



# **EUDAMED user guide**

## **UDI Devices**

Playground v 3.6  
2023

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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>

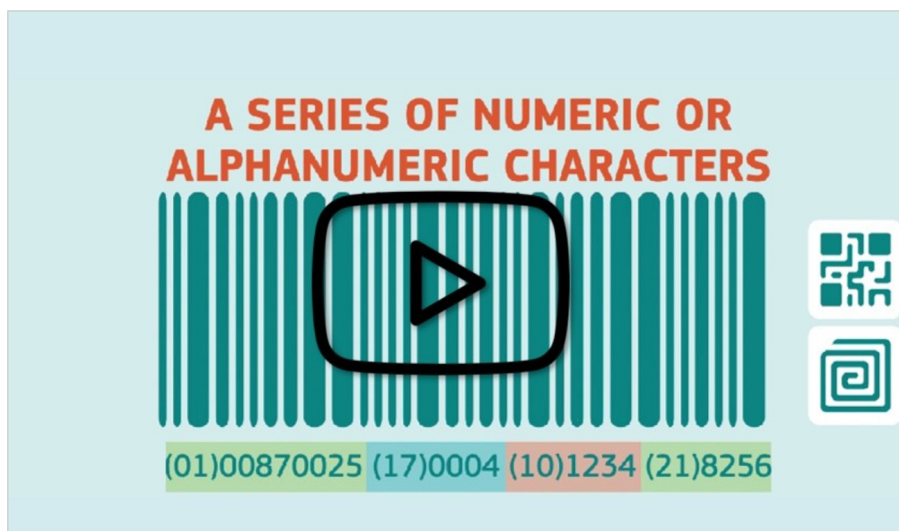


## WARNING

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



## VIDEO: What is a UDI?



## INFOGRAPHIC: Basic UDI-DI/UDI-ID concept

<sup>1</sup>For a wider understanding on how to use the platform, including FAQs and process infographics, visit the <https://webgate.ec.europa.eu/eudamed-play-help/en/welcome-to-the-eudamed-information-centre.html>. For information specific to UDI, visit the [UDI Helpdesk](#).

## IDENTIFIERS

What are the different identifiers?

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

Basic UDI-DI

UDI-DI

Package UDI-DI  
(If applicable)

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## 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 *User rights and profiles*, for more information on user rights and profiles.



### IMPORTANT

A Local Actor Administrator (LAA)/Local User Administrator (LUA) of your manufacturer must approve your user access request.

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

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# 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.

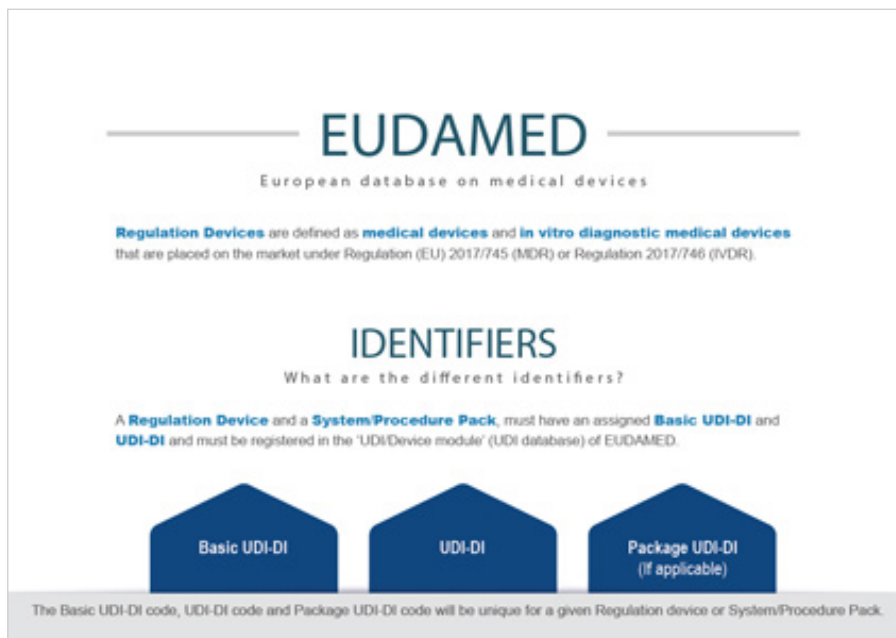
 **INFOGRAPHIC:** [UDI registration for regulation devices](#)

Playground



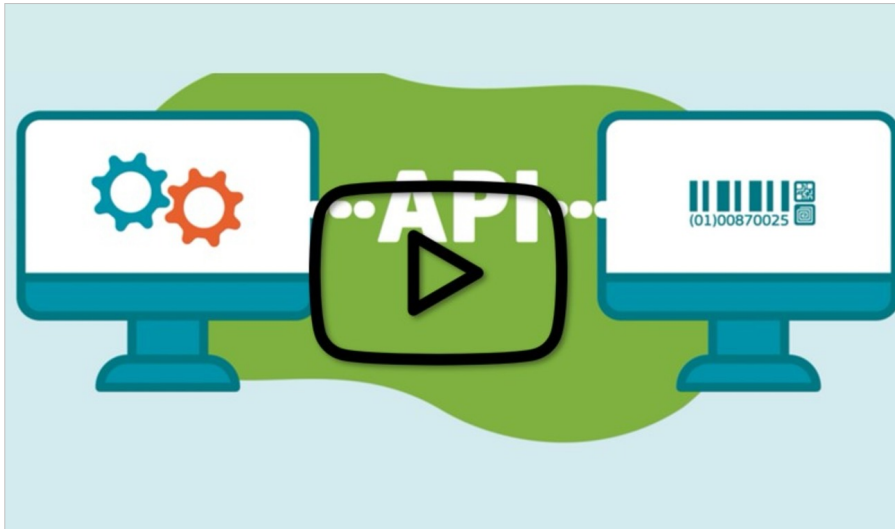
## 3.1 Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device

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



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

#### VIDEO: UDI and medical software devices



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

Welcome to EUDAMED

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

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

[See all the news](#)

#### Tasks

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

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

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



#### NOTE

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

### UDI-DI registration

#### Manufacturer identification

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

**\* Applicable regulation**

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

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

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

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

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

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

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

**Special device type**

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

**\* Special device type:**

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

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



**NOTE**

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

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

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

**Basic UDI-DI main information**

\* Issuing Entity:

\* Basic UDI-DI code:

**IMPORTANT**

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

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

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

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

**Authorised representative identification**

Organisation name: Belgian AR A

Eudamed actor ID: BE-AR-000000046

Address: Rue E, 1 1060 Brussels

Telephone number: -

Email: contact@belgian-ar-a.be

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

**Basic UDI-DI information**

\* Risk class:

---

\* Measuring function

☐ Yes ☐ No

\* Active device

☐ Yes ☐ No

\* Device intended to administer and/or remove medicinal product

☐ Yes ☐ No

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

Device model applicable

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

\* Device model:

Device Model\_Test

Device Name:

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

Save Save & Next >

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

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

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

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

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

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

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

**NOTE**


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

In [Annex 1 \[101\] – Device Certificate Information \[101\]](#) you can find the different cases in which Certificate information is needed and the type of certificate. (In summary, it is applicable for MDR risk class III and IIb and IVDR risk class B with self-patient testing/ near-patient testing, risk class D and C).

**Certificate information**

EU type-examination certificate if applicable

Yes ☒ No ☐

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

\* Enter NB number or name:

Certificate number:

Revision number:

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### 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:

**000000nnnnnnnnn (GTIN-8)**

**00nnnnnnnnnnnnnn (GTIN-12)**

**0nnnnnnnnnnnnnnn (GTIN-13)**

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

**UDI-DI identification**

UDI-DI identification

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

---

UDI-DI from another entity (secondary) applicable

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

\* Issuing Entity:  \* Secondary UDI-DI value:

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

\* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Trade name applicable

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

\* Trade name:  \* Select the language:

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

5. Enter the *Reference/Catalogue number*.

\* Reference/Catalogue number:

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

**\* Is the device directly marked?**

☒ Yes ☐ No

☐ Same as UDI-DI

**\* Issuing Entity:**

**\* Direct marking DI:**

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

**\* Is the device directly marked?**

☐ Yes ☒ No

**\* Quantity of device:**

**Issuing Entity:**

**Unit of Use DI:**

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

**\* Is the device directly marked?**

☐ Yes ☒ No

**\* Quantity of device:**

**\* Type of UDI-PI**

☐ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☐ Expiration date

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

**\* Quantity of device:**

**\* Type of UDI-PI**

☐ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☒ Expiration date

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

Additional product description:

Product Description

Select the language:

Bulgarian  
Croatian  
Czech  
Danish  
Dutch  
English

+ Add additional product description in another language

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

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

\* UDI-DI status

☐ No longer placed on the EU market

☒ Not intended for the EU market

☐ On the EU market

Save Save & Next >

### 3.1.4 Step 4: UDI-DI characteristics

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



#### NOTE

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

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

Clinical size applicable

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

Select type(s) of dimension you need

\* Type: Frequency

\* Precision: Range

\* Minimum: 50

\* Maximum: 60

\* Measure unit: hertz (Hz)

+ Add a type of dimension

You shall provide one of the following precision type:

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

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

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

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

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

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

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

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

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

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



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

☒ Yes ☐ No

**\* Category of CMR:**  
☒ 1A ☐ 1B

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

EC#:  CAS#:

[ECHA database >](#)

**\* Name of the substance:**

[Add a CMR substance](#)

Labelled for presence of substance(s) with endocrine-disrupting properties:  
☐ Yes ☐ No

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

**Storage/handling conditions, if applicable**

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

**\* Storage/handling conditions type:**

**\* Description:**

**\* Select the language:**

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

[Add another storage/handling condition](#)

**NOTE**


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

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

Critical warnings or contra-indications, if applicable

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

\* Critical warning type:

Caution: Contains of presence of... 

Defibrillation-proof type CF applied part

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

\* Description:

Test

Save Save & Next >

**NOTE**

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

### 3.1.5 Step 5: Device information

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

**Device information**

\* Reprocessed single use device

☐ Yes ☐ No

\* Intended purpose other than medical (Annex XVI)

☐ Yes ☐ No

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

\* Intended purpose other than medical (Annex XVI)

☒ Yes ☐ No

☒ Contact lenses

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

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

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

☐ High intensity electromagnetic radiation

☐ Brain electrostimulation

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

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

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

Yes ☒ No ☐

☒ I know the Actor ID/SRN

\* Enter Actor ID/SRN or name:

**NOTE**

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

Select the Actor from the list:

[Close](#)

### Select manufacturer

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

1 2 ... 19

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

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

Yes ☒ No

☐ I know the Actor ID/SRN

\* Product original manufacturer organisation name:

[Check registry](#)

Select the Organisation name from the list:

[Close](#)

### Select manufacturer

Organisation name **!**

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

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

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

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

Playground

[Change manufacturer](#)

\* Name (Manufacturer Name):

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

\* Street:  Street number:

Address line 2:

PO box:

\* City name:  I \* Postal code:

\* Country:  
 x v

Telephone:

Telephone format example: +32 x xxx xx xx

\* Email:

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

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

x Clinical Investigation '212121' is not registered in EUDAMED 🗑

\* Enter Clinical Investigation Number: 🗑

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

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**\* Tissues and cells**

Presence of human tissues or cells, or their derivatives:

☐ Yes ☒ No

Presence of animal tissues or cells, or their derivatives:

☐ Yes ☒ No

**\* Information on substances**

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

-- ▾

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

**\* Information on substances**

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

☒ Yes ☐ No

INN:

\* Name of the substance:

\* Select the language: -- ▾

+ [Add another language](#)

+ [Add a substance](#)

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

☐ Yes ☒ No

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

**\* Tissues and cells**

Presence of human tissues or cells, or their derivatives:

☐ Yes ☐ No


Presence of animal tissues or cells, or their derivatives:

☐ Yes ☐ No

Presence of cells or substances of microbial origin:

☐ Yes ☐ No

**\* 'New' Device**

☐ Yes ☐ No 

**NOTE**

A device shall be considered *new* if:

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

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

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

France ▼

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

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

[Select one or more countries >](#)

**NOTE**

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

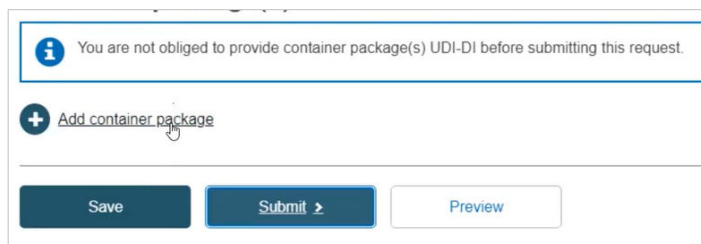
### 3.1.6 Step 6: Container package details



#### VIDEO: UDI carrier placing



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



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

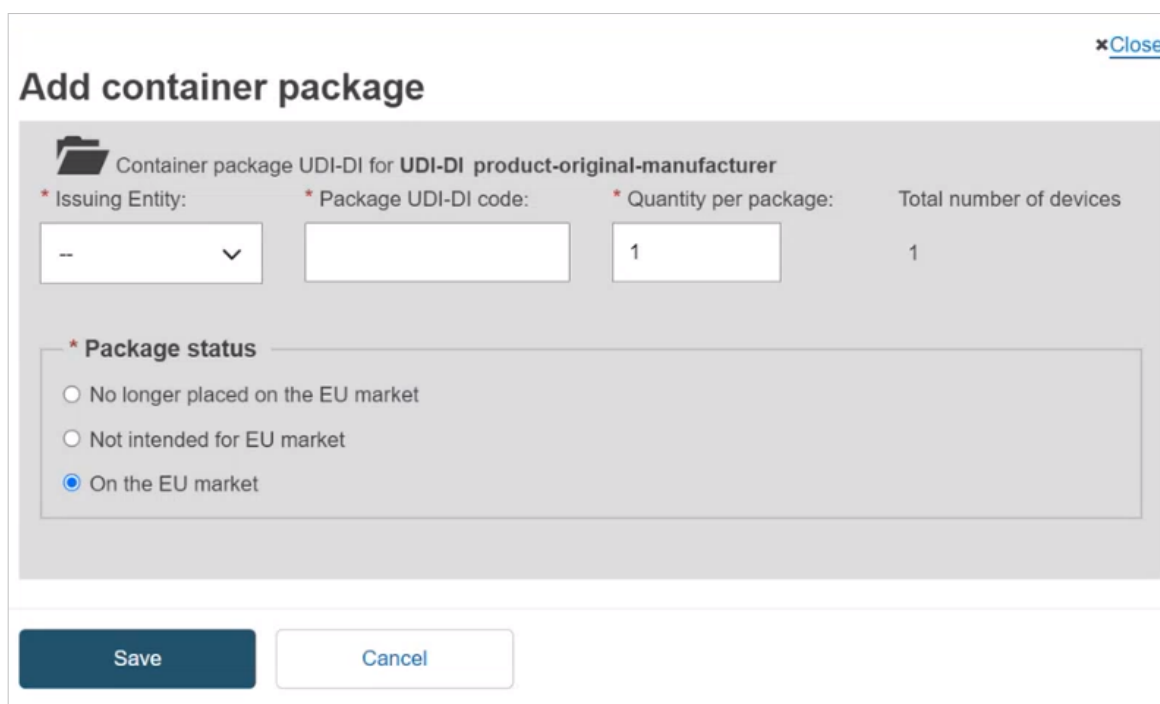
**+ Add container package**

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

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

**NOTE**

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



**Add container package** [\\*Close](#)

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

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

\* **Package status**

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

**Save** [Cancel](#)


**NOTE**

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

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




### Container package(s)

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

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


- ☐ [Root] UDI-DI: product-original-manufacturer (ICCBBA) | Status: On the EU market
  - ☒ UDI-DI: boxxx-6 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market

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

 Close


### Submission

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



**Status of your request**

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




**Outcome by email**

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

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

## Basic UDI-DI registration



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

### What do you want to do now?

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

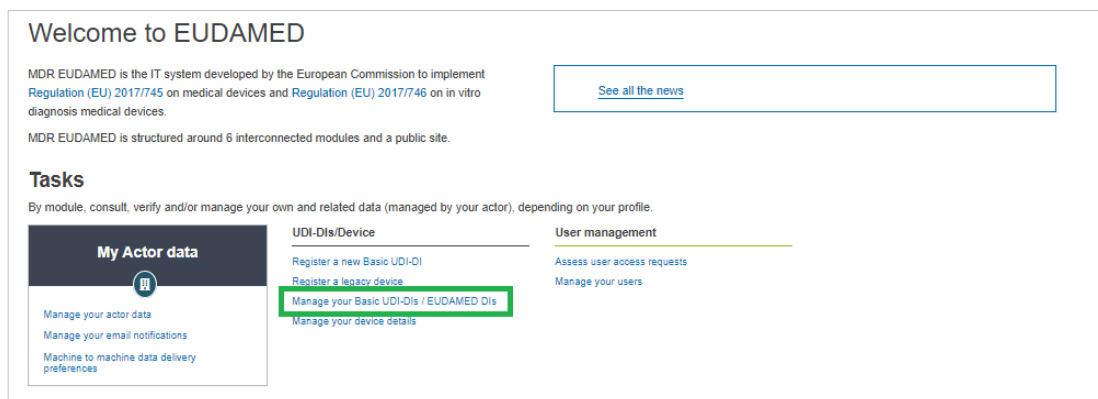
**IMPORTANT**

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

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

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

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



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

**IMPORTANT**

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

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter

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

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

Apply filters Clear all filters

Active filters: State: Draft Clear all filters

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

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

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter

Active filters: State: Registered Clear all filters

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

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

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

Add new UDI-DI to existing Basic UDI

**Manufacturer identification**

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

**Basic UDI-DI identification**

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

Basic UDI-DI code: 1234503276

Issuing Entity: GS1

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

No

Special device type: No

1 UDI-DI identification information

2 UDI-DI characteristics

3 Device information

4 Container package(s)

**UDI-DI identification**

UDI-DI identification

\* Issuing Entity:

\* UDI-DI code:

UDI-DI from another entity (secondary) applicable

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


\* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)


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

**Submission** [Close](#)

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

 **Status of your request**

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

 **Outcome by email**

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



### 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.

#### My Actor data

- Manage your actor data
- Manage your email notifications

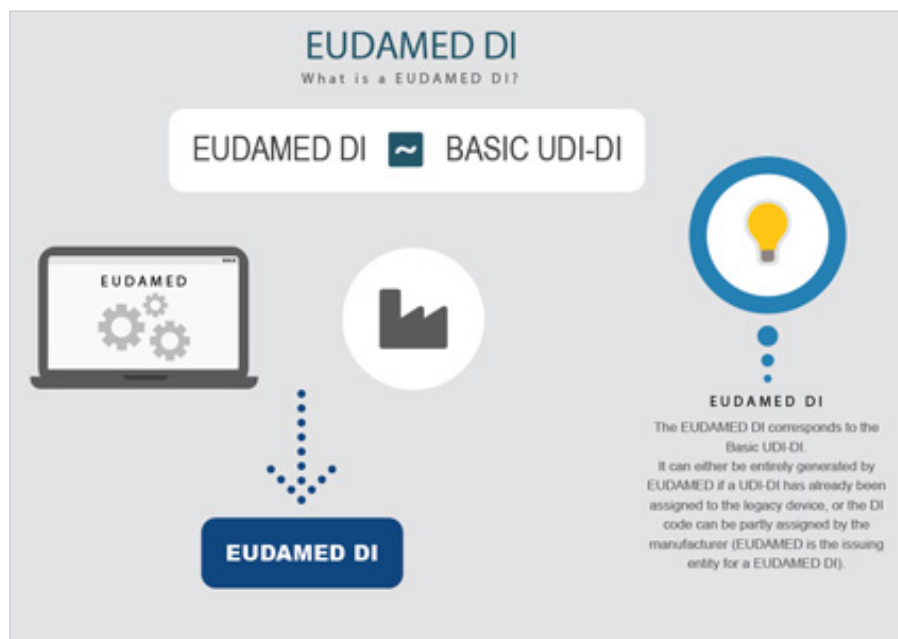
#### UDI-DIs/Device

- 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

## 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-000000041  
 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:

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

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

**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:

Save

Save &amp; Next &gt;

## 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 \[102\]](#) 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:

EC Certificate Full Quality Assurance System

Organisation name: EVPU a.s.

NB number: 1293

Address:

Telephone number: 421 42 44 03 600

Email: hudak@evpu.sk

[Change Notified Body](#)

\* Certificate number:

276898081

Revision number:

\* Expiry date:

2021-06-30

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 ▼

\* EUDAMED ID code: 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

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

\* Trade name: Trade\_Name\_01

\* Select the language: -- 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:

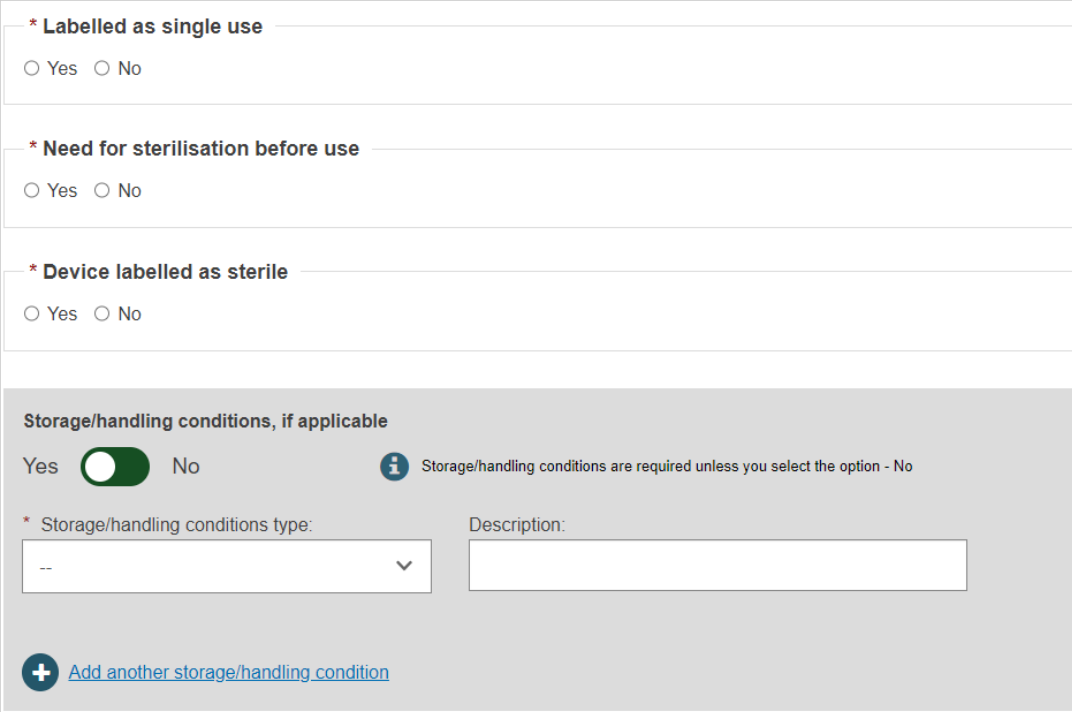
On the EU market

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

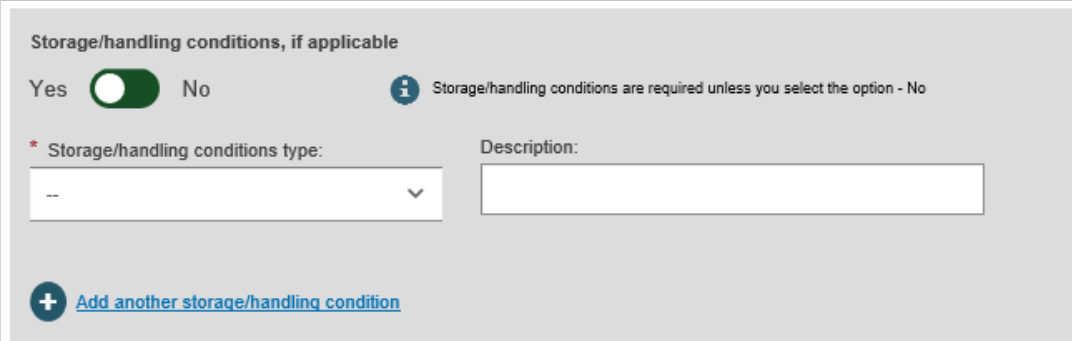
Yes ☒ No Storage/handling conditions are required unless you select the option - No

\* 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 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.

If **Yes**, there are two different ways to find the *Product original manufacturer* of the device:

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

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

Yes ☒ No

☒ I know the Actor ID/SRN

\* Enter Actor ID/SRN or name:

Check registry



### NOTE

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

Select the Actor from the list:

Playground

✕Close

### Select manufacturer

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

← Previous 1 2 ... 19 Next →

Close

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

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

Yes ☒ No

☐ I know the Actor ID/SRN

\* Product original manufacturer organisation name:

🔍 Check registry

Select the Organisation name from the list:

[Close](#)


## Select manufacturer

Organisation name ↴

PDasOrg (3)

PDasOrg (2)

MANUF-1(1)

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


Enter data manually

Cancel

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

[Change manufacturer](#)

\* Name (Manufacturer Name):

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

\* Street:

Street number:

Address line 2:

PO box:

\* City name:

\* Postal code:

\* Country:


Telephone:

Telephone format example: +32 x xxx xx xx

\* Email:


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 Member State 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:**

France 

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

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

[Select one or more countries](#) 

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](#)

Playground

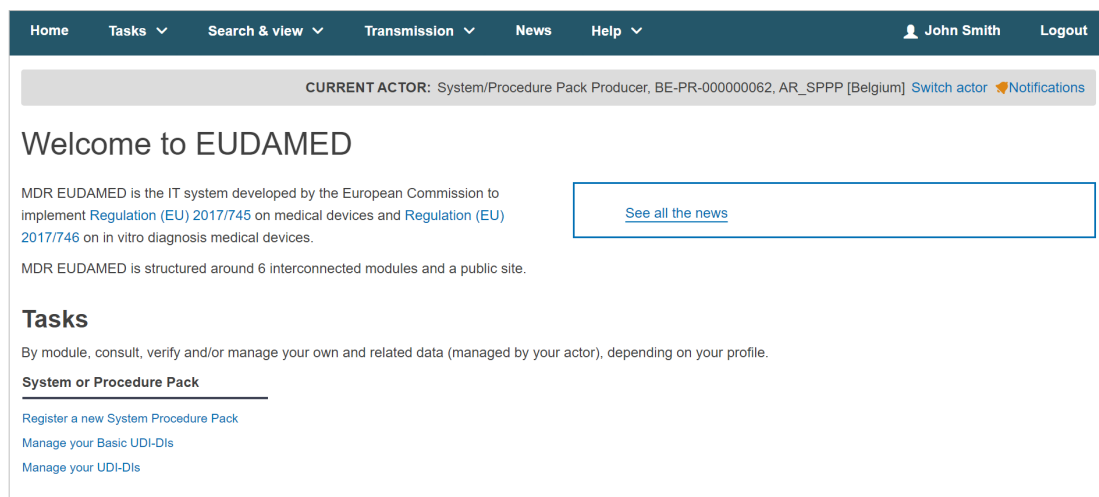
# 5 Registering System or Procedure Packs (SPP)

## 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**:



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



System or Procedure Pack registration

**Procedure pack producer identification**

Organisation name: AR\_SPPP  
 SRN: BE-PR-000000062  
 Address: 8606 Brussels  
 Telephone number: -  
 Email: ar\_sppp@abc.com

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

**Basic UDI-DI main information**

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

\* System or Procedure Pack type:

☐ Procedure Pack  
☐ System

[Save & Next >](#)

**NOTE**

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

**IMPORTANT**

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

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

System or Procedure Pack registration

**Procedure pack producer identification**

Organisation name: Health Pac  
 Actor ID/SRN: LJ-PR-000000062  
 Address: Oak St, 101 8008 Valuz  
 Telephone number: +34388876513  
 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:  
[Text area]

\* Select the language:  
--

+ Add another indication of medical purpose

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

\* Model:  
[Text field]

Name:  
[Text field]

**Save**    **Save & Next >**

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

**Producer identification**  
BE-PR-000000062\_AR\_SPPP

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

**Basic UDI-DI information**

\* Risk class:  
--

\* Indication of medical purpose:  
[Text area]

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

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

2017/745 on medical devices)

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

System or Procedure Pack type: Procedure Pack

\* Indication of medical purpose:

\* Select the language:

+ Add another indication of medical purpose

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

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

Device model applicable

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

\* Model:

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

Save Save & Next >

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

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

UDI-DI identification

\* Issuing Entity: GS1

\* UDI-DI code:



#### IMPORTANT

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

Playground

**NOTE**

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

For example:

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

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

**UDI-DI identification**

\* Issuing Entity:

GS1

\* UDI-DI code:

**UDI-DI from another entity (secondary) applicable**

Yes

No

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

\* Issuing Entity:

--

\* Secondary UDI-DI value:

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


\* Enter the nomenclature code (EMDN code):

Find

[Advanced search of device nomenclature](#)


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

**Trade name applicable**

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

\* Trade name:

\* Select the language:

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

5. Enter the *Reference/Catalogue number*:

\* Reference/Catalogue number:

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

\* **Type of UDI-PI**

☐ Lot or Batch number


☐ Serial number

☐ Manufacturing date

☒ Expiration date

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

Additional product description:

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

Select the language:

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

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

**\* UDI-DI status**

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

### 5.1.4 Step 4: UDI-DI characteristics

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

#### UDI-DI characteristics

**\* Need for sterilisation before use**

☐ Yes ☐ No

**\* Device labelled as sterile**

☐ Yes ☐ No

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

Storage/handling conditions, if applicable

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

**\* Storage/handling conditions type:**

OTHER \*

**\* Description:**

Test

**\* Select the language:**

-

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



#### NOTE

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

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

The screenshot shows a form titled "Critical warnings or contra-indications, if applicable". It has a toggle switch for "Yes" (which is turned on) and "No". A small information icon with text states: "Critical warning or contra-indications are required unless you select the option - No". Below this, there are two main input areas. On the left, "Critical warning type:" has a dropdown menu with options: "Caution: Contains of presence of..." and "Defibrillation-proof type CF applied part". On the right, "Description:" has a text input field containing the word "Test". At the bottom left of the form area is a blue button with a plus icon and the text "Add critical warnings or contra-indications". At the very bottom of the form are two buttons: "Save" and "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.

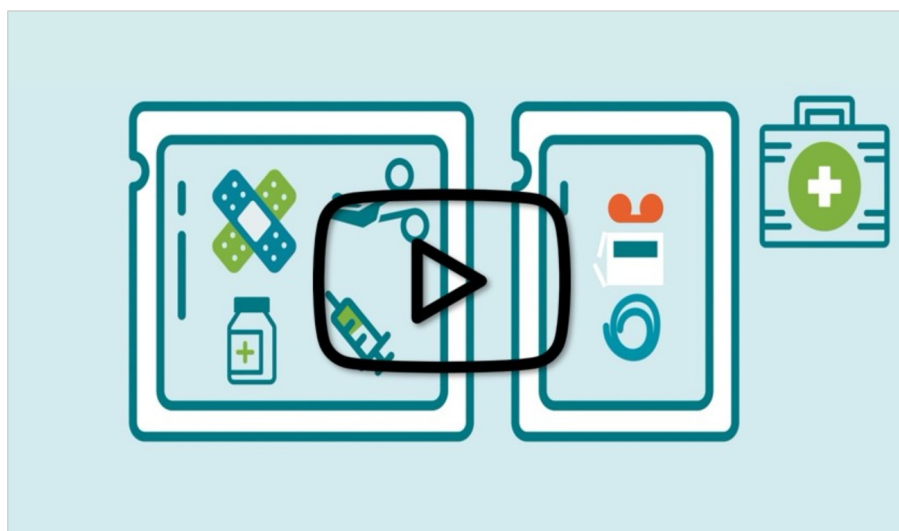
- Click on **Save** to save draft and finish later or **Save & Next** to move directly to the next step of the process:

The screenshot shows two buttons side-by-side: "Save" and "Save & Next >". A mouse cursor is pointing at the "Save & Next >" button.

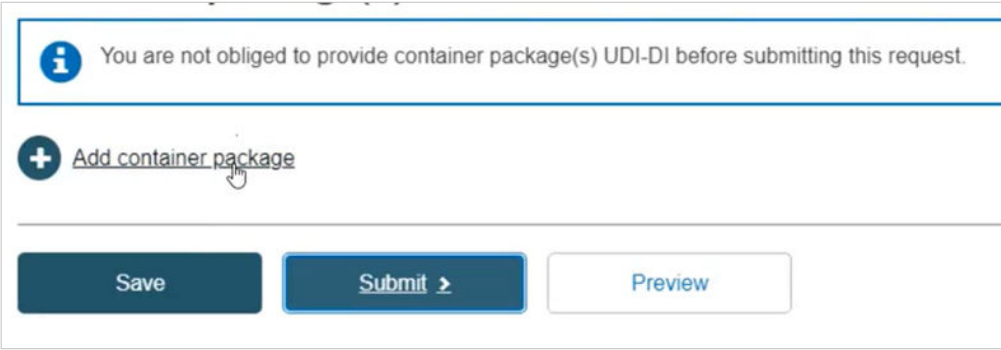
## 5.1.5 Step 5: Container package details



### VIDEO: UDI and Systems and Procedure Packs



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



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

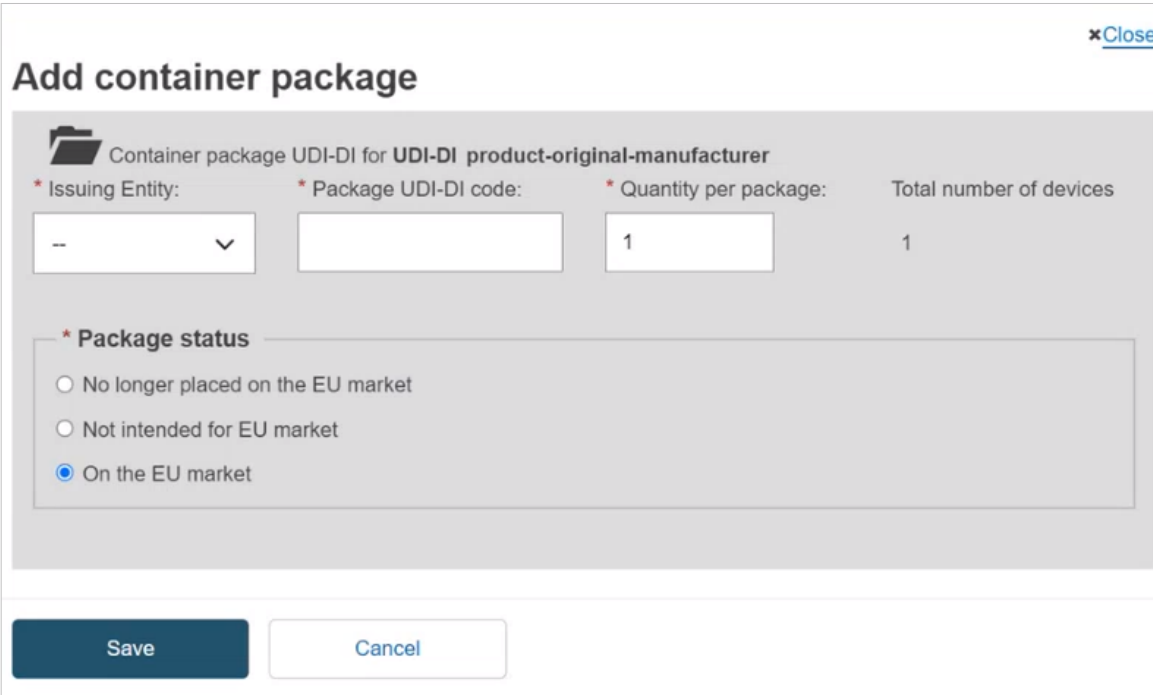
**+** [Add container package](#)

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

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

**NOTE**

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



**Add container package** [xClose](#)

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

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

**\* Package status**

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

**Save** **Cancel**


**NOTE**




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

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



**Container package(s)**

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

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


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

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

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

**Submission** ✕Close


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

 **Status of your request**

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

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

**Registration of System or Procedure Pack**

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

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

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

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

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

**Tasks**

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

**My Actor data**

Manage your actor data

Manage your email notifications

Machine to machine data delivery preferences

**User management**

Assess user access requests

Manage your users

**System or Procedure Pack**

Register a new System Procedure Pack

Manage your Basic UDI-DIs

Manage your UDI-DIs

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

Basic UDI-DI management for SPP

Go to device management Register new System or Procedure Pack

**Filter**

Basic UDI-DI code  Name  State

Risk class  System or Procedure Pack

**Apply filters** **Clear all filters**

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

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

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

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

Add a UDI-DI for a Basic UDI-DI

## 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:  
HIBCC

\* UDI-DI code:  
121212

UDI-DI from another entity (secondary) applicable

Yes ☒ No

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

\* Enter a nomenclature code (EMDN code):

Find

Advanced search of device nomenclature

Selected nomenclature codes

Code A01010101 HYPODERMIC NEEDLES FOR SYRINGE

[Remove nomenclature code](#)

Trade name applicable

Yes ☒ No

Trade name is required unless you select the option - No

\* Trade name:  
Trade\_Name

\* Select the language:  
Croatian

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

\* Reference/Catalogue number:

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

Critical warnings or contra-indications, if applicable

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

**\* Critical warning type:**

**Description**

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

Save

Save & Next >

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

## 5.2.3 Step 3: Container package details

To complete this step, please consult [Container Package Details \[47\]](#) of this guide.

Playground

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

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



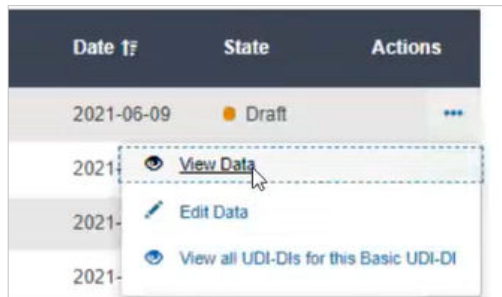
### NOTE

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.

The screenshot shows the 'Basic UDI-DIs / EUDAMED DIs management' page. It has a header with a 'Go to Device details management' link and two buttons: 'Register a new Basic UDI-DI' and 'Register Legacy Device'. Below the header, there is a 'Filter' dropdown and 'Active filters' showing 'State: Draft' and a 'Clear all filters' link. The main content area shows a table of registered devices. The table has columns for 'Basic UDI-DI/EUDAMED DI Code', 'Devices', 'Device model', 'Device Name', 'Risk class', 'Date', 'State', and 'Actions'. The table displays 9 entries, with the first 6 visible. The 'State' column shows '1st Draft' for the first two entries and 'Draft' for the others.

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
B-12121EL	1		Test	Class IIb	2021-04-01	1st Draft	...
1212112121U5	1		Test	Class IIa	2021-04-01	1st Draft	...
1211421211211EW	1		Device Name	Class IIa	2021-04-01	Draft	...
312121211212133383	2	Device Model_Test_CLASS IIa_v3	Device Name	Class IIa	2021-03-16	Draft	...
12121233333333343HC	1		test	Class I	2021-02-15	1st Draft	...
12345ABCBY	1		test	Class I	2021-02-05	1st Draft	...

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



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

Basic UDI-DI 1211421211211EW

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

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

Basic UDI-DI data

[Clinical Investigation](#)

[Certificates](#)

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

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

**Basic UDI-DI identification**

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

Basic UDI-DI code: 1211421211211EW

Issuing Entity: GS1

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

Special device type: No

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

### 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 \[53\]](#) to view a Draft Basic UDI-DI/EUDAMED DI in state *1st draft*, you have the option to delete this draft.

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

**Basic UDI-DI data** [Edit](#) [Delete](#)

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

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

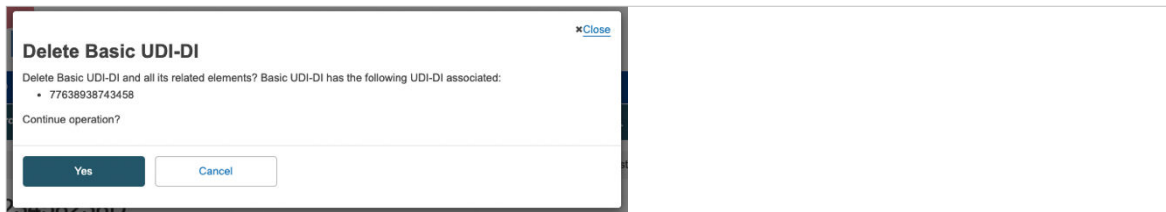
Basic UDI-DI code: 12345-test-udi-1-HL

Issuing Entity: GS1

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

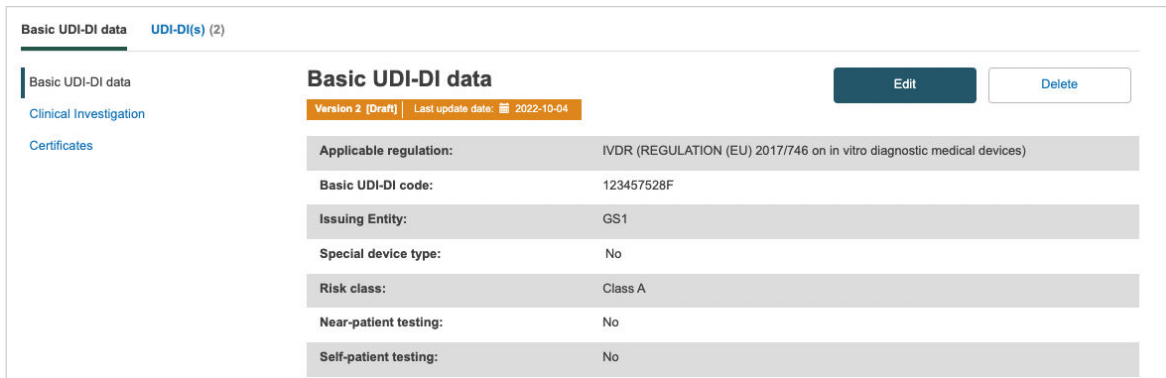
Risk class: Class IIb

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

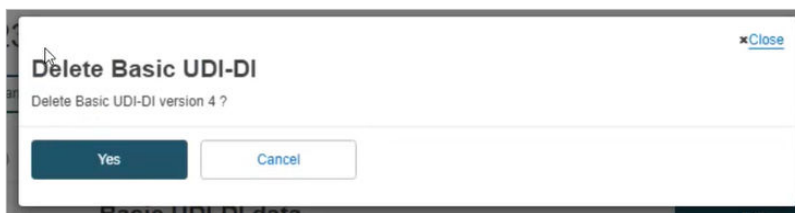


The system also warns about deletion of the UDIs under the *1st draft* device.

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



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



## 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 \[53\]](#) 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:

Playground

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 \[53\]](#) 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**

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

**Basic UDI-DI identification**

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

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

Issuing Entity: GS1

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

Risk class: Class IIb

Implantable: No

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

## 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:

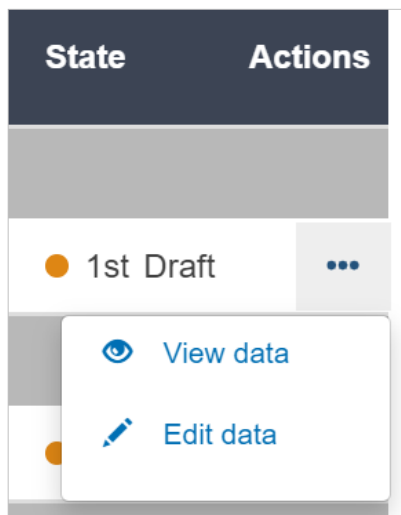
Showing 1 to 20 of 30 entries Show 20 entries per page

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-435345PL, Device Name: dsfdafd, Class IIb, MDD (Directive 93/42/EEC on Medical Devices)							
D-435345PL				2021-03-29	On the EU market	1st Draft	...
EUDAMED DI code: B-20001E6, Device Name: NameOfDevice2020201, Class IIb, MDD (Directive 93/42/EEC on Medical Devices)							
D-20001E6		CatalogueNumber1001010		2021-03-26	On the EU market	1st Draft	...
EUDAMED DI code: B-12335671, Device Name: 12335671, Class IIb, MDD (Directive 93/42/EEC on Medical Devices)							
12335671		12335671		2021-03-24	On the EU market	1st Draft	...
Basic UDI-DI code: 2021032320U7, Device Name: NameD123, Class I, MDR (REGULATION (EU) 2017/745 on medical devices)							
							+ Add a new UDI-DI

**NOTE**

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

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

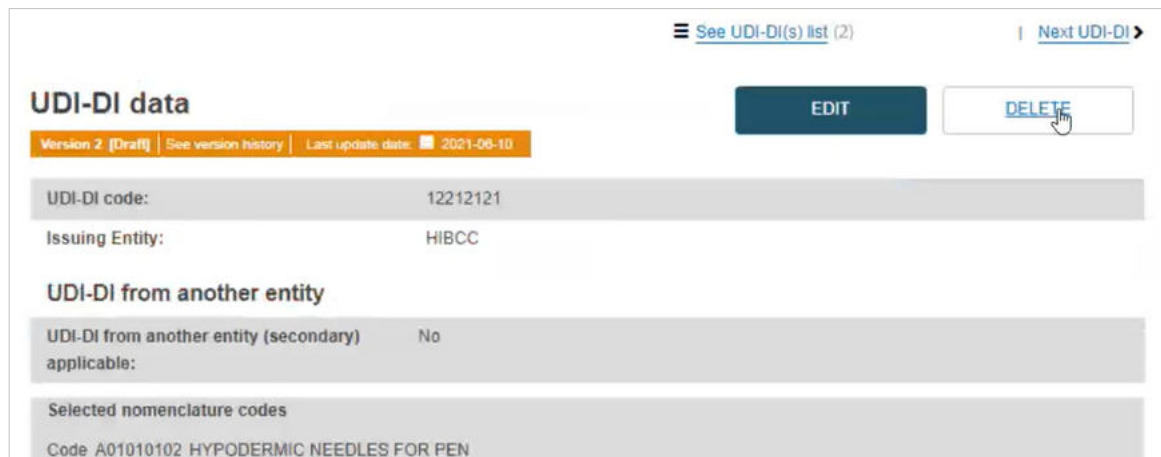


- You will see a summary of the details of your device:

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

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) to view a draft UDI-DI.

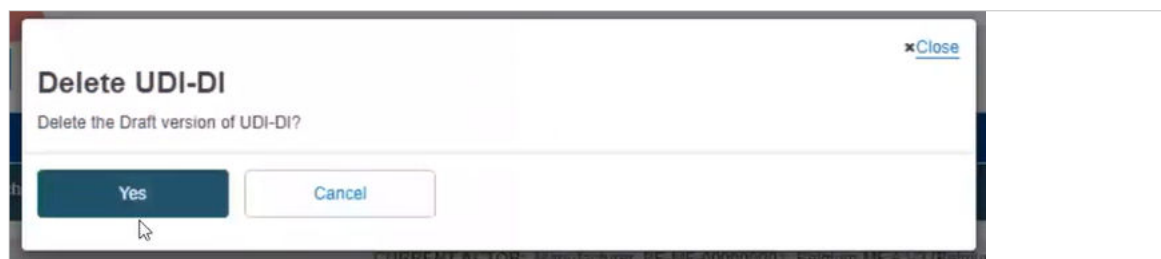
1. Once inside the desired Draft UDI-DI, click on **Delete**:



The screenshot shows the 'UDI-DI data' form. At the top right, there is a link 'See UDI-DI(s) list (2)' and a 'Next UDI-DI' button. Below the title, there are buttons for 'EDIT' and 'DELETE'. The 'DELETE' button is highlighted with a mouse cursor. The form contains the following fields:

- 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

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



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

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

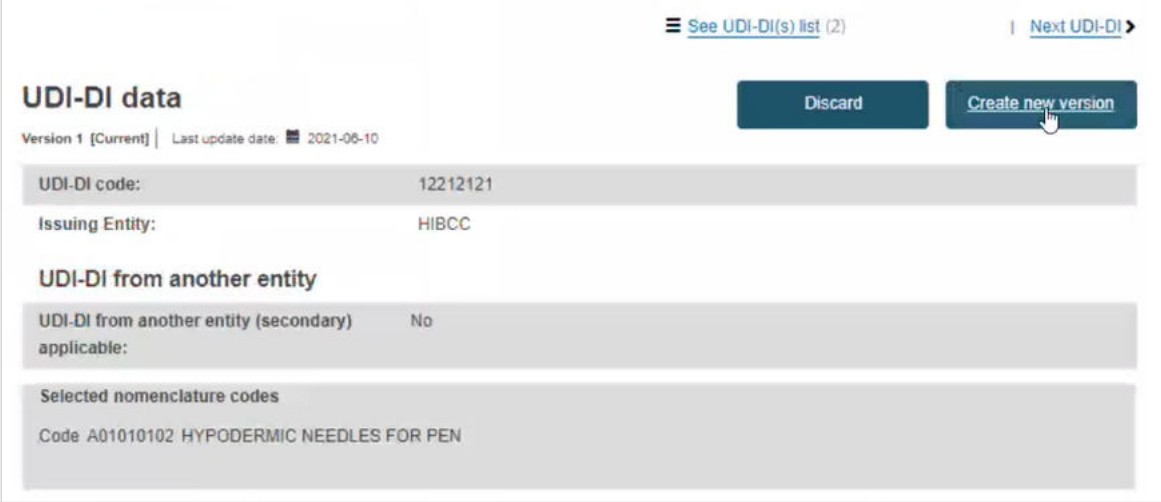
 **VIDEO: UDI assignment and updates**



nd

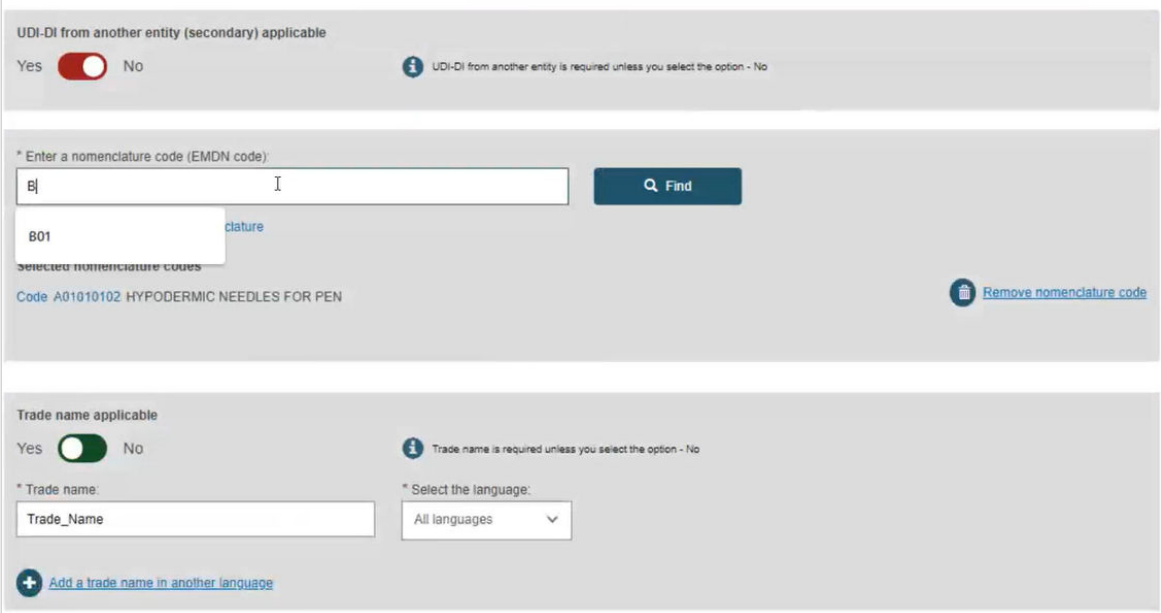
Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) to view a UDI-DI/EUDAMED ID.

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' section of the EUDAMED interface. At the top right, there are links for 'See UDI-DI(s) list (2)' and 'Next UDI-DI >'. Below these are two buttons: 'Discard' and 'Create new version'. The 'Create new version' button is highlighted with a mouse cursor. The 'UDI-DI data' section includes the following information:

- Version 1 [Current] | Last update date: 2021-05-10
- UDI-DI code: 12212121
- Issuing Entity: HIBCC
- UDI-DI from another entity
- UDI-DI from another entity (secondary) applicable: No
- Selected nomenclature codes
- Code A01010102 HYPODERMIC NEEDLES FOR PEN



The screenshot shows the 'UDI-DI from another entity (secondary) applicable' section and the 'Trade name applicable' section. The 'UDI-DI from another entity (secondary) applicable' section has a 'Yes' button (disabled) and a 'No' button (selected). Below this is a search bar for nomenclature codes with a 'Find' button. The 'Trade name applicable' section has a 'Yes' button (disabled) and a 'No' button (selected). Below this are input fields for 'Trade name' and 'Select the language'.

UDI-DI from another entity (secondary) applicable

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

\* Enter a nomenclature code (EMDN code):

B I

801  clature

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

Trade name applicable

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

\* Trade name:

\* Select the language:

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

**\* Is the device directly marked?**

☒ Yes ☐ No

☐ Same as UDI-DI

**\* Issuing Entity:**

**\* Direct marking DI:**

**Quantity of device:** 1

**\* Type of UDI-PI**

☒ Lot or Batch number

☐ Serial number

☐ Manufacturing date

☐ Expiration date

**Additional product description:**

**Select the language:**

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

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

**Clinical size**

**Clinical size applicable:** No

**Labelled as single use**

**\* Labelled as single use:** No

**Maximum number of reuses applicable:** No

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

**\* Device labelled as sterile:** No

**\* Containing latex:** No

**\* CMR/Endocrine disruptor**

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

☐ Yes ☒ No

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

☐ Yes ☒ No

**Storage/handling conditions, if applicable**

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

**Critical warnings or contra-indications, if applicable**

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

**\* UDI-DI status**

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

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

**NOTE**

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

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

**NOTE**

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

### Create new version of UDI-DI

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

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

Confirm

Cancel

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

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

Austria

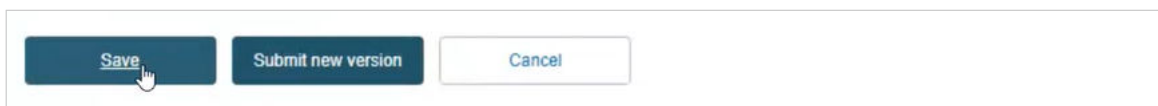
\* Member States where the device is or is to be made available on the market:

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

2. To finish the action you have two options:

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

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

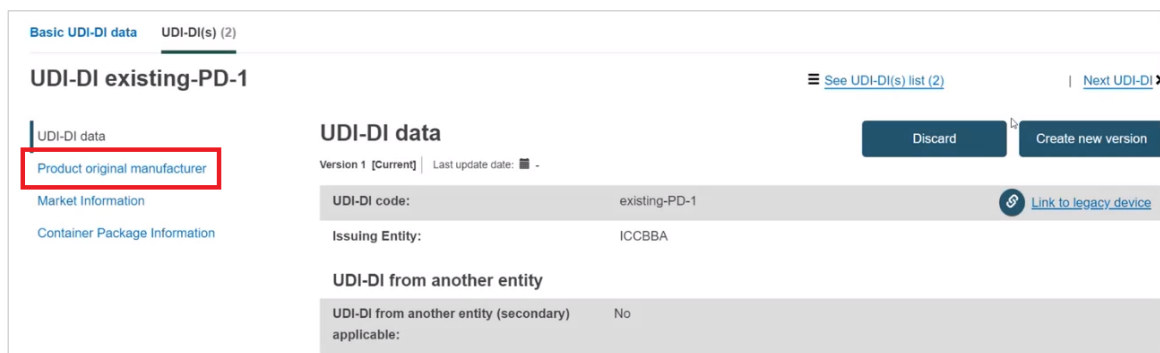


Buttons: **Save** (with a mouse cursor icon), **Submit new version**, and **Cancel**.

## 6.2.3 Update (create new version) for Product original manufacturer

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) to view a UDI-DI/EUDAMED ID.
2. Once inside the details of the selected UDI-DI, click on **Product original manufacturer** from the list on the left (or scroll down to the *Product original manufacturer* section):



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

3. Click on **Update**:



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

The *Product original manufacturer* page will appear.

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



### Natural or Legal Person update

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

\* Name (Manufacturer Name):

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

\* Street:  Street number:   
 Address line 2:

PO box:

\* City name:  \* Postal code:   
 \* Country:  x v  
 Telephone:

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


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

### Natural or Legal Person update

☒ I know the Actor ID/SRN

\* Enter Actor ID/SRN or name:

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



**Select manufacturer** ✕Close

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

Close

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

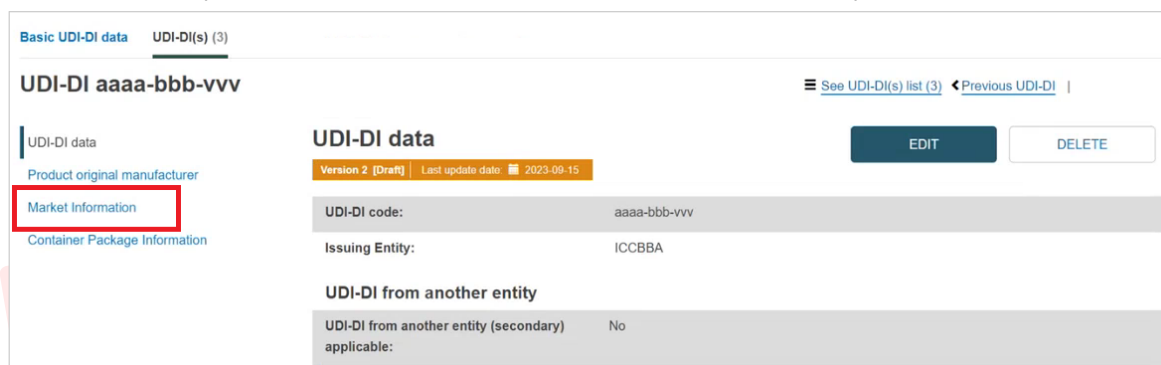
**NOTE**

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

## 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 \[58\]](#) to view a UDI-DI/EUDAMED ID.
- Once inside the details of the selected UDI-DI, click on **Market Information** from the list on the left (or scroll down to the *Market Information* section):



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

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

UDI-DI data EDIT DELETE

Version 2 [Draft] Last update date: 2023-09-15

UDI-DI code: aaaa-bbb-vvv

Issuing Entity: ICCBBA

UDI-DI from another entity

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

- Click on **Update countries**:

**Market Information**

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

[Update countries](#)

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

- Update the relevant fields under *Market Information*:

**Market information update**

Belgium From  To

Finland From  To

Greece From  To

Latvia From  To

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

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

**Market Information**

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

[Update countries](#)

Member State of the placing on the EU market of the Device:	Country	From	To
Member States where device is or is to be made available on the market:	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.

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) 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):

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

### UDI-DI existing-PD-1

[See UDI-DI\(s\) list \(2\)](#) | [Next UDI-DI](#)

UDI-DI data

Product original manufacturer

Market Information

**Container Package Information**

UDI-DI data

Version 1 [Current] | Last update date: -

UDI-DI code: existing-PD-1 [Link to legacy device](#)

Issuing Entity: ICCBBA

UDI-DI from another entity

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

Discard | Create new version

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

### Container Package Information

Version 3 | [See version history](#) | Last update date: 2023-09-15

[Create new version](#)

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

## Container package update

### Container package(s)


[+ Add container package](#)

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

Submit | Cancel

[✕Close](#)

## Add container package

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

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

\* Package status

☐ No longer placed on the EU market

☐ Not intended for EU market


☒ On the EU market


Save

Cancel

## Container package update

### Container package(s)

 [Add container package](#)

 [Update container package status](#)

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

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


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

Submit

Cancel

[✕Close](#)

## Update container package status

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

**Container package market status**

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

Confirm

Cancel

**NOTE**

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

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

### Container package update

#### Container package(s)

+ Add container package
🔄 Update container package status

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

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

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

Submit
Cancel

## 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.

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) to view a registered UDI-DI/EUDAMED ID.
- Once inside the details page of the selected UDI-DI, click on **Discard** on the top right corner:

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

UDI-DI existing-PD-1

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

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

Version 1 [Current] | Last update date: -

UDI-DI code: existing-PD-1 [Link to legacy device](#)

Issuing Entity: ICCBBA

UDI-DI from another entity

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

Discard Create new version

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

Discard UDI-DI

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

Yes Cancel

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:

Discard UDI-DI

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

Yes Cancel

## 6.2.7 Link a registered Regulation Device to a registered Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

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

## EUDAMED user guide

[Go to Device Details management](#)

Basic UDI-DI data   **UDI-DI(s) (3)**

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

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

Discard   Create new version

Version 1 [Current]   Last update date: -

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

Issuing Entity: ICCBBA

**UDI-DI from another entity**

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

**Selected nomenclature codes**

Code A0101010101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS

**Trade name**

Trade name applicable: No

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

**Is the device directly marked?**

Is the device directly marked?: No

Quantity of device: 1

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

European Commission > EUDAMED

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

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

**Link to a legacy device**

[Go back to view details page](#)

**-device-under-regulation**

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

**List of Legacy devices**

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

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

Search

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

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



B-12345756984170 (EUDAMED) - 12345756984170 - 789/654**89 - Aspirin	
EUDAMED DI code:	B-12345756984170
Reference/Catalogue number:	789/654**89
Trade name:	Aspirin Mandarin [DE]
UDI-DI / EUDAMED ID code (issuing entity):	<a href="#">12345756984170</a> (GS1)
Containing latex:	No
Labelled as single use:	No
Device labelled as sterile:	No
Need for sterilisation before use:	No
Reprocessed single use device:	No

Select this device

B-12345756984101 (EUDAMED) - 12345756984101 - 11114/4442/ - TName - 2	^
B-NL-14V6 (EUDAMED) - D-NL-14V6 - 159*4453/4478 - TName -2	^
B-Demo/TWTU (EUDAMED) - D-Demo/TWTU - 456/789	^
B-JKLMNOLR (EUDAMED) - D-JKLMNOLR - eee456*22	^
B-89197873912008 (EUDAMED) - 89197873912008 - Link test	^

4. A new pop-up window will appear. Click on **Confirm**:

Close

### Link to a legacy device

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

Confirm

Cancel



#### NOTE

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

Close

### Link to a legacy device

You cannot link UDI-DI **-device-under-regulation** to EUDAMED ID / UDI-DI **12345756984170**

!

The following characteristics do not match

- Active device
- Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma
- Device intended to administer and/or remove medicinal product
- Presence of animal tissues or cells, or their derivatives
- Labelled as single use

Cancel

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

European Commission > EUDAMED

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

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

✓ You have successfully created a link to the related legacy device

### Basic UDI-DI 12345-link-devices-SN

< Go to Device Details management

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

#### UDI-DI -device-under-regulation

See UDI-DI(s) list (3) < Previous UDI-DI

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

UDI-DI data

Version 1 [Current] Last update date: -

UDI-DI code: -device-under-regulation

Issuing Entity: ICCBBA

UDI-DI from another entity

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

Discard Create new version

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

Product original manufacturer

Market Information

Container Package Information

medicinal product derived from human blood or human plasma:

#### Related Device

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

Devices linked on: 2023-09-12

Remove the link to this device

#### Product original manufacturer

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

#### Market Information

Version 1 Last update date: 2023-08-12

Update countries

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

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

Country	From	To
Austria	-	-

#### Container Package Information

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

No container packages added

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

Product original manufacturer  
Market Information

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

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

**Related Device**

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

Devices linked on: 2023-09-12

**Product original manufacturer**

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

**Market Information** [Update countries](#)

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

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

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

## 6.2.8 Delete the link between a Regulation Device and a Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) and select the *Registered* option in the *State* field.

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

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

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

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

**Related Device**

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

Devices linked on: 2023-09-12

[Remove the link to this device](#)

**Product original manufacturer**

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

**Market Information** [Update countries](#)

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

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

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

**Container Package Information** [Add a container package UDI-DI for this UDI-DI](#)

No container packages added

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

xClose

### Link to a legacy device

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

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[58\]](#) to view a UDI-DI/EUDAMED ID.

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

### UDI-DI data

Version 2 [Draft]
**See version history**
Last update date: 2021-05-25

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

You will see a list of all versions:

### EUDAMED DI B-1231231UU

### Version history of EUDAMED ID

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

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

## EUDAMED DI B-1231231UU

[◀ Go back to the current version](#)

## Version history of EUDAMED ID D-1231231UU

[≡ See all version history \(1\)](#)

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

EUDAMED ID code:	D-1231231UU
------------------	-------------

Issuing Entity:	EUDAMED
-----------------	---------

## Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN
---

## Trade name

Trade name applicable:	No
------------------------	----

Reference/Catalogue number:	44545
-----------------------------	-------

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

Device status:	On the EU market
----------------	------------------

## Clinical size

Clinical size applicable:	No
---------------------------	----

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

Playground

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

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

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

Basic UDI-DI 44444SSP\_Shr\_1VM

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

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

Basic UDI-DI data

**Basic UDI-DI data** Create new version

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

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

## 7.1.1 Delete a draft Basic UDI-DI

1. Follow the steps in section [Manage your SPP Basic UDI-DI details \[78\]](#) 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

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

Basic UDI-DI 12344676768687687JC

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

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

Basic UDI-DI data Edit Delete

Applicable regulation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Basic UDI-DI code:	12344676768687687JC	
Issuing Entity:	GS1	
Risk class:	Class I	
Indication of medical purpose:	Indication of medical purpose	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 \[78\]](#) to view a Basic UDI-DI:

Basic UDI-DI management for SPP

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

Filter ▼

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

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

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

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



Basic UDI-DI 44444SSP\_Shr\_1VM

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

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


Basic UDI-DI data

**Basic UDI-DI data** Create new version

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

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

2. Update the desired details.

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

44444SSP\_Shr\_1VM [version: 2]

**Create a new version of 44444SSP\_Shr\_1VM**

Risk class: Class I

\* Indication of medical purpose:

SPPP test 1

\* Select the language: Greek

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

\* Device Name:

SPP\_Shr\_1

Save Submit new version Cancel

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

Save Submit new version Cancel

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

Basic UDI-DI 44444SSP\_Shr\_1VM

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

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

Basic UDI-DI data

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

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

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

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

- Follow the steps in section [Manage your SPP Basic UDI-DI details \[78\]](#) to view a Basic UDI-DI.
- 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
--

Playground

## Basic UDI-DI 44444SSP\_Shr\_1VM

[◀ Go back to the current version](#)

## Version history of Basic UDI-DI 44444SSP\_Shr\_1VM

[≡ See all version history \(1\)](#)

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

## Basic UDI-DI identification

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

Basic UDI-DI code: 44444SSP\_Shr\_1VM

Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

Risk class: Class I

Indication of medical purpose:

Indication of medical purpose

Language

SPPP test 1

Croatian

Name:

SPP\_Shr\_1

## 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:

Playground

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:

Show 20 entries per page

Status	State	Actions
On the EU market	Registered	...
On the EU market	Registered	View data
On the EU market	Registered	...

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

Playground

Basic UDI-DI 44444SSP\_Shr\_1VM

[Go to device management](#)

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

UDI-DI 44444SSP\_Shr\_1VM [See UDI-DI\(s\) list \(1\)](#)

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

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

UDI-DI 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

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

## 7.2.1 Delete a draft UDI-DI

1. Follow the steps in section [Manage your SPP UDI-DI details \[83\]](#) to view a Draft UDI-DI.
2. Once inside the draft, click on **Delete**:

Playground

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

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

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

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

UDI-DI code: 34675806754T9

Issuing Entity: HIBCC

**UDI-DI from another entity**

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

**Selected nomenclature codes**

Code A010102 BUTTERFLY NEEDLES

**Trade name**

Trade name applicable: Yes

Trade name: system 1All languages

Reference/Catalogue number: 543

**Type of UDI-PI**

Serial number: Yes

Manufacturing date: Yes

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

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

UDI-DI status: On the EU market

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

**Delete UDI-DI** [Close](#)

Delete the Draft version of UDI-DI?

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

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

1. Follow the steps in [Manage your SPP UDI-DI details \[83\]](#) 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-	<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>	

[+ Add a UDI-DI for a Basic UDI-DI](#)

- 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** Create new version

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

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

- Update the necessary details.

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

Create a new version of UDI-DI 44444SSP\_Shr\_1VM [version: 2]

UDI-DI: 44444SSP\_Shr\_1VM

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

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

Selected nomenclature codes  
Code A010204 NEEDLES AND KITS - AMNIOCENTESIS Remove nomenclature code

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

Reference/catalogue number: SPPP\_Shr\_1

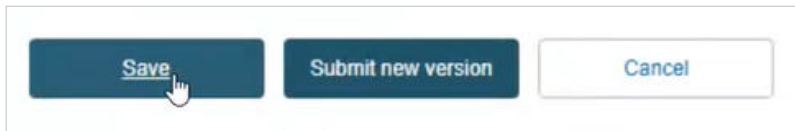
Type of UDI-PI  
\* Manufacturing date: Yes

\* Additional product description:  
 test

\* Select the language:  
Bulgarian × ▼

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

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



## 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 \[83\]](#) to view a specific UDI-DI:

 A screenshot of the 'Basic UDI-DI 44444SSP\_Shr\_1VM' page. At the top, there's a header with the title and a 'Go to device management' button. Below the header, there are tabs for 'Basic UDI-DI data' and 'UDI-DI(s) (1)'. The main content area shows 'UDI-DI 44444SSP\_Shr\_1VM' with a 'See UDI-DI(s) list (1)' link. On the left, there's a sidebar with 'UDI-DI data' and 'Container Package Information'. The main content area displays 'UDI-DI data' for 'Version 1 [Current]' with a 'Last update date: 2021-05-17'. It includes fields for 'UDI-DI code: 44444SSP\_Shr\_1VM', 'Issuing Entity: HIBCC', 'UDI-DI from another entity' (with a sub-field 'UDI-DI from another entity (secondary) applicable: No'), and 'Selected nomenclature codes' (with a sub-field 'Code A010204 NEEDLES AND KITS - AMNIOCENTESIS'). There are 'Discard' and 'View latest draft version' buttons at the top right.

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

 A screenshot of the 'Basic UDI-DI 44444SSP\_Shr\_1VM' page, showing the 'Container Package Information' section. The sidebar on the left has 'Container Package Information' selected. The main content area shows 'UDI-DI 44444SSP\_Shr\_1VM' with a 'See UDI-DI(s) list (1)' link. The 'Container Package Information' section is visible, showing 'Version 3' and 'Last update date: 2023-09-15'.

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


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

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




## Container package update

### Container package(s)


 [Add container package](#)

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

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

 [Close](#)

### Add container package

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

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

\* Package status

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

## 7.2.4 Discard SPP registered UDI-DIs

1. Follow the steps in section [Manage your SPP UDI-DI details \[83\]](#) to view a chosen Registered UDI-DI:

Playground

UDI-DI details management for SPP

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

Filter ▼

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

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

UDI-DI code	Trade name	Reference/Catalogue number	Nomenclature code	Sterile	Date	Status	State	Actions
Basic UDI-DI: 44444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) <a href="#">Add a new UDI-DI</a>								
44444SSP_Shr_1VM		SPPP_Shr_1			2021-05-17	On the EU market	Registered	...
Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) <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	...

- 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](#)

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

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

Discard UDI-DI

Details of the Basic UDI-DI and of the associated UDI-PI will be Discarded (not). 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

1. Follow the steps in section [Manage your SPP UDI-DI details \[83\]](#) to view a UDI-DI for the SPP.
2. 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: 2021-06-10

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

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

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

[Go back to the current version](#)

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

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

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

[Go back to the current version](#)

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

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

**Basic UDI-DI identification**

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

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

Issuing Entity: GS1

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

Risk class: Class IIb

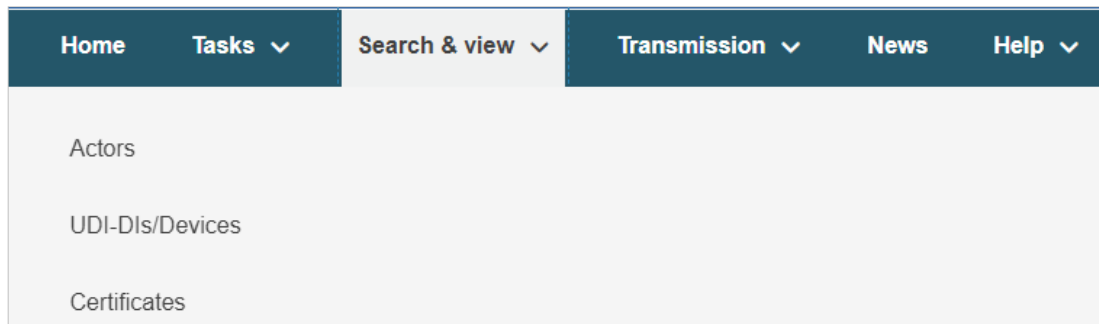
Implantable: No

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

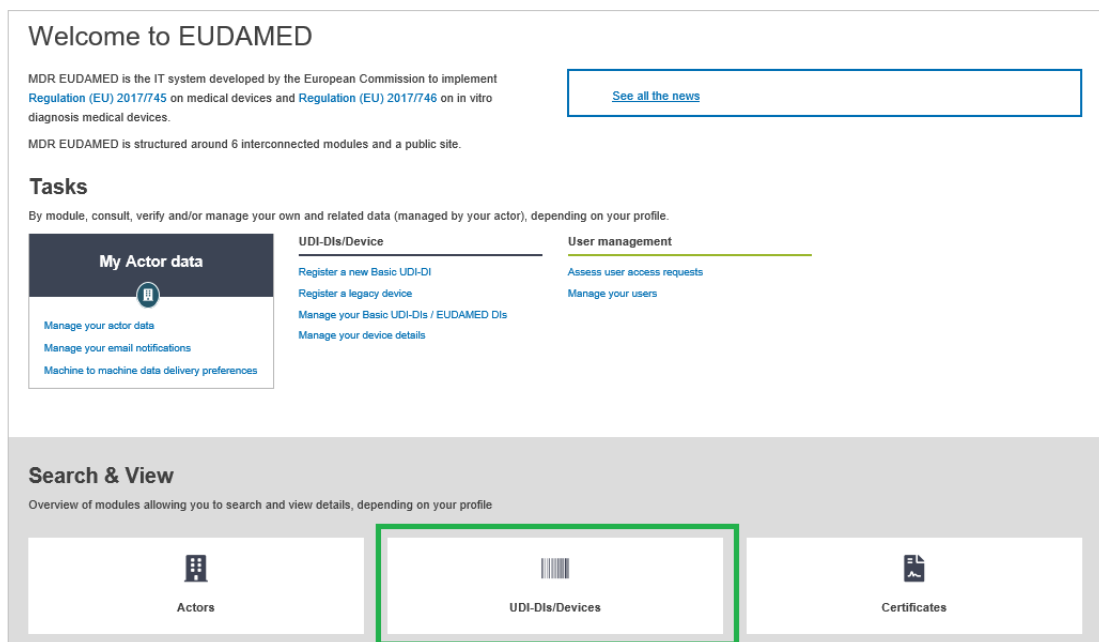
You can return to the version history list by clicking on **See all version history** on the top right corner.

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

Scopes

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

**Results option**  
☒ Include historical version

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

Showing 1 to 20 of 150 entries Show  entries per page

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

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

**Producer information**

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

**Basic UDI-DI details**  
 Version 1 - [Current] - Last update date: 2021-03-29

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

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

System or Procedure Pack type: Procedure Pack

## 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 \[92\]](#) to search and view a device or system or procedure pack.
2. Inside the search page, select the filters for your search, activate the option to include historical versions (toggle just above the **Search** button) and click on **Search**:

☒ Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED DI:

Basic UDI-DI/ EUDAMED DI:

Status:

Model:

Name:

Trade name:

Applicable regulation:

Risk class:

Nomenclature code:

Reference/Catalogue number:

Country:

Scopes  
 You can select more than one value

Competent Authority:

NB identification:

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

**Results option**  
☒ Include historical version

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

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

## 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 \[92\]](#) to search and view a device or a system or procedure pack. On the search page, activate the top filter (**Only enable search filters available for bulk XML download**) so that you can only enter search criteria that can be used for search results that can be downloaded in an XML format, and enter your search criteria. Enter the search criteria of your choice, and click on **Search**:

☒ Only enable search filters available for bulk XML download

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

Scopes  
You can select more than one value

---

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

**Results option**  
☐ Include historical version

[Search](#) [Generate XML file](#) [Clear search](#)

- Click on **Generate XML file**:

[Search](#) [Generate XML file](#) [Clear search](#)



**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).

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

**Download** [Close](#)

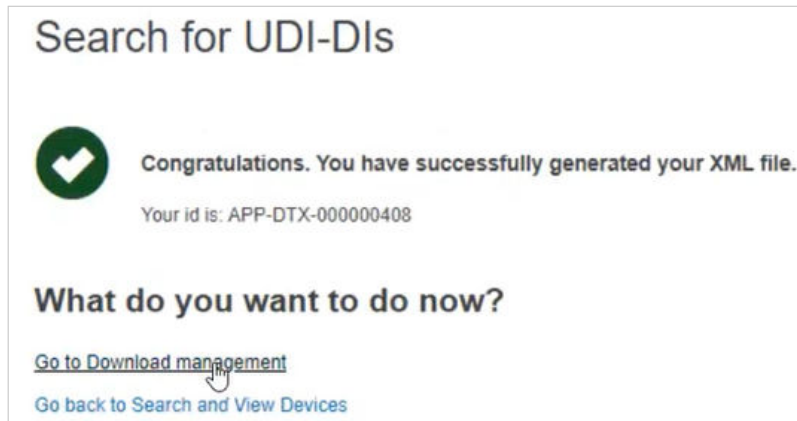
Are you sure you want to generate XML file...?

[Confirm](#) [Cancel](#)

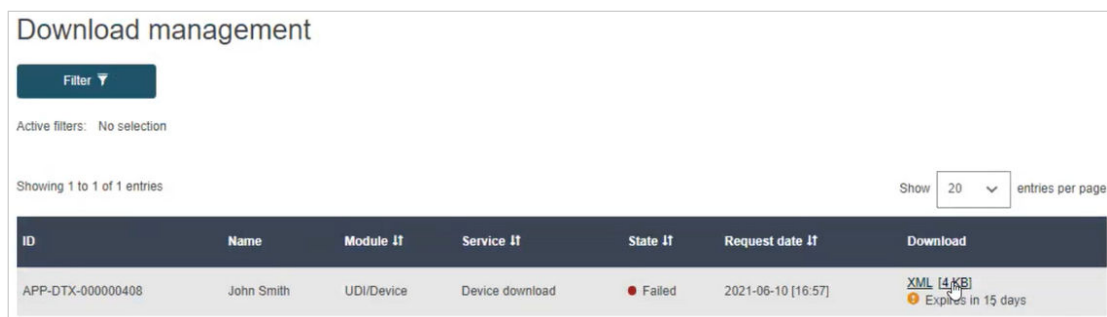
- The system will inform you that the action has been successful. Click on **Go to Download Management** under the question *What do you want to do now?*:

Playground





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



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

1. Follow the steps in [Search & View historical versions of Devices, System and/or Procedure Packs \[94\]](#) to view the details of a Device or System or Procedure Pack.
2. Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product original manufacturer or Container Package) and click on **See version history**:

Playground

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

**Clinical Investigation(s)**

Clinical Investigation

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

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

Basic UDI-DI 22091test23\_09EC

[Go back to the current version](#)

**Historical version for Basic UDI-DI 22091test23\_09EC**

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

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

Playground

Basic UDI-DI 22091test23\_09EC

[Go back to the current version](#)

**Historical version for Basic UDI-DI 22091test23\_09EC**

Version 3 [History] - Last update date: 2021-09-23

[See all version history \(4\)](#) [Previous version \[v2\]](#) [Next version \[v4\]](#)

**Manufacturer information**

Basic UDI-DI data  
Clinical Investigation  
List of UDI-DIs for the Basic UDI-DI

**Manufacturer information**

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

**Authorised Representative**

Organisation name: Belgium AR A v5  
Eudamed actor ID: BE-AR-000000021  
Address: Brussels  
Telephone number: -  
Email: public-contact@belgium-ar-a.com

**Basic UDI-DI data**

Version 3 [History] | Last update date: 2021-09-23

**Basic UDI-DI identification**

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

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

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

- Inside a version, click on the links 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	Ib	Implantable = No	EU type-examination certificate (Annex X)	
MDR	Ib	Implantable=Yes, Suture/ Staples= Yes	EU type-examination certificate (Annex X)	
MDR	Ib	Implantable=Yes, Suture/ Staples= No	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided EU technical documentation assessment certificate (Annex IX Chapter II)
MDR	III	Any	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided EU technical documentation assessment certificate (Annex IX Chapter II)
IVDR	B	Self-patient testing= Yes or Near Patient Testing = Yes		EU technical documentation assessment certificate (Annex IX Chapter II)
IVDR	C	Self-patient testing= No, Near Patient Testing = No	EU type-examination certificate (Annex X)	
IVDR	C	Self-patient testing= Yes or Near Patient Testing = Yes	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided EU technical documentation assessment certificate (Annex IX Chapter II)
IVDR	D	Any	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided EU technical documentation assessment certificate (Annex IX Chapter II)

Colour-code description.

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

# 10 Annex 2 – Legacy Device certificate types

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

Playground

