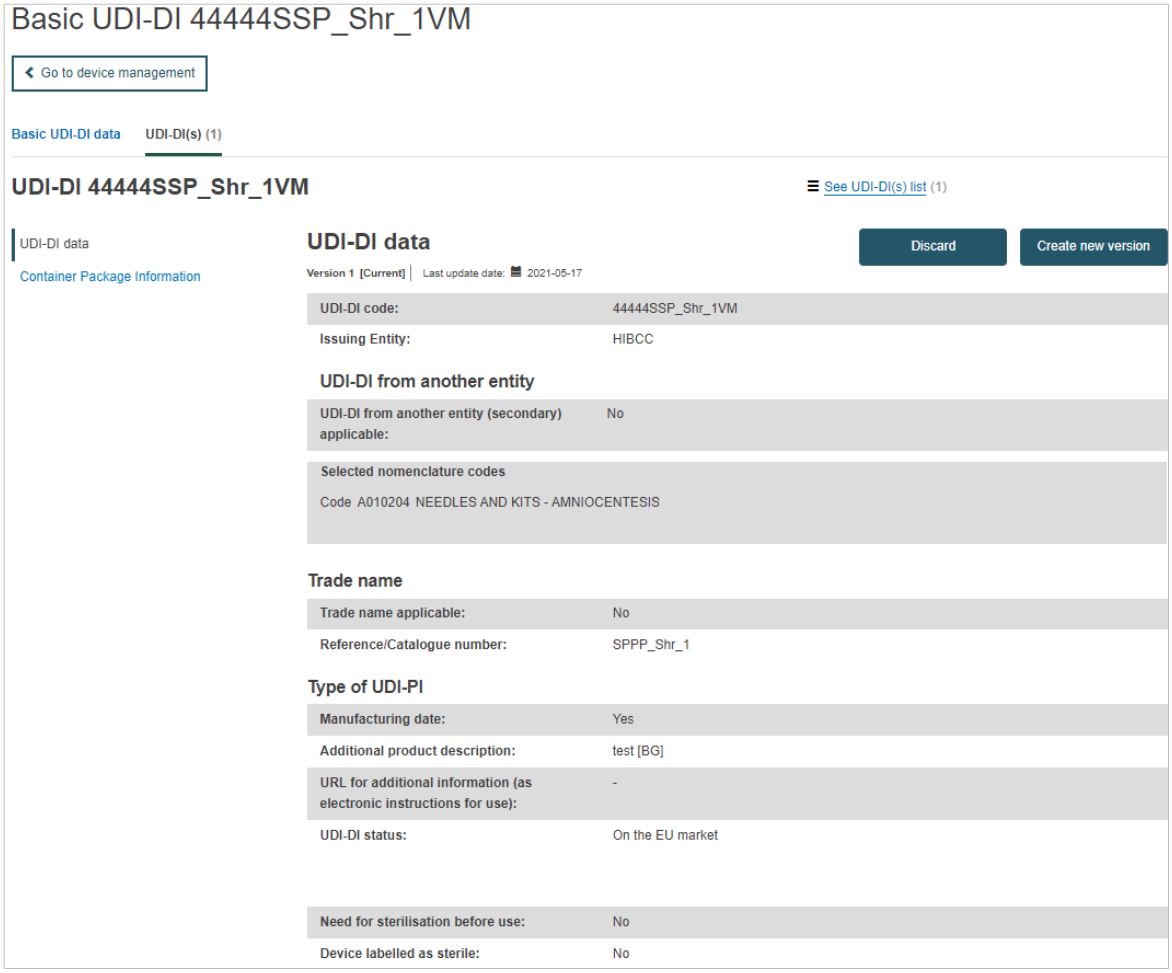
2. In order to find the desired UDI-DI, click on the “Filter” button and choose the right parameters:



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



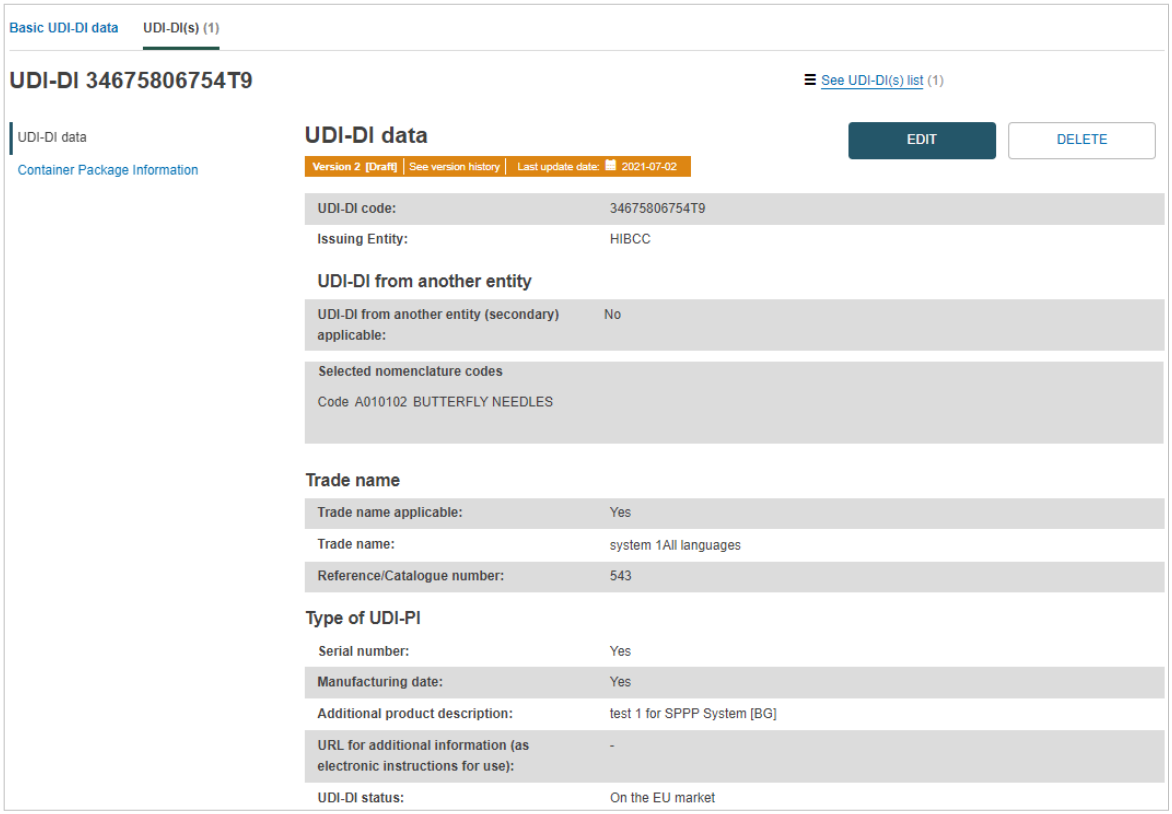
4. You will see a summary of the details concerning your chosen system or procedure pack UDI-DI:



7.2.1. Delete a Draft UDI-DI

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

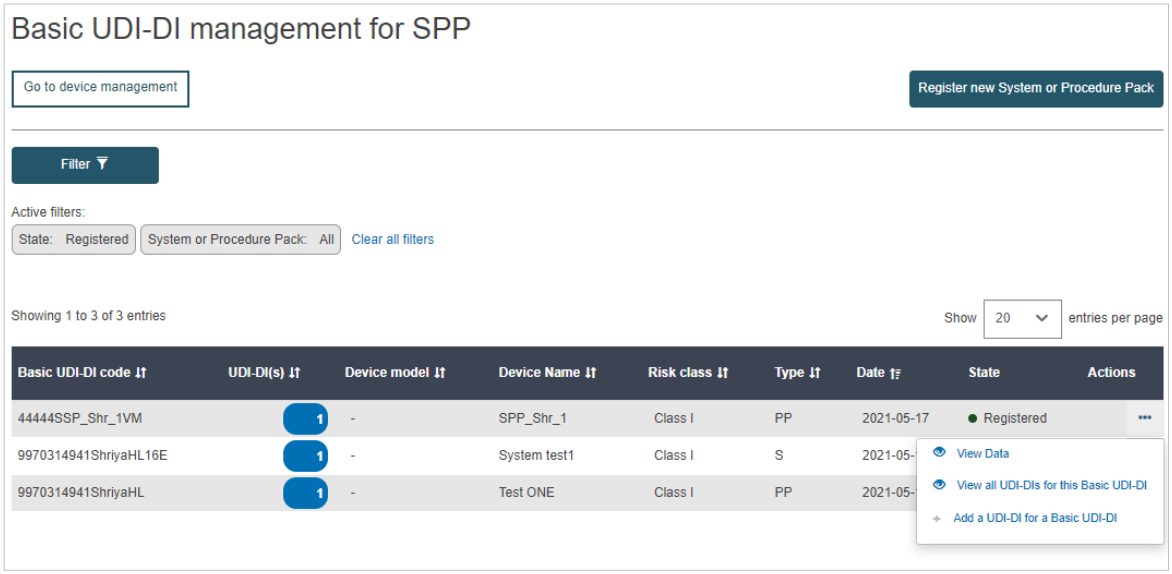
2. Once inside the summary of the chosen Draft UDI-DI, click on “Delete” on the top right corner:



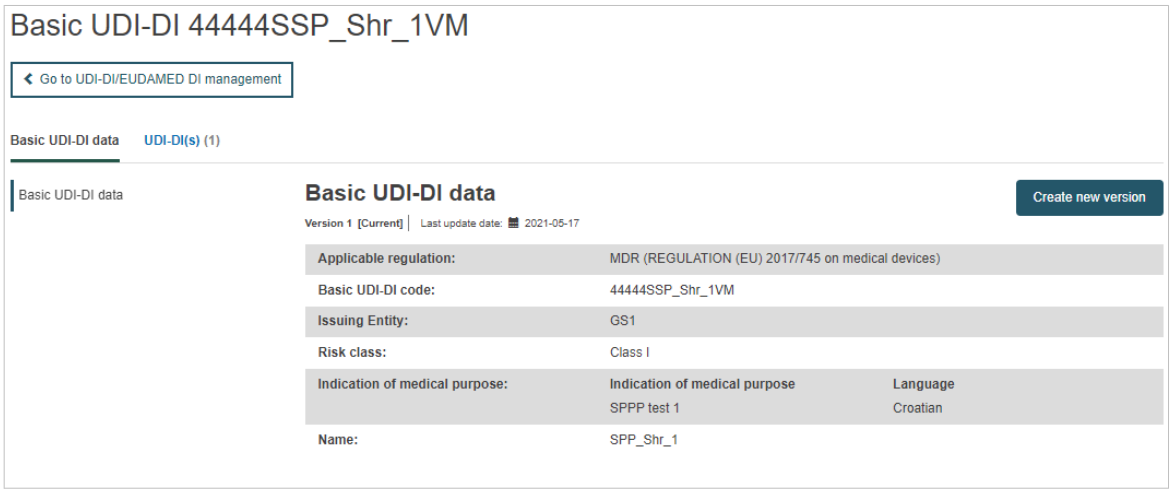
3. A pop-up message will ask you to confirm the action by clicking on “Yes”:

7.2.2. Update (create new version) for UDI-DI

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

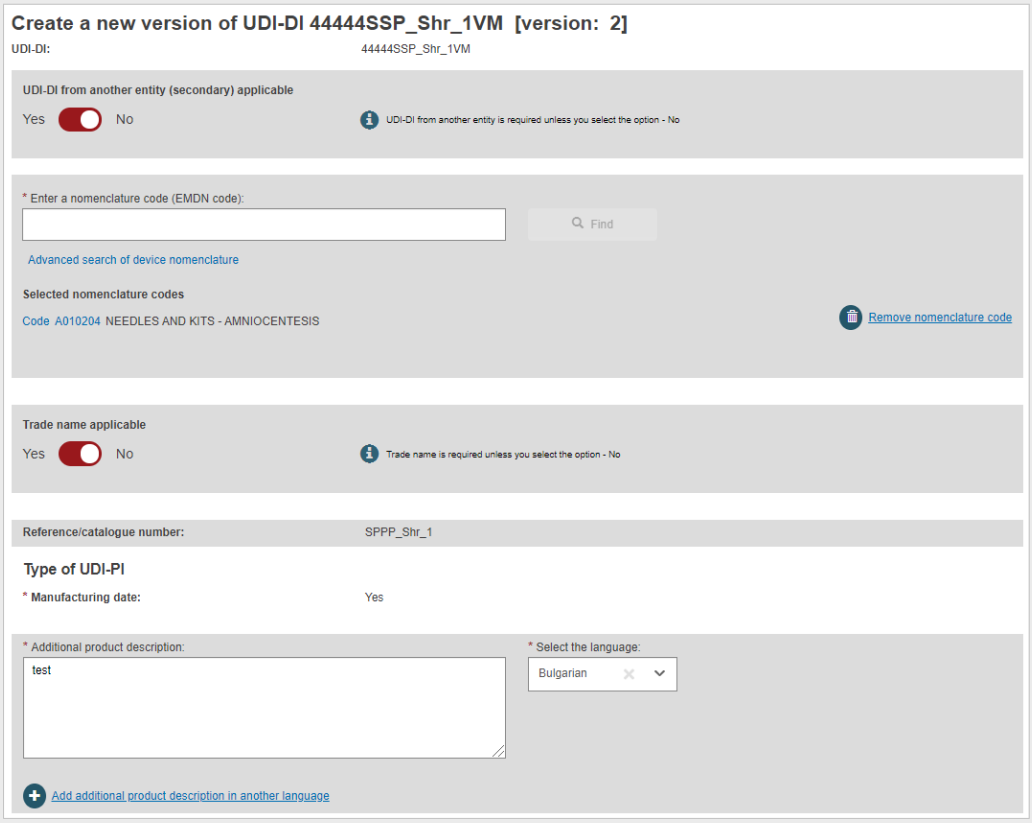


2. Once inside the summary for the chosen UDI-DI, click on “Create new version” on the top right corner:



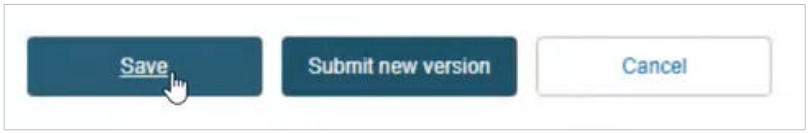
3. Update the necessary details.

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



4. To finish the action you have two options:
   a. Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are unsure about the update.

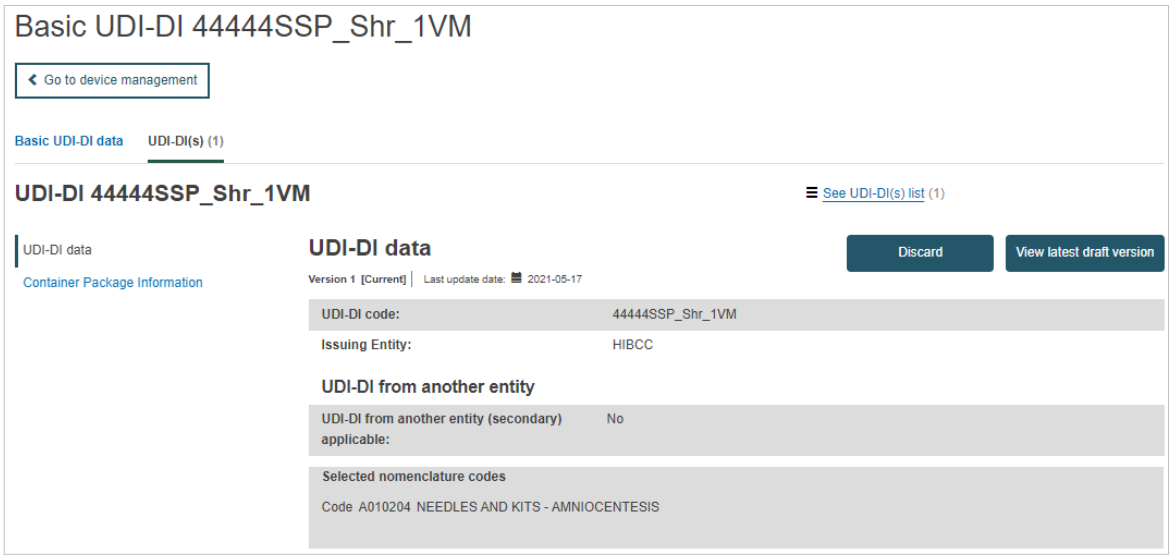
b. Click on “Submit new version”, if you are sure about the update and wish to finalise it.
Otherwise, you can press “Cancel” to cancel the update.



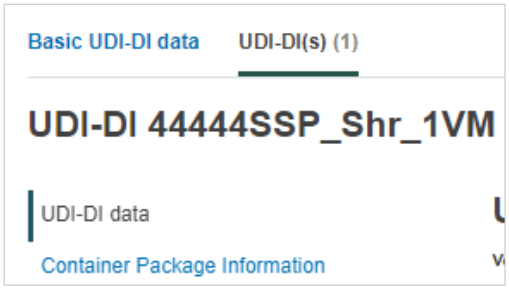
7.2.3. Update (create new version) for Container Packages

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

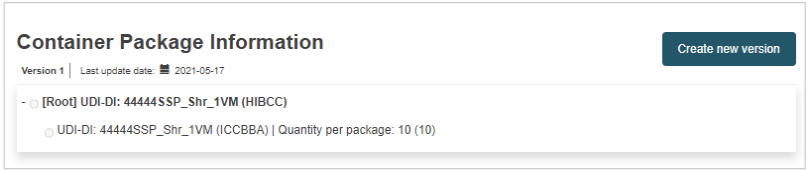
1. Follow the steps in section 7.2 to view a specific UDI-DI:



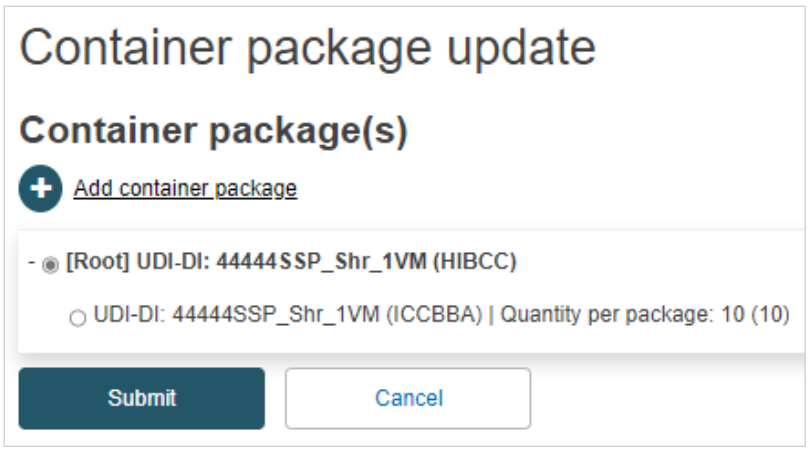
2. Once inside the summary of the chosen UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):



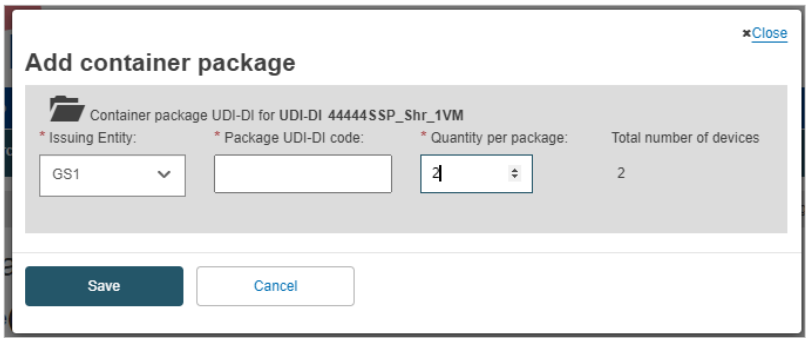
3. Click on “Create new version” in the Container Package section:



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

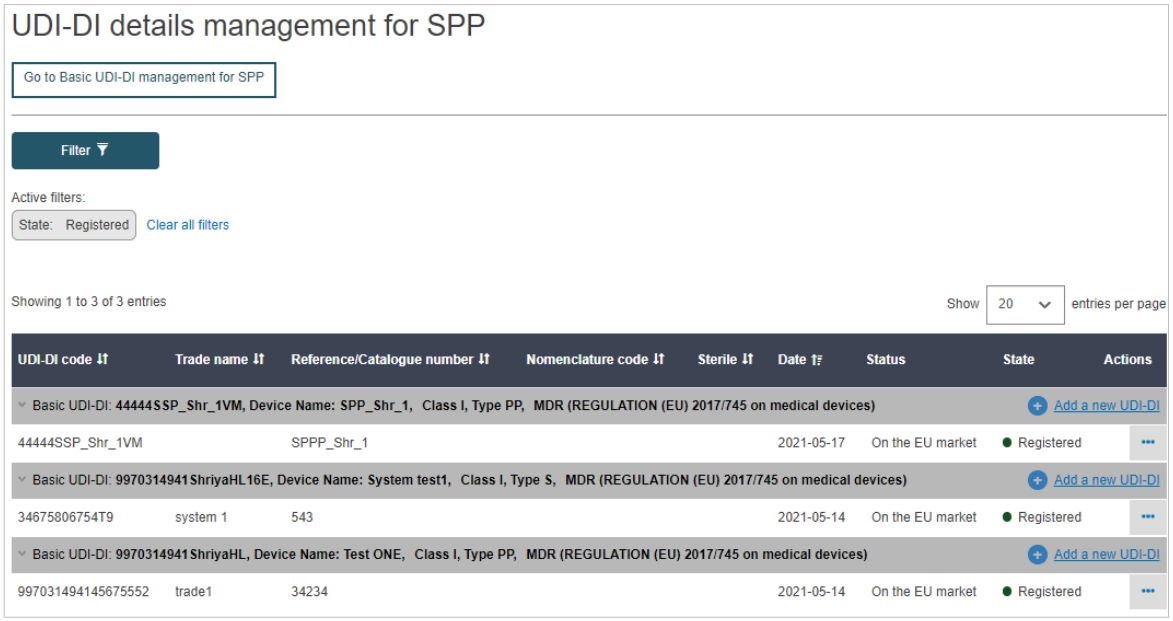


5. Insert the package details in the pop-up window and click on “Save”:

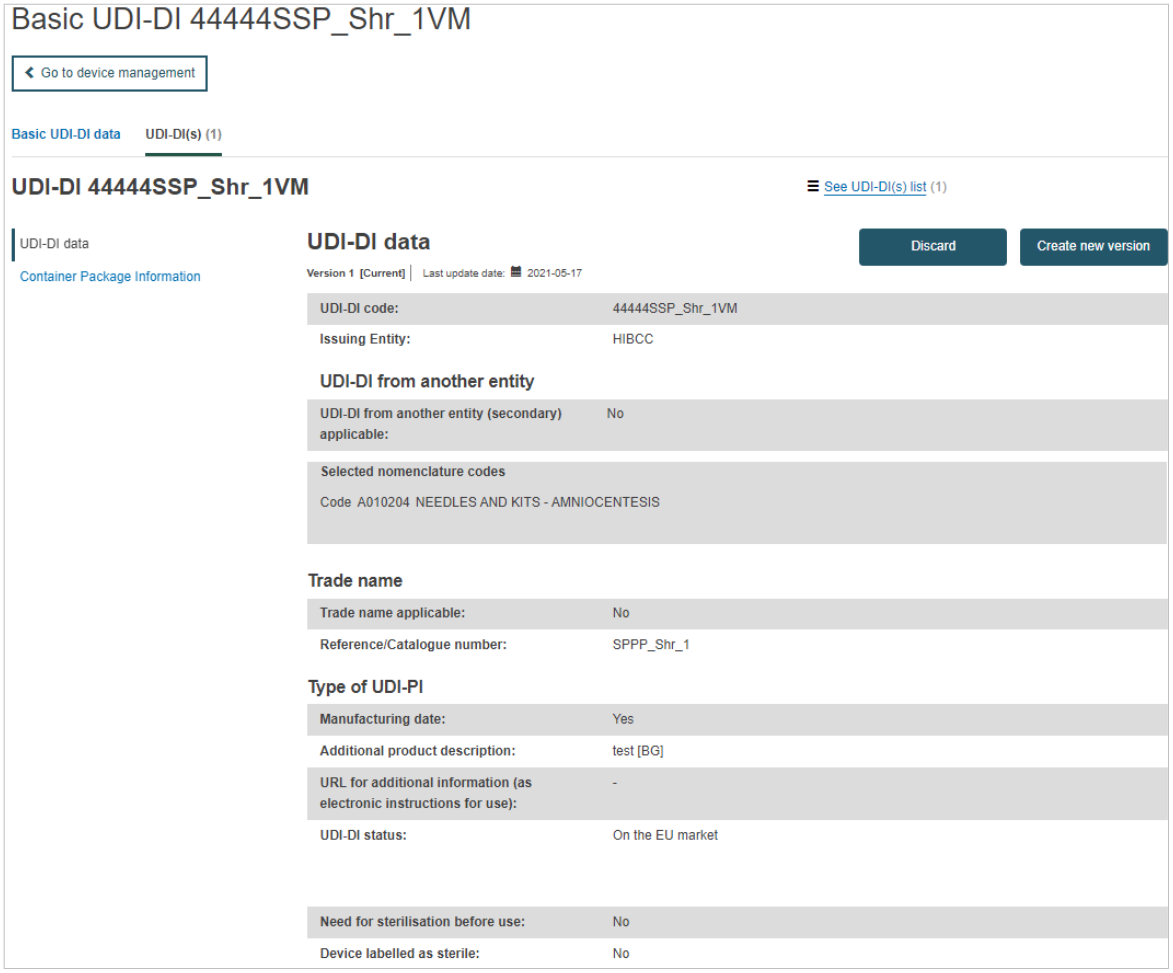


7.2.4. Discard Registered UDI-DIs

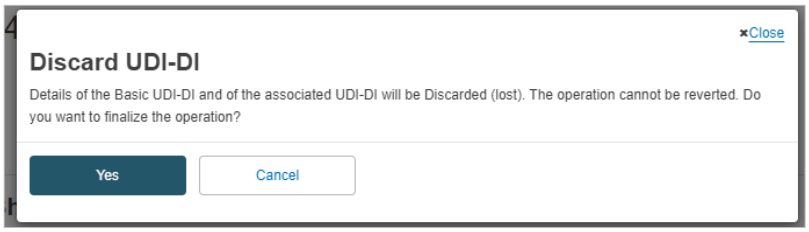
1. Follow the steps in Section 7.2 to view a chosen Registered UDI-DI:



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



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

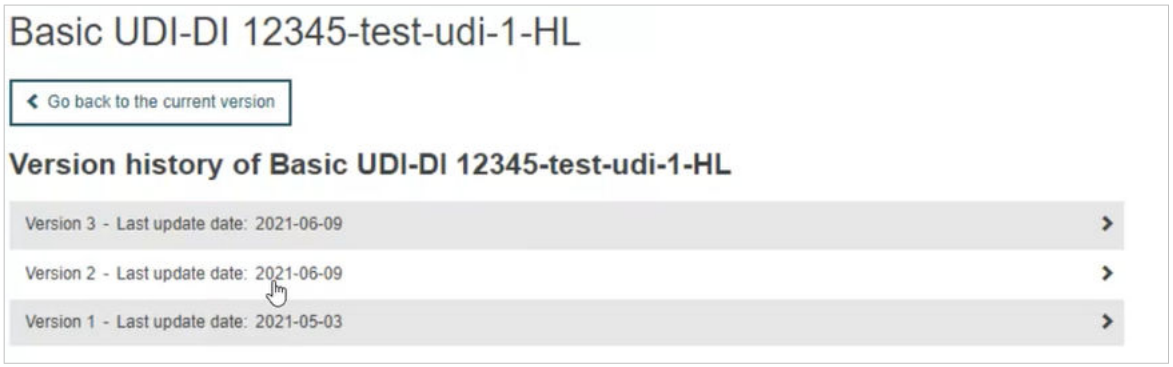


7.2.5. View historical versions for UDI-DI and associated entities

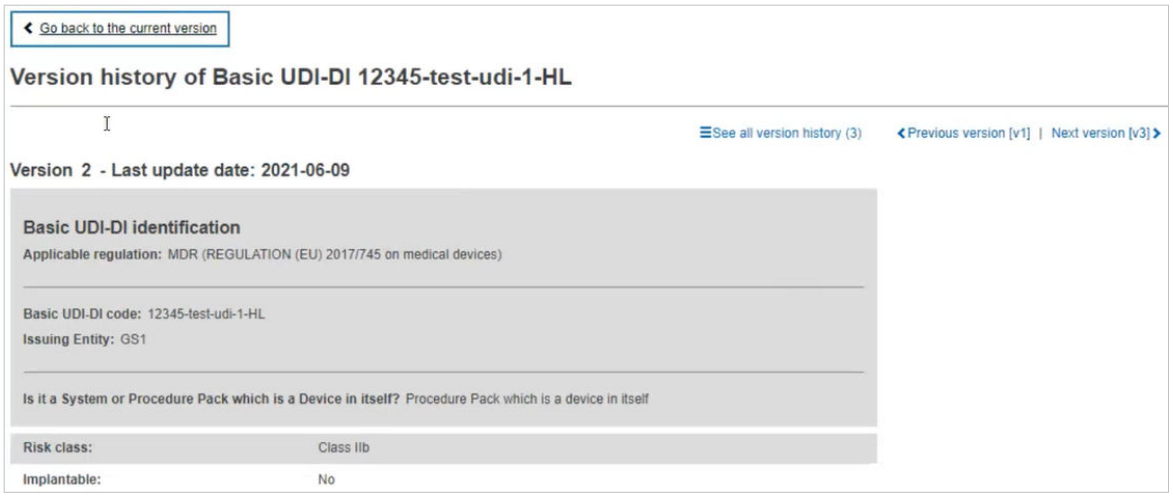
1. Follow the steps in section 7.2 to view a UDI-DI for the SPP.

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

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



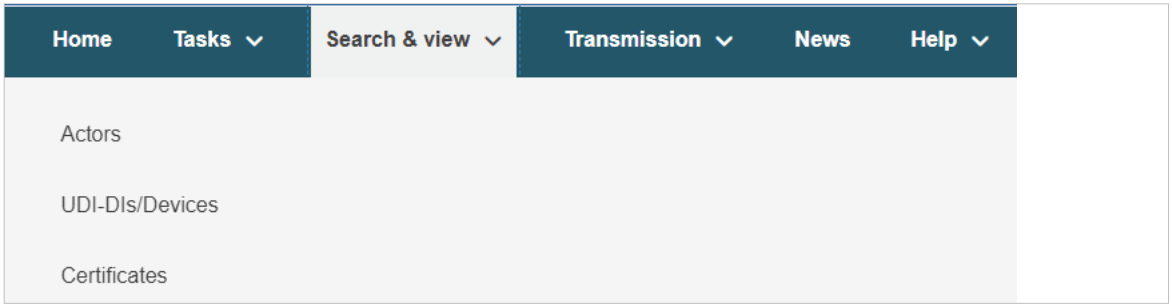
4. Click on the version you wish to view to access its detailed summary:



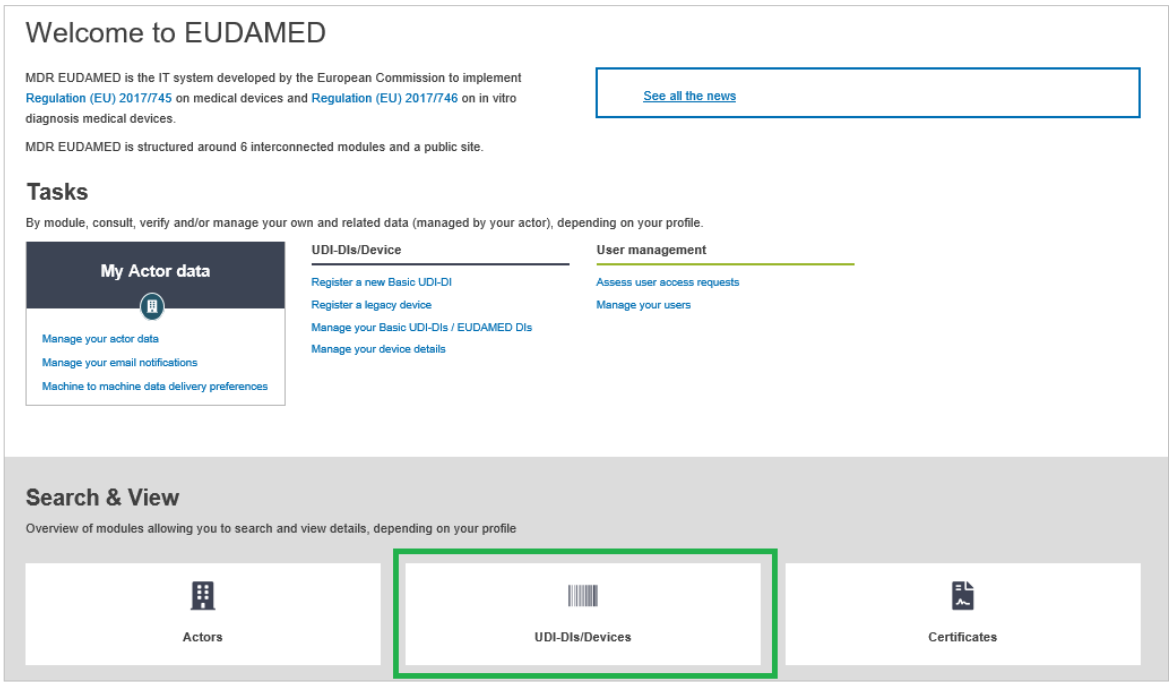
You can return to the version history list by clicking on “See all version history” on the top right corner.

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

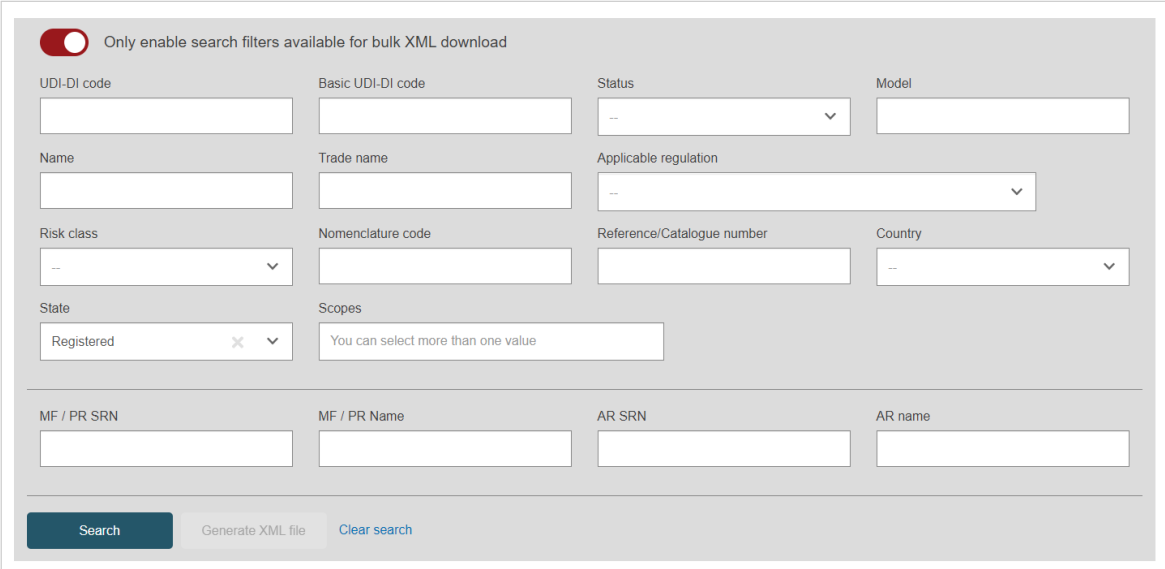
1. On the header menu, click on “Search & View”, then “UDI-DIs/Devices”:



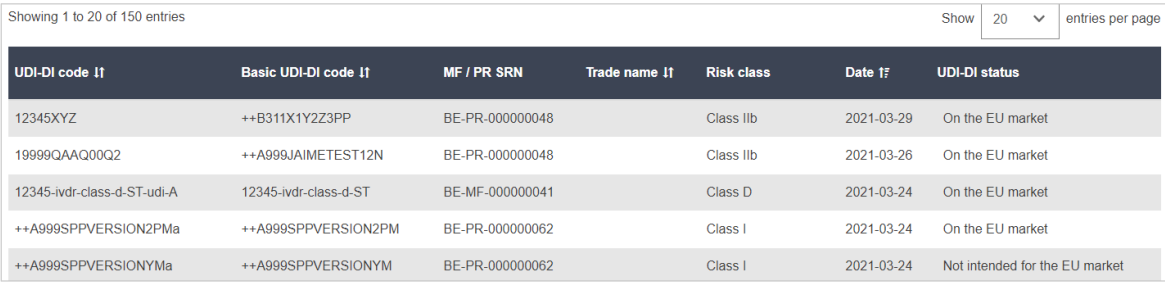
Alternatively, use the option available in the dashboard called ‘Search and View’:



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



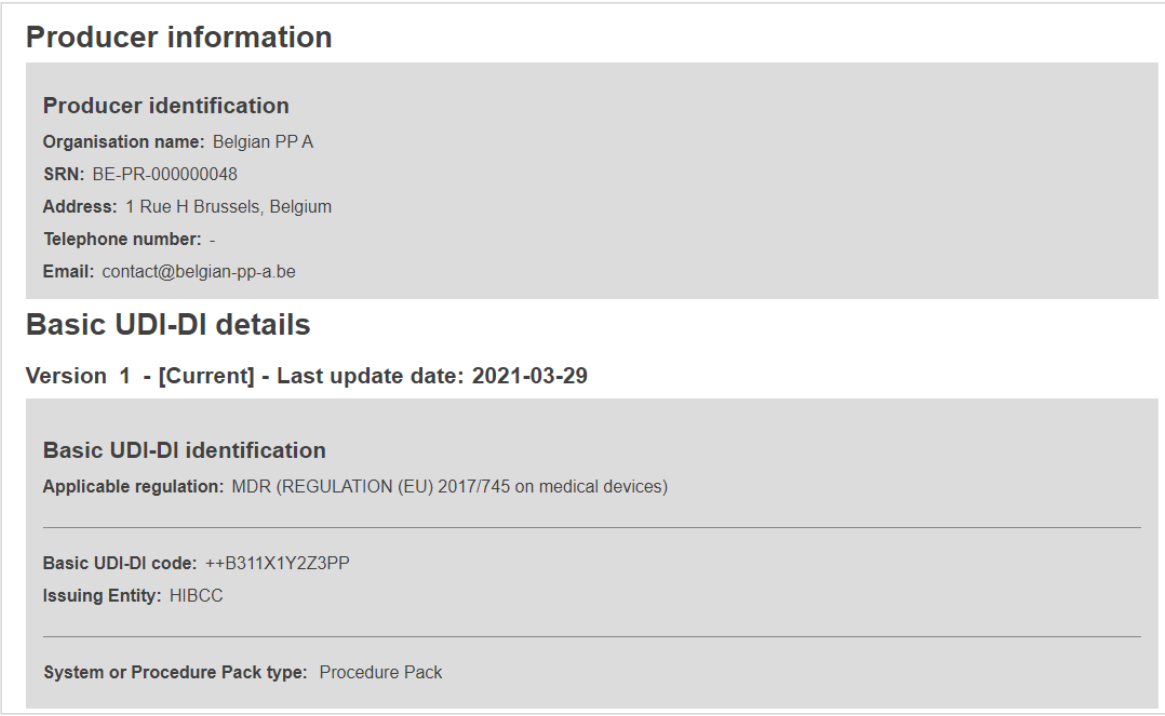
3. Once you are have entered the right search filters, click on “Search”. A list of Devices (UDI-DIs/EUDAMED IDs) and System or Procedure Packs will appear:



Showing 1 to 20 of 150 entries — Show 20 entries per page

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

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



Producer information

Producer identification

Organisation name: Belgian PP A
SRN: BE-PR-000000048
Address: 1 Rue H Brussels, Belgium
Telephone number: -
Email: contact@belgian-pp-a.be

Basic UDI-DI details

Version 1 - [Current] - Last update date: 2021-03-29

Basic UDI-DI identification

Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)

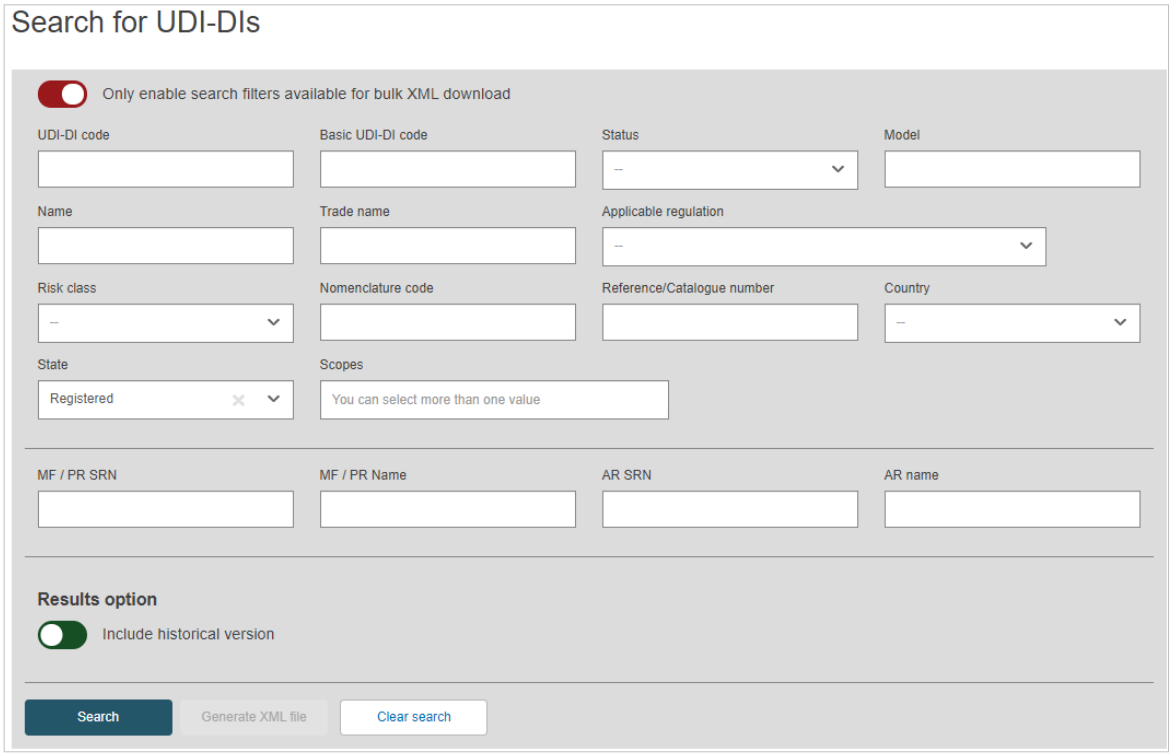
Basic UDI-DI code: ++B311X1Y2Z3PP
Issuing Entity: HIBCC

System or Procedure Pack type: Procedure Pack

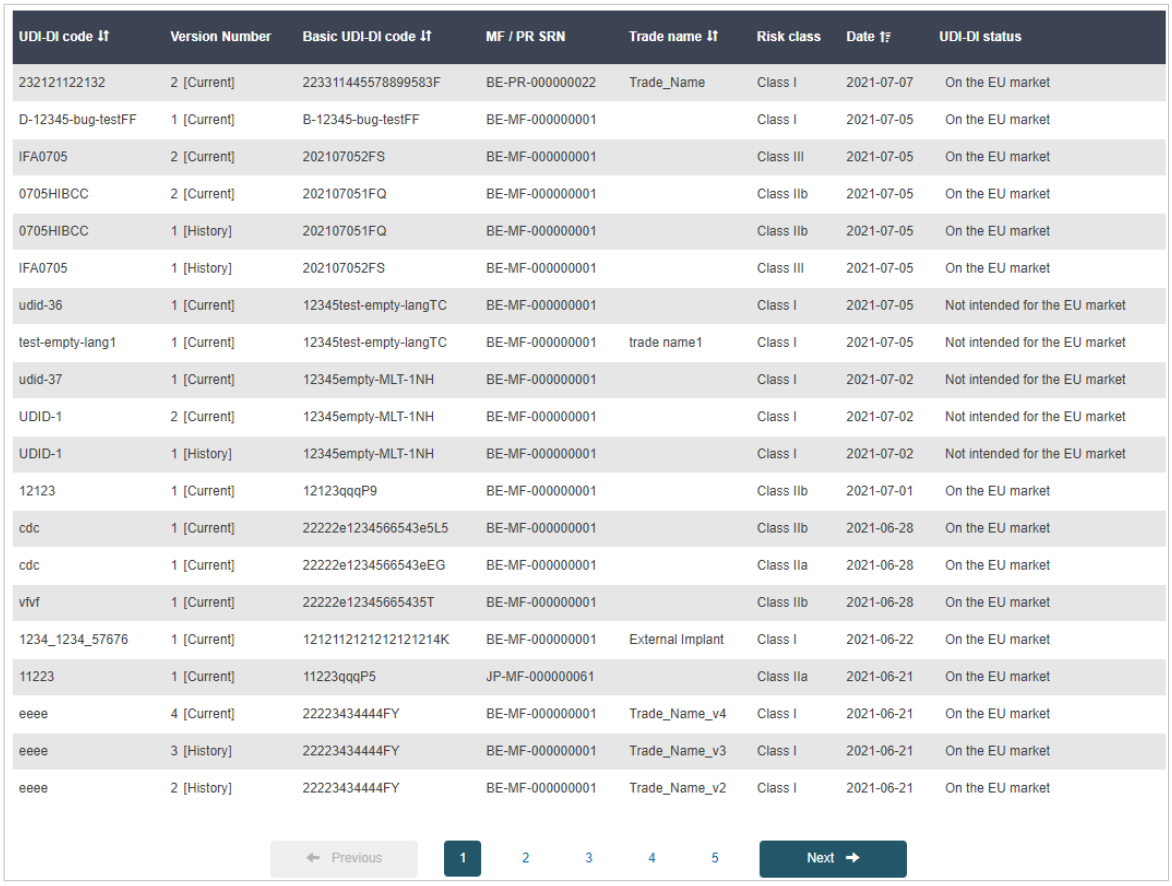
8.1. Search and View historical versions of Devices and System or Procedure Packs

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

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



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

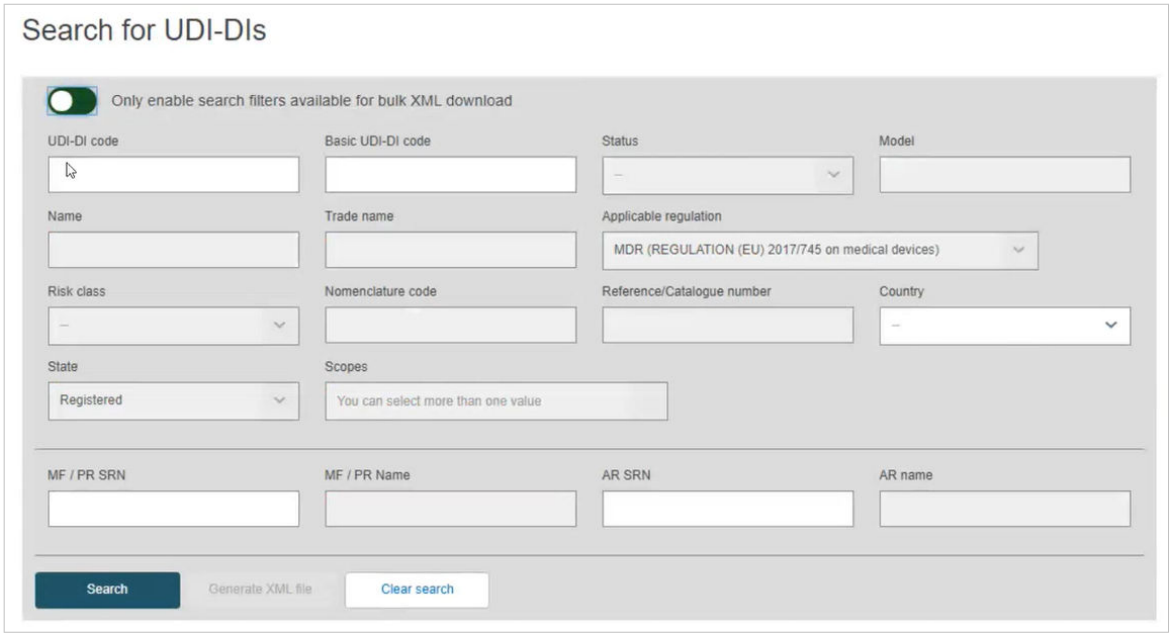


UDI-DI code	Version Number	Basic UDI-DI code	MF / PR SRN	Trade name	Risk class	Date	UDI-DI status
232121122132	2 [Current]	2233114455788995 83F	BE-PR-000000022	Trade_Name	Class I	2021-07-07	On the EU market
D-12345-bug-testFF	1 [Current]	B-12345-bug-testFF	BE-MF-000000001		Class I	2021-07-05	On the EU market
IFA0705	2 [Current]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
0705HIBCC	2 [Current]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
0705HIBCC	1 [History]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
IFA0705	1 [History]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
udid-36	1 [Current]	12345test-empty-langTC	BE-MF-000000001		Class I	2021-07-05	Not intended for the EU market
test-empty-lang1	1 [Current]	12345test-empty-langTC	BE-MF-000000001	trade name1	Class I	2021-07-05	Not intended for the EU market
udid-37	1 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	2 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	1 [History]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
12123	1 [Current]	12123qqqP9	BE-MF-000000001		Class IIb	2021-07-01	On the EU market
cdc	1 [Current]	22222e1234566543e5L5	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
cdc	1 [Current]	22222e1234566543eEG	BE-MF-000000001		Class IIa	2021-06-28	On the EU market
vfvf	1 [Current]	22222e12345665435T	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
1234_1234_57676	1 [Current]	121211212121212214K	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

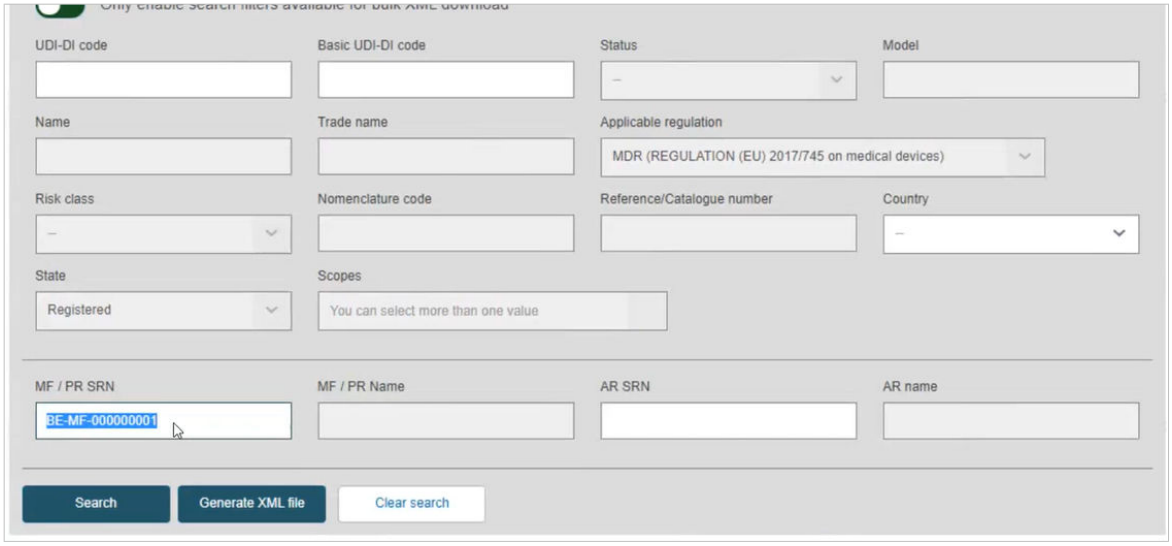
8.2. Download Devices and System or Procedure Packs in a structure format

NOTE
You can only download your own device or system/procedure pack structure format.

1. Follow the steps in section 8 to search and view a device or system or procedure pack.
2. On the search page, activate the top filter so that you only include the search results that can be downloaded in an XML format, and enter your search criteria:



3. Enter the search criteria of your choice, and click on “Search”:

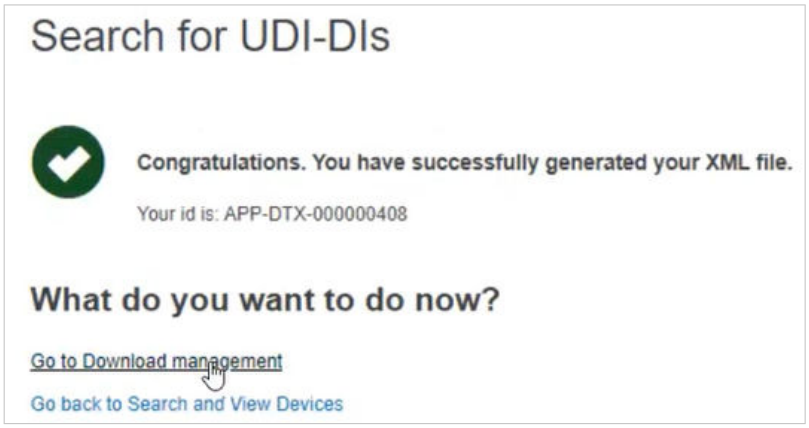


4. Click on “Generate XML file”:

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 case there are more pages of results).

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

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

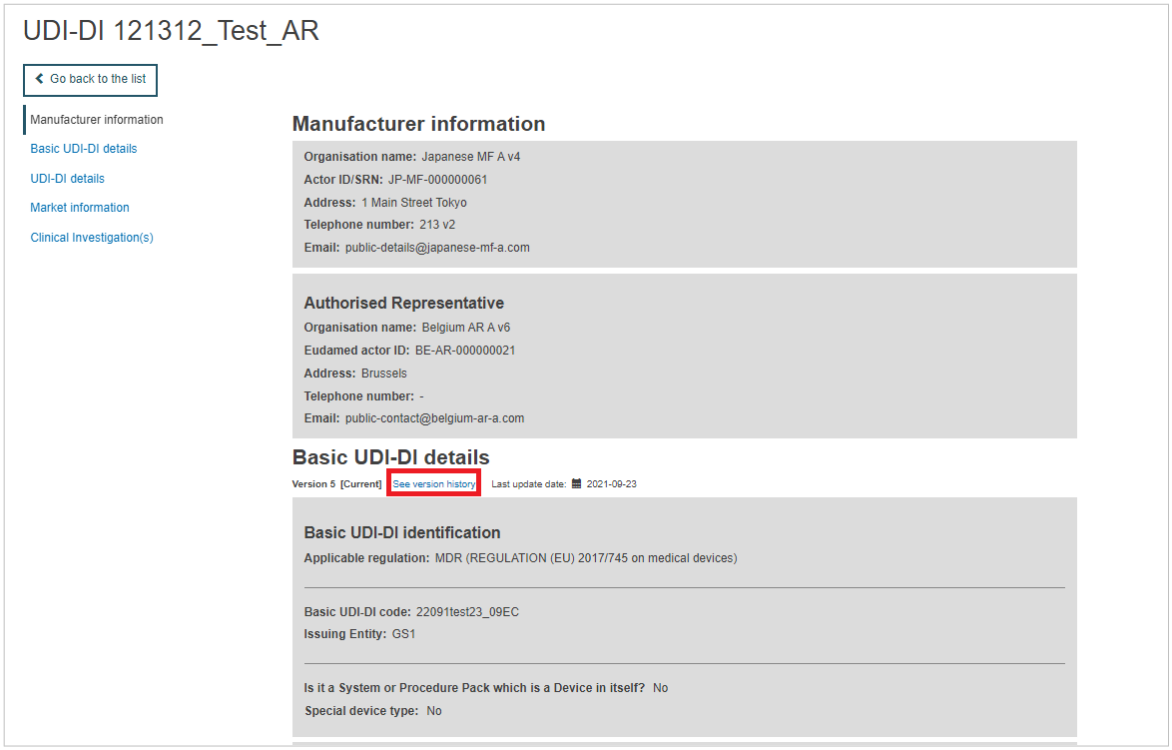


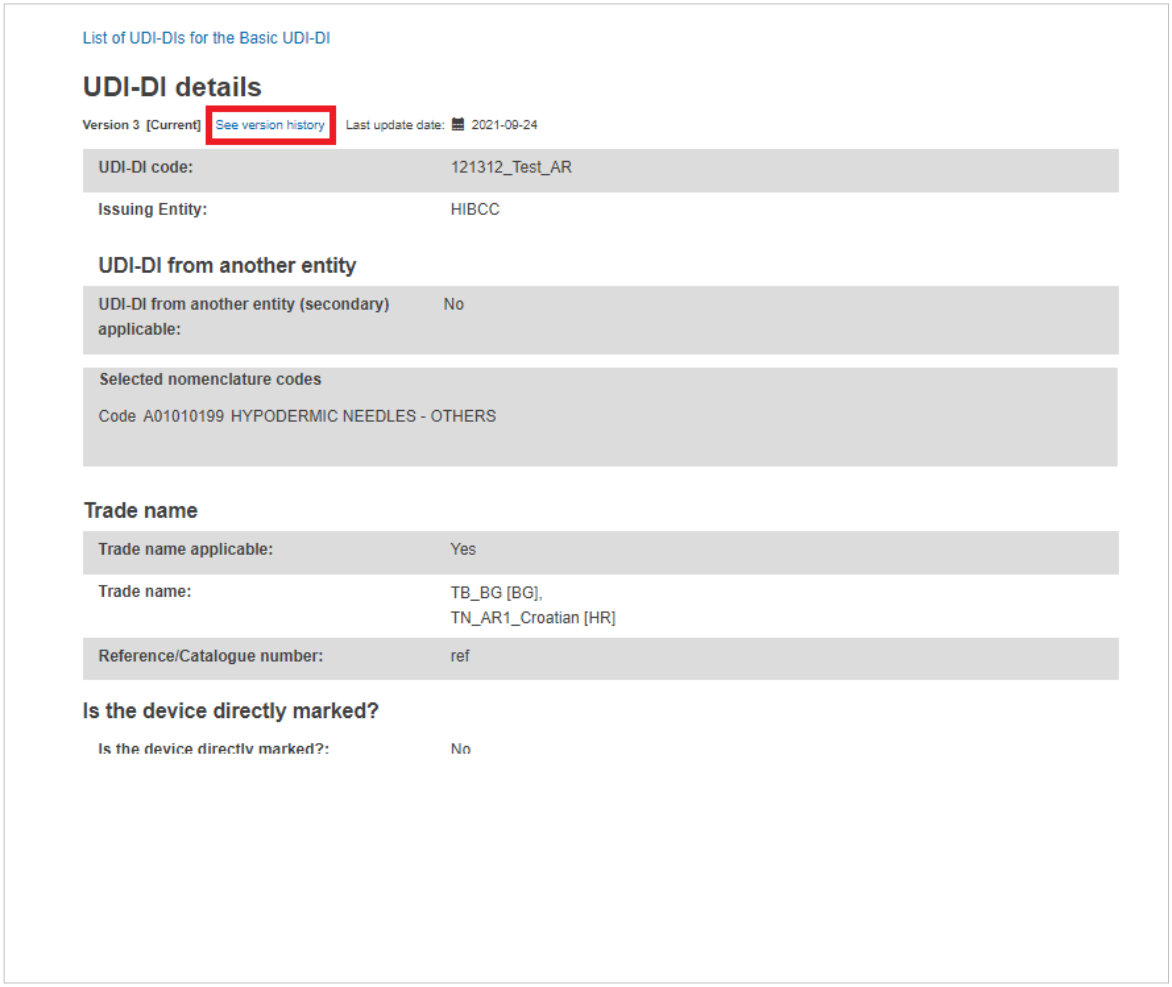
7. You can download the generated XML file by clicking on it under the “Download” column:

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

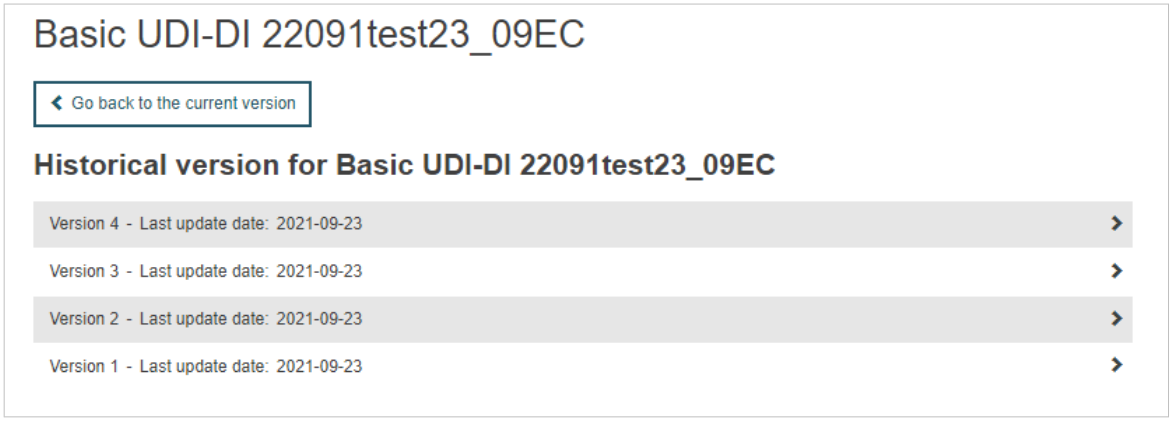
1. Follow the steps in section 8.1 to view the details of a Device or SPP.

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

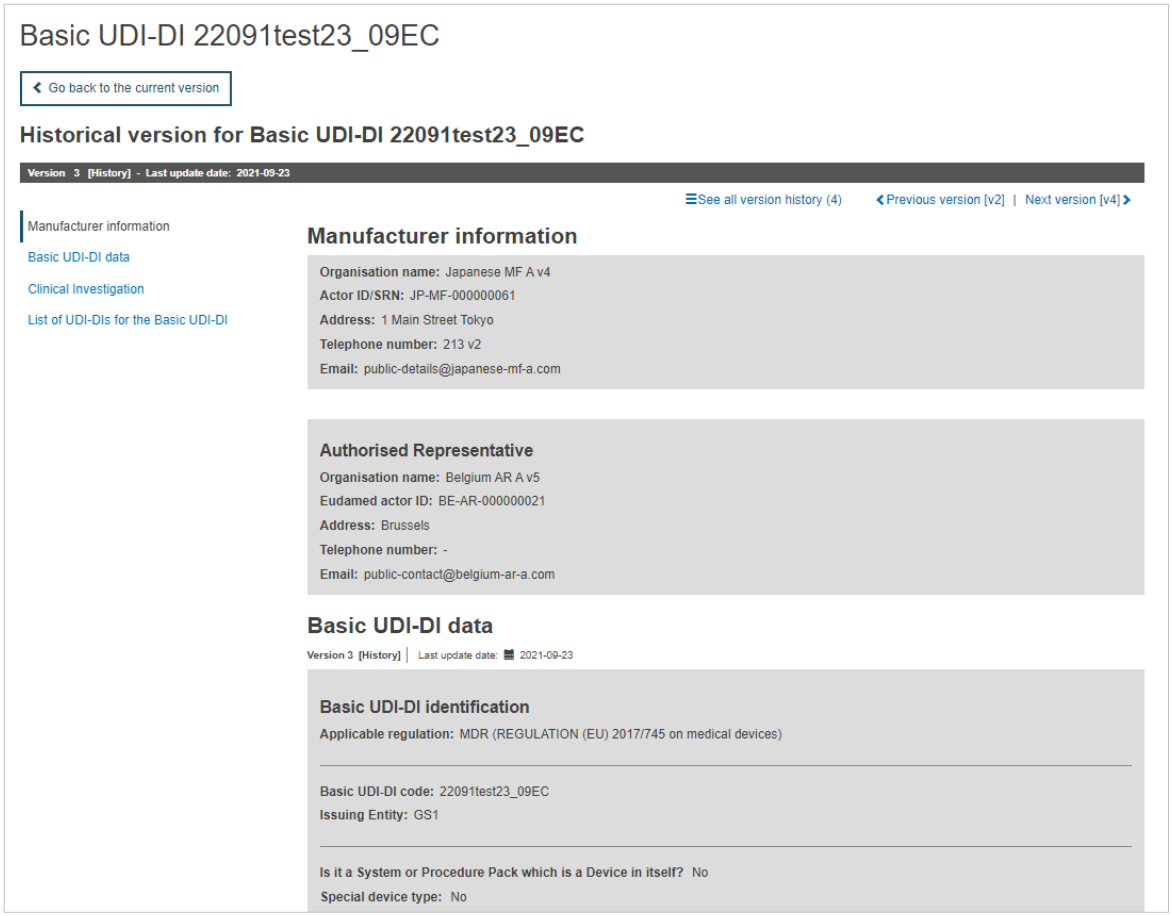

UDI-DI 121312_Test_AR
Go back to the list
Manufacturer information
Basic UDI-DI details
UDI-DI details
Market information
Clinical Investigation(s)
Manufacturer information
Organisation name: Japanese MF A v4
Actor ID/SRN: JP-MF-000000061
Address: 1 Main Street Tokyo
Telephone number: 213 v2
Email: public-details@japanese-mf-a.com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


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

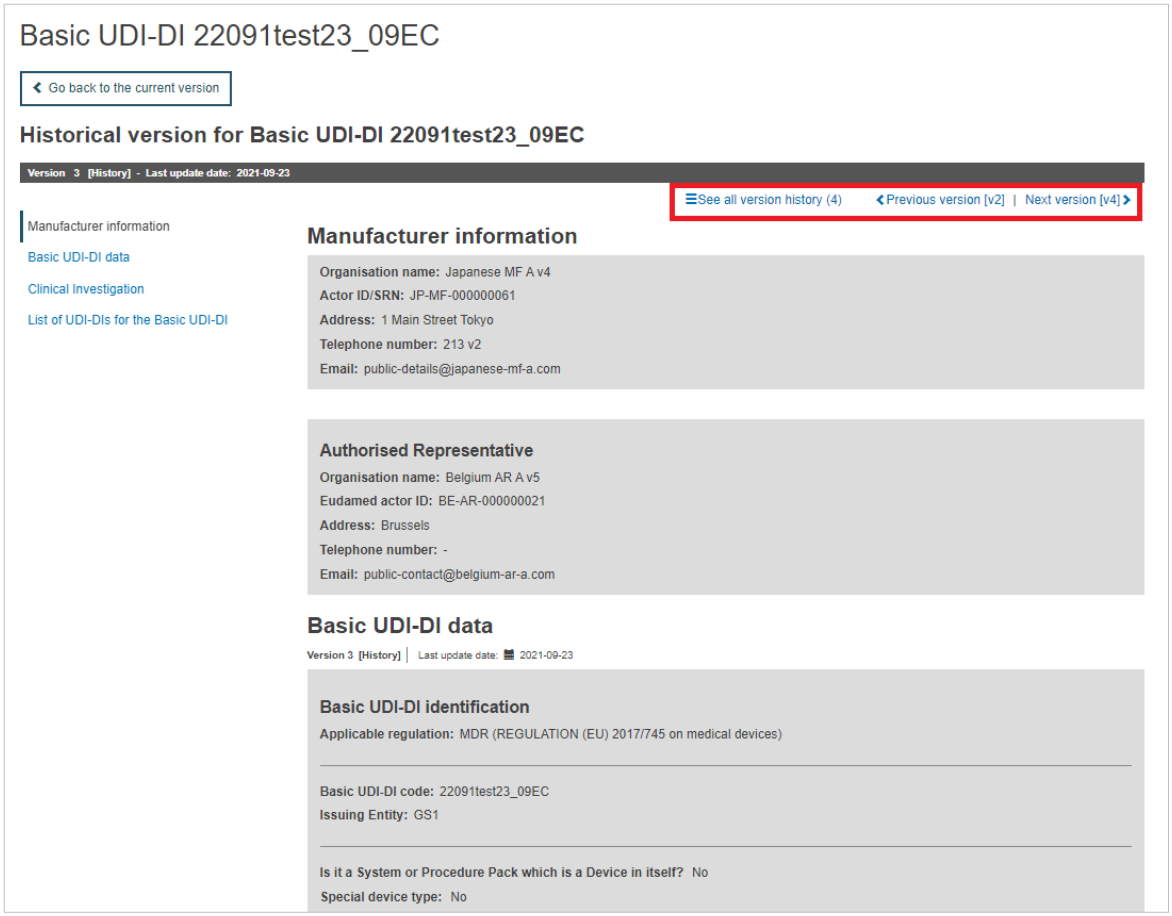
3. You will see a list of all old versions for the selected entity (we will continue the example presenting the version history of the Basic UDI-DI):



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



5. Inside a version, you can browse through the different versions by clicking on the arrows 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

9. Annex 1 – Device Certificate Information

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

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

Colour code description

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

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

10. Annex 2 – Legacy Device Certificate Types

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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