



# **EUDAMED user guide**

## **UDI Devices**

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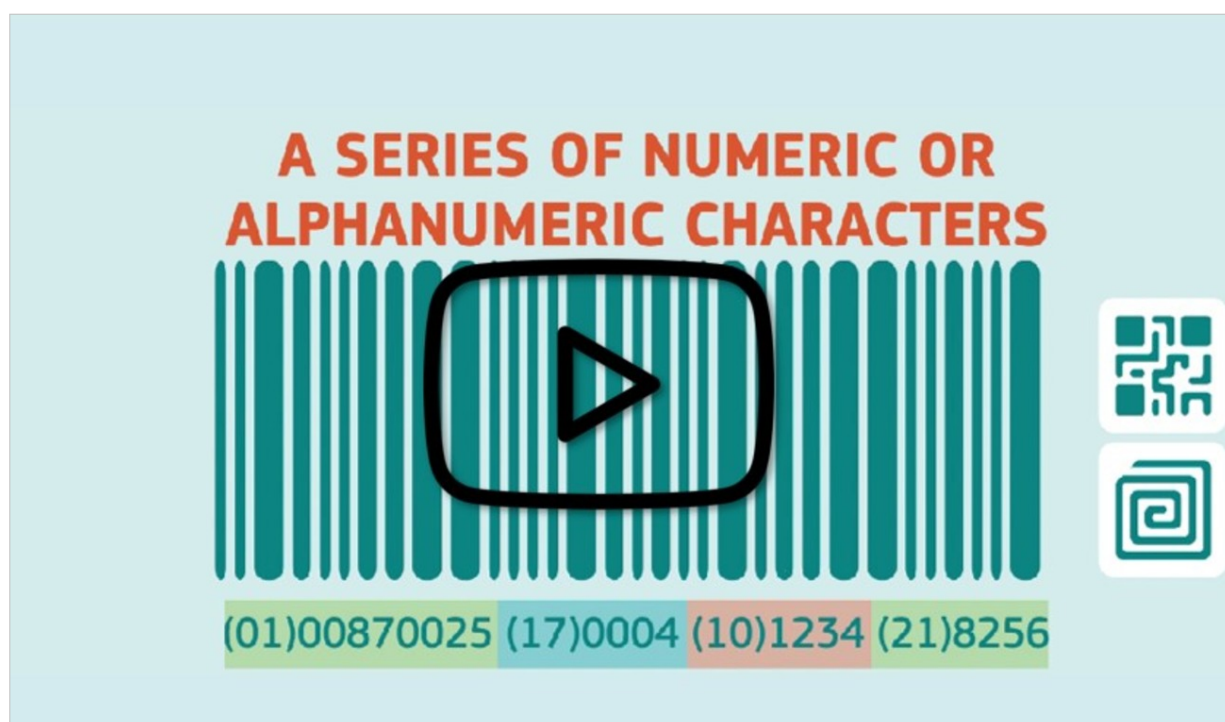
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# 1 Introduction

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.<sup>1</sup>

## VIDEO: What is a UDI?



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



# INFOGRAPHIC: What are device identifiers?

**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 user guide for Economic Operators (EO) available for download on the [EUDAMED landing page](#).



### NOTE

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



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

<sup>2</sup>See the [Economic Operators user guide](#), Section 1.2.3, for more information on user rights and profiles.



**IMPORTANT**

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

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



# 3 Registering Regulation Devices

## **VIDEO: Registering Regulation Devices**



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

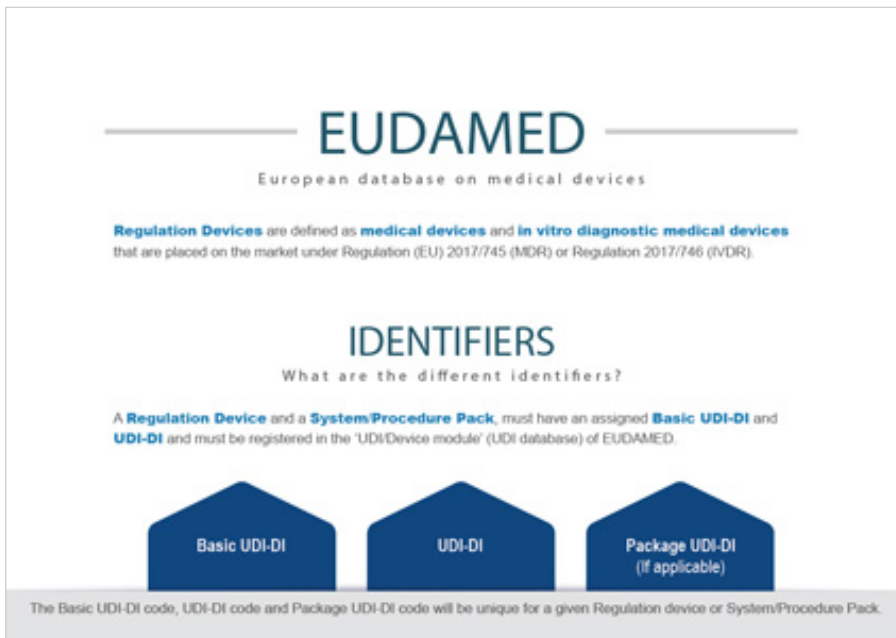
You will be asked to enter EUDAMED via your EU Login account.

 **INFOGRAPHIC:** [Registration process for Regulation devices](#)



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

### INFORGRAPHIC: UDI identifier



### 3.1.1 Step 1: Basic UDI-DI identification information

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

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


**UDI-DIs/Device**

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

**User management**

- Assess user access requests
- Manage your users

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

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*<sup>3</sup>):

**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



**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:



**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:

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

**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

- 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

- 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 Name:

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

### 3.1.2 Step 2: Certificate information (when applicable)

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

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

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

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

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



**NOTE**

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

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

**Certificate information**

EU type-examination certificate if applicable

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

\* Enter NB number or name:

Q Find

Certificate number:

Revision number:

Save

Save & Next >

### 3.1.3 Step 3: UDI-DI identification information

#### ▶ VIDEO: UDI carrier and display formats



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



#### **IMPORTANT**

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

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

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



**NOTE**

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

For example:

**000000nnnnnnnn (GTIN-8)**

**00nnnnnnnnnnnn (GTIN-12)**

**0nnnnnnnnnnnnn (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:

REF\_TEST

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

- 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* or *Not intended for the EU market* and click on **Save** or **Save & Next**:

\* UDI-DI status

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.

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  $\geq 1$ , the device is considered as a non-Single use Device having a limited number of reuses (the value provided)

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

**\* Need for sterilisation before use**

Yes  No

---

**\* Device labelled as sterile**

Yes  No

---

**\* Containing latex**

Yes  No

*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:**

OTHER \*

**\* 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**:



**NOTE**

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

### 3.1.5 Step 5: Device information

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

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

**\* 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

3. Select **Yes** or **No** if the device was designed and manufactured by another legal or natural person.

If **Yes**, enter the Actor ID/SRN or name of the other legal or natural person that designed and manufactured the device. Click **Find** to see the search outcome. If registered as manufacturer in EUDAMED, the system will provide a list of matching records from which you can select one, and the system will retrieve the information:

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

Yes  No

I know the SRN

\* Enter SRN or name:



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

Yes  No i Street information is required unless you select the option - No

PO box:

Latitude:  Longitude:   
Latitude format example: -15.4543 Longitude format example: 178.34354353

\* City name:  \* Postal code:

\* Country:

Telephone:   
Telephone format example: +32 x xxx xx xx

\* Email:

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

**Clinical Investigation**

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

✘ Clinical Investigation '212121' is not registered in EUDAMED

\* Enter Clinical Investigation Number:

6. 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.

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



\* 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 >](#)

Save Save & Next >



**NOTE**


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


### 3.1.6 Step 6: Container package details

 **VIDEO: UDI carrier placing**



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

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

 [Add container package](#)

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



**NOTE**




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

**Add container package** ✕Close

Container package UDI-DI for UDI-DI 76766766

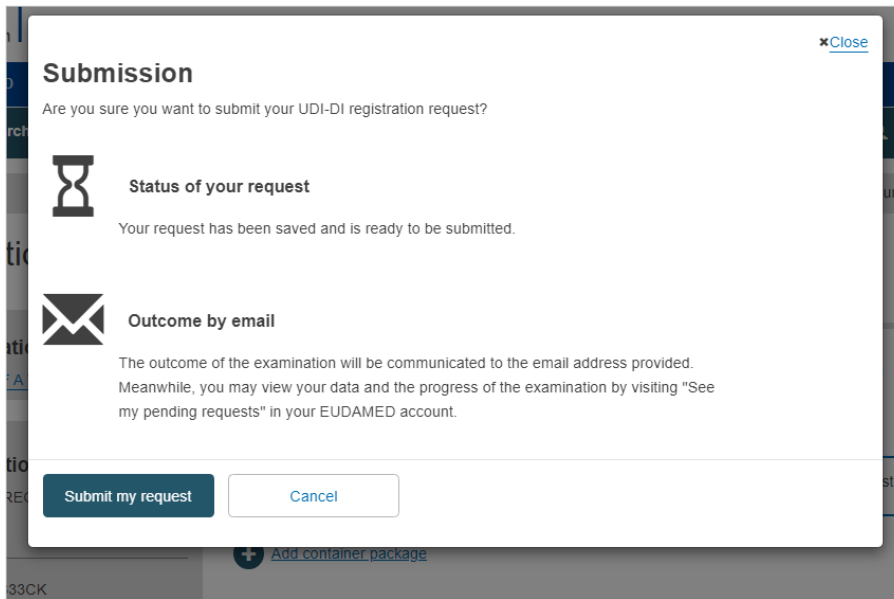
* Issuing Entity:	* Package UDI-DI value:	* Quantity per package:	Total number of devices
HIBCC	5455678	3	9

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

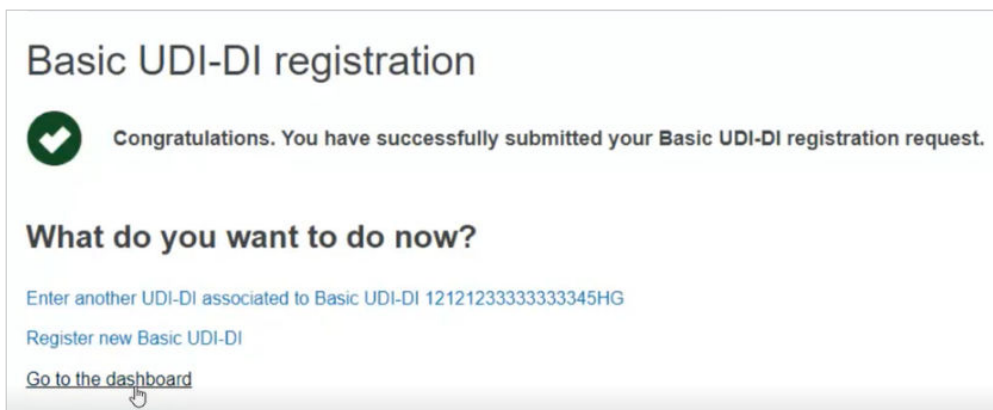
 [Add container package](#)  [Edit container package](#)  [Delete container package](#)

- [Root] UDI-DI: 76766766 (HIBCC)
  - UDI-DI: 5455678 (HIBCC) | Quantity per package: 3 (9)
  - UDI-DI: 767676 (HIBCC) | Quantity per package: 9 (81)

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



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



**!** **IMPORTANT**

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

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

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

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

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

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
12211121212121YZ	1		Test	Class IIa	2021-03-31	1st Draft	...
1111184FG4G228694YC	1	DeviceModelZZZ	DeviceNameZZZ	Class IIb	2021-03-19	1st Draft	...

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

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-		View Data
1234501VP	1	Model 1	Name 1A	Class III	2021-03-		View all UDI-DIs for this Basic UDI-DI
B-555908900698	1	MyModel111	MyDeviceName111	Class I	2021-03-		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	...

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

Add new UDI-DI to existing Basic UDI

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

**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

**UDI-DI identification**

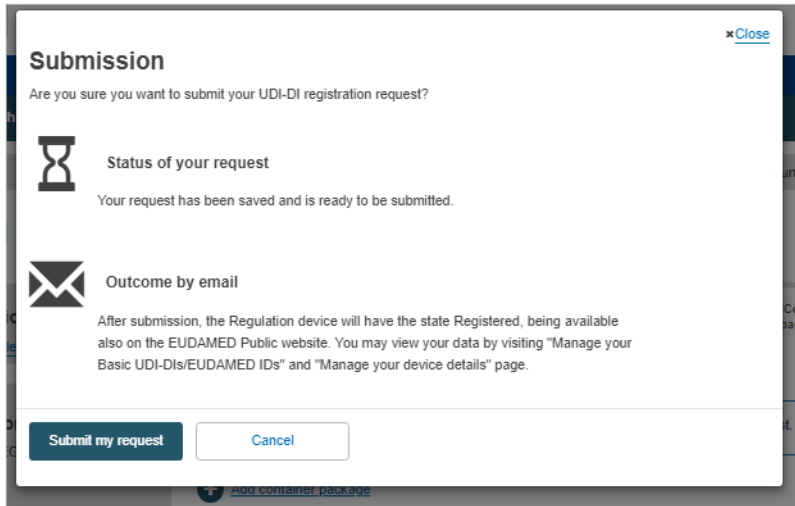
UDI-DI identification

\* 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

\* 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:



**IMPORTANT**

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

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

# 4 Registering Legacy Devices

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

## 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.

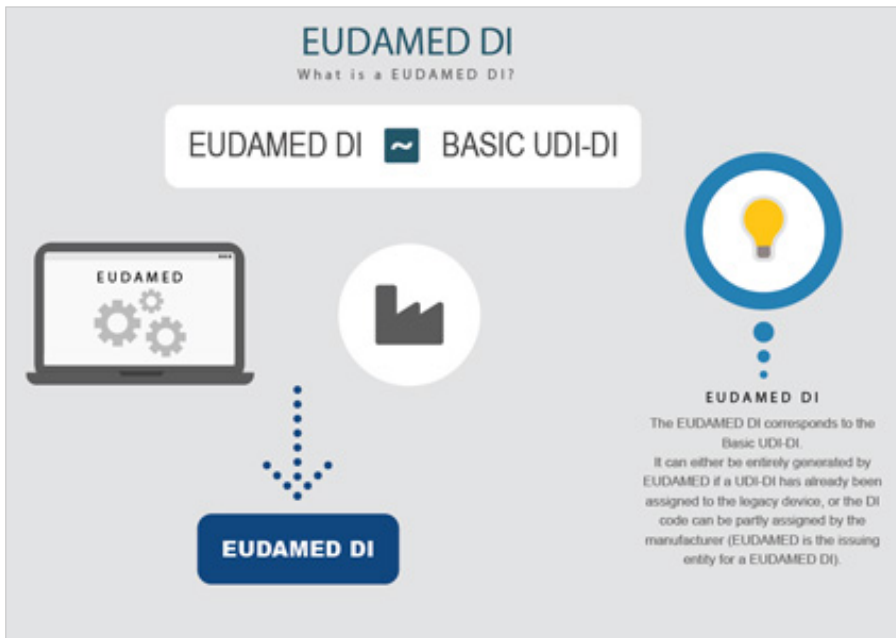
[See all the news](#)

### Tasks

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

<div style="background-color: #333; color: white; padding: 5px; text-align: center; font-weight: bold;">My Actor data</div> <div style="text-align: center; margin: 5px 0;"> </div> <ul style="list-style-type: none"> <li style="margin-bottom: 5px;"><a href="#">Manage your actor data</a></li> <li><a href="#">Manage your email notifications</a></li> </ul>	<p><b>UDI-DIs/Device</b></p> <hr style="border: 0.5px solid #ccc;"/> <ul style="list-style-type: none"> <li style="margin-bottom: 5px;"><a href="#">Register a new Basic UDI-DI</a></li> <li style="margin-bottom: 5px;"><a href="#">Register a legacy device</a></li> <li style="margin-bottom: 5px;"><a href="#">Manage your Basic UDI-DIs / EUDAMED DIs</a></li> <li><a href="#">Manage your Devices details</a></li> </ul>	<p><b>User management</b></p> <hr style="border: 0.5px solid #ccc;"/> <ul style="list-style-type: none"> <li style="margin-bottom: 5px;"><a href="#">Assess user access requests</a></li> <li><a href="#">Manage your users</a></li> </ul>
---	--	--

## INFOGRAPHIC: Identifiers of a legacy device



## 4.1 Step 1: EUDAMED DI identification information

1. Select the applicable legislation:

Legacy Device registration

**Manufacturer identification**

Organisation name: Belgian MF A  
 SRN: BE-MF-00000041  
 Address: Rue A, 1 1060 Brussels  
 Telephone number: -  
 Email: public-contact@belgian-mf-a.be

**\* Applicable Legislation**

IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)

MDD (Directive 93/42/EEC on Medical Devices)

AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

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



### NOTE

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

For example:

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

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

UDI-DI assigned for the current legacy Device?

Yes  No

\* Issuing Entity:

\* UDI-DI code:

\* Generate a EUDAMED-DI based on your UDI-DI code provided above:



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

**Basic UDI-DI main information**

\* Is it a kit?  
 Yes  No

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

\* Special device type:  
 Software

If there is only one AR with an active Mandate with the 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

- On the left you will see a summary of the device characteristics. Choose a “*Risk class*” from the list and select **Yes** or **No** for each of the options.

Legacy device registration

1 EUDAMED DI information    2 Certificate information    3 Device identification information    4 Device characteristics    5 Device information

**Manufacturer identification**  
 BE-MF-000000041, Belgian MFA

**EUDAMED DI identification**  
 Applicable legislation: IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)  
 EUDAMED DI code: B-56909  
 Issuing Entity: EUDAMED  
 Kit: No  
 Special device type: Software

**EUDAMED DI information**

\* Risk class:

\* Near-patient testing  
 Yes  No

\* Self-patient testing  
 Yes  No

\* Companion diagnostic  
 Yes  No

\* Reagent  
 Yes  No

\* Instrument  
 Yes  No

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

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

\* Device model:

Device Name:

- Click on **Save** to save your draft and complete it later, or **Save & Next** to save it as a draft and continue with the following steps:



## 4.2 Step 2: Certificate information

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



### NOTE

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

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

Several identification details for several certificates can be entered:

### Certificate information

Item #1 ▼

\* Certificate Type:

**Organisation name:** EVPU a.s. ✎ Change Notified Body

**NB number:** 1293

**Address:**

**Telephone number:** 421 42 44 03 600

**Email:** hudak@evpu.sk

\* Certificate number:       Revision number:

\* Expiry date:    
YYYY-MM-DD

## 4.3 Step 3: Device identification information

EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED ID generated based on the provided/generated EUDAMED DI. EUDAMED ID has the same code as the EUDAMED DI, except that it is with a “D-“ prefix instead of the “B-“ prefix):

**Device identification**

\* Issuing Entity: EUDAMED \*D-LM100X3PL

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

\* Enter the nomenclature code (EMDN code):  Find

[Advanced search of device nomenclature](#)

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

**Trade name applicable**

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

\* Trade name: Trade\_Name\_01 \*-- I

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

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

\* Reference/Catalogue number:

**Additional product description:** **Select the language:** -- ×

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

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

\* Device status: On the EU market

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

\* Device status:

On the EU market

On the EU market

No longer placed on the EU market

## 4.4 Step 4: Device characteristics

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

\* Labelled as single use

Yes  No

\* Need for sterilisation before use

Yes  No

\* Device labelled as sterile

Yes  No

Storage/handling conditions, if applicable

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

\* Storage/handling conditions type:  Description:

**+** [Add another storage/handling condition](#)

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

Storage/handling conditions, if applicable

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

\* Storage/handling conditions type:  Description:

**+** [Add another storage/handling condition](#)

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

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](#)

## 4.5 Step 5: Device information

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

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

Yes  No

I know the SRN

\* Enter SRN or name:

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

Yes  No ⓘ Street information is required unless you select the option - No

PO box:

Latitude:  Longitude:   
Latitude format example: -15.4543 Longitude format example: 178.34354353

\* City name:  \* Postal code:

\* Country:

Telephone:   
Telephone format example: +32 x xxx xx xx

\* Email:

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

**Clinical Investigation**

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

Clinical investigation conducted inside EU?:

Yes  No

[+ Add new Clinical Investigation](#)

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

**\* 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

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

Belgium ▼

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

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

-- ▼

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

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

---

Save

Submit >

Preview

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

**Legacy Device registration**

Congratulations. You have successfully submitted your Legacy device registration request.

**What do you want to do now?**

[Register a legacy device](#)

[Go to the dashboard](#)

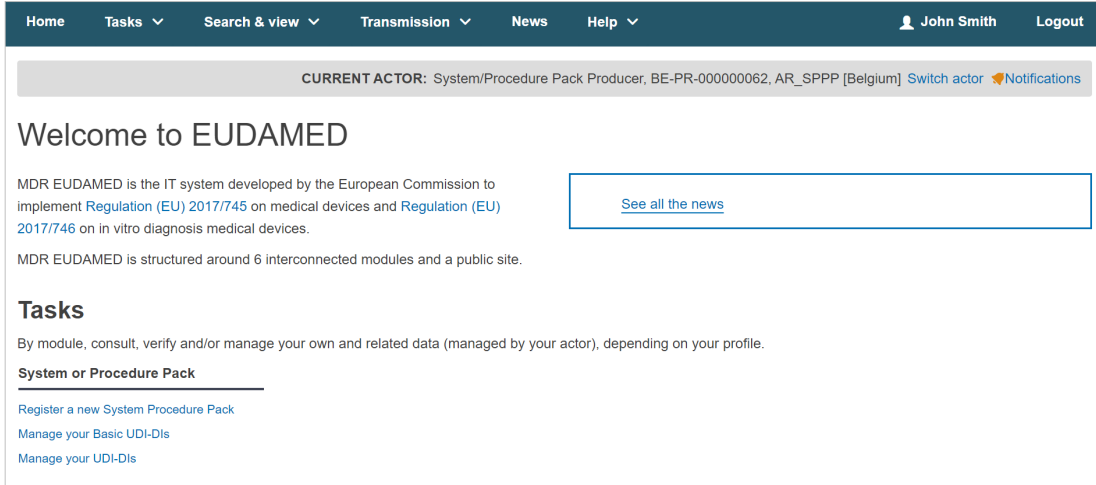
# 5 Registering System or Procedure Packs (SPP)

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

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

### 5.1.1 Step 1: Basic UDI-DI main information

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



The screenshot shows the EUDAMED dashboard interface. At the top, there is a navigation bar with links for Home, Tasks, Search & view, Transmission, News, and Help. The user is logged in as John Smith, with a Logout button. Below the navigation bar, the current actor is identified as 'System/Procedure Pack Producer, BE-PR-00000062, AR\_SPPP [Belgium]'. The main content area includes a 'Welcome to EUDAMED' message, a 'See all the news' button, and a 'Tasks' section. Under the 'System or Procedure Pack' sub-section, the 'Register a new System Procedure Pack' link is highlighted with a blue box.

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-00000062  
 Address: 8686 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: LJ-PR-00000062  
 Address: Oak St, 101 8088 Vauxor  
 Telephone number: +34389879513  
 Email: eudamed@manufacturer.com

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

**Basic UDI-DI main information**

\* Issuing Entity:  \* Basic UDI-DI code:

❗ 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 >**

## 5.1.2 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:

[+ Add another indication of medical purpose](#)

\* Select the language:  
--

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

\* Model:

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 information

Basic UDI-DI identification

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

Basic UDI-DI code: 1212112121212DL

\* Risk class:  
--

\* Indication of medical purpose:    \* Select the language:

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

2017745 on medical devices)

Basic UDI-DI code: 12121121212DL  
Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

\* Indication of medical purpose: [Text area]

\* Select the language: [Dropdown menu]

+ 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: [Text input field]

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

Save Save & Next >

### 5.1.3 Step 3: UDI-DI identification information

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

UDI-DI identification

UDI-DI identification

\* Issuing Entity: [Dropdown menu with GS1 selected]

\* UDI-DI code: [Text input field]



#### IMPORTANT

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



**NOTE**

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

For example:

- **000000nnnnnnnn (GTIN-8)**
- **00nnnnnnnnnnnn (GTIN-12)**
- **0nnnnnnnnnnnnnn (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 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:

Select the language:

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

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

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

**\* UDI-DI status**

Not intended for the EU market

On the EU Market

### 5.1.4 Step 4: UDI-DI characteristics

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

Progress bar: 1. Basic UDI-DI information (checked), 2. UDI-DI identification information (checked), 3. UDI-DI characteristics (active), 4. Container package(s)

**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: \* Description:

Caution: Contains of presence of...

Defibrillation-proof type CF applied part

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

Test

Save
Save & Next >



**NOTE**

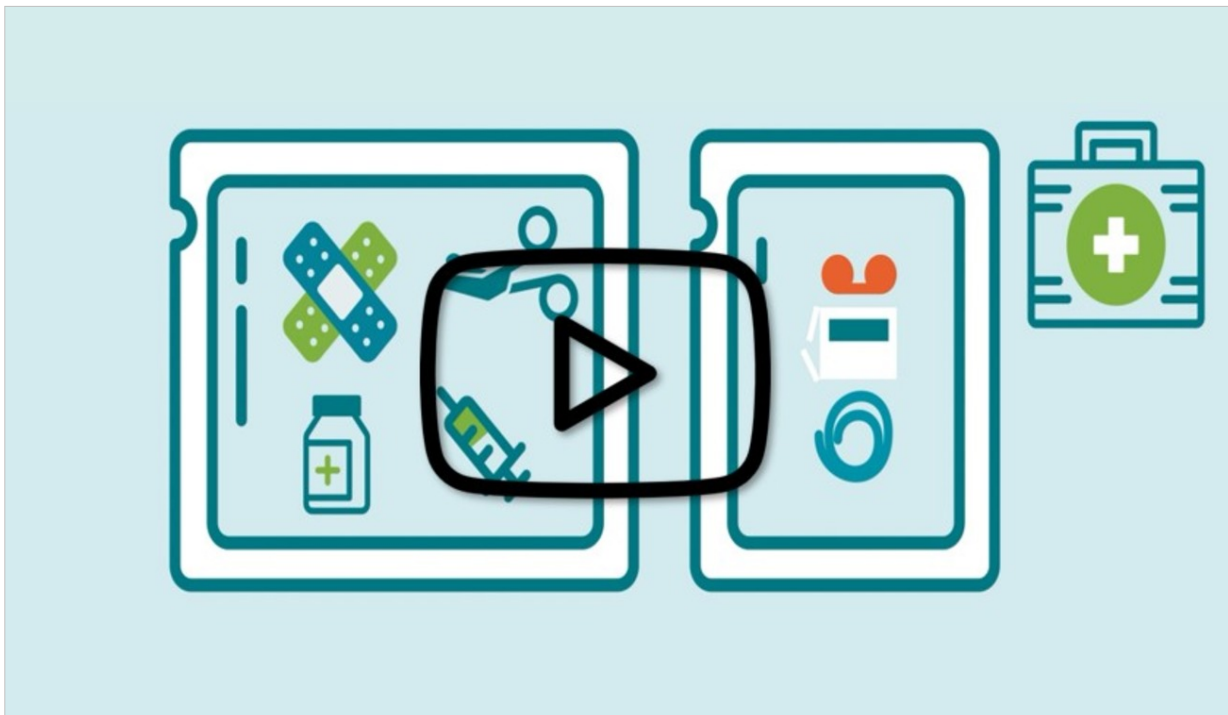
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the language in which the description is given.

- 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 >

### 5.1.5 Step 5: Container package details

**VIDEO: UDI and Systems and Procedure Packs**



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

The screenshot shows a notification bar at the top with an information icon and the text: "You are not obliged to provide container package(s) UDI-DI before submitting this request." Below the notification is a button with a plus icon and the text "Add container package". At the bottom of the interface are three buttons: "Save", "Submit >", and "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*, and click on **Save**:



**NOTE**

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

The screenshot shows a dialog box titled "Add container package" with a "Close" button in the top right corner. The dialog contains a table with the following data:

* Issuing Entity:	* Package UDI-DI value:	* Quantity per package:	Total number of devices
HIBCC	5455678	3	9

At the bottom of the dialog are "Save" and "Cancel" buttons.

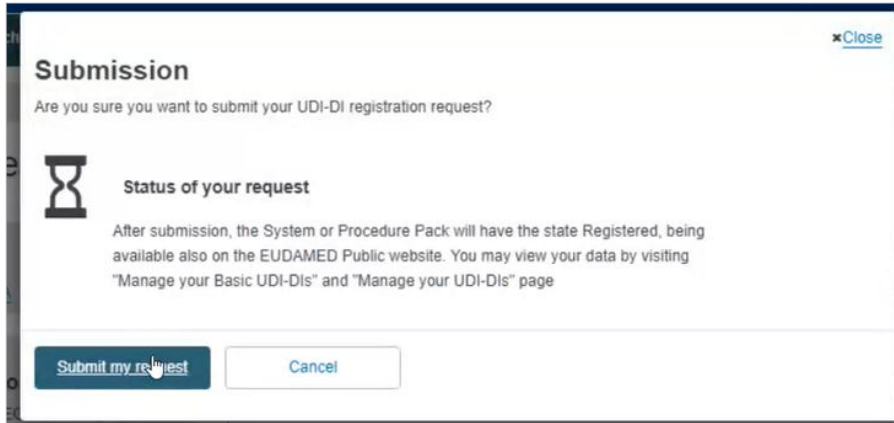
2. Select the generated information and click on **Submit**:

The screenshot shows a list of container packages with three action buttons at the top: "Add container package", "Edit container package", and "Delete container package". The list contains the following items:

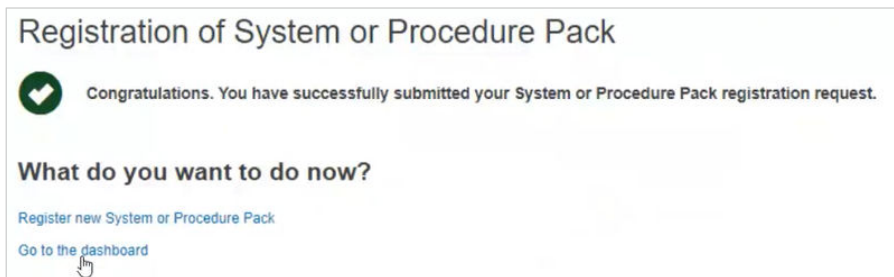
- [Root] UDI-DI: 76766766 (HIBCC)
- UDI-DI: 5455678 (HIBCC) | Quantity per package: 3 (9)
- UDI-DI: 767676 (HIBCC) | Quantity per package: 9 (81)

At the bottom of the interface are three buttons: "Save", "Submit >", and "Preview".

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

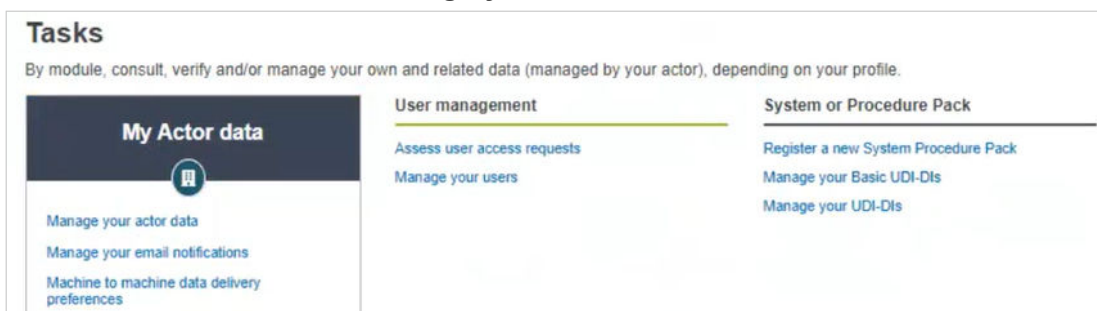


Upon submission, you will see a message that you have successfully submitted a SPP registration request:



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

- On the Dashboard, select **Manage your Basic 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

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

### 5.2.1 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:  \* 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

\* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

Selected nomenclature codes

Code **A01010101** HYPODERMIC NEEDLES FOR SYRINGE **i** [Remove nomenclature code](#)

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](#)

\* 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

## 5.2.2 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 **i** Storage/handling conditions are required unless you select the option - No

Critical warnings or contra-indications, if applicable

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

\* Critical warning type:

**+** [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).

## 5.2.3 Step 3: Container package details

To complete this step, please consult [Section 5.1.5 \[42\] Container Package Details \[42\]](#) of this guide.

# 6 Manage your own device information

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

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

The screenshot shows the EUDAMED dashboard for a manufacturer. At the top, it says 'CURRENT ACTOR: Manufacturer, BE-MF-00000001, Belgium MFA V3 [Belgium]'. Below this is a 'Welcome to EUDAMED' message and a 'See all the news' button. The 'Tasks' section is divided into three columns: 'My Actor data', 'User management', and 'UDI-DIs/Device'. Under 'UDI-DIs/Device', the option 'Manage your Basic UDIs / EUDAMED DIs' is highlighted.

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



### NOTE

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

Basic UDI-DIs / EUDAMED DIs management

Go to Device details management > Register a new Basic UDI-DI Register Legacy Device

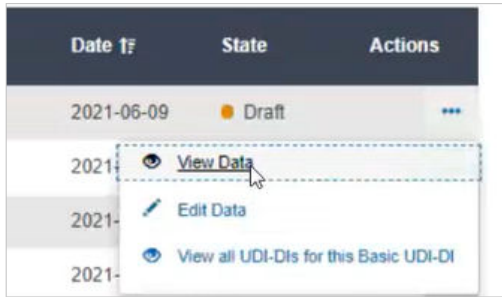
Filter ▾

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

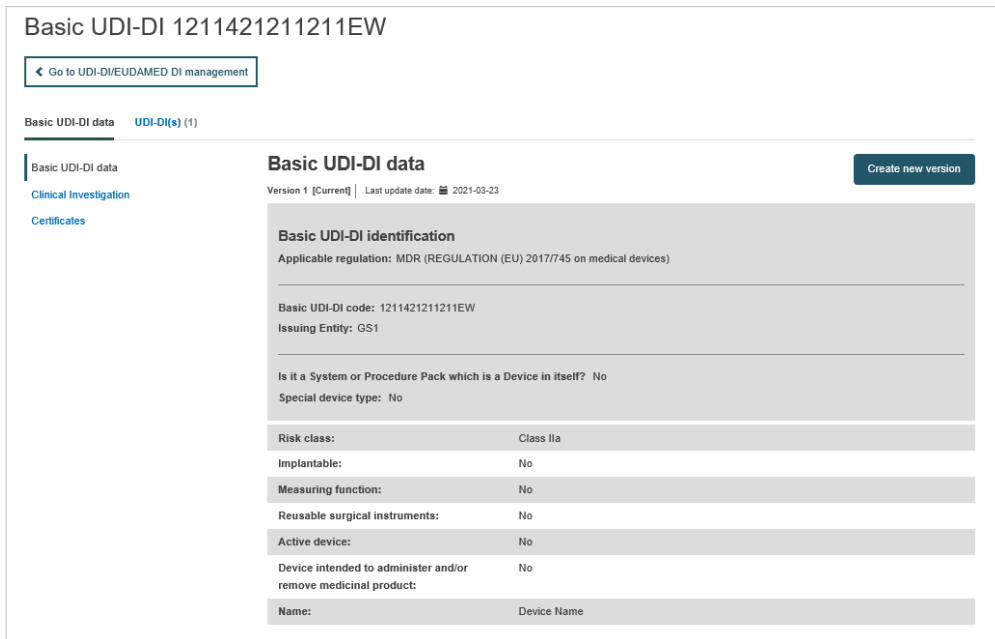
Showing 1 to 9 of 9 entries Show 20 entries per page

Basic UDI-DI/EUDAMED DI Code <i>IT</i>	Devices <i>IT</i>	Device model <i>IT</i>	Device Name <i>IT</i>	Risk class	Date <i>IT</i>	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:



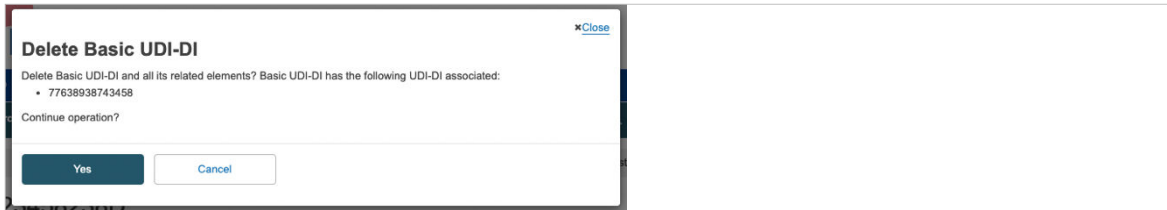
### 6.1.1 Delete a draft Basic UDI-DI/EUDAMED DI

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

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

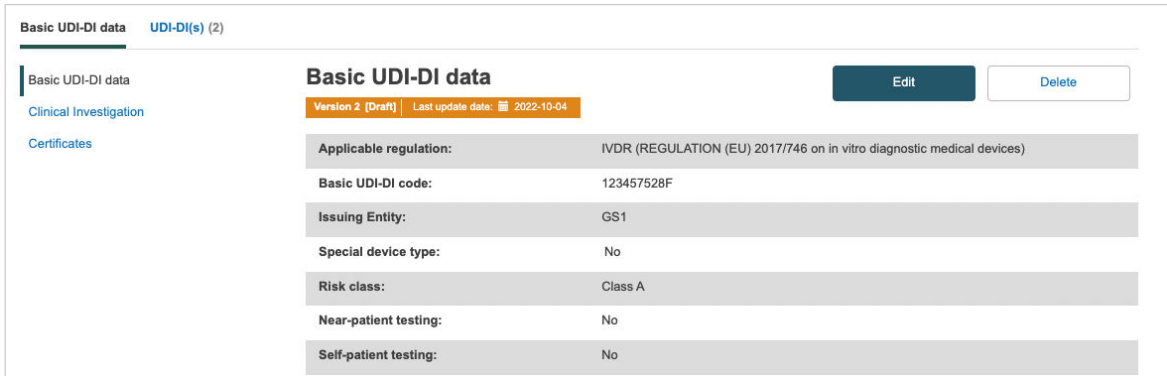


A pop-up will ask you to confirm the *delete* action:

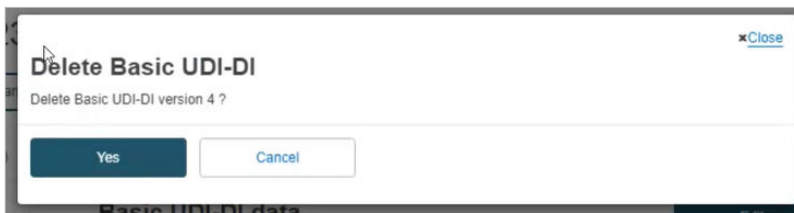


The system also warns about deletion of the UDIs under the *1st draft* device.

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



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



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

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

- 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.

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

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

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

**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

- 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	>

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

[Go back to the current version](#)

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

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

**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



# 6.2 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

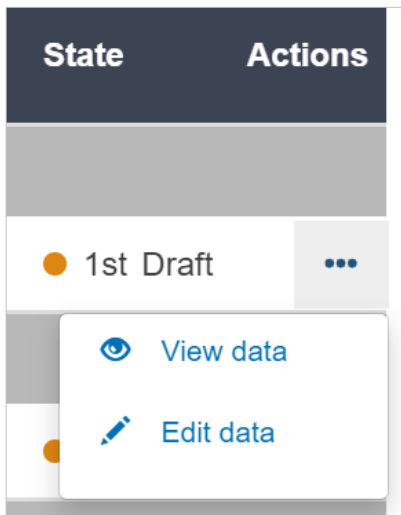
UDI-DI/EUDAMED ID Code II	Trade name II	Reference/Catalogue number II	Nomenclature code II	Date f†	Status	State	Actions
▼ EUDAMED DI code: <b>B-435345PL</b> , Device Name: dsfdafd, Class IIb, MDD (Directive 93/42/EEC on Medical Devices)							
D-435345PL				2021-03-29	On the EU market	● 1st Draft	...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



**NOTE**

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

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

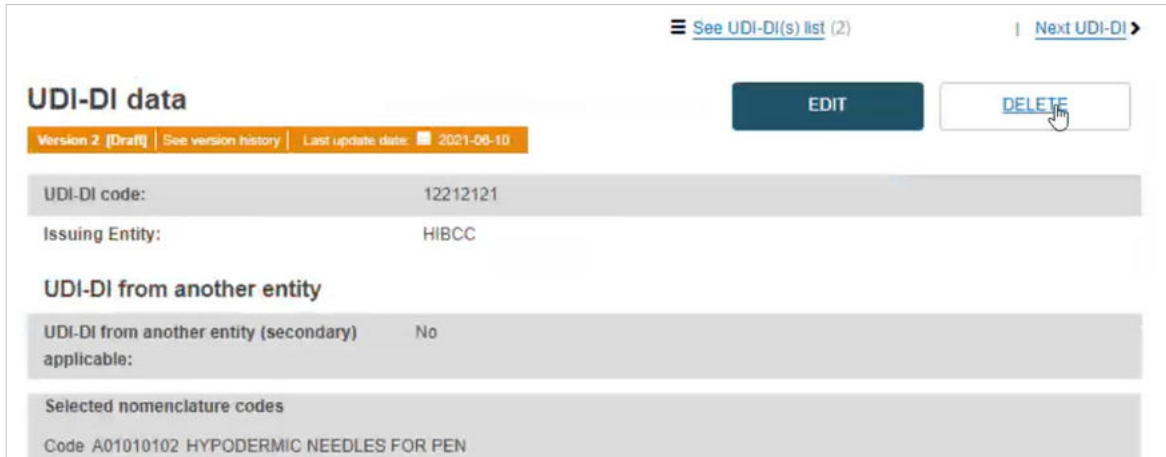


4. You will see a summary of the details of your device:

## 6.2.1 Delete a draft UDI-DI/EUDAMED ID

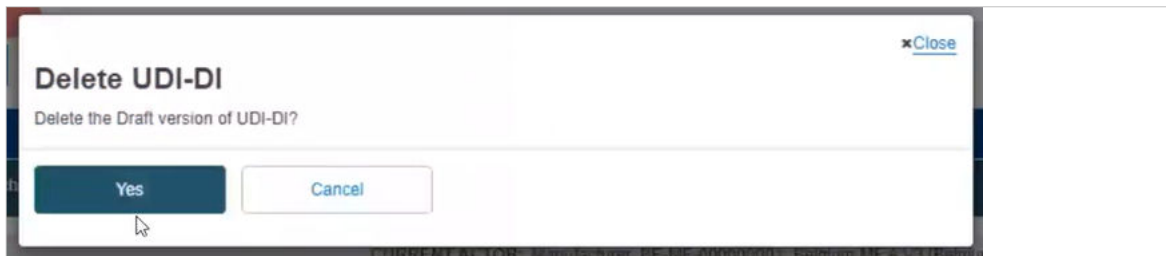
Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[53\]](#) to view a draft UDI-DI.

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



The screenshot shows the 'UDI-DI data' page. At the top right, there are links for 'See UDI-DI(s) list (2)' and 'Next UDI-DI >'. Below the title, there are 'EDIT' and 'DELETE' buttons. 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'.

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



The screenshot shows a 'Delete UDI-DI' confirmation dialog box. The title is 'Delete UDI-DI' and the message is 'Delete the Draft version of UDI-DI?'. There are two buttons: 'Yes' and 'Cancel'. A 'Close' button is visible in the top right corner of the dialog.

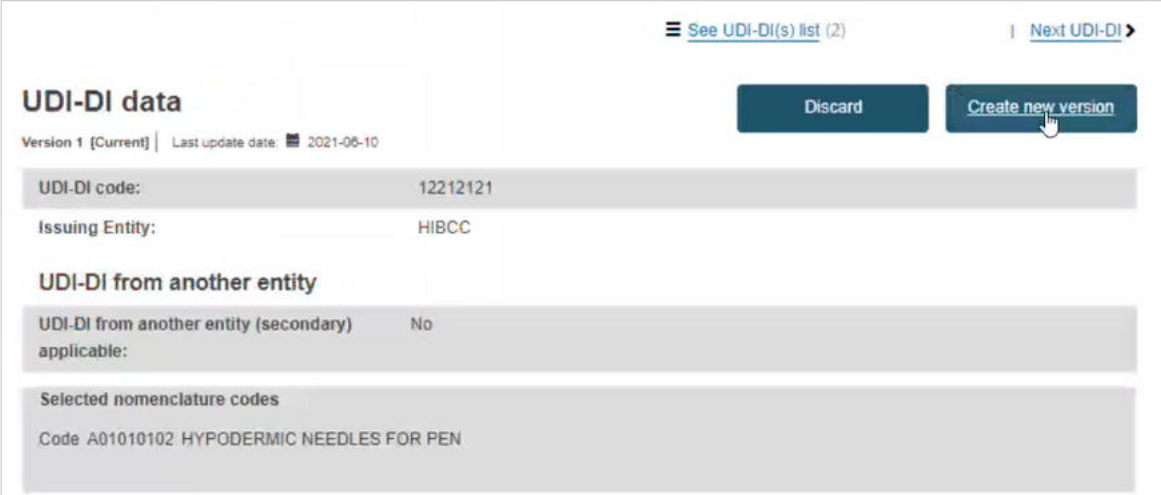
## 6.2.2 Update (create a new version) for UDI-DI/ EUDAMED ID

### VIDEO: UDI assignment and updates



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

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



The screenshot shows the 'UDI-DI data' page in EUDAMED. At the top right, there are links for 'See UDI-DI(s) list (2)' and 'Next UDI-DI >'. Below the title, there are two buttons: 'Discard' and 'Create new version'. A mouse cursor is pointing at the 'Create new version' button. The page displays the following information:

Version 1 [Current]	Last update date: 2021-06-10
UDI-DI code:	12212121
Issuing Entity:	HIBCC
<b>UDI-DI from another entity</b>	
UDI-DI from another entity (secondary) applicable:	No
<b>Selected nomenclature codes</b>	
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):  
   
 801 clature  
 Selected nomenclature codes  
 Code A01010102 HYPODERMIC NEEDLES FOR PEN Remove nomenclature code

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

\* Trade name:  \* Select the language:   
Add a trade name in another language

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

### 6.2.3 Update (create new version) for Product Designer

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[53\]](#) to view a UDI-DI/EUDAMED ID.
2. Once inside the details of the selected UDI-DI, click on **Product Designer** from the list on the left (or scroll down to the *Product Designer* section):

Basic UDI-DI data UDI-DI(s) (2)

UDI-DI 12212121 See UDI-DI(s) list (2) Next UDI-DI >

UDI-DI data

Version 2 [Draft] See version history Last update date: 2021-06-10

UDI-DI code: 12212121

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

3. Click on **Update**:

**Product designer** Update

Version 1 [Current] | Last update date: 2021-06-10

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

Original equipment manufacturer organisation:

Organisation name:	Test
Street information, if applicable:	Yes
Street:	test
Street number:	-
Address line 2:	-
PO box:	-
City name:	BBBB v2
Postal code:	1111
Country:	Albania
Telephone:	-

4. Update the information under *Product Designer*:

**Natural or Legal Person update**

I know the SRN

\* 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:

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

## 6.2.4 Update (create new version) for Market Information

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[53\]](#) 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):

UDI-DI data This device is not currently linked with any other devices

**Product designer** Update

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

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

Original equipment manufacturer organisation:

Organisation name: Test\_v2

Street information, if applicable: Yes

Street: test

Street number: -

Address line 2: -

PO box: -

City name: BBBB v2

Postal code: 1111

Country: Albania

Telephone: -

Email: t@t.com

**Market Information** Update countries

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	-	-

- Click on **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](#)

Submit Cancel

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

Market Information			
Version 2   <a href="#">See version history</a>   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	-	-

## 6.2.5 Update (create new version) for Container Packages

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[53\]](#) to view a UDI-DI/EUDAMED ID.
2. Once inside the details of the selected UDI-DI, click on **Container Package information** from the list on the left (or scroll down to the relevant section):

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



**Add container package** ✕Close

Container package UDI-DI for UDI-DI 12212121

* Issuing Entity:	* Package UDI-DI code:	* Quantity per package:	Total number of devices
HIBCC	12121212	5	5

**Save**

**Container package update**

**Container package(s)**

[+ Add container package](#) [Update container package status](#)

- [Root] UDI-DI: 12212121 (HIBCC)
  - UDI-DI: 3232 (HIBCC) | Quantity per package: 3 (3)
  - UDI-DI: 12121212 (HIBCC) | Quantity per package: 5 (5)
    - UDI-DI: 212121 (HIBCC) | Quantity per package: 4 (20)

**Submit**

**Update container package status** ✕Close

Container package UDI-DI 3232

**Container package market status**

No longer placed on the EU market  On The Market

**Confirm**

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

**Container package update**

**Container package(s)**

[Update container package status](#)

- [Root] UDI-DI: 12212121 (HIBCC)
  - UDI-DI: 3232 (HIBCC) | No longer placed on the EU market
  - UDI-DI: 12121212 (HIBCC) | Quantity per package: 5 (5)
    - UDI-DI: 212121 (HIBCC) | Quantity per package: 4 (20)

**Submit**

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



### IMPORTANT

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

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[53\]](#) to view a registered UDI-DI/EUDAMED ID.
2. Once inside the details page of the selected UDI-DI, click on **Discard** on the top right corner:

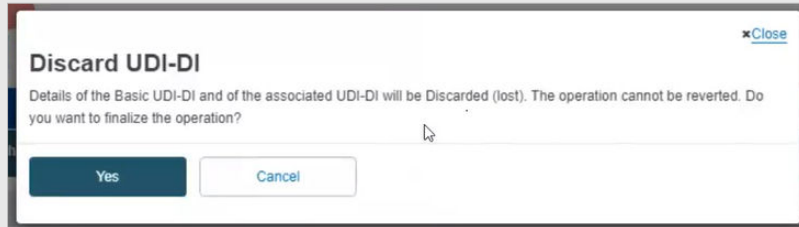
3. Confirm whether you wish to discard the registered UDI-DI:

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



**CAUTION**

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



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

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

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

**EUDAMED-DI D-1231231UU** [See UDI-DI\(s\) list \(1\)](#)

UDI-DI data

[Product designer](#)

[Market Information](#)

**UDI-DI data**

Version 2 [Draft] | [See version history](#) | Last update date: 2021-05-25

[EDIT](#) [DELETE](#)

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

2. 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**

<b>EUDAMED ID code:</b>	D-1231231UU
<b>Issuing Entity:</b>	EUDAMED
<b>Selected nomenclature codes</b>	
Code A01010102 HYPODERMIC NEEDLES FOR PEN	

**Trade name**

<b>Trade name applicable:</b>	No
<b>Reference/Catalogue number:</b>	44545
<b>URL for additional information (as electronic instructions for use):</b>	-
<b>Device status:</b>	On the EU market

**Clinical size**

<b>Clinical size applicable:</b>	No
----------------------------------	----

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

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

## 7.1 Manage your SPP Basic UDI-DI details

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

### 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	UDI-DI(s)	Device model	Device Name	Risk class	Type	Date	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	...

2. 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

- 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 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	

### 7.1.1 Delete a draft Basic UDI-DI

- Follow the steps in section [Manage your SPP Basic UDI-DI details \[65\]](#) 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	rferfefrefre	vddgv	Class I	PP	2021-06-		Edit Data
1212112121212DL	0	-		-	PP	2021-06-		View all UDI-DIs for this Basic UDI-DI

- 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	Language
	indication	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

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

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

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-		<a href="#">View Data</a>
9970314941ShriyaHL	1	-	Test ONE	Class I	PP	2021-05-		<a href="#">View all UDI-DIs for this Basic UDI-DI</a> <a href="#">Add a UDI-DI for a Basic UDI-DI</a>

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 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	

### 7.1.3 View historical version for Basic UDI-DI

1. Follow the steps in section [Manage your SPP Basic UDI-DI details \[65\]](#) to view a Basic UDI-DI.
2. Once inside the details page for the selected Basic UDI-DI, click on **See version history** at the top of the table:

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

<b>Risk class:</b>	Class I	
<b>Indication of medical purpose:</b>	Indication of medical purpose	Language
	SPPP test 1	Croatian
<b>Name:</b>	SPP_Shr_1	

## 7.2 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)								<a href="#">+ Add a new UDI-DI</a>
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)								<a href="#">+ Add a new UDI-DI</a>
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)								<a href="#">+ Add a new UDI-DI</a>
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:

Showing 20 entries per page

Status	State	Actions
On the EU market	Registered	⋮
On the EU market	Registered	⋮
On the EU market	Registered	⋮

*(Note: In the original image, a 'View data' menu item is highlighted over the second entry's actions menu.)*

- 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 [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**

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

## 7.2.1 Delete a draft UDI-DI

1. Follow the steps in section [Manage your SPP UDI-DI details \[70\]](#) to view a Draft UDI-DI.
2. Once inside the draft, click on **Delete**:

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

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

UDI-DI data **EDIT** DELETE

Container Package Information Version 2 [Draft] | See version history | Last update date: 2021-07-02

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:

[Close](#)

**Delete UDI-DI**

Delete the Draft version of UDI-DI?

**Yes**
Cancel

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

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

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

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

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	

Create new version

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

\* Enter a nomenclature code (EMDN code):

Advanced search of device nomenclature

Selected nomenclature codes

Code A010204 NEEDLES AND KITS - AMNIOCENTESIS Remove nomenclature code

Trade name applicable

Yes  No  i 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:

test

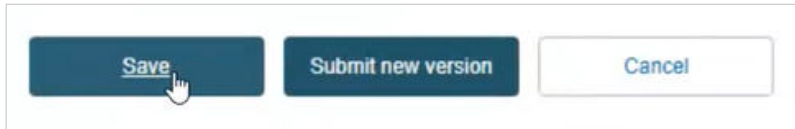
+ Add additional product description in another language

\* Select the language:

Bulgarian
×
▼

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

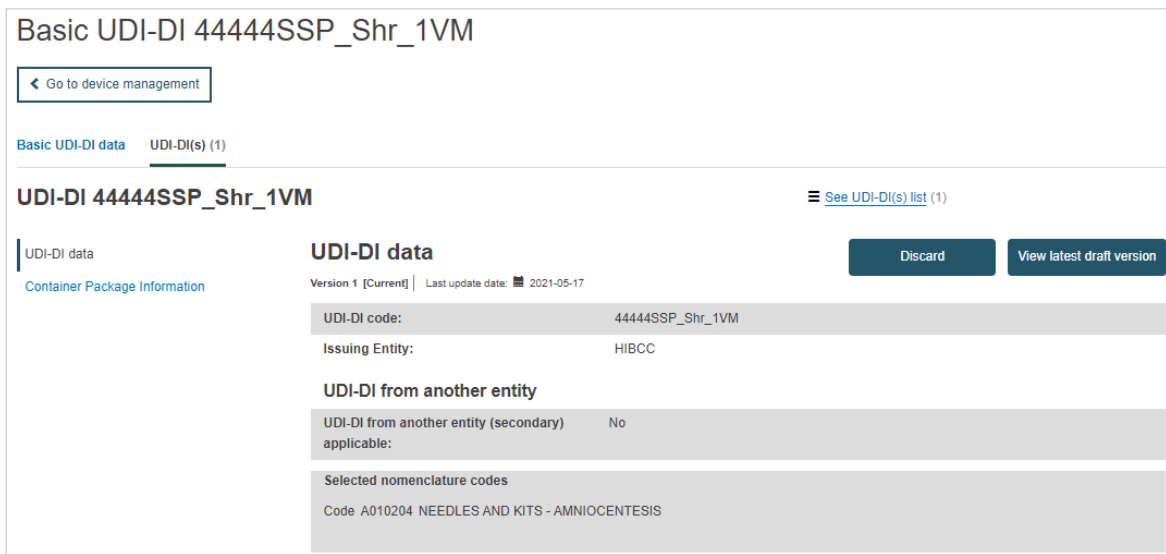
Otherwise, you can press **Cancel** to cancel the update.



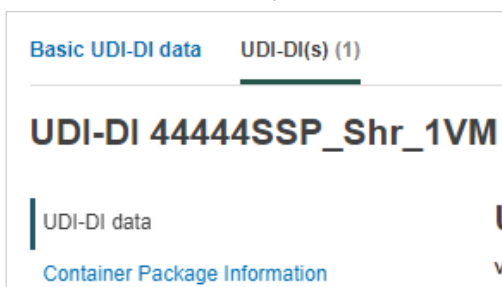
## 7.2.3 Update (create new version) for Container Packages

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

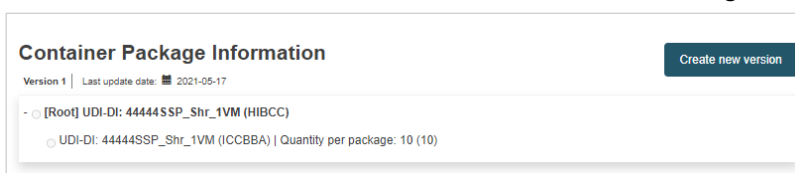
1. Follow the steps in section [Manage your SPP UDI-DI details \[70\]](#) to view a specific UDI-DI:



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



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



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

## Container package update

### Container package(s)

[+ Add container package](#)

-  [Root] UDI-DI: 44444SSP\_Shr\_1VM (HIBCC)

UDI-DI: 44444SSP\_Shr\_1VM (ICCBBA) | Quantity per package: 10 (10)

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 44444SSP\_Shr\_1VM

* Issuing Entity:	* Package UDI-DI code:	* Quantity per package:	Total number of devices
<input type="text" value="GS1"/>	<input type="text"/>	<input type="text" value="2"/>	2

## 7.2.4 Discard SPP registered UDI-DIs

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

UDI-DI details management for SPP

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

Active filters:  [Clear all filters](#)

Showing 1 to 3 of 3 entries Show  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) <span style="float: right;"><a href="#">+ Add a new UDI-DI</a></span>								
44444SSP_Shr_1VM		SPPP_Shr_1			2021-05-17	On the EU market	Registered	<a href="#">⋮</a>
Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) <span style="float: right;"><a href="#">+ Add a new UDI-DI</a></span>								
34675806754T9	system 1	543			2021-05-14	On the EU market	Registered	<a href="#">⋮</a>
Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) <span style="float: right;"><a href="#">+ Add a new UDI-DI</a></span>								
997031494145675552	trade1	34234			2021-05-14	On the EU market	Registered	<a href="#">⋮</a>

2. Once inside the details page of the chosen UDI-DI, click on **Discard** on 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
<b>UDI-DI from another entity</b>	
UDI-DI from another entity (secondary) applicable:	No
<b>Selected nomenclature codes</b>	
Code	A010204 NEEDLES AND KITS - AMNIOCENTESIS
<b>Trade name</b>	
Trade name applicable:	No
Reference/Catalogue number:	SPPF_Shr_1
<b>Type of UDI-PI</b>	
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 \(1\)](#)

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	

- 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-PI will be Discarded (soft). The operation cannot be reverted. Do you want to finalize the operation?

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

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

- Follow the steps in section [Manage your SPP UDI-DI details \[70\]](#) to view a UDI-DI for the SPP.
- Once inside the details of the chosen UDI-DI, click on **See version history** on the top of the table:

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

Version 4 [Current] | [See version history](#) | Last update date: 2021-08-10

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**

I [See all version history \(3\)](#) [← Previous version \[v1\]](#) | [Next version \[v3\] ▶](#)

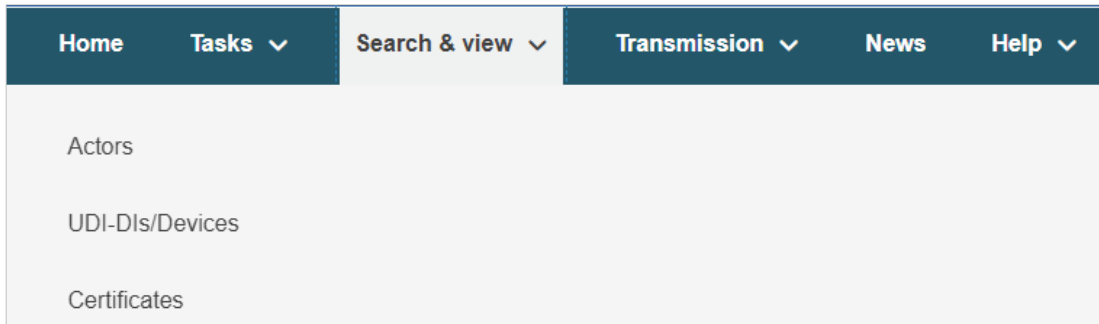
**Version 2 - Last update date: 2021-06-09**

<b>Basic UDI-DI identification</b>	
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

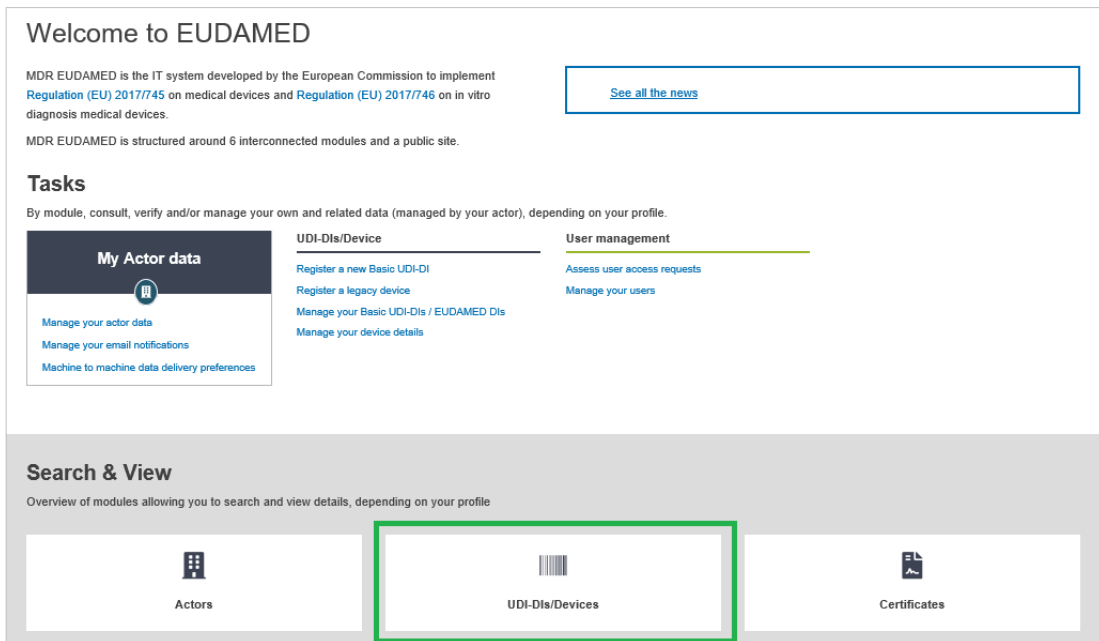
You can return to the version history list by clicking on **See all version history** on the top right corner.

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

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



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



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

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED ID   
  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

- 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 <input type="button" value="↑"/>	Basic UDI-DI code <input type="button" value="↑"/>	MF / PR SRN	Trade name <input type="button" value="↑"/>	Risk class	Date <input type="button" value="↑"/>	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

- 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

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

1. Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[79\]](#) to search and view a device or system or procedure pack.
2. Inside the search page, select the filters for your search, activate the option to include historical versions (toggle just above the **Search** button) and click on **Search**:

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED DI:

Basic UDI-DI/ EUDAMED DI:

Status: --  x v

Model:

Name:

Trade name:

Applicable regulation: --  x v

Risk class: --  x v

Nomenclature code:

Reference/Catalogue number:

Country: --  x v

Scopes

---

Competent Authority: --  x v

NB identification: --  x v

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

---

**Results option**  
 Include historical version

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

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

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

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:

---

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

**Results option**

Include historical version

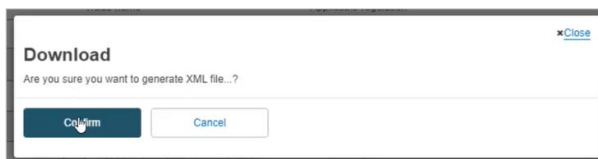
2. Click on **Generate XML file**:



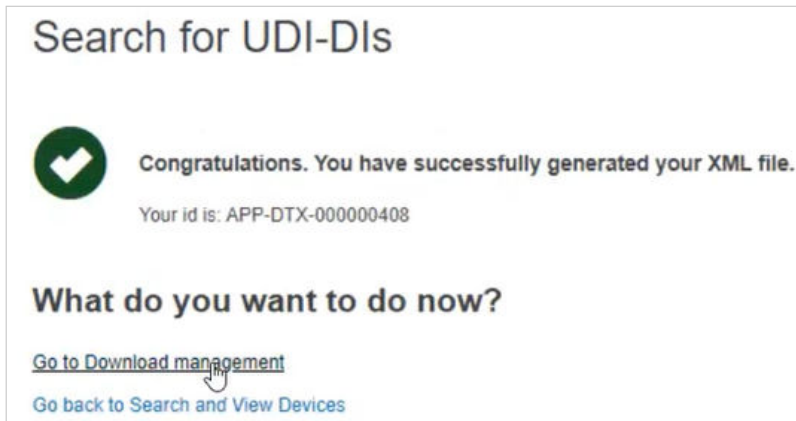
**NOTE**

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

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




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



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







Download management

Filter 

Active filters: No selection

Showing 1 to 1 of 1 entries

Show  entries per page

ID	Name	Module 	Service 	State 	Request date 	Download
APP-DTX-000000408	John Smith	UDI/Device	Device download	 Failed	2021-06-10 [16:57]	<a href="#">XML [4 KB]</a>  Expires in 15 days

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

- Follow the steps in [Search & View historical versions of Devices, System and/or Procedure Packs \[81\]](#) to view the details of a Device or System or Procedure Pack.
- Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product Designer or Container Package) and click on **See version history**:



UDI-DI 121312\_Test\_AR

[Go back to the list](#)

- Manufacturer information
- Basic UDI-DI details
- UDI-DI details
- Market information
- Clinical Investigation(s)

### Manufacturer information

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

### Authorised Representative

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

### Basic UDI-DI details

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

### Basic UDI-DI identification

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

---

Basic UDI-DI code: 22091test23\_09EC  
 Issuing Entity: GS1

---

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

List of UDI-DIs for the Basic UDI-DI

### UDI-DI details

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

UDI-DI code: 121312\_Test\_AR

Issuing Entity: HIBCC

### UDI-DI from another entity

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

### Selected nomenclature codes

Code A01010199 HYPODERMIC NEEDLES - OTHERS

### Trade name

Trade name applicable: Yes

Trade name: TB\_BG [BG], TN\_AR1\_Croatian [HR]

Reference/Catalogue number: ref

### Is the device directly marked?

Is the device directly marked?: No

**Market information**

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

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

**Clinical Investigation(s)**

Clinical Investigation

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

- 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	>

- 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

5. Inside a version, click on the links on 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

# 9 Annex 1 – device certificate information

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

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

Colour-code description.

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

# 10 Annex 2 – Legacy Device certificate types

The Annex presents the certificate types that can be used when registering a Legacy Device.

Certificate types depend on the applicable legislation of the Device.

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

