



EUDAMED user guide

UDI Devices

Production v 2.14.1
2024



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1 Introduction

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

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

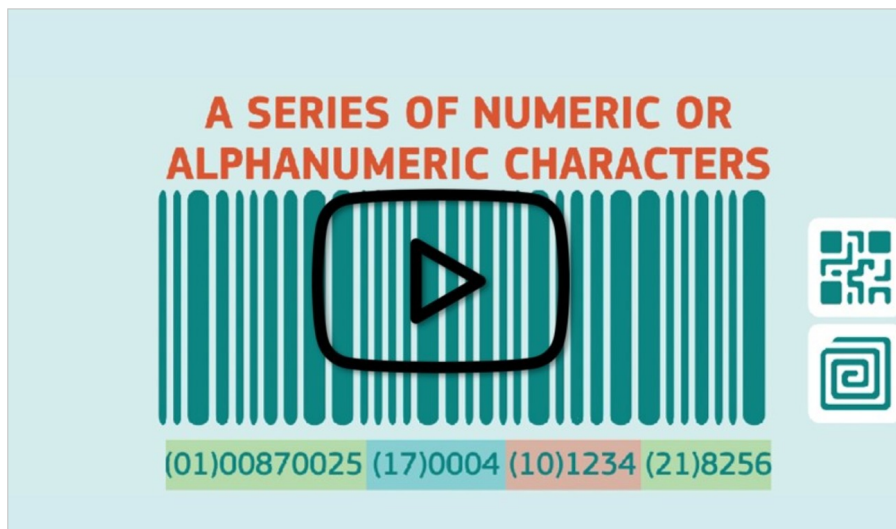


WARNING

EUDAMED does not contain all constraints defined in the MDR/IVDR, guidance and good practices, and therefore, it is not because something is possible in EUDAMED that it is necessarily allowed.



VIDEO: What is a UDI?



INFOGRAPHIC: Basic UDI-DI/UDI-ID concept

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

IDENTIFIERS

What are the different identifiers?

A **Regulation Device** and a **System/Procedure Pack** must have an assigned **Basic UDI-DI** and **UDI-DI**, and they must be registered in the 'UDI/Device module' (UDI database) of EUDAMED.

Basic UDI-DI

UDI-DI

Package UDI-DI
(If applicable)

2 Getting started

What I need to access EUDAMED:

1. EU Login (ECAS) account

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

2. User profile registration in EUDAMED

For information on how to gain access to EUDAMED, please consult the [Economic Operators user guide](#).



NOTE

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



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

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



NOTE

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

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



IMPORTANT

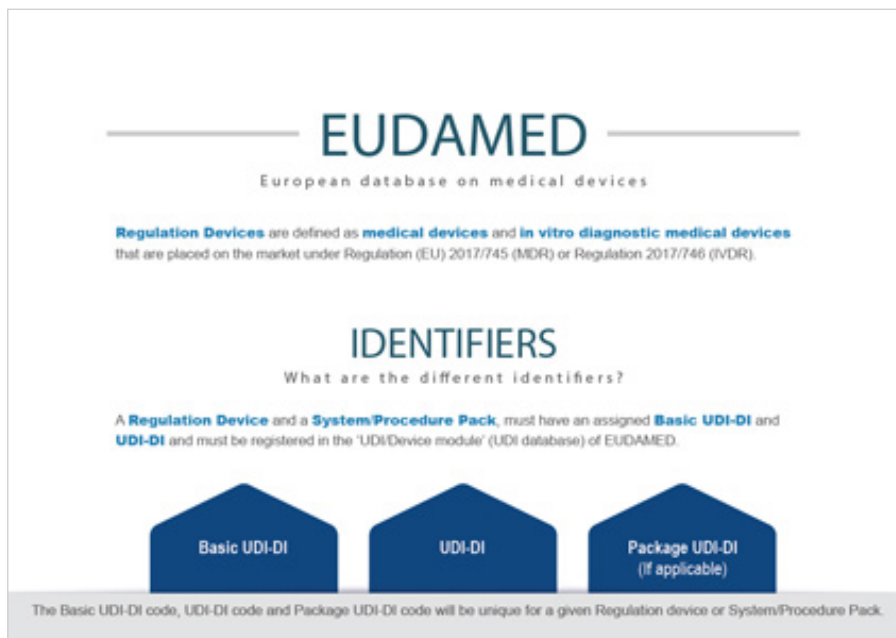
A Local Actor Administrator (LAA)/Local User Administrator (LUA) of your manufacturer must approve your user access request (If you don't have a second user with LAA/LUA profile, please refer to the [Economic Operators user guide](#), Section *Requesting access as a second LAA user to an existing registered actor*).

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



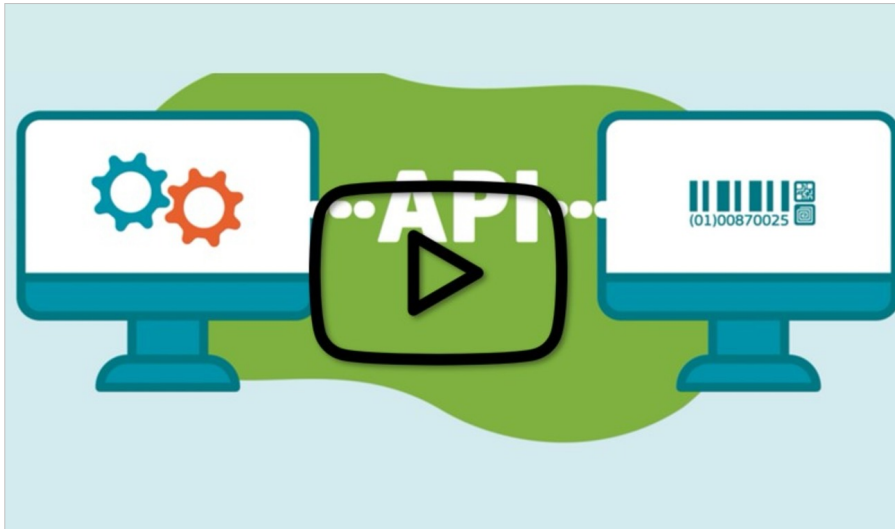
3.1 Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device

 **INFOGRAPHIC:** [Basic UDI-DI/UDI-ID concept](#)



3.1.1 Step 1: Basic UDI-DI identification information

VIDEO: UDI and medical software devices



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

Welcome to EUDAMED


MDR EUDAMED is the IT system developed by the European Commission to implement [Regulation \(EU\) 2017/745](#) on medical devices and [Regulation \(EU\) 2017/746](#) on in vitro diagnosis medical devices.

MDR EUDAMED is structured around 6 interconnected modules and a public site.

[See all the news](#)

Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

| My Actor data | UDI-DIs/Device | User management |
|--|---|--|
|  Manage your actor data Manage your email notifications | Register a new Basic UDI-DI Register a legacy device Manage your Basic UDI-DIs / EUDAMED DIs Manage your Devices details | Assess user access requests Manage your users |

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



NOTE

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

UDI-DI registration

Manufacturer identification

Organisation name: Test MF
Actor ID/SRN: LI-MF-000000104
Address: Oak St, 101 8088 Vaduz
Telephone number: +343 8987 65 13
Email: eudamed@manufacturer.com

*** Applicable regulation**

☐ MDR (REGULATION (EU) 2017/745 on medical devices)
☐ IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)

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

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

Is it a System or Procedure Pack which is a Device in itself?

Yes ☒ No ☐
 Is it a System or Procedure Pack which is a Device in itself is required unless you select the option - No

☐ Procedure Pack which is a Device in itself
☐ System which is a Device in itself

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

Special device type

Yes ☒ No ☐
 Special device type is required unless you select the option - No

*** Special device type:**

☐ Orthopedic
☐ Rigid Gas Permeable (RGP) & Made-to-Order Soft Contact Lenses
☐ Software
☐ Standard soft contact lenses

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

**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**:

Basic UDI-DI main information

* Issuing Entity:

* Basic UDI-DI code:

Save & Next >

**IMPORTANT**

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

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

4. Non-EU Manufacturers will have to select the authorised representative for the Basic UDI-DI amongst those with which they have an active mandate registered in EUDAMED.

If there is only one authorised representative with an active Mandate with the non-EU manufacturer, it will be automatically retrieved:

Authorised representative identification

Organisation name: Belgian AR A

Eudamed actor ID: BE-AR-000000046

Address: Rue E, 1 1060 Brussels

Telephone number: -

Email: contact@belgian-ar-a.be

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

Basic UDI-DI information

* Risk class:

* Measuring function

☐ Yes ☐ No

* Active device

☐ Yes ☐ No

* Device intended to administer and/or remove medicinal product

☐ Yes ☐ No

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

Device model applicable

Yes ☒ No ☐ Device model is required by default unless you select the option - No

* Device model:

Device Model_Test

Device Name:

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:

Save Save & Next >

3.1.2 Step 2: Certificate information (when applicable)

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

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

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

Additionally, more information on the certificate type could be required depending on the risk class and properties specified for the Basic UDI-DI. For the NB, enter some or all of

the NB name or number, click **Find** and choose the correct Notified Body from the new window.

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

**NOTE**


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

In [Annex 1 – Device Certificate Information \[90\]](#) you can find the different cases in which Certificate information is needed and the type of certificate. (In summary, it is applicable for MDR risk class III and IIb and IVDR risk class B with self-patient testing/ near-patient testing, risk class D and C).

Certificate information

EU type-examination certificate if applicable

Yes ☒ No ☐

 EU type-examination certificate is required unless you select the option - No

* Enter NB number or name:

Certificate number:

Revision number:

3.1.3 Step 3: UDI-DI identification information

VIDEO: UDI carrier and display formats



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

**IMPORTANT**

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

Exception: the same UDI-DI can be used for a Legacy Device and its Regulation Device equivalent.

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

**NOTE**

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

For example:

000000nnnnnnnnnn (GTIN-8)

00nnnnnnnnnnnnnn (GTIN-12)

0nnnnnnnnnnnnnnn (GTIN-13)

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

UDI-DI identification

UDI-DI identification

* Issuing Entity:

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

Yes ☒ No ☐ **i** UDI-DI from another entity is required unless you select the option - No

* Issuing Entity:

* Secondary UDI-DI value:

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

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Trade name applicable

Yes ☒ No ☐ **i** Trade name is required unless you select the option - No

* Trade name:

* Select the language:

+ [Add a trade name in another language](#)

5. Enter the *Reference/Catalogue number*.

* Reference/Catalogue number:

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

*** Is the device directly marked?**

☒ Yes ☐ No

☐ Same as UDI-DI

*** Issuing Entity:**

*** Direct marking DI:**

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

*** Is the device directly marked?**

☐ Yes ☒ No

*** Quantity of device:**

Issuing Entity:

Unit of Use DI:

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

*** Is the device directly marked?**

☐ Yes ☒ No

*** Quantity of device:**

*** Type of UDI-PI**

☐ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☐ Expiration date

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

*** Quantity of device:**

*** Type of UDI-PI**

☐ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☒ Expiration date

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

Additional product description:

Product Description

Select the language:

Bulgarian
Croatian
Czech
Danish
Dutch
English

+ Add additional product description in another language

URL for additional information (as electronic instructions for use):

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

* UDI-DI status

☐ No longer placed on the EU market

☒ Not intended for the EU market

☐ On the EU market

Save Save & Next >

3.1.4 Step 4: UDI-DI characteristics

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



NOTE

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

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

Clinical size applicable

Yes ☒ No ☐ *i* Clinical size is required unless you select the option - No

Select type(s) of dimension you need

* Type: Frequency

* Precision: Range

* Minimum: 50

* Maximum: 60

* Measure unit: hertz (Hz)

+ Add a type of dimension

You shall provide one of the following precision type:

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

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

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

When device is not labelled as single use you will be asked to provide the number of reuses if applicable:

- If the *Maximum number of reuses* is not applicable, then the device is considered as a non-Single Use Device and the device does not have a maximum number of reuses (infinite number of reuses)
- If value provided is ≥ 1 , the device is considered as a non-Single use Device having a limited number of reuses (the value provided)

The screenshot shows a form section titled '* Labelled as single use'. It contains two radio buttons: 'Yes' and 'No', with 'No' selected. Below this is a grey box titled 'Maximum number of reuses applicable'. Inside this box, there are two radio buttons: 'Yes' (selected) and 'No'. To the right of the 'No' button is an information icon and the text 'Maximum number of reuses is required unless you select the option - No'. Below the radio buttons is a paragraph of text: 'If applicable, should be understood to cover those devices where based on clinical evidence and as a result of the risk management process, a manufacturer has demonstrated a maximum number of reuses, which should not be surpassed. [MDCG 2018-1](#) provides further information.' Below this text is a label '* Maximum number of reuses:' followed by a text input field containing the number '2'.

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

The screenshot shows three form sections, each with a title and two radio buttons ('Yes' and 'No'). The first section is titled '* Need for sterilisation before use'. The second section is titled '* Device labelled as sterile'. The third section is titled '* Containing latex'.


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

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

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

☒ Yes ☐ No


*** Category of CMR:**
☒ 1A ☐ 1B

 At least one of these fields (EC# or CAS#) must be filled in.

EC#: CAS#:

[ECHA database >](#)

*** Name of the substance:**


 [Add a CMR substance](#)

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

☐ Yes ☐ No



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


Storage/handling conditions, if applicable


Yes ☒ No ☐  Storage/handling conditions are required unless you select the option - No

*** Storage/handling conditions type:**

*** Description:**

*** Select the language:**
  

 [Add storage/handling conditions in another language](#)

 [Add another storage/handling condition](#)

**NOTE**


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

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

Critical warnings or contra-indications, if applicable

Yes ☒ No ☐ Critical warning or contra-indications are required unless you select the option - No

* Critical warning type:

Caution: Contains of presence of... 

Defibrillation-proof type CF applied part

+ [Add critical warnings or contra-indications](#)

* Description:

Test

Save Save & Next >

**NOTE**

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

3.1.5 Step 5: Device information

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

Device information

* Reprocessed single use device

☐ Yes ☐ No

* Intended purpose other than medical (Annex XVI)

☐ Yes ☐ No

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

* Intended purpose other than medical (Annex XVI)

☒ Yes ☐ No

☒ Contact lenses

☒ Products intended to be totally or partially introduced in the human body

☐ Substances, combinations of substances, or items intended for filling by injection

☐ Equipment intended to be used to reduce, remove or destroy adipose tissue

☐ High intensity electromagnetic radiation

☐ Brain electrostimulation

- Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person.
If Yes, there are two different ways to find the *Product original manufacturer* of the device:


- Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRN or name of the *Product original manufacturer* of the device and click **Check registry**:

Is the device designed and manufactured by another legal or natural person?

Yes ☒ No ☐

☒ I know the Actor ID/SRN

* Enter Actor ID/SRN or name:

 Check registry

**NOTE**

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

Select the Actor from the list:

[✕Close](#)

Select manufacturer

| Actor ID/SRN ↕ | Organisation name ↕ |
|-----------------|-----------------------------|
| NL-MF-000000041 | Medical Device Manufacturer |
| AU-MF-000004268 | Trusted NonEUMF |
| AS-MF-000004249 | Non_EU_MF_R3.3_Shriya |
| BE-MF-000004247 | Bel_MF_R3.3_Shriya |
| US-MF-000003888 | The Americans |
| US-MF-000004107 | Ohio Pharmaceuticals |
| CO-MF-000004129 | Non_EU_MF_3.2_Shriya |
| BE-MF-000004128 | MF_BE_R3.2_Shriya |
| EL-MF-000004067 | VIANEX S.A. |
| AI-MF-000004047 | AR Aguilla Ionut 2nd |

← Previous
1
2
...
19
Next →

Close

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

Is the device designed and manufactured by another legal or natural person?

Yes ☒ No

☐ I know the Actor ID/SRN

* Product original manufacturer organisation name:

[Check registry](#)

Select the Organisation name from the list:

[Close](#)

Select manufacturer

Organisation name ↑

- PDasOrg (3)
- PDasOrg (2)
- MANUF-1(1)


i Select the relevant result above. If there are no results or they are not applicable, please select the option 'Enter data manually'

[Enter data manually](#) [Cancel](#)

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

[Change manufacturer](#)

* Name (Manufacturer Name):



Street information, if applicable
 Yes ☒ No ☐  Street information is required unless you select the option - No

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:


* Country:  



Telephone:


Telephone format example: +32 x xxx xx xx

* Email:

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

Clinical Investigation
 Yes ☒ No ☐  Clinical Investigation is required unless you select the option - No

 Clinical Investigation '212121' is not registered in EUDAMED 

* Enter Clinical Investigation Number: 

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

☐ Yes ☒ No

Presence of animal tissues or cells, or their derivatives:

☐ Yes ☒ No

*** Information on substances**

Presence of a substance which, if used separately, may be considered to be a medicinal product:

☐ Yes ☐ No

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:

☐ Yes ☐ No

* Member State where the Device is to or has been first placed on the EU market:

-- ▾

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

*** Information on substances**

Presence of a substance which, if used separately, may be considered to be a medicinal product:

☒ Yes ☐ No

INN:

* Name of the substance:

* Select the language: -- ▾

+ [Add another language](#)

+ [Add a substance](#)

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:

☐ Yes ☒ No

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

☐ Yes ☐ No


Presence of animal tissues or cells, or their derivatives:

☐ Yes ☐ No

Presence of cells or substances of microbial origin:

☐ Yes ☐ No

*** 'New' Device**

☐ Yes ☐ No 

**NOTE**

A device shall be considered *new* if:

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

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

* Member State where the Device is to or has been first placed on the EU market:

France ▼

Member States where the device is or is to be made available on the market:

| | | | | | | | |
|---------|------|----------------------|--|----|----------------------|--|--|
| Finland | From | <input type="text"/> | | To | <input type="text"/> | | |
| | | YYYY-MM-DD | | | YYYY-MM-DD | | |
| France | From | <input type="text"/> | | To | <input type="text"/> | | |
| | | YYYY-MM-DD | | | YYYY-MM-DD | | |

[Select one or more countries >](#)

**NOTE**

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

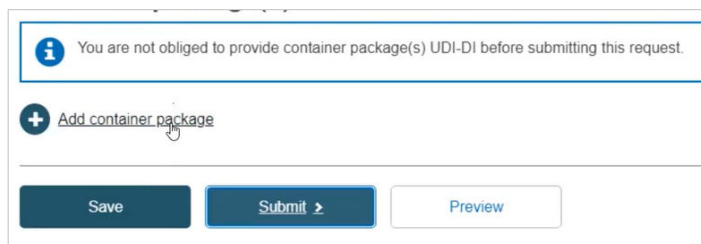
3.1.6 Step 6: Container package details



VIDEO: UDI carrier placing



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



You are not obliged to provide container package(s) UDI-DI before submitting this request.

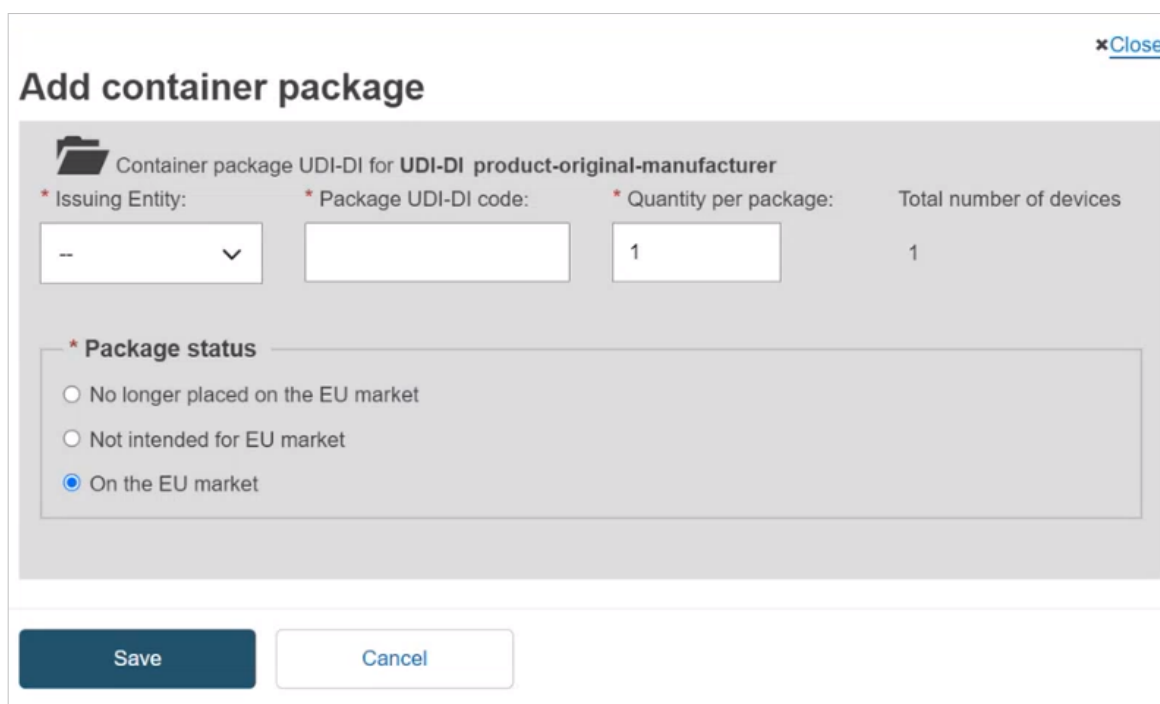
[+ Add container package](#)

[Save](#) [Submit](#) [Preview](#)

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

**NOTE**

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



[*Close](#)

Add container package

Container package UDI-DI for UDI-DI product-original-manufacturer

| * Issuing Entity: | * Package UDI-DI code: | * Quantity per package: | Total number of devices |
|--------------------------------|------------------------|--------------------------------|-------------------------|
| <input type="text" value="-"/> | <input type="text"/> | <input type="text" value="1"/> | 1 |

* Package status

☐ No longer placed on the EU market
☐ Not intended for EU market
☒ On the EU market

[Save](#) [Cancel](#)

**NOTE**

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

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

Container package(s)

 You are not obliged to provide container package(s) UDI-DI before submitting this request.

[+ Add container package](#) [✎ Edit container package](#) [🗑 Delete container package](#)

☐ [Root] UDI-DI: product-original-manufacturer (ICCBBA) | Status: On the EU market

☒ UDI-DI: boxxx-6 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market

Save


Submit >

Preview


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

Submission

Are you sure you want to submit your UDI-DI registration request?

**Status of your request**

Your request has been saved and is ready to be submitted.

**Outcome by email**


The outcome of the examination will be communicated to the email address provided. Meanwhile, you may view your data and the progress of the examination by visiting "See my pending requests" in your EUDAMED account.

Submit my request

Cancel

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

Basic UDI-DI registration

 Congratulations. You have successfully submitted your Basic UDI-DI registration request.

What do you want to do now?

[Enter another UDI-DI associated to Basic UDI-DI 1212123333333345HG](#)
[Register new Basic UDI-DI](#)
[Go to the dashboard](#)

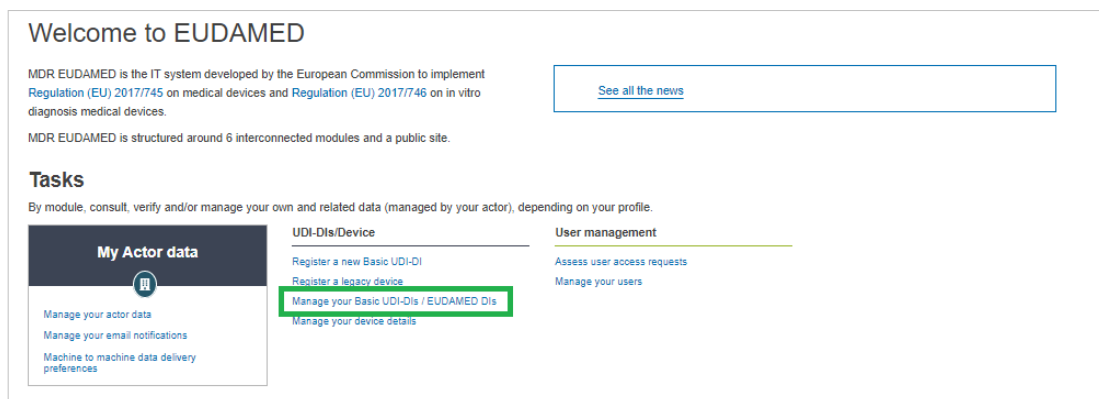
**IMPORTANT**

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

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

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

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



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

**IMPORTANT**

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

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

Basic UDI-DIs / EUDAMED DIs management

[Go to Device details management](#) [Register a new Basic UDI-DI](#) [Register Legacy Device](#)

Filter

Applicable regulation: -- Risk class: -- State: Registered

Device type: You can select more than one value Basic UDI-DI/EUDAMED DI Code: SRN AR:

Apply filters Clear all filters

Active filters: State: Draft Clear all filters

Showing 1 to 12 of 12 entries Show 20 entries per page

| Basic UDI-DI/EUDAMED DI Code | Devices | Device model | Device Name | Risk class | Date | State | Actions |
|------------------------------|---------|----------------|---------------|------------|------------|-----------|---------|
| 122111212121Y2 | 1 | | Test | Class IIa | 2021-03-31 | 1st Draft | ... |
| 111184FG4G228694YC | 1 | DeviceModelZZZ | DeviceNameZZZ | Class IIb | 2021-03-19 | 1st Draft | ... |

- 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*:

Basic UDI-DIs / EUDAMED DIs management

[Go to Device details management](#) [Register a new Basic UDI-DI](#) [Register Legacy Device](#)

Filter

Active filters: State: Registered Clear all filters

Showing 1 to 20 of 21 entries Show 20 entries per page

| Basic UDI-DI/EUDAMED DI Code | Devices | Device model | Device Name | Risk class | Date | State | Actions |
|------------------------------|---------|--------------|-----------------|------------|------------|--|---------|
| 1234503276 | 1 | Model OP | | Class IIb | 2021-03-30 | Registered | ... |
| 1234503072 | 1 | Model 88 | | Class IIb | 2021-03-30 | View Data | ... |
| 1234501VP | 1 | Model 1 | Name 1A | Class III | 2021-03-30 | View all UDI-DIs for this Basic UDI-DI | ... |
| B-555908900698 | 1 | MyModel111 | MyDeviceName111 | Class I | 2021-03-30 | + Add a UDI-DI to this Basic UDI-DI | ... |
| 1234500VM | 1 | Model 550 | | Class IIa | 2021-03-08 | Registered | ... |
| 123450046Z | 2 | Model 9 | | Class IIb | 2021-03-08 | Registered | ... |
| B-2203615490541 | 1 | Model abc | Name abc | Class IIa | 2021-03-04 | Registered | ... |

- Complete the series of steps required for the registration of a UDI-DI for an existing Basic UDI-DI (*Step 3: UDI-DI identification information* [12], *Step 4: UDI-DI Characteristics* [15], *Step 5: Device information* [18], *Step 6: Container Package Details* [23]):

Add new UDI-DI to existing Basic UDI

Manufacturer identification

[BE-MF-000000004, Alexandru Release Manufacturer](#)

Basic UDI-DI identification

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

Basic UDI-DI code: 1234503276

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself?

No

Special device type: No

1 UDI-DI identification information

2 UDI-DI characteristics

3 Device information

4 Container package(s)

UDI-DI identification

UDI-DI identification

* Issuing Entity:

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

Yes ☒ No ☐

UDI-DI from another entity is required unless you select the option - No


* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)


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

Submission [Close](#)

Are you sure you want to submit your UDI-DI registration request?

 **Status of your request**

Your request has been saved and is ready to be submitted.

 **Outcome by email**

After submission, the Regulation device will have the state Registered, being available also on the EUDAMED Public website. You may view your data by visiting "Manage your Basic UDIs/EUDAMED IDs" and "Manage your device details" page.

Submit my request **Cancel**



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*.

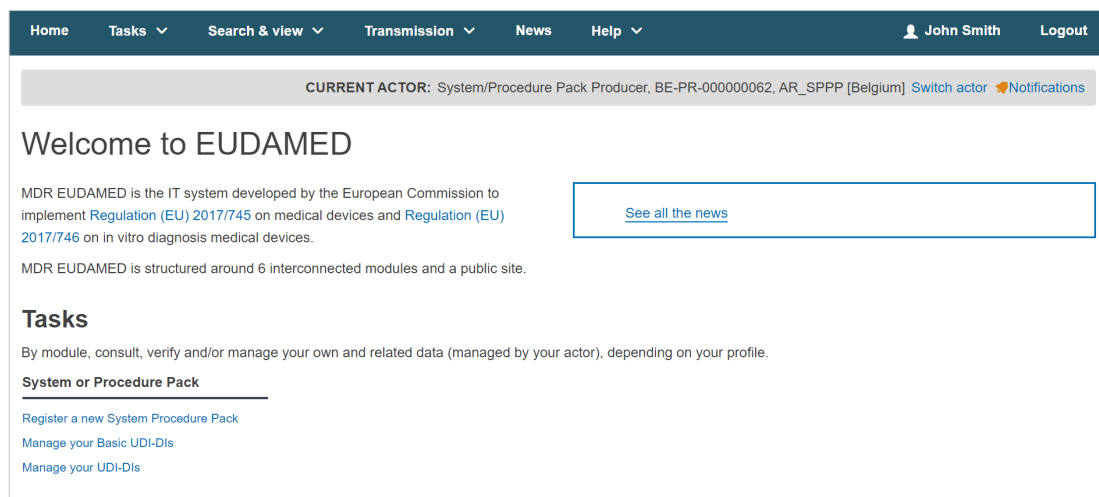
4 Registering System or Procedure Packs (SPP)

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

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

4.1.1 Step 1: Basic UDI-DI main information

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



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

System or Procedure Pack registration

Procedure pack producer identification

| | |
|--------------------|-----------------|
| Organisation name: | AR_SPPP |
| SRN: | BE-PR-000000062 |
| Address: | 8606 Brussels |
| Telephone number: | - |
| Email: | ar_sppp@abc.com |

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

Basic UDI-DI main information

* Issuing Entity:

--

* Basic UDI-DI code:

* System or Procedure Pack type:

☐ Procedure Pack
☐ System

Save & Next >



NOTE

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



IMPORTANT

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

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

System or Procedure Pack registration

Procedure pack producer identification

| | |
|--------------------|--------------------------|
| Organisation name: | Health Pac |
| Actor ID/SRN: | LI-PR-000000062 |
| Address: | Oak St, 101 8008 Vallet |
| Telephone number: | +34388876513 |
| Email: | eudamed@manufacturer.com |

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

Basic UDI-DI main information

* Issuing Entity:

GSI

* Basic UDI-DI code:

123457528F

Duplicate device identified

- 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:

*** System or Procedure Pack type:**

☐ Procedure Pack

☐ System

Save & Next >

4.1.2 Step 2: Basic UDI-DI information

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

System or Procedure Pack registration

1 Basic UDI-DI information **2** UDI-DI identification information **3** UDI-DI characteristics **4** Container package(s)

Producer identification
BE-PR-000000062_AR_SPPP

Basic UDI-DI identification
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Basic UDI-DI code: 1212112121212DL
Issuing Entity: GS1
System or Procedure Pack type: Procedure Pack

Basic UDI-DI information

* Risk class:
--

* Indication of medical purpose:
[Text area for medical purpose]

* Select the language:
--

+ Add another indication of medical purpose

Device model applicable
Yes ☒ No ☐ Device model is required by default unless you select the option - No

* Model:
[Text input for model]

Name:
[Text input for name]

Save **Save & Next >**

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

Producer identification
BE-PR-000000062_AR_SPPP

Basic UDI-DI identification
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Basic UDI-DI code: 1212112121212DL

Basic UDI-DI information

* Risk class:
--

* Indication of medical purpose:
[Text area for medical purpose]

* Select the language:
[Drop-down list for language]

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

2017/745 on medical devices)

Basic UDI-DI code: 1212112121212DL
Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

* Indication of medical purpose:

* Select the language:

+ Add another indication of medical purpose

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

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

Device model applicable

Yes ☒ No ☐ Device model is required by default unless you select the option - No

* Model:

- 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:

Save Save & Next >

4.1.3 Step 3: UDI-DI identification information

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

UDI-DI identification

* Issuing Entity: GS1

* UDI-DI code:



IMPORTANT

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

**NOTE**

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

For example:

- **000000nnnnnnnnn (GTIN-8)**
- **00nnnnnnnnnnnnnn (GTIN-12)**
- **0nnnnnnnnnnnnnnn (GTIN-13)**

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

UDI-DI identification

UDI-DI identification

* Issuing Entity:

GS1

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

Yes ☒ No ☐

UDI-DI from another entity is required unless you select the option - No

* Issuing Entity:

--

* Secondary UDI-DI value:

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


* Enter the nomenclature code (EMDN code):

Find


[Advanced search of device nomenclature](#)


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

Trade name applicable

Yes ☒ No ☐  Trade name is required unless you select the option - No

* Trade name:

* Select the language: 

 [Add a trade name in another language](#)

5. Enter the *Reference/Catalogue number*:

* Reference/Catalogue number:

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

* **Type of UDI-PI**

☐ Lot or Batch number


☐ Serial number

☐ Manufacturing date


☒ Expiration date

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

Additional product description:

 [Add additional product description in another language](#)

Select the language:



- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English

URL for additional information (as electronic instructions for use):

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

*** UDI-DI status**

☐ No longer placed on the EU market
☒ Not intended for the EU market
☐ On the EU market

4.1.4 Step 4: UDI-DI characteristics

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

UDI-DI characteristics

*** Need for sterilisation before use**

☐ Yes ☐ No

*** Device labelled as sterile**

☐ Yes ☐ No

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

Storage/handling conditions, if applicable

Yes ☒ No ☐
Storage/handling conditions are required unless you select the option - No

*** Storage/handling conditions type:**

OTHER *

*** Description:**

Test

*** Select the language:**

—

[+ Add storage/handling conditions in another language](#)
[+ Add another storage/handling condition](#)



NOTE

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

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

Critical warnings or contra-indications, if applicable

Yes ☒ No ☐ Critical warning or contra-indications are required unless you select the option - No

* Critical warning type:

Caution: Contains of presence of...
Defibrillation-proof type CF applied part

* Description: Test

+ [Add critical warnings or contra-indications](#)

Save Save & Next >

**NOTE**

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

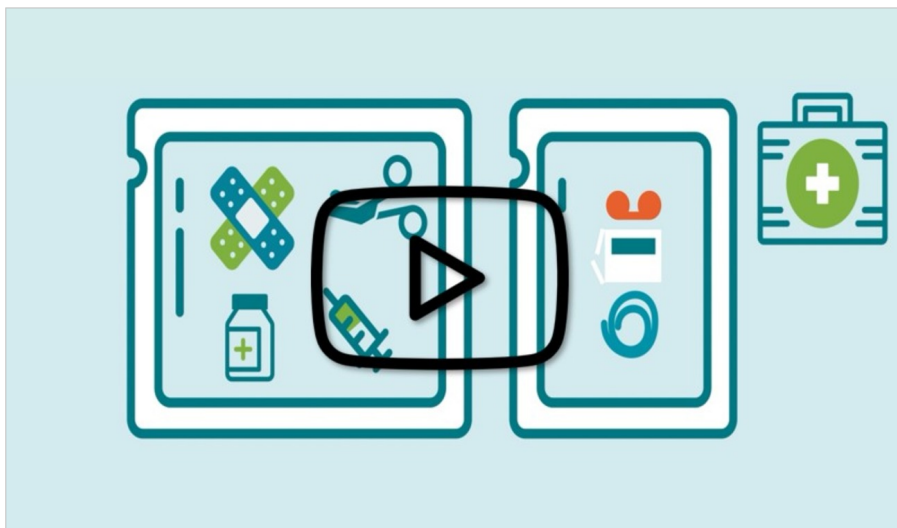
- Click on **Save** to save draft and finish later or **Save & Next** to move directly to the next step of the process:

Save Save & Next >

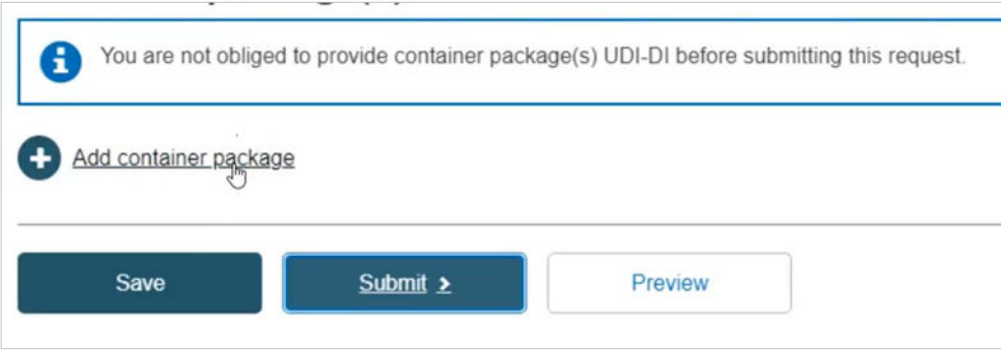
4.1.5 Step 5: Container package details



VIDEO: UDI and Systems and Procedure Packs



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



i You are not obliged to provide container package(s) UDI-DI before submitting this request.

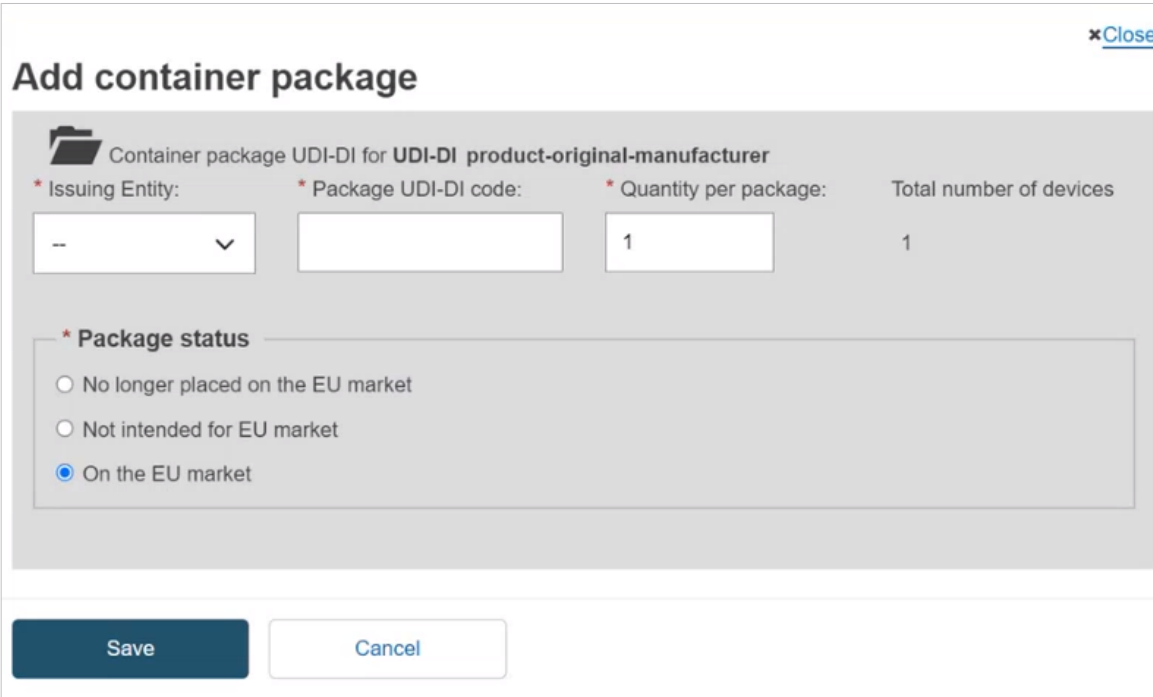
+ [Add container package](#)

Save **Submit >** [Preview](#)

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

**NOTE**

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



Add container package [xClose](#)

Container package UDI-DI for UDI-DI product-original-manufacturer

| * Issuing Entity: | * Package UDI-DI code: | * Quantity per package: | Total number of devices |
|-------------------|------------------------|-------------------------|-------------------------|
| - v | | 1 | 1 |

*** Package status**

☐ No longer placed on the EU market
☐ Not intended for EU market
☒ On the EU market


Save **Cancel**




**NOTE**

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

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

Container package(s)

 You are not obliged to provide container package(s) UDI-DI before submitting this request.

 [Add container package](#)
 [Edit container package](#)
 [Delete container package](#)


- ☐ [Root] UDI-DI: product-original-manufacturer (ICCBBA) | Status: On the EU market

☒ UDI-DI: boxxx-6 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market

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

Submission ✕Close


Are you sure you want to submit your UDI-DI registration request?

 **Status of your request**

After submission, the System or Procedure Pack will have the state Registered, being available also on the EUDAMED Public website. You may view your data by visiting "Manage your Basic UDI-DIs" and "Manage your UDI-DIs" page

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

Registration of System or Procedure Pack

 Congratulations. You have successfully submitted your System or Procedure Pack registration request.

What do you want to do now?

[Register new System or Procedure Pack](#)
[Go to the dashboard](#)

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

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

Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

My Actor data

Manage your actor data

Manage your email notifications

Machine to machine data delivery preferences

User management

Assess user access requests

Manage your users

System or Procedure Pack

Register a new System Procedure Pack

Manage your Basic UDI-DIs

Manage your UDI-DIs

- 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**:

Basic UDI-DI management for SPP

Go to device management Register new System or Procedure Pack

Filter

Basic UDI-DI code Name State

Risk class System or Procedure Pack

Apply filters **Clear all filters**

State dropdown menu: Draft, Discarded, **Draft**, Registered, Submitted

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

- 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:

| Basic UDI-DI code | UDI-DI(s) | Device model | Device Name | Risk class | Type | Date | State | Actions |
|---------------------|-----------|--------------|-------------|------------|------|------------|------------|--|
| 12121121212DL | 1 | - | Device Name | Class IIa | PP | 2021-06-10 | Registered | ... |
| 12345KT-Devices-3BY | 1 | - | test | Class I | PP | 2021-05-2 | | View Data |
| 223311445578899583F | 1 | SPP_Model | | Class I | S | 2021-04-0 | | View all UDI-DIs for this Basic UDI-DI |

Add a UDI-DI for a Basic UDI-DI

4.2.1 Step 1: UDI-DI identification information

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

1

UDI-DI identification information

2

UDI-DI characteristics

3

Container package(s)

UDI-DI identification

UDI-DI identification

* Issuing Entity:

HIBCC

* UDI-DI code:

121212

UDI-DI from another entity (secondary) applicable

Yes ☒ No ☐

i

UDI-DI from another entity is required unless you select the option - No

* Enter a nomenclature code (EMDN code):

Find

[Advanced search of device nomenclature](#)

Selected nomenclature codes

Code A01010101 HYPODERMIC NEEDLES FOR SYRINGE

Remove nomenclature code

Trade name applicable

Yes ☒ No ☐

i

Trade name is required unless you select the option - No

* Trade name:

Trade_Name

* Select the language:

Croatian

+ Add a trade name in another language

* Reference/Catalogue number:

Ref_12134

REF_TEST

Ref_12134

☐ Manufacturing date

☐ Expiration date

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

Save

Save & Next

4.2.2 Step 2: UDI-DI characteristics

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

UDI-DI characteristics

*** Need for sterilisation before use**

☐ Yes ☒ No

*** Device labelled as sterile**

☐ Yes ☒ No

Storage/handling conditions, if applicable

Yes ☒ No Storage/handling conditions are required unless you select the option - No

Critical warnings or contra-indications, if applicable

Yes ☒ No Critical warning or contra-indications are required unless you select the option - No

*** Critical warning type:**

Description

[Add critical warnings or contra-indications](#)

Save

Save & Next >

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

4.2.3 Step 3: Container package details

To complete this step, please consult [Container Package Details \[36\]](#) of this guide.

5 Manage your own device information

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

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

The screenshot shows the EUDAMED dashboard for a manufacturer. At the top, it says 'Welcome to EUDAMED' and provides information about the system. Below this, there are two main sections: 'My Actor data' and 'Tasks'. The 'Tasks' section is divided into 'User management' and 'UDI-DIs/Device'. Under 'UDI-DIs/Device', there are links for 'Register a new Basic UDI-DI', 'Register a legacy device', 'Manage your Basic UDI-DIs / EUDAMED DIs', and 'Manage your device details'. The 'Manage your Basic UDI-DIs / EUDAMED DIs' link is highlighted with a mouse cursor.

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



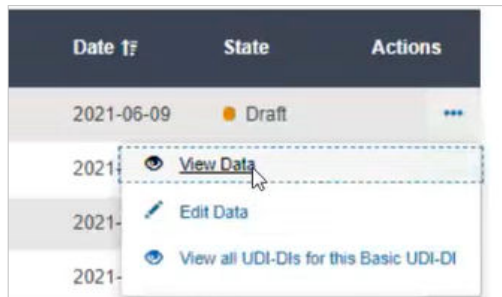
NOTE

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

The screenshot shows the 'Basic UDI-DIs / EUDAMED DIs management' page. It has a header with a 'Go to Device details management' link and two buttons: 'Register a new Basic UDI-DI' and 'Register Legacy Device'. Below the header, there is a 'Filter' dropdown and 'Active filters' showing 'State: Draft' and a 'Clear all filters' link. The page indicates 'Showing 1 to 9 of 9 entries' and a 'Show 20 entries per page' dropdown. The main content is a table with the following columns: Basic UDI-DI/EUDAMED DI Code, Devices, Device model, Device Name, Risk class, Date, State, and Actions.

| Basic UDI-DI/EUDAMED DI Code | Devices | Device model | Device Name | Risk class | Date | State | Actions |
|------------------------------|---------|--------------------------------|-------------|------------|------------|-----------|---------|
| B-12121EL | 1 | | Test | Class IIb | 2021-04-01 | 1st Draft | ... |
| 1212112121U5 | 1 | | Test | Class IIa | 2021-04-01 | 1st Draft | ... |
| 1211421211211EW | 1 | | Device Name | Class IIa | 2021-04-01 | Draft | ... |
| 312121211212133383 | 2 | Device Model_Test_CLASS IIa_v3 | Device Name | Class IIa | 2021-03-16 | Draft | ... |
| 1212123333333343HC | 1 | | test | Class I | 2021-02-15 | 1st Draft | ... |
| 12345ABCBY | 1 | | test | Class I | 2021-02-05 | 1st Draft | ... |

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



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

Basic UDI-DI 1211421211211EW

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data UDI-DI(s) (1)

Basic UDI-DI data

[Clinical Investigation](#)

[Certificates](#)

Basic UDI-DI data Create new version

Version 1 [Current] | Last update date: 2021-03-23

Basic UDI-DI identification

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

Basic UDI-DI code: 1211421211211EW

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself? No

Special device type: No

| | |
|--|-------------|
| Risk class: | Class IIa |
| Implantable: | No |
| Measuring function: | No |
| Reusable surgical instruments: | No |
| Active device: | No |
| Device intended to administer and/or remove medicinal product: | No |
| Name: | Device Name |

5.1.1 Delete a draft Basic UDI-DI/EUDAMED DI

After following steps 1, 2 and 3 from [Manage your device Basic UDI-DI/EUDAMED DI details \[42\]](#) to view a Draft Basic UDI-DI/EUDAMED DI in state *1st draft*, you have the option to delete this draft.

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

Basic UDI-DI data Edit Delete

Version 4 [Draft] | See version history | Last update date: 2021-06-09

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

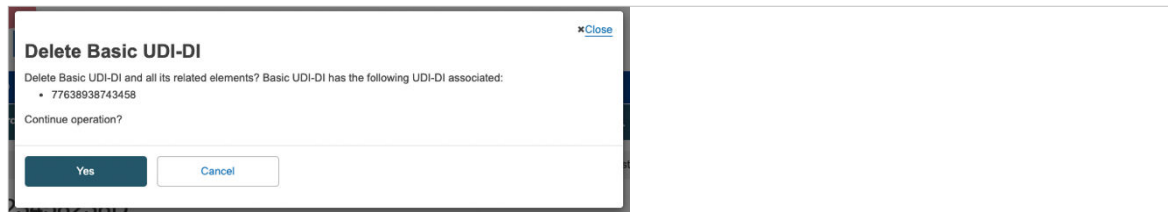
Basic UDI-DI code: 12345-test-udi-1-HL

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself?: Procedure Pack which is a device in itself

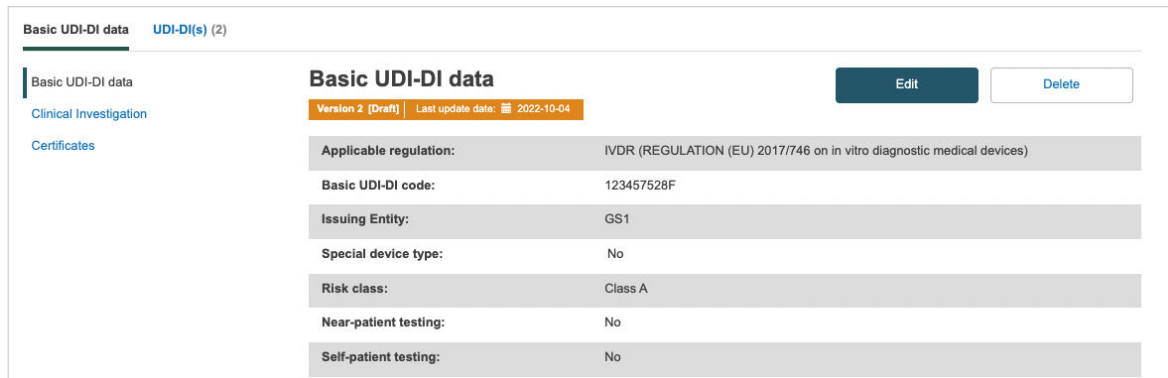
Risk class: Class IIb

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

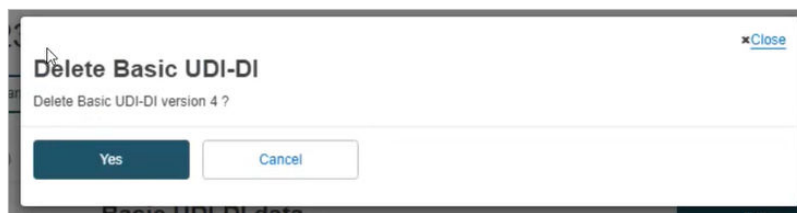


The system also warns about deletion of the UDIs under the *1st draft* device.

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



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



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

Follow the steps in section [Manage your device Basic UDI-DI/EUDAMED DI details \[42\]](#) to view a Basic UDI-DI/EUDAMED DI.

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

Basic UDI-DI 1211421211211EW

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data **UDI-DI(s) (1)**

Basic UDI-DI data
[Clinical Investigation](#)
[Certificates](#)

Basic UDI-DI data [Create new version](#)

Version 1 [Current] | Last update date: 2021-03-23

Basic UDI-DI identification

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

Basic UDI-DI code: 1211421211211EW
 Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself? No
 Special device type: No

| | |
|--|-------------|
| Risk class: | Class IIa |
| Implantable: | No |
| Measuring function: | No |
| Reusable surgical instruments: | No |
| Active device: | No |
| Device intended to administer and/or remove medicinal product: | No |
| Name: | Device Name |

2. Update the desired details:

12345-test-udi-1-HL [version: 4]

Create a new version of 12345-test-udi-1-HL

| | |
|--|-----------|
| Risk class: | Class IIb |
| Implantable: | No |
| Measuring function: | Yes |
| Reusable surgical instruments: | No |
| Active device: | No |
| Device intended to administer and/or remove medicinal product: | No |

Device model applicable
 Yes ☒ No ☐ [Device model applicable](#)

* Device Name:

| | |
|--|-----|
| Presence of human tissues or cells, or their derivatives: | Yes |
| Presence of animal tissues or cells, or their derivatives: | No |

[Save](#) [Submit new version](#) [Cancel](#)

3. To complete the action:

a. Click on **Save** to save to your registration as a draft and continue at a later point.

[Save](#) [Submit new version](#) [Cancel](#)

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

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

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

Follow the steps in section [Manage your device Basic UDI-DI/EUDAMED DI details \[42\]](#) to view a Basic UDI-DI/EUDAMED DI.

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

Basic UDI-DI data

Version 4 [Current] | [See version history](#) | Last update date: 2021-06-10

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

Basic UDI-DI code: 12345-test-udi-1-HL

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself?: Procedure Pack which is a device in itself

[Create new version](#)

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

Basic UDI-DI 12345-test-udi-1-HL

[Go back to the current version](#)

Version history of Basic UDI-DI 12345-test-udi-1-HL

Version 3 - Last update date: 2021-06-09 >

Version 2 - Last update date: 2021-06-09 >

Version 1 - Last update date: 2021-05-03 >

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

[Go back to the current version](#)

Version history of Basic UDI-DI 12345-test-udi-1-HL

Version 2 - Last update date: 2021-06-09

Basic UDI-DI identification

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

Basic UDI-DI code: 12345-test-udi-1-HL

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself? Procedure Pack which is a device in itself

Risk class: Class IIb

Implantable: No

[See all version history \(3\)](#) [Previous version \[v1\]](#) [Next version \[v3\]](#)

5.2 Manage your device UDI-DI/EUDAMED ID details

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

Welcome to EUDAMED

MDR EUDAMED is the IT system developed by the European Commission to implement [Regulation \(EU\) 2017/745](#) on medical devices and [Regulation \(EU\) 2017/746](#) on in vitro diagnosis medical devices.

MDR EUDAMED is structured around 6 interconnected modules and a public site.

[See all the news](#)

Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

My Actor data

- Manage your actor data
- Manage your email notifications
- Machine to machine data delivery preferences

UDI-DIs/Device

- Register a new Basic UDI-DI
- Register a legacy device
- Manage your Basic UDI-DIs / EUDAMED DIs
- Manage your device details**

User management

- Assess user access requests
- Manage your users

Search & View

Overview of modules allowing you to search and view details, depending on your profile

Actors

UDI-DIs/Devices

Certificates

2. You will see a list:

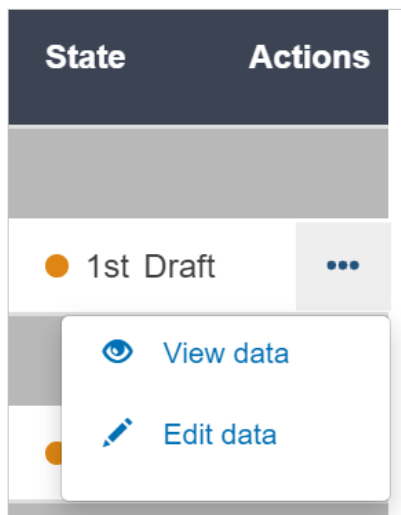
Showing 1 to 20 of 30 entries Show 20 entries per page

| UDI-DI/EUDAMED ID Code II | Trade name II | Reference/Catalogue number II | Nomenclature code II | Date f† | Status | State | Actions |
|---|---------------|-------------------------------|----------------------|------------|------------------|-------------|--------------------|
| ▼ EUDAMED DI code: B-435345PL, Device Name: dsfdafd, Class IIb, MDD (Directive 93/42/EEC on Medical Devices) | | | | | | | |
| D-435345PL | | | | 2021-03-29 | On the EU market | ● 1st Draft | ... |
| ▼ EUDAMED DI code: B-20001E6, Device Name: NameOfDevice2020201, Class IIb, MDD (Directive 93/42/EEC on Medical Devices) | | | | | | | |
| D-20001E6 | | CatalogueNumber1001010 | | 2021-03-26 | On the EU market | ● 1st Draft | ... |
| ▼ EUDAMED DI code: B-12335671, Device Name: 12335671, Class IIb, MDD (Directive 93/42/EEC on Medical Devices) | | | | | | | |
| 12335671 | | 12335671 | | 2021-03-24 | On the EU market | ● 1st Draft | ... |
| ▼ Basic UDI-DI code: 2021032320U7, Device Name: NameD123, Class I, MDR (REGULATION (EU) 2017/745 on medical devices) | | | | | | | |
| | | | | | | | + Add a new UDI-DI |

**NOTE**

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

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

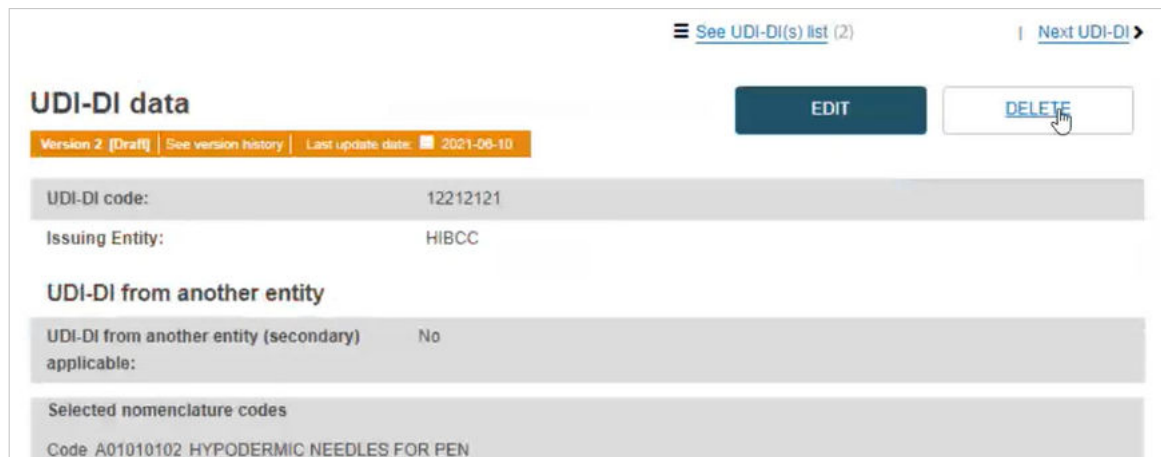


- You will see a summary of the details of your device:

5.2.1 Delete a draft UDI-DI/EUDAMED ID

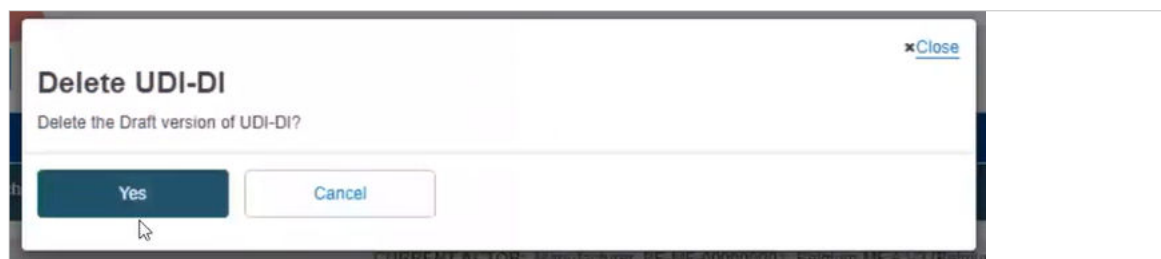
Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a draft UDI-DI.

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



The screenshot shows the 'UDI-DI data' page. At the top right, there is a link 'See UDI-DI(s) list (2)' and a 'Next UDI-DI' button. Below the title, there are buttons for 'EDIT' and 'DELETE'. A status bar indicates 'Version 2 [Draft]', 'See version history', and 'Last update date: 2021-06-10'. The main data fields are: 'UDI-DI code: 12212121', 'Issuing Entity: HIBCC', 'UDI-DI from another entity' section with 'UDI-DI from another entity (secondary) applicable: No', and 'Selected nomenclature codes' with 'Code A01010102 HYPODERMIC NEEDLES FOR PEN'. A mouse cursor is pointing at the 'DELETE' button.

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



The screenshot shows a 'Delete UDI-DI' confirmation dialog. The title is 'Delete UDI-DI' and the text says 'Delete the Draft version of UDI-DI?'. There are two buttons: 'Yes' and 'Cancel'. A mouse cursor is pointing at the 'Yes' button. A 'Close' button is in the top right corner.

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

 **VIDEO: UDI assignment and updates**



Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

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

The screenshot shows the EUDAMED UDI-DI details page. At the top right, there are links for 'See UDI-DI(s) list (2)' and 'Next UDI-DI >'. Below these, there are two buttons: 'Discard' and 'Create new version'. The 'Create new version' button is highlighted with a mouse cursor. The main section is titled 'UDI-DI data' and shows 'Version 1 [Current]' and 'Last update date: 2021-05-10'. The 'UDI-DI code' is '12212121' and the 'Issuing Entity' is 'HIBCC'. Below this, there is a section titled 'UDI-DI from another entity' with a toggle for 'UDI-DI from another entity (secondary) applicable' set to 'No'. The 'Selected nomenclature codes' section shows 'Code A01010102 HYPODERMIC NEEDLES FOR PEN'. Below this, there is a section for 'UDI-DI from another entity (secondary) applicable' with a toggle set to 'No' and an information icon. The next section is for 'Enter a nomenclature code (EMDN code)' with a search bar containing 'B' and 'I', a 'Find' button, and a dropdown menu showing '801' and 'clature'. Below this, there is a section for 'Trade name applicable' with a toggle set to 'Yes' and an information icon. The 'Trade name' field contains 'Trade_Name' and the 'Select the language' dropdown is set to 'All languages'. At the bottom, there is a link to 'Add a trade name in another language'.

See UDI-DI(s) list (2) | Next UDI-DI >

UDI-DI data

Version 1 [Current] | Last update date: 2021-05-10

UDI-DI code: 12212121

Issuing Entity: HIBCC

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable: No

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

UDI-DI from another entity (secondary) applicable

Yes ☐ No ☒ *UDI-DI from another entity is required unless you select the option - No*

* Enter a nomenclature code (EMDN code):

B I

801 clature

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

Trade name applicable

Yes ☒ No ☐ *Trade name is required unless you select the option - No*

* Trade name: Trade_Name

* Select the language: All languages

+ [Add a trade name in another language](#)

*** Is the device directly marked?**

☒ Yes ☐ No

☐ Same as UDI-DI

*** Issuing Entity:**

*** Direct marking DI:**

Quantity of device: 1

*** Type of UDI-PI**

☒ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☐ Expiration date

Additional product description:

Select the language:

[+ Add additional product description in another language](#)

URL for additional information (as electronic instructions for use):

Clinical size

Clinical size applicable: No

Labelled as single use

*** Labelled as single use:** No

Maximum number of reuses applicable: No

*** Need for sterilisation before use:** No

*** Device labelled as sterile:** No

*** Containing latex:** No

*** CMR/Endocrine disruptor**

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

☐ Yes ☒ No

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

☐ Yes ☒ No

Storage/handling conditions, if applicable

Yes ☒ No ☐ Storage/handling conditions are required unless you select the option - No

Critical warnings or contra-indications, if applicable

Yes ☒ No ☐ Critical warning or contra-indications are required unless you select the option - No

*** UDI-DI status**

☒ On the EU market ☐ No longer placed on the EU market

*** Member State where the Device is to or has been first placed on the EU market:**

**NOTE**

The available options for the UDI-DI status depend on the initial status of the device.

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

**NOTE**

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

Create new version of UDI-DI

You are about to create a new version of UDI-DI medical-device-01

You have updated the device/system or procedure pack status to 'No longer placed on the EU market'. Since this device/system or procedure pack is linked to container package(s), the system will automatically change the status of the linked container package(s) to 'No longer placed on the EU market'.

Confirm

Cancel

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

* Member State where the Device is to or has been first placed on the EU market:

Austria

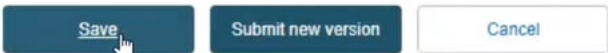
* Member States where the device is or is to be made available on the market:

* [Select one or more countries >](#)

2. To finish the action you have two options:

- **Save** to save the updated details without submitting the new version.

- **Submit new version**, if you wish to finalise the update.

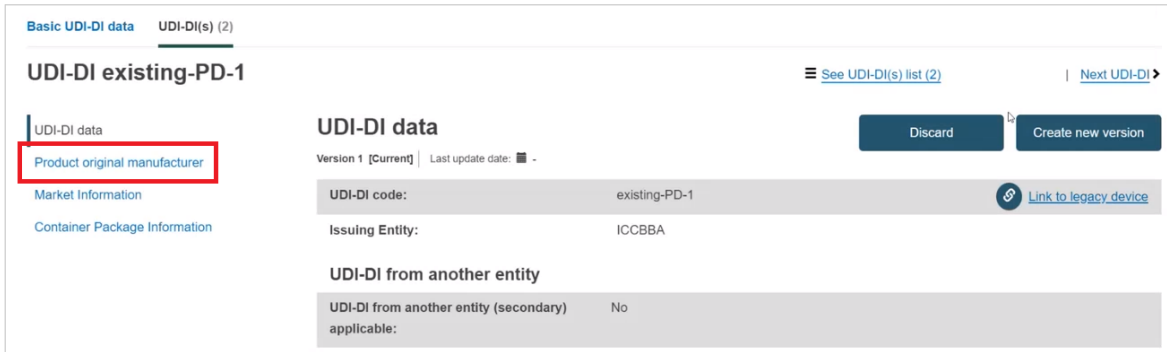


Buttons: **Save** (with a mouse cursor icon), **Submit new version**, and **Cancel**.

5.2.3 Update (create new version) for Product original manufacturer

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.
2. Once inside the details of the selected UDI-DI, click on **Product original manufacturer** from the list on the left (or scroll down to the *Product original manufacturer* section):



The screenshot shows the 'UDI-DI existing-PD-1' page. On the left sidebar, under 'UDI-DI data', the 'Product original manufacturer' link is highlighted with a red box. The main content area shows 'UDI-DI data' for 'Version 1 [Current]' with a last update date of '-'. It includes fields for 'UDI-DI code' (existing-PD-1), 'Issuing Entity' (ICCBBA), and a section for 'UDI-DI from another entity' with a 'No' response. Buttons for 'Discard' and 'Create new version' are visible on the right.

3. Click on **Update**:



The screenshot shows the 'Product original manufacturer' page for 'Version 4 [Current]' with a last update date of '2023-09-12'. A red box highlights the 'Update' button in the top right corner. The page contains a form with the question 'Is the device designed and manufactured by another legal or natural person?' answered 'Yes'. Below this, there are fields for 'Original equipment manufacturer organisation', 'Organisation name' (PDasOrg (3)), 'Address' (AAA, 30, AAA, Afghanistan), 'Telephone number' (-), and 'Email' (aaa@aaa.af).

The *Product original manufacturer* page will appear.

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

Natural or Legal Person update

☐ I know the Actor ID/SRN [Change manufacturer](#)

* Name (Manufacturer Name):

Street information, if applicable
 Yes ☒ No ☐ Street information is required unless you select the option - No

* Street: Street number:
 Address line 2:

PO box:

* City name: * Postal code:
 * Country: × v
 Telephone:

- Or you can update the *Product original manufacturer* to an actor that is already registered in EUDAMED.

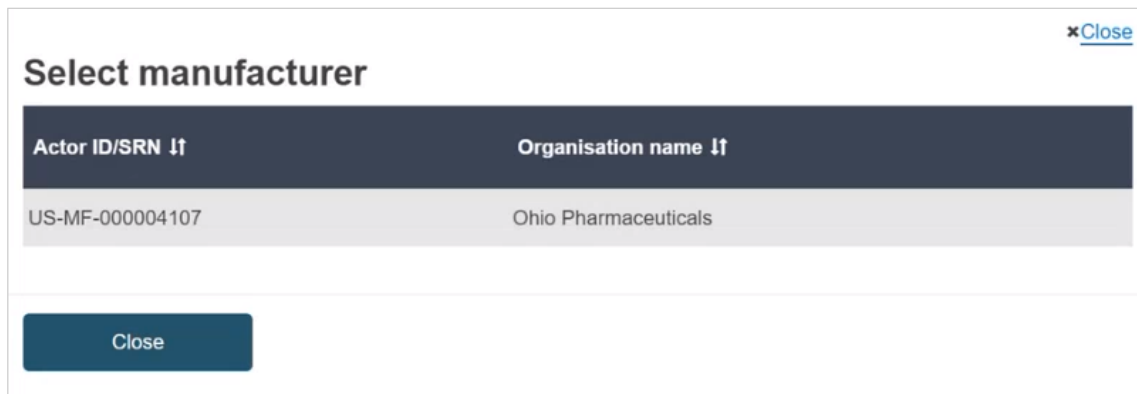
Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRN or name of the *Product original manufacturer* of the device and click on **Check registry**:

Natural or Legal Person update

☒ I know the Actor ID/SRN

* Enter Actor ID/SRN or name:

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



Select manufacturer ✕Close

| Actor ID/SRN ↕ | Organisation name ↕ |
|-----------------|----------------------|
| US-MF-000004107 | Ohio Pharmaceuticals |

Close

- 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 original manufacturer* information.

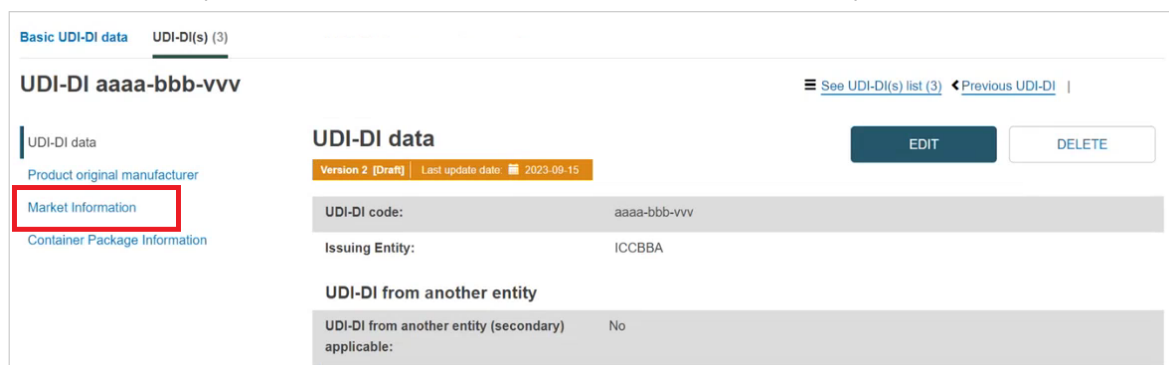
**NOTE**

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

5.2.4 Update (create new version) for Market Information

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.
- Once inside the details of the selected UDI-DI, click on **Market Information** from the list on the left (or scroll down to the *Market Information* section):



Basic UDI-DI data **UDI-DI(s) (3)**

UDI-DI aaaa-bbb-vvv See UDI-DI(s) list (3) Previous UDI-DI

UDI-DI data Version 2 [Draft] Last update date: 2023-09-15 EDIT DELETE

Product original manufacturer

Market Information

Container Package Information

UDI-DI code: aaaa-bbb-vvv

Issuing Entity: ICCBBA

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable: No

- Click on **Update countries**:

Market Information

Version 1 | Last update date: 2021-06-10

Member State of the placing on the EU market of the Device: Belgium

| Member States where device is or is to be made available on the market: | Country | From | To |
|---|---------|------|----|
| | Belgium | - | - |
| | Finland | - | - |
| | Greece | - | - |

[Update countries](#)

- Update the relevant fields under *Market Information*:

Market information update

Belgium From To

Finland From To

Greece From To

Latvia From To

* [Select one or more countries](#)

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

Market Information

Version 2 | [See version history](#) | Last update date: 2021-06-10

Member State of the placing on the EU market of the Device: Belgium

| Member States where device is or is to be made available on the market: | Country | From | To |
|---|---------|------|------------|
| | Belgium | - | - |
| | Finland | - | - |
| | Greece | - | 2021-06-09 |
| | Italy | - | - |
| | Latvia | - | - |

[Update countries](#)

5.2.5 Update (create new version) for Container Packages

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

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


The screenshot shows the 'UDI-DI existing-PD-1' page. On the left sidebar, 'Container Package Information' is highlighted with a red box. The main content area shows 'UDI-DI data' for 'Version 1 [Current]' with a last update date of '-'. The 'UDI-DI code' is 'existing-PD-1' and the 'Issuing Entity' is 'ICCBBA'. There is a 'Link to legacy device' button. Below this, the 'UDI-DI from another entity' section shows 'No' for 'applicable'.

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

The screenshot shows the 'Container Package Information' section. The 'Create new version' button is highlighted with a red box. Below the button, there is a list of container packages with the first one selected: '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'. Below the list, there are 'Submit' and 'Cancel' buttons.

[✕Close](#)

Add container package

 Container package UDI-DI for **UDI-DI product-original-manufacturer**

* Issuing Entity:

—

▼

* Package UDI-DI code:

* Quantity per package:

Total number of devices

1

* Package status

☐ No longer placed on the EU market

☐ Not intended for EU market


☒ On the EU market


Save

Cancel

Container package update

Container package(s)

 [Add container package](#)

 [Update container package status](#)

☐ [Root] UDI-DI: u-123123MI9N (HIBCC) | Status: On the EU market

☒ UDI-DI: Cp-1-1-1 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market


☐ UDI-DI: CP-1-1-2 (ICCBBA) | Quantity per package: 5 (50) | Status: On the EU market

Submit

Cancel

[✕Close](#)

Update container package status

 Container package UDI-DI **Cp-1-1-1**

Container package market status

☒ On the EU market

☐ No longer placed on the EU market

☐ Not intended for EU market

Confirm

Cancel

Manage your own device information

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**NOTE**

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

- Click on **Submit** to finalise the container package update:

Container package update

Container package(s)

+ Add container package
🔄 Update container package status

- ☐ [Root] UDI-DI: u-123123MI9N (HIBCC) | Status: On the EU market

- ☒ UDI-DI: Cp-1-1-1 (ICCBBA) | Quantity per package: 10 (10) | Status: No longer placed on the EU market

- ☐ UDI-DI: CP-1-1-2 (ICCBBA) | Quantity per package: 5 (50) | Status: No longer placed on the EU market

Submit
Cancel

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

**IMPORTANT**

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

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a registered UDI-DI/EUDAMED ID.
- Once inside the details page of the selected UDI-DI, click on **Discard** at the top right corner:

The screenshot shows the 'UDI-DI existing-PD-1' page. On the left is a sidebar with 'UDI-DI data' and sub-links: 'Product original manufacturer', 'Market Information', and 'Container Package Information'. The main content area is titled 'UDI-DI data' and shows 'Version 1 [Current]' with a 'Last update date' of '-'. Below this is a table with 'UDI-DI code' as 'existing-PD-1' and 'Issuing Entity' as 'ICCBBA'. A 'Link to legacy device' button is next to the code. Below the table is a section 'UDI-DI from another entity' with a row 'UDI-DI from another entity (secondary) applicable:' set to 'No'. At the top right, there are links 'See UDI-DI(s) list (2)' and 'Next UDI-DI'. Two buttons, 'Discard' and 'Create new version', are at the top right of the main content area; the 'Discard' button is highlighted with a red rectangle.

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

The screenshot shows a 'Discard UDI-DI' dialog box. It contains the text: 'Details of the UDI-DI will be Discarded (lost). The operation cannot be reverted. Do you want to finalize the operation?'. At the bottom are two buttons: 'Yes' (highlighted with a mouse cursor) and 'Cancel'. A 'Close' button is in the top right corner.

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



CAUTION

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

The screenshot shows a 'Discard UDI-DI' dialog box with a warning message: 'Details of the Basic UDI-DI and of the associated UDI-DI will be Discarded (lost). The operation cannot be reverted. Do you want to finalize the operation?'. At the bottom are 'Yes' and 'Cancel' buttons. A 'Close' button is in the top right corner.

5.2.7 Link a registered Regulation Device to a registered Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

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

EUDAMED user guide

[Go to Device Details management](#)

Basic UDI-DI data **UDI-DI(s) (3)**

UDI-DI -device-under-regulation See UDI-DI(s) list (3) Previous UDI-DI

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

Discard Create new version

Version 1 [Current] Last update date: -

UDI-DI code: -device-under-regulation [Link to legacy device](#)

Issuing Entity: ICCBBA

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable: No

Selected nomenclature codes

Code A0101010101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS

Trade name

Trade name applicable: No

Reference/Catalogue number: 12345-link-devices-SN

Is the device directly marked?

Is the device directly marked?: No

Quantity of device: 1

2. A new page is displayed that contains details on the selected registered regulation device and a list with all possible compatible legacy devices to be linked to:

European Commission > EUDAMED

Home Tasks Search & view Data transfer News Help MF (CONFIRMER) Logout

CURRENT ACTOR: Manufacturer, NL-MF-000000041, Medical Device Manufacturer [Netherlands] [Notifications](#)

Link to a legacy device

[Go back to view details page](#)

-device-under-regulation

| | |
|------------------------------------|--------------------------|
| Basic UDI-DI code: | 12345-link-devices-SN |
| Reference/Catalogue number: | 12345-link-devices-SN |
| Trade name: | - |
| UDI-DI code: | -device-under-regulation |
| Containing latex: | No |
| Labelled as single use: | Yes |
| Device labelled as sterile: | No |
| Need for sterilisation before use: | No |
| Reprocessed single use device: | No |

List of Legacy devices

The legacy devices listed below may be compatible with your regulation device and can potentially be linked to it. Once you select the device you want to link, the system will verify that the Basic UDI-DI/UDI characteristics match between the regulation device and the legacy device before creating the link.

Select the EUDAMED ID from the list or search for a specific EUDAMED ID/UDI-DI

| | |
|---|---|
| B-device-under-directives (EUDAMED) - device-under-directives - -device-under-directives | ^ |
| B-PD-orgNU (EUDAMED) - D-PD-orgNU - 123/7778855 | ^ |
| B-PD-orgNU (EUDAMED) - D-PD-orgNU - 123/7778855 | ^ |
| B-12345756984170 (EUDAMED) - 12345756984170 - 789/654**89 - Aspirin | ^ |
| B-12345756984101 (EUDAMED) - 12345756984101 - 11114/4442/ - TName - 2 | ^ |
| B-NL-14V6 (EUDAMED) - D-NL-14V6 - 159*4453/4478 - TName - 2 | ^ |
| B-Demo/TWTU (EUDAMED) - D-Demo/TWTU - 456/789 | ^ |
| B-JKLMNOLR (EUDAMED) - D-JKLMNOLR - eee456*22 | ^ |
| B-89197873912008 (EUDAMED) - 89197873912008 - Link test | ^ |
| B-my-legacy (EUDAMED) - my-legacy - aaa/bnbn | ^ |

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

- ×

Close

Link to a legacy device

You are about to link UDI-DI -**device-under-regulation** to a legacy device EUDAMED ID / UDI-DI **device-under-directives**

Confirm

Cancel

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

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

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

Product original manufacturer
Market Information

Presence of a substance which, if used separately, may be considered to be a medicinal product: -

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma: -

Related Device

Related Regulation Device: [-device-under-regulation](#) (link to the Regulation Device)

Devices linked on: 2023-09-12

Product original manufacturer

Is the device designed and manufactured by another legal or natural person?: No

Market Information

Update countries

Version 1 | Last update date: 2023-09-12

Member State of the placing on the EU market of the Device: Austria

| Member States where device is or is to be made available on the market: | Country | From | To |
|---|---------|------|----|
| | Austria | - | - |



NOTE

See the [Legacy Devices - user guide](#) for further details on Legacy Devices.

5.2.8 Delete the link between a Regulation Device and a Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) and select the *Registered* option in the *State* field.

- Once inside the desired registered regulation device click on *Remove the link to this device* under the *Related Device* section:

UDI-DI data
Product original manufacturer
Market Information
Container Package Information

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma: -

Related Device

Related Legacy Device: [device-under-directives](#) (link to the Legacy Device)

Devices linked on: 2023-09-12

Remove the link to this device

Product original manufacturer

Is the device designed and manufactured by another legal or natural person?: No

Market Information

Update countries

Version 1 | Last update date: 2023-09-12

Member State of the placing on the EU market of the Device: Austria

| Member States where device is or is to be made available on the market: | Country | From | To |
|---|---------|------|----|
| | Austria | - | - |

Container Package Information

Add a container package UDI-DI for this UDI-DI

No container packages added

2. A pop-up window is displayed. Click on **Confirm**:

Link to a legacy device

You are about to link UDI-DI -device-under-regulation to a legacy device EUDAMED ID / UDI-DI device-under-directives

Confirm

Cancel

**NOTE**

See the [Legacy Devices - user guide](#) for further details on Legacy Devices.

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

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

UDI-DI data

Version 2 [Draft]

See version history

Last update date: 2021-05-25

EDIT

DELETE

| | |
|---|------------------|
| EUDAMED ID code: | D-1231231UU |
| Issuing Entity: | EUDAMED |
| Selected nomenclature codes Code A01010102 HYPODERMIC NEEDLES FOR PEN | |
| Trade name | |
| Trade name applicable: | No |
| Reference/Catalogue number: | 44545 |
| URL for additional information (as electronic instructions for use): | - |
| Device status: | On the EU market |

You will see a list of all versions:

EUDAMED DI B-1231231UU

[◀ Go back to the current version](#)

Version history of EUDAMED ID

Version 1 - Last update date: 2021-05-25



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

EUDAMED DI B-1231231UU

[◀ Go back to the current version](#)

Version history of EUDAMED ID D-1231231UU

[≡ See all version history \(1\)](#)

Version 1 - Last update date: 2021-05-25

EUDAMED ID code: D-1231231UU

Issuing Entity: EUDAMED

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

Trade name

Trade name applicable: No

Reference/Catalogue number: 44545

URL for additional information (as electronic instructions for use): -

Device status: On the EU market

Clinical size

Clinical size applicable: No

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

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

6.1 Manage your SPP Basic UDI-DI details

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

Welcome to EUDAMED

MDR EUDAMED is the IT system developed by the European Commission to implement [Regulation \(EU\) 2017/745](#) on medical devices and [Regulation \(EU\) 2017/746](#) on in vitro diagnosis medical devices.

MDR EUDAMED is structured around 6 interconnected modules and a public site.

[See all the news](#)

Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)



NOTE

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

Basic UDI-DI management for SPP

[Go to device management](#) [Register new System or Procedure Pack](#)

[Filter](#)

Active filters: [State: Registered](#) [System or Procedure Pack: All](#) [Clear all filters](#)

Showing 1 to 3 of 3 entries Show 20 entries per page

| Basic UDI-DI code ^{IT} | UDI-DI(s) ^{IT} | Device model ^{IT} | Device Name ^{IT} | Risk class ^{IT} | Type ^{IT} | Date ^{IT} | State | Actions |
|---------------------------------|-------------------------|----------------------------|---------------------------|--------------------------|--------------------|--------------------|------------|---------|
| 44444SP_Shr_1VM | 1 | - | SPP_Shr_1 | Class I | PP | 2021-06-29 | Registered | ... |
| 9970314941ShnyaHL16E | 1 | - | System test1 | Class I | S | 2021-05-14 | Registered | ... |
| 9970314941ShnyaHL | 1 | - | Test ONE | Class I | PP | 2021-05-14 | Registered | ... |

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

Showing 1 to 3 of 3 entries

Show entries per page

| Basic UDI-DI code | UDI-DI(s) | Device model | Device Name | Risk class | Type | Date | State | Actions |
|-----------------------|-----------|--------------|--------------|------------|------|------------|------------|---|
| 44444SSP_Shr_1VM | 1 | - | SPP_Shr_1 | Class I | PP | 2021-06-29 | Registered | ... |
| 9970314941ShriyaHL16E | 1 | - | System test1 | Class I | S | 2021-05- | | View Data |
| 9970314941ShriyaHL | 1 | - | Test ONE | Class I | PP | 2021-05- | | View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI |

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data UDI-DI(s) (1)

Basic UDI-DI data

Basic UDI-DI data Create new version

Version 1 [Current] | Last update date: 2021-05-17

| | | |
|--------------------------------|---|----------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 44444SSP_Shr_1VM | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Croatian |
| Name: | SPP_Shr_1 | |

6.1.1 Delete a draft Basic UDI-DI

1. Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Draft Basic UDI-DI:

Basic UDI-DI management for SPP

[Go to device management](#) Register new System or Procedure Pack

Filter

Active filters: State: Draft System or Procedure Pack: All [Clear all filters](#)

Showing 1 to 4 of 4 entries

Show entries per page

| Basic UDI-DI code | UDI-DI(s) | Device model | Device Name | Risk class | Type | Date | State | Actions |
|---------------------|-----------|--------------|------------------|------------|------|------------|-----------|--|
| 12344676768687687JC | 0 | - | name | Class I | S | 2021-06-22 | 1st Draft | ... |
| 12344767686867QH | 0 | - | system pack name | Class IIa | S | 2021-06- | | View Data |
| 1234543233234324XU | 0 | rferfrefre | vddgv | Class I | PP | 2021-06- | | Edit Data |
| 1212112121212DL | 0 | - | | - | PP | 2021-06- | | View all UDI-DIs for this Basic UDI-DI |

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

Basic UDI-DI 12344676768687687JC

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data UDI-DI(s) (0)

Basic UDI-DI data Edit Delete

| | | |
|--------------------------------|---|---------------------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 12344676768687687JC | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose indication | Language English |
| Name: | name | |

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

Delete Basic UDI-DI ✕Close

Delete Basic UDI-DI and all its related elements? Basic UDI-DI has no associated UDI-DIs.
Continue operation?

Yes Cancel

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

Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Basic UDI-DI:

Basic UDI-DI management for SPP

[Go to device management](#) Register new System or Procedure Pack

Filter ▼

Active filters: State: Registered System or Procedure Pack: All [Clear all filters](#)

Showing 1 to 3 of 3 entries Show 20 entries per page

| Basic UDI-DI code | UDI-DI(s) | Device model | Device Name | Risk class | Type | Date | State | Actions |
|-----------------------|-----------|--------------|--------------|------------|------|------------|------------|---|
| 4444SSP_Shr_1VM | 1 | - | SPP_Shr_1 | Class I | PP | 2021-05-17 | Registered | ... |
| 9970314941ShriyaHL16E | 1 | - | System test1 | Class I | S | 2021-05- | | View Data |
| 9970314941ShriyaHL | 1 | - | Test ONE | Class I | PP | 2021-05- | | View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI |

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data UDI-DI(s) (1)


Basic UDI-DI data

Basic UDI-DI data Create new version

Version 1 [Current] | Last update date: 2021-05-17

| | | |
|--------------------------------|---|----------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 44444SSP_Shr_1VM | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Croatian |
| Name: | SPP_Shr_1 | |

2. Update the desired details.

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

44444SSP_Shr_1VM [version: 2]

Create a new version of 44444SSP_Shr_1VM


Risk class: Class I

* Indication of medical purpose:

SPPP test 1

* Select the language:

Greek × ▼

 [Add another indication of medical purpose](#)

* Device Name:

SPP_Shr_1

Save Submit new version Cancel

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

Save Submit new version Cancel

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data **UDI-DI(s) (1)**

Basic UDI-DI data

Basic UDI-DI data [Create new version](#)

Version 2 [Current] | [See version history](#) | Last update date: 2021-06-29

| | | |
|--------------------------------|---|----------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 44444SSP_Shr_1VM | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Greek |
| Name: | SPP_Shr_1 | |

6.1.3 View historical version for Basic UDI-DI

1. Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Basic UDI-DI.
2. Once inside the details page for the selected Basic UDI-DI, click on *See version history* at the top of the table:

Basic UDI-DI 44444SSP_Shr_1VM

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data **UDI-DI(s) (1)**

Basic UDI-DI data

Basic UDI-DI data [Create new version](#)

Version 2 [Current] | [See version history](#) | Last update date: 2021-06-29

| | | |
|--------------------------------|---|----------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 44444SSP_Shr_1VM | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Greek |
| Name: | SPP_Shr_1 | |

Basic UDI-DI 44444SSP_Shr_1VM

[Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

| |
|--|
| Version 1 - Last update date: 2021-05-17 |
|--|

Basic UDI-DI 44444SSP_Shr_1VM

[◀ Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

[≡ See all version history \(1\)](#)

Version 1 - Last update date: 2021-05-17

Basic UDI-DI identification

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

Basic UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

| | | |
|--------------------------------|-------------------------------|----------|
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Croatian |
| Name: | SPP_Shr_1 | |

6.2 Manage your SPP UDI-DI details

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

Tasks

By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.

System or Procedure Pack

[Register a new System Procedure Pack](#)[Manage your Basic UDI-DIs](#)[Manage your UDI-DIs](#)

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

UDI-DI details management for SPP


[Go to Basic UDI-DI management for SPP](#)

Filter ▼

Active filters:
 State: Registered [Clear all filters](#)

Showing 1 to 3 of 3 entries Show 20 entries per page

| UDI-DI code ID | Trade name ID | Reference/Catalogue number ID | Nomenclature code ID | Sterile ID | Date ID | Status | State | Actions |
|---|---------------|-------------------------------|----------------------|------------|------------|------------------|------------|---------|
| Basic UDI-DI: 4444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | | | | | | | |
| 4444SSP_Shr_1VM | | SPPP_Shr_1 | | | 2021-05-17 | On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | | | | | | | |
| 34675806754T9 | system 1 | 543 | | | 2021-05-14 | On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | | | | | | | |
| 997031494145675552 | trade1 | 34234 | | | 2021-05-14 | On the EU market | Registered | ... |



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

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

Show 20 entries per page

| Status | State | Actions |
|---|------------|---------|
| Basic UDI-DI: 4444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | |
| On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | |
| On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) + Add a new UDI-DI | | |
| On the EU market | Registered | ... |

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to device management](#)

Basic UDI-DI data UDI-DI(s) (1)

UDI-DI 44444SSP_Shr_1VM [See UDI-DI\(s\) list \(1\)](#)

UDI-DI data [Container Package Information](#)

Version 1 [Current] | Last update date: 2021-05-17

UDI-DI data [Discard](#) [Create new version](#)

| | |
|-----------------|------------------|
| UDI-DI code: | 44444SSP_Shr_1VM |
| Issuing Entity: | HIBCC |

UDI-DI from another entity

| | |
|--|----|
| UDI-DI from another entity (secondary) applicable: | No |
|--|----|

Selected nomenclature codes

| | |
|------|--|
| Code | A010204 NEEDLES AND KITS - AMNIOCENTESIS |
|------|--|

Trade name

| | |
|-----------------------------|------------|
| Trade name applicable: | No |
| Reference/Catalogue number: | SPPP_Shr_1 |

Type of UDI-PI

| | |
|--|------------------|
| Manufacturing date: | Yes |
| Additional product description: | test [BG] |
| URL for additional information (as electronic instructions for use): | - |
| UDI-DI status: | On the EU market |

| | |
|------------------------------------|----|
| Need for sterilisation before use: | No |
| Device labelled as sterile: | No |

6.2.1 Delete a draft UDI-DI

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a Draft UDI-DI.
2. Once inside the draft, click on **Delete**:

Basic UDI-DI data UDI-DI(s) (1)

UDI-DI 34675806754T9 [See UDI-DI\(s\) list \(1\)](#)

UDI-DI data [Container Package Information](#)

UDI-DI data [Version 2 \[Draft\]](#) [See version history](#) [Last update date: 2021-07-02](#) [EDIT](#) [DELETE](#)

UDI-DI code: 34675806754T9

Issuing Entity: HIBCC

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable: No

Selected nomenclature codes

Code A010102 BUTTERFLY NEEDLES

Trade name

Trade name applicable: Yes

Trade name: system 1All languages

Reference/Catalogue number: 543

Type of UDI-PI

Serial number: Yes

Manufacturing date: Yes

Additional product description: test 1 for SPPP System [BG]

URL for additional information (as electronic instructions for use): -

UDI-DI status: On the EU market

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

Delete UDI-DI [Close](#)

Delete the Draft version of UDI-DI?

[Yes](#) [Cancel](#)

6.2.2 Update (create new version) for UDI-DI

1. Follow the steps in [Manage your SPP UDI-DI details \[72\]](#) to view a UDI-DI.

Basic UDI-DI management for SPP

[Go to device management](#) [Register new System or Procedure Pack](#)

[Filter](#)

Active filters: [State: Registered](#) [System or Procedure Pack: All](#) [Clear all filters](#)

Showing 1 to 3 of 3 entries Show 20 entries per page

| Basic UDI-DI code | UDI-DI(s) | Device model | Device Name | Risk class | Type | Date | State | Actions |
|-----------------------|-----------|--------------|--------------|------------|------|------------|------------|---|
| 44444SSP_Shr_1VM | 1 | - | SPP_Shr_1 | Class I | PP | 2021-05-17 | Registered | ... |
| 9970314941ShriyaHL16E | 1 | - | System test1 | Class I | S | 2021-05- | | View Data |
| 9970314941ShriyaHL | 1 | - | Test ONE | Class I | PP | 2021-05- | | View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI |

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to UDI-DI/EUDAMED DI management](#)

Basic UDI-DI data UDI-DI(s) (1)


Basic UDI-DI data

Basic UDI-DI data [Create new version](#)

Version 1 [Current] | Last update date: 2021-05-17

| | | |
|--------------------------------|---|----------|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) | |
| Basic UDI-DI code: | 44444SSP_Shr_1VM | |
| Issuing Entity: | GS1 | |
| Risk class: | Class I | |
| Indication of medical purpose: | Indication of medical purpose | Language |
| | SPPP test 1 | Croatian |
| Name: | SPP_Shr_1 | |

- Update the necessary details.

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

Create a new version of UDI-DI 44444SSP_Shr_1VM [version: 2]

UDI-DI: 44444SSP_Shr_1VM

UDI-DI from another entity (secondary) applicable
Yes ☒ No [UDI-DI from another entity is required unless you select the option - No](#)

* Enter a nomenclature code (EMDN code):
 [Find](#)
[Advanced search of device nomenclature](#)

Selected nomenclature codes
Code A010204 NEEDLES AND KITS - AMNIOCENTESIS [Remove nomenclature code](#)

Trade name applicable
Yes ☒ No [Trade name is required unless you select the option - No](#)

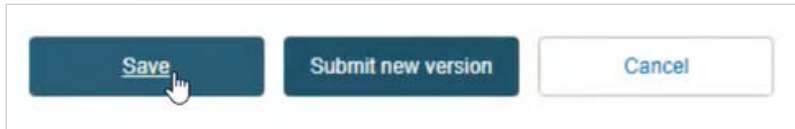
Reference/catalogue number: SPPP_Shr_1

Type of UDI-PI
* Manufacturing date: Yes

* Additional product description:
 [Add additional product description in another language](#)

* Select the language:
Bulgarian [X](#) [v](#)

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



6.2.3 Update (create new version) for Container Packages

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

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a specific UDI-DI:

 A screenshot of the 'Basic UDI-DI 44444SSP_Shr_1VM' page. At the top, there's a header with the title and a 'Go to device management' button. Below the header, there are tabs for 'Basic UDI-DI data' and 'UDI-DI(s) (1)'. The 'UDI-DI(s) (1)' tab is active, showing 'UDI-DI 44444SSP_Shr_1VM' with a 'See UDI-DI(s) list (1)' link. On the left, there's a sidebar with 'UDI-DI data' and 'Container Package Information'. The main content area shows 'UDI-DI data' for 'Version 1 [Current]' with a 'Last update date' of '2021-05-17'. It includes fields for 'UDI-DI code' (44444SSP_Shr_1VM), 'Issuing Entity' (HIBCC), 'UDI-DI from another entity' (No), and 'Selected nomenclature codes' (Code A010204 NEEDLES AND KITS - AMNIOCENTESIS). There are 'Discard' and 'View latest draft version' buttons at the top right.

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

 A screenshot of the 'Container Package Information' section. It shows the 'UDI-DI 44444SSP_Shr_1VM' title. On the left, there's a sidebar with 'UDI-DI data' and 'Container Package Information'. The 'Container Package Information' section is highlighted.


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

 A screenshot of the 'Container Package Information' section. It shows the 'Container Package Information' title. Below the title, there's a 'Version 3' label, a 'See version history' link, and a 'Last update date' of '2023-09-15'. A 'Create new version' button is highlighted with a red rectangle. Below the button, there's a text field containing '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'.

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


Container package update

Container package(s)


 [Add container package](#)

☒ [Root] UDI-DI: u-122323CilbPAY (HIBCC) | Status: On the EU market

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

 [Close](#)

Add container package

 Container package UDI-DI for **UDI-DI product-original-manufacturer**

| * Issuing Entity: | * Package UDI-DI code: | * Quantity per package: | Total number of devices |
|--------------------------------|------------------------|--------------------------------|-------------------------|
| <input type="text" value="-"/> | <input type="text"/> | <input type="text" value="1"/> | 1 |

* Package status

☐ No longer placed on the EU market
☐ Not intended for EU market
☒ On the EU market

6.2.4 Discard SPP registered UDI-DIs

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a chosen Registered UDI-DI:

UDI-DI details management for SPP

[Go to Basic UDI-DI management for SPP](#)

Filter ▼

Active filters:
State: Registered [Clear all filters](#)

Showing 1 to 3 of 3 entries Show 20 entries per page

| UDI-DI code | Trade name | Reference/Catalogue number | Nomenclature code | Sterile | Date | Status | State | Actions |
|---|------------|----------------------------|-------------------|---------|------------|------------------|------------|---------|
| Basic UDI-DI: 44444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI | | | | | | | | |
| 44444SSP_Shr_1VM | | SPPP_Shr_1 | | | 2021-05-17 | On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI | | | | | | | | |
| 34675806754T9 | system 1 | 543 | | | 2021-05-14 | On the EU market | Registered | ... |
| Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI | | | | | | | | |
| 997031494145675552 | trade1 | 34234 | | | 2021-05-14 | On the EU market | Registered | ... |

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to device management](#)

Basic UDI-DI data UDI-DI(s) (1)

UDI-DI 44444SSP_Shr_1VM [See UDI-DI\(s\) list \(1\)](#)

UDI-DI data [Container Package Information](#)

Version 1 [Current] | Last update date: 2021-05-17

[Discard](#) [Create new version](#)

UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: HIBCC

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable: No

Selected nomenclature codes

Code A010204 NEEDLES AND KITS - AMNIOCENTESIS

Trade name

Trade name applicable: No

Reference/Catalogue number: SPPP_Shr_1

Type of UDI-PI

Manufacturing date: Yes

Additional product description: test [BG]

URL for additional information (as electronic instructions for use): -

UDI-DI status: On the EU market

Need for sterilisation before use: No

Device labelled as sterile: No

UDI-DI data [See UDI-DI\(s\) list \(1\)](#) [Discard](#) [Create new version](#)

Version 1 [Current] | Last update date: 2021-05-17

UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: HIBCC

UDI-DI from another entity

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

Discard UDI-DI [Close](#)

Details of the Basic UDI-DI and of the associated UDI-DI will be Discarded (not). The operation cannot be reverted. Do you want to finalize the operation?

[Yes](#) [Cancel](#)

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

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a UDI-DI for the SPP.
2. Once inside the details of the chosen UDI-DI, click on *See version history* at the top of the table:

Basic UDI-DI data Create new version

Version 4 [Current] | [See version history](#) | Last update date: 2021-06-10

| | |
|--|---|
| Applicable regulation: | MDR (REGULATION (EU) 2017/745 on medical devices) |
| Basic UDI-DI code: | 12345-test-udi-1-HL |
| Issuing Entity: | GS1 |
| Is it a System or Procedure Pack which is a Device in itself?: | Procedure Pack which is a device in itself |

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

Basic UDI-DI 12345-test-udi-1-HL

[Go back to the current version](#)

Version history of Basic UDI-DI 12345-test-udi-1-HL

| | |
|--|---|
| Version 3 - Last update date: 2021-06-09 | > |
| Version 2 - Last update date: 2021-06-09 | > |
| Version 1 - Last update date: 2021-05-03 | > |

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

[Go back to the current version](#)

Version history of Basic UDI-DI 12345-test-udi-1-HL

Version 2 - Last update date: 2021-06-09

Basic UDI-DI identification

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

Basic UDI-DI code: 12345-test-udi-1-HL

Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself? Procedure Pack which is a device in itself

Risk class: Class IIb

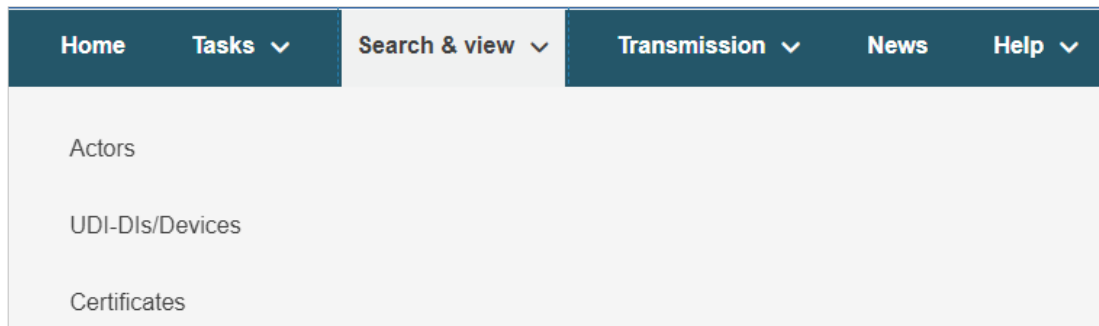
Implantable: No

[See all version history \(3\)](#) [Previous version \[v1\]](#) [Next version \[v3\]](#)

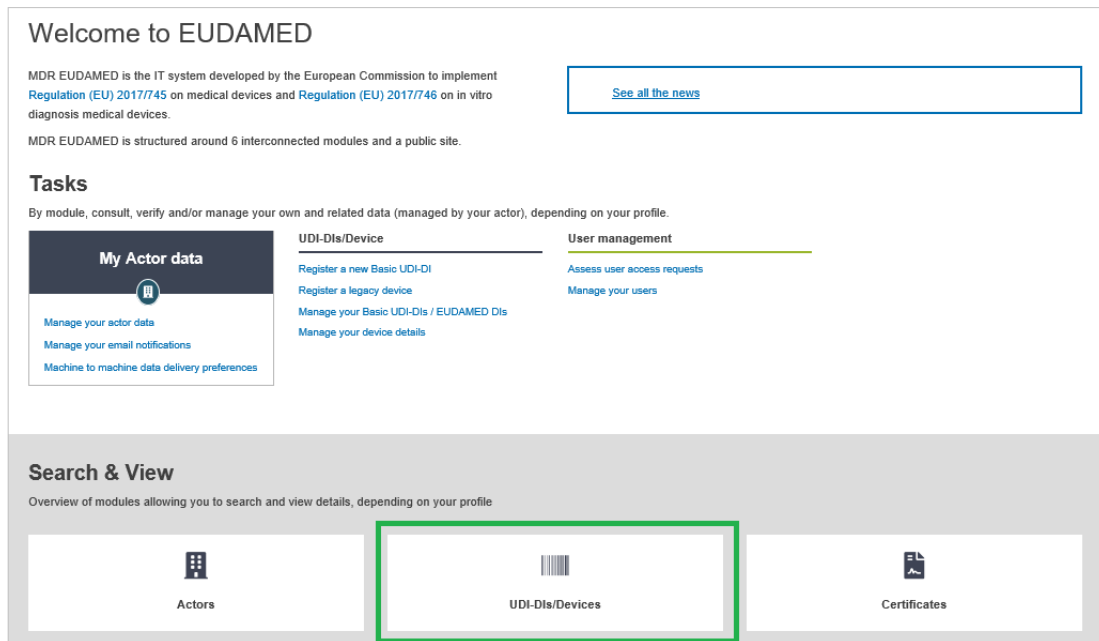
You can return to the version history list by clicking on *See all version history* at the top right corner.

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

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



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



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

☒ Only enable search filters available for bulk XML download

| | | | |
|--|--|---|---|
| UDI-DI/ EUDAMED ID <input type="text"/> | Basic UDI-DI/ EUDAMED DI <input type="text"/> | Status -- <input type="button" value="x"/> <input type="button" value="v"/> | Model <input type="text"/> |
| Name <input type="text"/> | Trade name <input type="text"/> | Applicable regulation -- <input type="button" value="x"/> <input type="button" value="v"/> | |
| Risk class -- <input type="button" value="x"/> <input type="button" value="v"/> | Nomenclature code <input type="text"/> | Reference/Catalogue number <input type="text"/> | Country -- <input type="button" value="x"/> <input type="button" value="v"/> |

Scopes

| | | | |
|---|---|--|--------------------------------------|
| Competent Authority -- <input type="button" value="x"/> <input type="button" value="v"/> | NB identification -- <input type="button" value="x"/> <input type="button" value="v"/> | MF / PR Actor ID/SRN <input type="text"/> | MF / PR Name <input type="text"/> |
| AR Actor ID/SRN <input type="text"/> | AR name <input type="text"/> | | |

Results option
☒ Include historical version

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

Showing 1 to 20 of 150 entries Show entries per page

| UDI-DI code ¹ | Basic UDI-DI code ¹ | MF / PR SRN | Trade name ¹ | Risk class | Date ¹ | UDI-DI status |
|-----------------------------|--------------------------------|-----------------|-------------------------|------------|-------------------|--------------------------------|
| 12345XYZ | ++B311X1Y2Z3PP | BE-PR-000000048 | | Class IIb | 2021-03-29 | On the EU market |
| 19999QAAQ00Q2 | ++A999JAIMETEST12N | BE-PR-000000048 | | Class IIb | 2021-03-26 | On the EU market |
| 12345-ivdr-class-d-ST-udi-A | 12345-ivdr-class-d-ST | BE-MF-000000041 | | Class D | 2021-03-24 | On the EU market |
| ++A999SPPVERSION2PMa | ++A999SPPVERSION2PM | BE-PR-000000062 | | Class I | 2021-03-24 | On the EU market |
| ++A999SPPVERSIONYMa | ++A999SPPVERSIONYM | BE-PR-000000062 | | Class I | 2021-03-24 | Not intended for the EU market |

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

Producer information

Producer identification
 Organisation name: Belgian PPA
 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

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

1. Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[81\]](#) to search and view a device or system or procedure pack.
2. Inside the search page, select the filters for your search, activate the option to include historical versions (toggle just above the **Search** button) and click on **Search**:

☒ Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED DI

Basic UDI-DI/ EUDAMED DI

Status

Model

Name

Trade name

Applicable regulation

Risk class

Nomenclature code

Reference/Catalogue number

Country

Scopes

Competent Authority

NB identification

MF / PR Actor ID/SRN

MF / PR Name

AR Actor ID/SRN

AR name

Results option
☒ Include historical version

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

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

← Previous
1
2
3
4
5
Next →

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



NOTE

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

- Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[81\]](#) to search and view a device or a system or procedure pack. On the search page, activate the top filter (**Only enable search filters available for bulk XML download**) so that you can only enter search criteria that can be used for search results that can be downloaded in an XML format, and enter your search criteria. Enter the search criteria of your choice, and click on **Search**:

☒ Only enable search filters available for bulk XML download

| | | | |
|--|--|--|-------------------------------|
| UDI-DI/ EUDAMED DI <input type="text"/> | Basic UDI-DI/ EUDAMED DI <input type="text"/> | Status -- ▾ | Model <input type="text"/> |
| Name <input type="text"/> | Trade name <input type="text"/> | Applicable regulation -- ▾ | |
| Risk class -- ✕ ▾ | Nomenclature code <input type="text"/> | Reference/Catalogue number <input type="text"/> | Country -- ✕ ▾ |

Scopes
You can select more than one value

| | | | |
|---|--------------------------------------|---|---------------------------------|
| MF / PR Actor ID/SRN NL-MF-000000041 | MF / PR Name <input type="text"/> | AR Actor ID/SRN <input type="text"/> | AR name <input type="text"/> |
|---|--------------------------------------|---|---------------------------------|

Results option

☐ Include historical version

- Click on **Generate XML file**:



NOTE

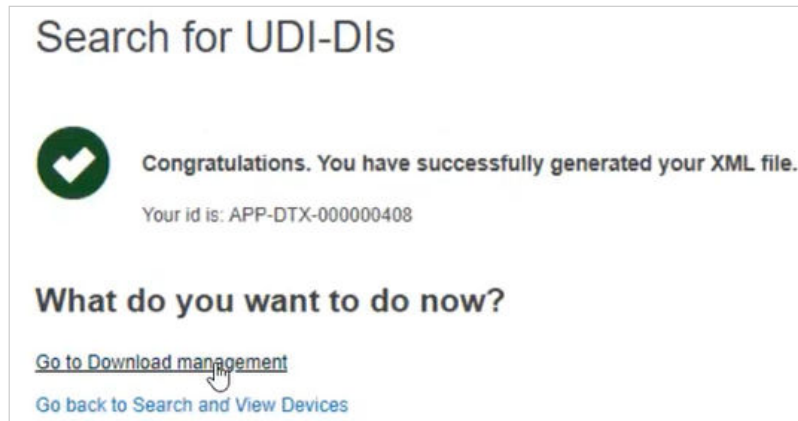
Only what is shown on the result list will be included in the generated file and not all the results of your search. If the search yields multiple pages of results, you will need to download an XML file for each page to capture all the data.

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

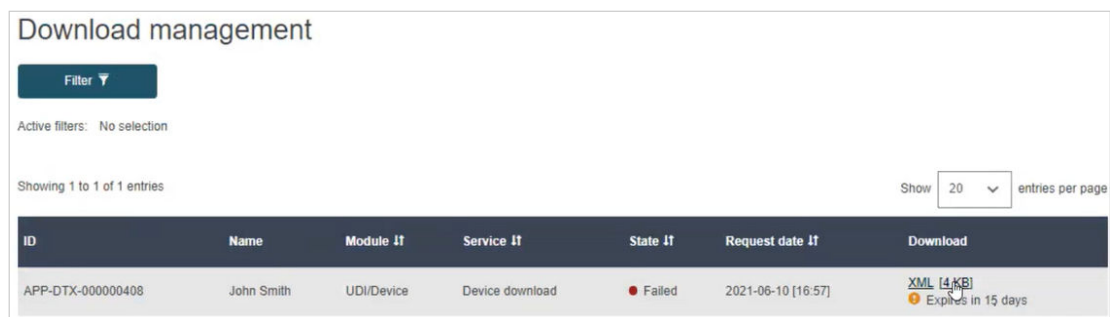
Download ✕ Close

Are you sure you want to generate XML file...?

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



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



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

1. Follow the steps in [Search & View historical versions of Devices, System and/or Procedure Packs \[83\]](#) to view the details of a Device or System or Procedure Pack.
2. Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product original manufacturer or Container Package) and click on *See version history*:

UDI-DI 121312_Test_AR

[Go back to the list](#)

[Manufacturer information](#)
[Basic UDI-DI details](#)
[UDI-DI details](#)
[Market information](#)
[Clinical Investigation\(s\)](#)

Manufacturer information

Organisation name: Japanese MF A v4
Actor ID/SRN: JP-MF-000000061
Address: 1 Main Street Tokyo
Telephone number: 213 v2
Email: public-details@japanese-mf-a.com

Authorised Representative

Organisation name: Belgium AR A v6
Eudamed actor ID: BE-AR-000000021
Address: Brussels
Telephone number: -
Email: public-contact@belgium-ar-a.com

Basic UDI-DI details

Version 5 [Current] [See version history](#) Last update date: 2021-09-23

Basic UDI-DI identification

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

Basic UDI-DI code: 220911est23_09EC
Issuing Entity: GS1

Is it a System or Procedure Pack which is a Device in itself? No
Special device type: No

List of UDI-DIs for the Basic UDI-DI

UDI-DI details

Version 3 [Current] [See version history](#) Last update date: 2021-09-24

| | |
|-----------------|----------------|
| UDI-DI code: | 121312_Test_AR |
| Issuing Entity: | HIBCC |

UDI-DI from another entity

| | |
|--|----|
| UDI-DI from another entity (secondary) applicable: | No |
|--|----|

Selected nomenclature codes

| |
|--|
| Code A01010199 HYPODERMIC NEEDLES - OTHERS |
|--|

Trade name

| | |
|-----------------------------|-------------------------------------|
| Trade name applicable: | Yes |
| Trade name: | TB_BG [BG], TN_AR1_Croatian [HR] |
| Reference/Catalogue number: | ref |

Is the device directly marked?

| | |
|---------------------------------|----|
| Is the device directly marked?: | No |
|---------------------------------|----|

Market information

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

| | | | |
|---|---------|--|--|
| Member State of the placing on the EU market of the Device: | Belgium | | |
|---|---------|--|--|

| | | | |
|---|-------------|------|----|
| Member States where device is or is to be made available on the market: | Country | From | To |
| | Belgium | - | - |
| | Iceland | - | - |
| | Ireland | - | - |
| | Malta | - | - |
| | Netherlands | - | - |

Clinical Investigation(s)

Clinical Investigation

| | |
|--|----|
| Clinical Investigation, if applicable: | No |
|--|----|

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

Basic UDI-DI 22091test23_09EC

[Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

| | |
|--|---|
| Version 4 - Last update date: 2021-09-23 | > |
| Version 3 - Last update date: 2021-09-23 | > |
| Version 2 - Last update date: 2021-09-23 | > |
| Version 1 - Last update date: 2021-09-23 | > |

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

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

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

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

8 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) |

