



EUDAMED user guide

UDI Devices

Playground v 3.11.0
2025

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1 Introduction

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

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

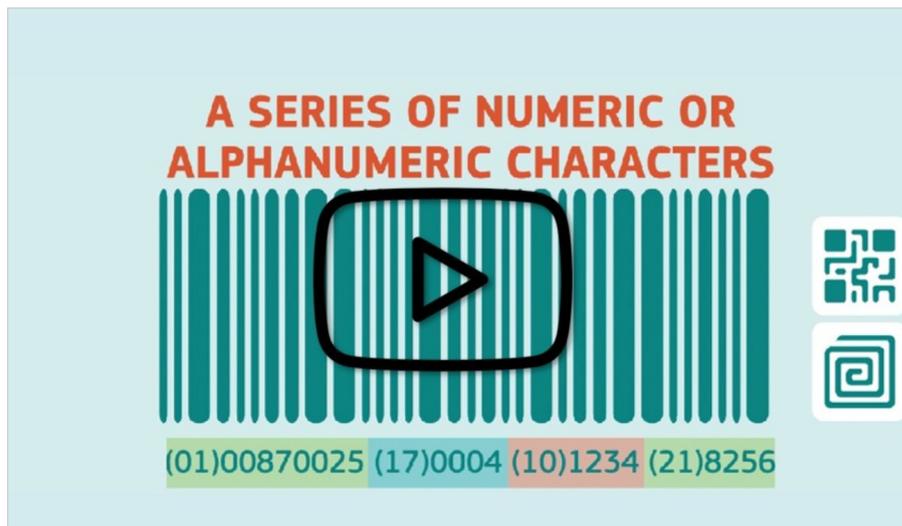


WARNING

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



VIDEO: What is a UDI?



INFOGRAPHIC: Basic UDI-DI/UDI-ID concept

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

IDENTIFIERS

What are the different identifiers?

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



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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 [Economic Operators user guide](#).

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 profile² as either:

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



NOTE

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



IMPORTANT

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

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

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

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-DI without a UDI-DI.

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

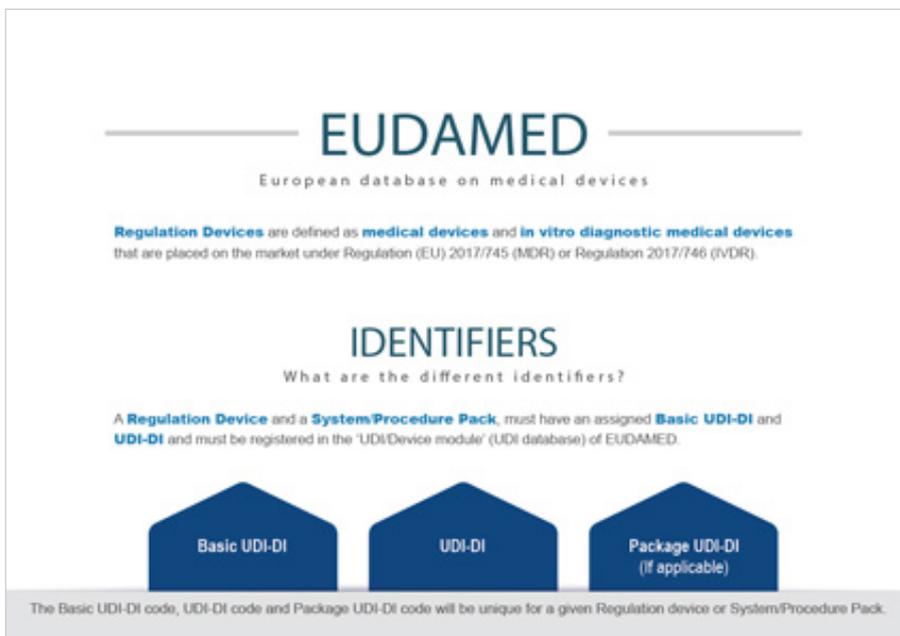
 **INFOGRAPHIC:** [UDI registration for regulation devices](#)

Playground



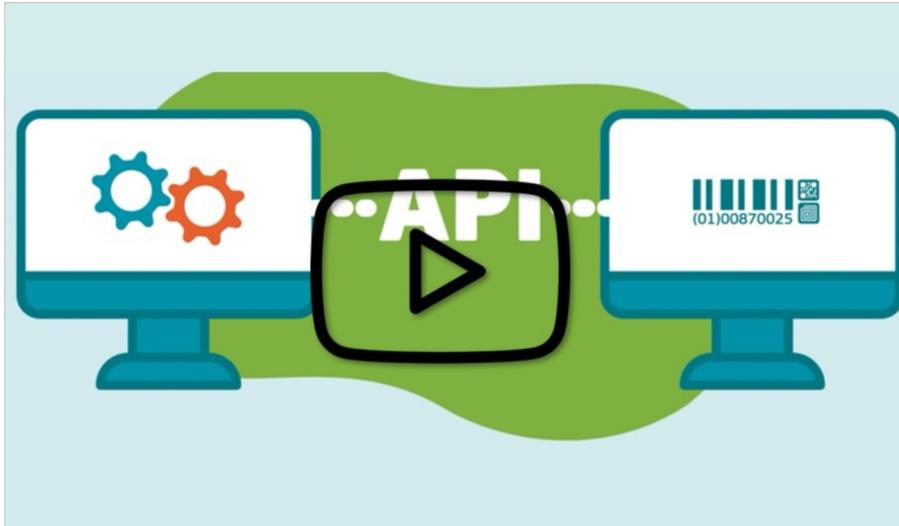
3.1 Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device

 **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.

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

2. Next, enter the Basic UDI-DI information. Select the applicable regulation.



NOTE

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

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UDI-DI registration

Manufacturer identification

Organisation name: Test MF
 Actor ID/SRN: LI-MF-00000104
 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 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 i Is it a System or Procedure Pack which is a Device in itself is required unless you select the option - No

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

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

Special device type

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

*** Special device type:**

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

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



NOTE

If one of the following Special Device types is selected, the Master UDI-DI applies:

- Standard soft contact lenses
- Standard Rigid Gas Permeable (RGP) contact lenses
- Made to order soft contact lenses
- Made to order Rigid Gas Permeable (RGP) contact lenses.

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

Save & Next >



IMPORTANT

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

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

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

If there is only one Authorised Representative with an active mandate with the non-EU Manufacturer, it will be automatically retrieved:

Authorised representative identification

Organisation name: Belgian AR A
 Eudamed actor ID: BE-AR-000000046
 Address: Rue E, 1 1060 Brussels
 Telephone number: -
 Email: contact@belgian-ar-a.be

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

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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 you selected *No*, 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 later, or on **Save & Next** to save it as a draft and continue directly with the following steps:

3.1.2 Step 2: Certificate information (if applicable)

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

For 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 – Device Certificate Information \[103\]](#) you can find the different cases in which Certificate information is needed and the type of certificate. (In summary, it is applicable for MDR risk class III and IIb and IVDR risk class B with self-patient testing/near-patient testing, risk class D and C).

Certificate information

EU type-examination certificate if applicable

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

* Enter NB number or name:

Q Find

Certificate number:

Revision number:

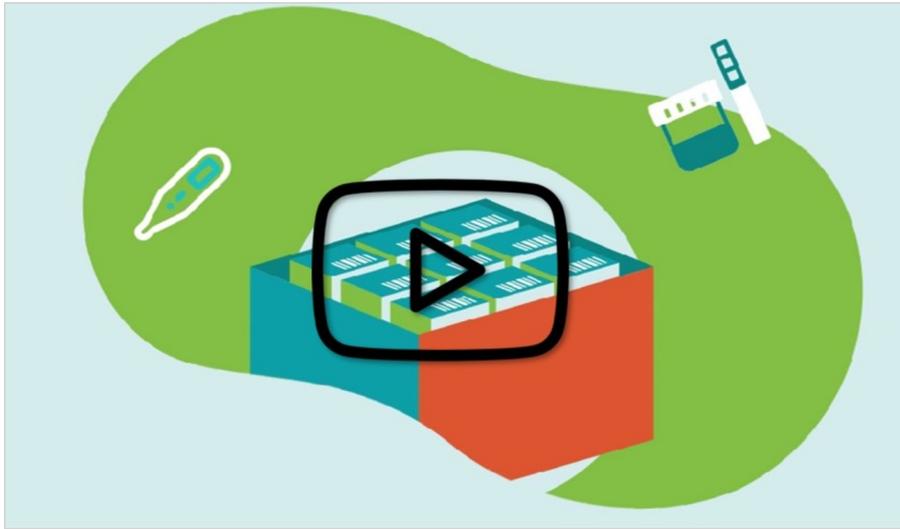
Save

Save & Next ➤

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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 shorter than 14 digits (check digit included), when populating EUDAMED field please add leading zero(s) until you reach 14 digits.

For example:

000000nnnnnnnn (GTIN-8)

00nnnnnnnnnnnn (GTIN-12)

0nnnnnnnnnnnnnn (GTIN-13)



NOTE

When registering a Master UDI-DI code, a specific format validation algorithm is applied when the issuing entity is GS1:

- For **Standard soft contact lenses** and **Standard Rigid Gas Permeable (RGP) contact lenses** the system applies the GMN format validation algorithm.
- For **Made-to-order soft contact lenses** and **Made-to-order Rigid Gas Permeable (RGP) contact lenses** the system applies the GTIN UDI-DI format validation algorithm.

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity: * Secondary UDI-DI value:

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

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Trade name applicable

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

* Trade name: * Select the language:

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

5. Enter the *Reference/Catalogue number*.

* Reference/Catalogue number:

REF_TEST



NOTE

For a Master UDI-DI, if there are multiple Reference/Catalogue numbers, you may enter 'many' as the value:

Reference/Catalogue number

i If you have more than one Reference/Catalogue number, please enter the word 'many'

* Reference/Catalogue number:

many

- 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:



NOTE

Direct Marking UDI-DI is not applicable for a Master UDI-DI. The field is set to *No* and it is greyed out.

- 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 (UoU 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:

2

Issuing Entity:

Unit of Use DI:



NOTE

The *Unit of Use DI* and its *Issuing Entity* fields are not applicable for a Master UDI-DI. They are set to *No* and they are greyed out.

8. If the base quantity is **less than two**, then no Unit of Use DI (UoU 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



NOTE

For a Master UDI-DI, please indicate the maximum number of devices for the *Quantity of Device*:

Quantity of device

i Please indicate the maximum number of devices.

* Quantity of device:

9. Select the *Type of UDI-PI*.
10. Enter any additional pertinent information about the device, select the language in which the additional information is provided and enter a URL (web address) for additional information online if applicable:

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):

11. 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**:

Playground

*** UDI-DI status**

No longer placed on the EU market

Not intended for the EU market

On the EU market

3.1.4 Step 4: UDI-DI characteristics

- Specify clinical size for the UDI-DI if applicable 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 of description. 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 provided 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:

* Precision: * Minimum: * Maximum: * Measure unit:

[+ Add a type of dimension](#)

You must provide one of the following precision types:

- 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 dimensions, but only one dimension for a given type.

- Specify if the device is labelled as *single use*.
When the device is not labelled *single use* you must provide the number of reuses if applicable:

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

*** Labelled as single use**

Yes No

Maximum number of reuses applicable

Yes No Maximum number of reuses is required unless you select the option - No

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.

*** Maximum number of reuses:**

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

*** Need for sterilisation before use**

Yes No

*** Device labelled as sterile**

Yes No

*** Containing latex**

Yes No



NOTE

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

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

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*** 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

i 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. Fill in the *Storage/handling conditions* section:

Storage/handling conditions, if applicable

Yes No **i** 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

For Storage/handling conditions type *Other*, users must enter the Description of the *Storage/handling condition type* and the description's language.

6. Fill in *Critical warnings or contra-indications*, and click **Save** or **Save & Next**:

Critical warnings or contra-indications, if applicable

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

*** Critical warning type:**

*** Description:**

+ Add critical warnings or contra-indications

Save **Save & Next >**

**NOTE**

For Critical warning or contra-indications type *Other*, users must enter the Description of the Critical warning or contra-indications *type* and the description's language.

3.1.5 Step 5: Device information

1. For MDR, specify if it is a reprocessed single use device and if 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

2. If you select *Yes* for the *Intended purpose*, 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

**NOTE**

When registering a Master UDI-DI for contact lenses, if you select *Yes* for Annex XVI, the list of possible choices will not be displayed, as it is already predefined.

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

If **Yes**, there are two 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

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

Select the Actor from the list:

[Close](#)

Select manufacturer

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

← Previous 1 2 ... 19 Next →

Close

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

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

Yes No

I know the Actor ID/SRN

* Product original manufacturer organisation name:

[Check registry](#)

Select the Organisation name from the list:

[Close](#)

Select manufacturer

Organisation name ↓

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

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

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

If the Organisation name is not on 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: * Postal code:

* Country:

Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

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

Clinical Investigation

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

✘ Clinical Investigation '212121' is not registered in EUDAMED

* Enter Clinical Investigation Number:

5. When registering under MDR, select **Yes** or **No** to fill 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

Presence of cells or substances of microbial origin:

Yes No

*** 'New' Device**

Yes No 

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 fill information on tissues and cells and 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 >](#)

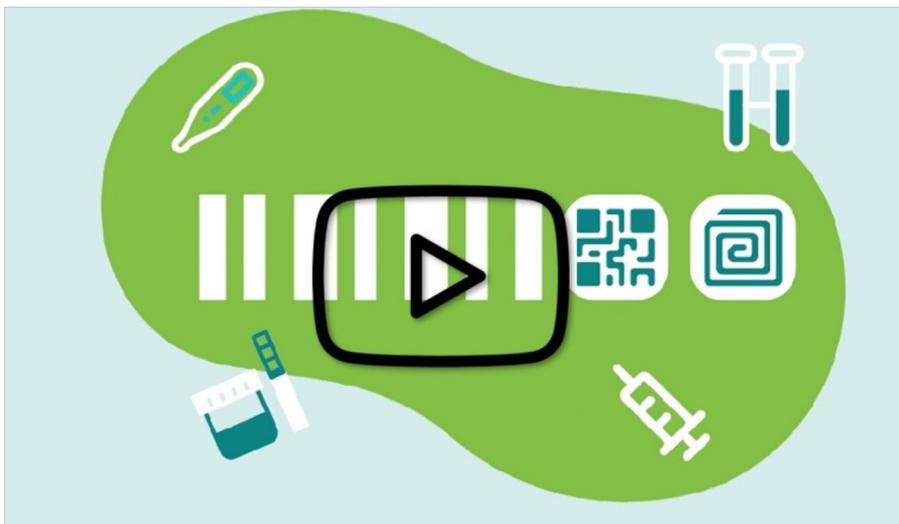


NOTE

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:

Each package level requires a unique UDI-DI assignment.

Start by registering the container package associated with the root UDI-DI (also known as the primary UDI-DI). You may 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.



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.



NOTE

When registering a Master UDI-DI code, a specific format validation algorithm is applied when the issuing entity is GS1:

- For **Standard soft contact lenses** and **Standard Rigid Gas Permeable (RGP) contact lenses** the system applies the GMN format validation algorithm.
- For **Made-to-order soft contact lenses** and **Made-to-order Rigid Gas Permeable (RGP) contact lenses** the system applies the GTIN format validation algorithm.

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

Container package(s)

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

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

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

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

Save

Submit >

Preview

3. Confirm your submission in the pop-up window:

✕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.

Submit my request

Cancel

4. The screen will display a success message:

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

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

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

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

My Actor data	UDI-DIs/Device	User management
<ul style="list-style-type: none"> Manage your actor data Manage your email notifications Machine to machine data delivery preferences 	<ul style="list-style-type: none"> Register a new Basic UDI-DI Register a legacy device Manage your Basic UDI-DIs / EUDAMED DIs Manage your device details 	<ul style="list-style-type: none"> Assess user access requests Manage your users

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

 **IMPORTANT**

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

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter

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

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

Apply filters Clear all filters

Active filters: State: Draft Clear all filters

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
122111212121Y2	1		Test	Class IIa	2021-03-31	1st Draft	...
1111184FG4G228694YC	1	DeviceModelZZZ	DeviceNameZZZ	Class IIb	2021-03-19	1st Draft	...

- From the results, find the Basic UDI-DI for which you wish to add a new UDI-DI. Click on the three dots on the right and click on *Add a UDI-DI to this Basic UDI-DI / Add a Master 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	M0del 88		Class IIb	2021-03-		View Data
1234501VP	1	Model 1	Name 1A	Class III	2021-03-		View all UDI-DIs for this Basic UDI-DI
B-555908900698	1	MyModel111	MyDeviceName111	Class I	2021-03-		Add a UDI-DI to this Basic UDI-DI
1234500VM	1	Model 550		Class IIa	2021-03-08	Registered	...
123450046Z	2	Model 9		Class IIb	2021-03-08	Registered	...
B-2203615490541	1	Model abc	Name abc	Class IIa	2021-03-04	Registered	...

- Complete the steps required for the registration of a UDI-DI for an existing Basic UDI-DI (*Step 3: UDI-DI identification information [11], Step 4: UDI-DI Characteristics [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 i UDI-DI from another entity is required unless you select the option - No

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Submission xClose

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*.

Playground

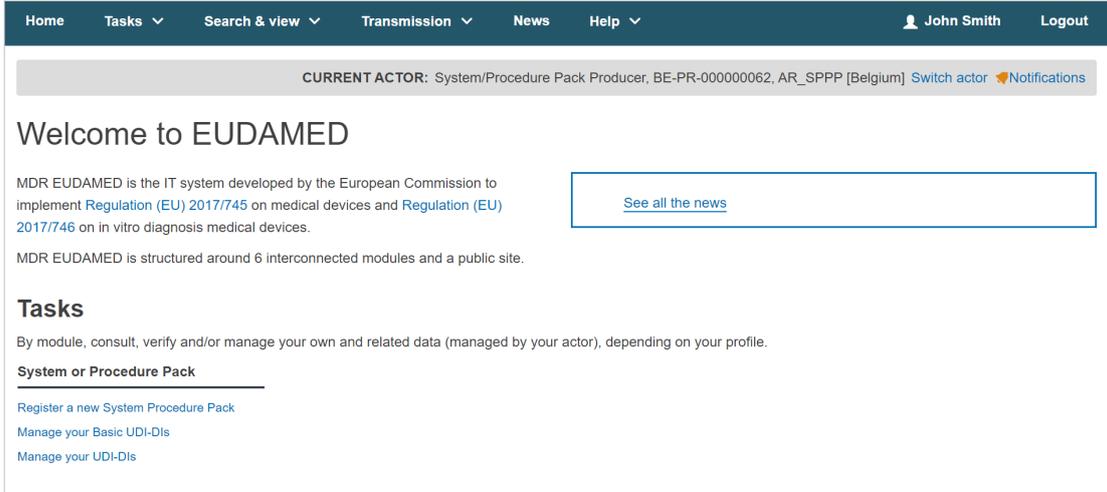
4 Registering System or Procedure Packs (SPP)

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

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

4.1.1 Step 1: Basic UDI-DI main information

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



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

2. Next, specify the *Issuing Entity* and the *Basic UDI-DI code*:

Playground

System or Procedure Pack registration

Procedure pack producer identification

Organisation name: AR_SPPP
 SRN: BE-PR-00000062
 Address: 8686 Brussels
 Telephone number: -
 Email: ar_sppp@abc.com

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

* System or Procedure Pack type:

Procedure Pack
 System

[Save & Next >](#)

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

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

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

System or Procedure Pack registration

Procedure pack producer identification

Organisation name: Health Pac
 Actor ID/SRN: LJ-PR-00000062
 Address: Oak St, 101 8088 Vauxor
 Telephone number: +34389879513
 Email: eudamed@manufacturer.com

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

❗ Duplicate device identified.

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

Playground

*** System or Procedure Pack type:**

Procedure Pack
 System

Save & Next >

4.1.2 Step 2: Basic UDI-DI information

Enter the Basic UDI-DI information:

System or Procedure Pack registration

1 2 3 4
 Basic UDI-DI information UDI-DI identification information UDI-DI characteristics 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:

* 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:

Name:

Save **Save & Next >**

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

Producer identification: [BE-PR-000000062_AR_SPPP](#)

Basic UDI-DI identification information

Basic UDI-DI identification

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

Basic UDI-DI code: 1212112121212DL

* Risk class:

* Indication of medical purpose:

* Select the language:

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

2017745 on medical devices)

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

System or Procedure Pack type: Procedure Pack

* Indication of medical purpose: [Text area]

* Select the language: [Dropdown menu]

+ Add another indication of medical purpose

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

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

Device model applicable

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

* Model: [Text input field]

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

Save Save & Next >

4.1.3 Step 3: UDI-DI identification information

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: [Dropdown menu with GS1 selected]

* UDI-DI code: [Text input field]



IMPORTANT

The UDI-DI code 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 shorter than 14 digits (check digit included), when populating EUDAMED field please add leading zero(s) until you reach 14 digits.

For example:

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity: * Secondary UDI-DI value:

3. Enter the EMDN code, click **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):

Playground

5. Enter the *Reference/Catalogue number*.
6. Select the *Type of UDI-PI*.
7. Enter any additional pertinent information about the System or Procedure Pack, select the language of the additional information and enter a URL (web address) for additional information online, if applicable:

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**:

4.1.4 Step 4: UDI-DI characteristics

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

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

UDI-DI characteristics

* Need for sterilisation before use

Yes No

* Device labelled as sterile

Yes No

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

Storage/handling conditions, if applicable

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

* Storage/handling conditions type: OTHER *

* Description: Test

* Select the language: -

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

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



NOTE

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

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

Playground

Critical warnings or contra-indications, if applicable

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

* Critical warning type:

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

* Description:
 Test

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

Save **Save & Next >**



NOTE

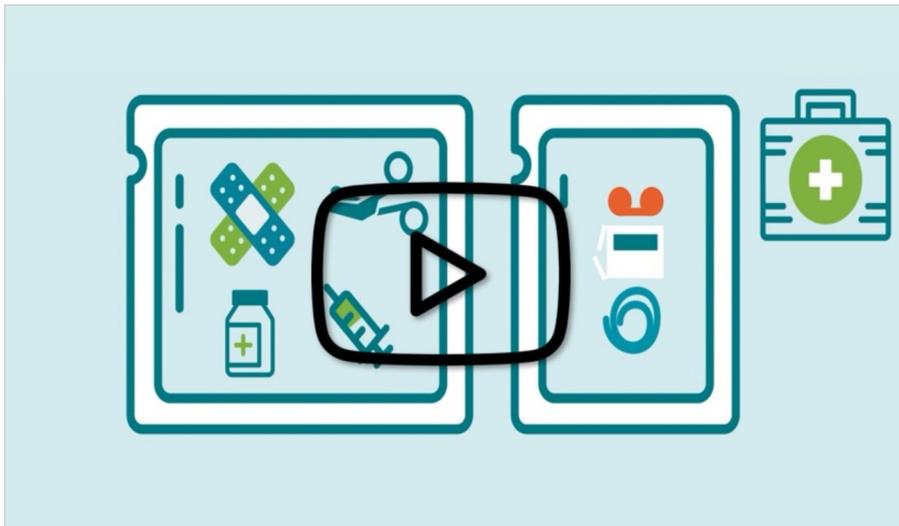
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the description's language.

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

Save **Save & Next >**

4.1.5 Step 5: Container package details

VIDEO: UDI and Systems and Procedure Packs



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

 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.

[xClose](#)

Add container package

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

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

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

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

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

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

Save

Submit >

Preview

- On the pop-up window, click on **Submit my Request**:

xClose

Submission

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

Submit my request

Cancel

Upon submission, a success message will be displayed on the screen:

Registration of System or Procedure Pack

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

What do you want to do now?

[Register new System or Procedure Pack](#)

[Go to the dashboard](#)

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

- 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 filters**:

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

Note: The State dropdown menu is open, showing options: Draft, Discarded, Draft (selected), Registered, Submitted.

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

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

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

4.2.1 Step 1: UDI-DI identification information

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

Playground

1

UDI-DI
identification
information

2

UDI-DI
characteristics

3

Container
package(s)

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

Selected nomenclature codes

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

Trade name applicable

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

* Trade name: * Select the language:

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

* Reference/Catalogue number:

Ref_12134

REF_TEST

Ref_12134 **i**

Manufacturing date

Expiration date

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

Save

Save & Next

4.2.2 Step 2: UDI-DI characteristics

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

UDI-DI characteristics

* Need for sterilisation before use

Yes No

* Device labelled as sterile

Yes No

Storage/handling conditions, if applicable

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

Critical warnings or contra-indications, if applicable

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

* Critical warning type:

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

Save **Save & Next >**

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

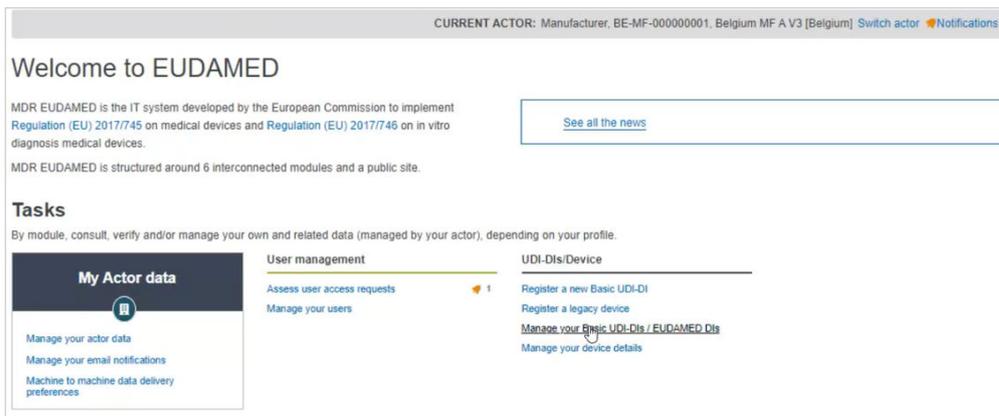
4.2.3 Step 3: Container package details

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

5 Manage your own device information

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

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



Dashboard screenshot showing the 'Manage your Basic UDI-DI / EUDAMED DIs' option under the 'UDI-DIs/Device' section.

Tasks:

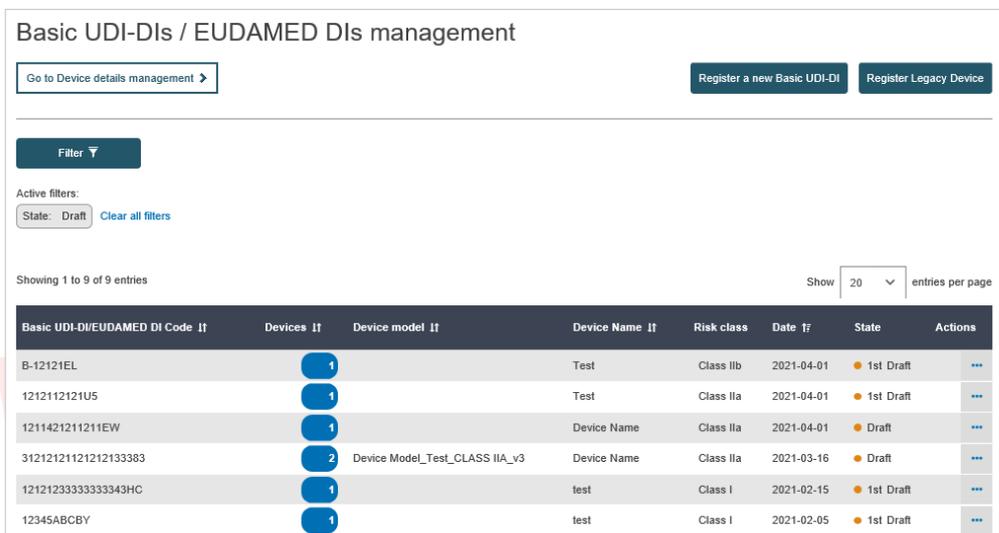
- User management
 - Assess user access requests
 - Manage your users
- UDI-DIs/Device
 - Register a new Basic UDI-DI
 - Register a legacy device
 - Manage your Basic UDI-DIs / EUDAMED DIs
 - Manage your device details

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



NOTE

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



Basic UDI-DIs / EUDAMED DIs management

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

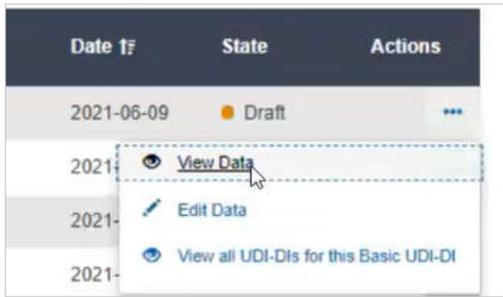
Filter

Active filters: State: Draft Clear all filters

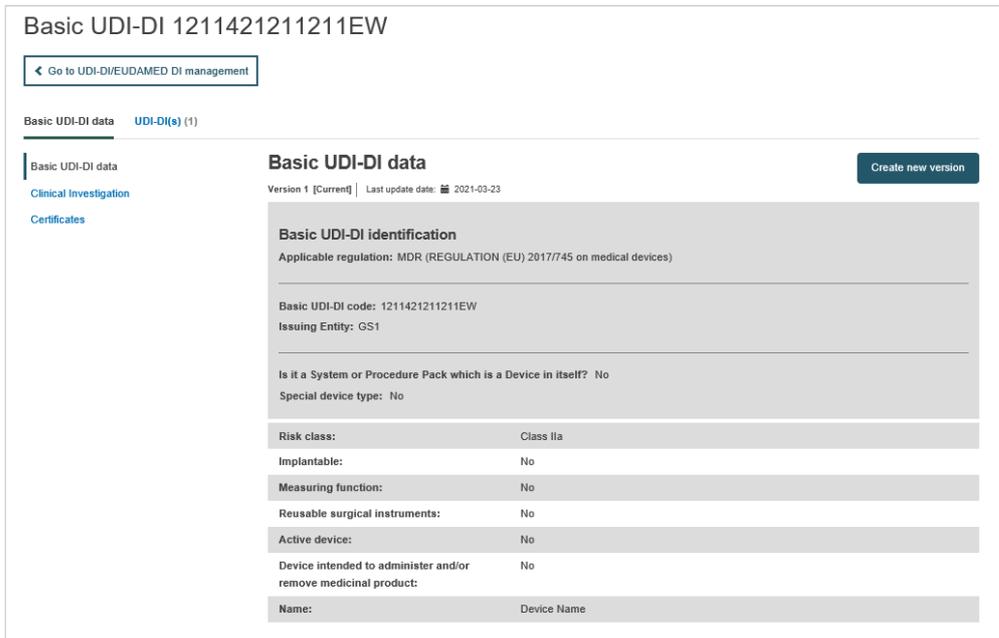
Showing 1 to 9 of 9 entries Show 20 entries per page

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

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



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



5.1.1 Delete a draft Basic UDI-DI/EUDAMED DI

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

- Inside the *View details* page of the desired 1st draft, click on **Delete**:



A pop-up window will ask you to confirm the delete action.

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

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

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

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

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

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

- 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 i Device model applicable

* Device Name:

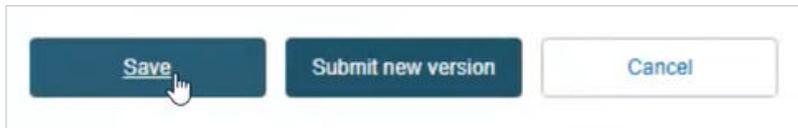
version 3

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:

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



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

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

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

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

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

Basic UDI-DI data 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

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

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

[← Go back to the current version](#)

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

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

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

[← Go back to the current version](#)

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

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

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

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

Basic UDI-DI code: 12345-test-udi-1-HL
 Issuing Entity: GS1

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

Risk class: Class IIb
 Implantable: No

5.2 Manage your device UDI-DI/EUDAMED ID details

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

Playground

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 50 entries Show entries per page

(Master) UDI-DI/EUDAMED ID	Trade name	Reference/Catalogue number	Nomenclature code	Date	Status	State	Actions
Basic UDI-DI code: 12345-DDD-05-6Z, Device Model: AAA, Class IIb, MDR (REGULATION (EU) 2017/745 on medical devices)							
12311ss	AAA	099OPP		2024-06-25	On the EU market	1st Draft	...
EUDAMED DI code: B-nlkoIVD, Device Name: odjcouwbfk, Class I, MDD (Directive 93/42/EEC on Medical Devices)							
D-nlkoIVD				2024-06-25	On the EU market	1st Draft	...
Basic UDI-DI code: 888888888888B, Device Model: test delete master UDI, Class I, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new Master UDI-DI							
opo-91910	test delete master UDI	R0191		2024-06-25	On the EU market	Draft	...
EUDAMED DI code: B-ivdd+generalFA, Device Model: AAA, IVD Annex II List A, IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)							
D-ivdd+generalFA				2024-06-21	On the EU market	1st Draft	...
EUDAMED DI code: B-aimddP8, Device Model: SSw, AIMDD, AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)							
D-aimddP8				2024-06-21	On the EU market	1st Draft	...
EUDAMED DI code: B-mdd+cert6F, Device Model: ggg, Class III, MDD (Directive 93/42/EEC on Medical Devices)							
D-mdd+cert6F				2024-06-21	On the EU market	1st Draft	...
Basic UDI-DI code: 7777777777770UZ, Device Name: aaaaaaaaaa, Class I, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new Master UDI-DI							
HIB-020nbf		q1211sdrw		2024-06-18	On the EU market	1st Draft	...
Basic UDI-DI code: 12345-master-udi-di-1-6C, Device Model: Master UDI-DI model, Class III, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI							
12345756984101	sdsdfcd	as23r43x		2024-06-18	On the EU market	1st Draft	...

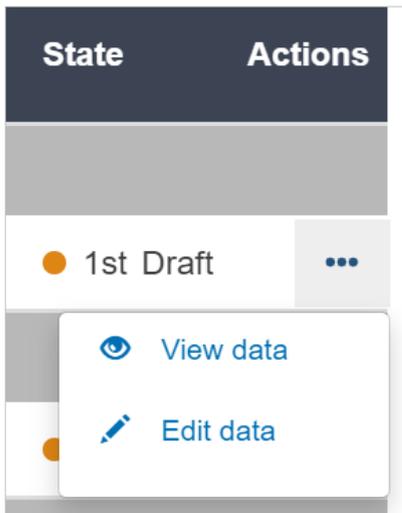
Playground



NOTE

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

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



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

Playground

UDI-DI u-123123MI9N See UDI-DI(s) list (1)

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

UDI-DI data EDIT DELETE

Version 6 [Draft] [See version history](#) Last update date: 2023-08-15

UDI-DI code: u-123123MI9N

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS

Trade name

Trade name applicable: No

Reference/Catalogue number: fghgf

Is the device directly marked?

Is the device directly marked?: No

Quantity of device: 1

Type of UDI-PI

Lot or Batch number: Yes

Additional product description: gh [BG]

5.2.1 Delete a draft UDI-DI/EUDAMED ID

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) to view a draft UDI-DI.

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

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

UDI-DI data EDIT DELETE

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

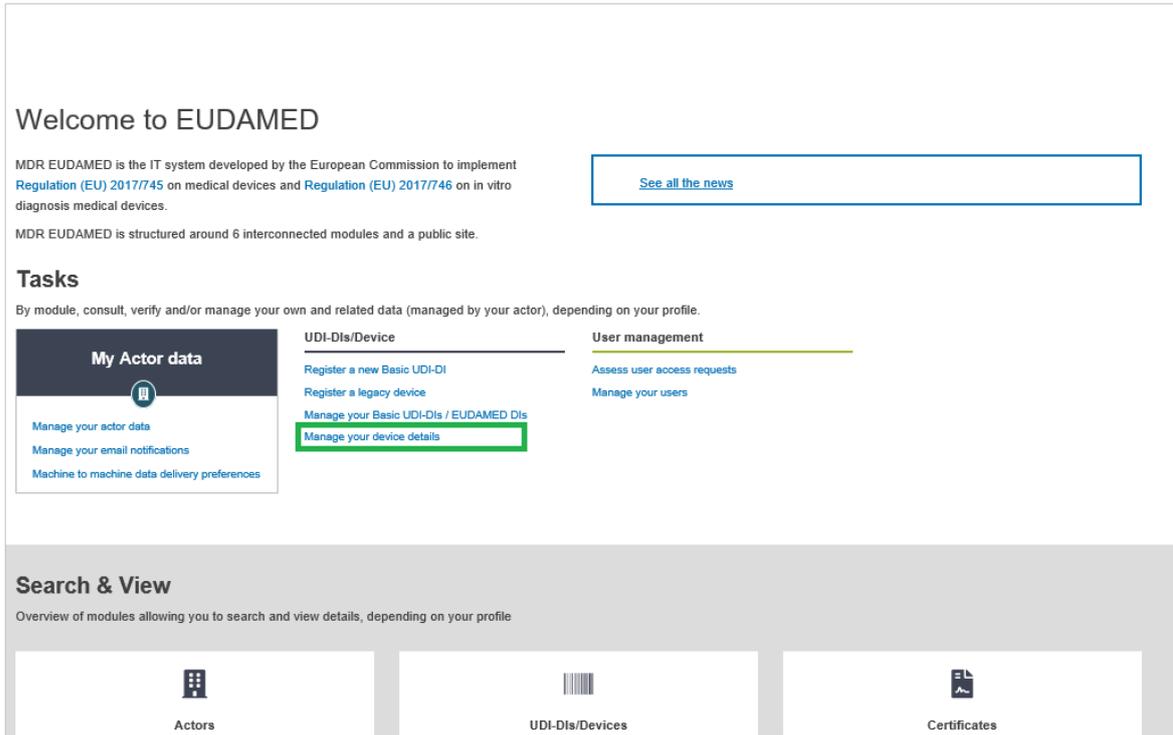
Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

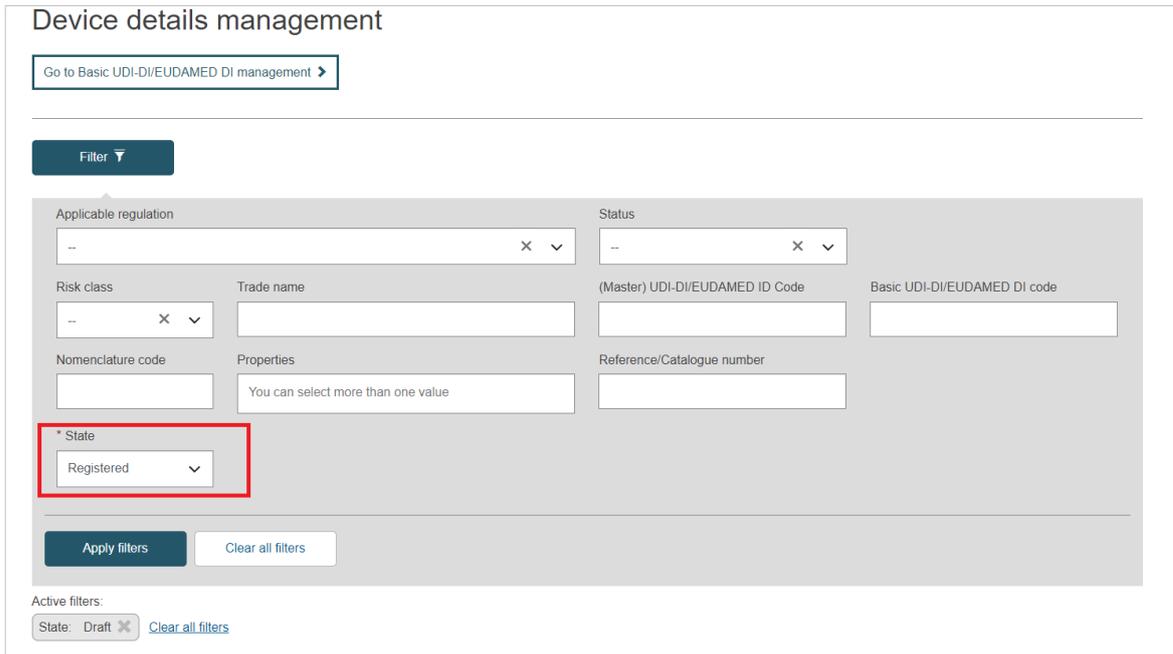
- A pop-up message will ask you to confirm the delete action.

5.2.2 View details of a registered UDI-DI/EUDAMED ID

- On the dashboard, click on *Manage your device details*:



2. Select the option *Registered* in the *State* field and click on **Apply filters**:



3. A list of devices will be displayed. Click on *View data* under the three dots of the desired entry:

Playground

Showing 1 to 20 of 454 entries Show entries per page

UDI-DI/EUDAMED ID Code	Trade name	Reference/Catalogue number	Nomenclature code	Date	Status	State	Actions
Basic UDI-DI code: 77777777770UZ, Device Name: aaaaaaaaaa, Class I, MDR (REGULATION (EU) 2017/745 on medical devices)							+ Add a new Master UDI-DI
188727_00	aaaaaaaaa	0101912		2024-06-17	On the EU market	Registered	...
Basic UDI-DI code: 109784903285972P5, Device Name: DV_NM-BRB, Class IIa, MDR (REGULATION (EU) 2017/745 on medical devices)							+ Add a new UDI-DI
BRB-cd-1		brb-dev-rn		2024-06-11	On the EU market	Registered	...
Basic UDI-DI code: 12345-24.Q1-Ilb-mfs-2-XU, Device Model: 12345-24.Q1-Ilb-mfs-2-XU, Class IIb, MDR (REGULATION (EU) 2017/745 on medical devices)							View data
brb-test-code		BRB-RN		2024-06-11	On the EU market	Registered	...
12345-24.Q1-Ilb-mfs-2-XU8	Generic Device Name_Device 1	12345-24.Q1-Ilb-mfs-2-XU		2024-06-03	On the EU market	Registered	...
Basic UDI-DI code: 12345-family-mudi-1-Q4, Device Model: My model, Class IIa, MDR (REGULATION (EU) 2017/745 on medical devices)							+ Add a new Master UDI-DI

4. You will see a summary of your device details, divided into the following subsections:
- UDI-DI details:

UDI-DI details

Discard
Create new version

Version 1 [Current] | Last update date: 📅 2024-06-20

UDI-DI code:	00125877641269	🔗 Link to legacy device
Issuing Entity:	GS1	

UDI-DI from another entity

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

Selected nomenclature codes

Code L010101 MONOBLOCK SURGICAL SCALPELS, REUSABLE

Trade name

Trade name applicable:	No
Reference/Catalogue number:	BRB-CECP-2

Is the device directly marked?

Is the device directly marked?:	No
Quantity of device:	1

Playground



NOTE

Master UDI-DI *Details* section for a registered Master UDI-DI:

Master UDI-DI details

Discard
Create new version

Version 2 [Current] | [See version history](#) | Last update date: 📅 2024-06-21

Master UDI-DI code:	188727_00
Issuing Entity:	HIBCC

Master UDI-DI from another entity

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

Selected nomenclature codes

Code G030299 DIGESTIVE ENDOSCOPY, HAEMOSTASIS DEVICES - OTHER

Code D01010102 GLUTARALDEHYDE, ACIDIC SOLUTION FOR THE DISINFECTION OF MEDICAL DEVICES

Trade name

Trade name applicable:	Yes
Trade name:	aaaaaaaaaa v2
Reference/Catalogue number:	0101912

Is the device directly marked?

Is the device directly marked?:	No
Quantity of device:	1

Playground

Type of UDI-PI	
Expiration date:	Yes
Additional product description:	Description_Generic_EN [EN], Description_FR [FR]
URL for additional information (as electronic instructions for use):	www.yoursite.com/
Status of the UDI-DI/Device	
UDI-DI/Device status:	On the EU market
Clinical size	
Clinical size applicable:	Yes
Clinical size #1:	(Type): Acidity, (Precision): Value, (Value): 4.0, (Measure unit): Adult
Labelled as single use	
Labelled as single use:	No
Maximum number of reuses applicable:	No
Maximum number of reuses:	-
Need for sterilisation before use:	No
Device labelled as sterile:	No
Containing latex:	No

The *UDI-DI/Device sub-status* subsection will become visible under the *UDI-DI/Device status* subsection once a final Field Safety Notice (FSN – Vigilance module) has been registered for the selected UDI-DI/EUDAMED ID referenced in the corresponding Field Safety Corrective Action (FSCA – Vigilance module).

Playground



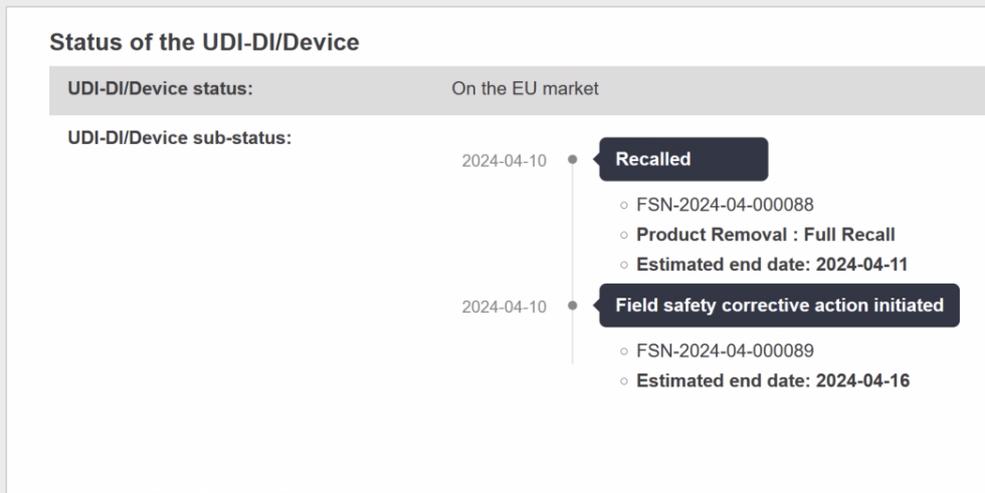
NOTE

The sub-status of the device will be set to *Field safety corrective action initiated* if any of the following manufacturer actions are selected in the corresponding FSCA:

- IFU or labeling change
- Software Upgrade
- On-site modification/inspection by
- Customer information only
- Other

The sub-status of the device will be set to *Recalled* if any of the following manufacturer actions are selected in the corresponding FSCA:

- Product Removal - Partial Recall (Lot/Batch/Model)
- Product Removal - Full Recall



Playground



NOTE

When the FSCA status transitions to *Action completed*, the system will remove the corresponding device sub-status:

Type of UDI-PI	
Expiration date:	Yes
Additional product description:	Description_Generic_EN [EN], Description_FR [FR]
URL for additional information (as electronic instructions for use):	www.yoursite.com/
Status of the UDI-DI/Device	
UDI-DI/Device status:	On the EU market
UDI-DI characteristics	
Clinical size	
Clinical size applicable:	Yes
Clinical size #1:	(Type): Acidity, (Precision): Value, (Value): 4.0, (Measure unit): Adult

If the FSCA status referencing the device transitions to *In progress*, the sub-status will be displayed again.

CMR/Endocrine disruptor

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

CMR substances

Category of CMR:	1A
EC#:	-
CAS#:	-
Name of the substance:	Device_Substance_Endocrine [EN]

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

Endocrine-disrupting properties

EC#:	-
CAS#:	-
Name of the substance:	Device_Substance_Endocrine [EN]

Storage/handling conditions

Storage/handling conditions, if applicable:	Yes
Storage/handling condition #1:	(Type) Protect from heat and radioactive sources - (Description) Text EN_1 [All languages]

Critical warnings or contra-indications

Critical warnings or contra-indications, if applicable: Yes

Critical warning #1: (Type) Do not resterilize - (Description) CW Text [All languages]

Critical warning #2: (Type) Biological risks - (Description) CW Text 2 [All languages]

Reprocessed single use device: No

Intended purpose other than medical (Annex XVI): Yes
Brain electrostimulation

Information on substances

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: Yes

INN Name: -
Name of the substance: Device_Substance_Human_Product
Language: English

Related Device

This device is not currently linked with any other devices

- Product original manufacturer:

Product original manufacturer

Version 1 [Current] | Last update date: 2024-04-15

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

Original equipment manufacturer actor:

Organisation name:
Address:
Telephone number:
Email:
Actor ID/SRN:

- Market Information:

Market Information Update countries

Version 1 | Last update date: 2024-04-15

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

Member States where device is or is to be made available on the market:	Country	From	To
	Belgium	2015-12-10	-

- Container Package Information:

Container Package Information Create new version

Version 1 | Last update date: 2024-04-10

- [Root] UDI-DI: device-2-1 (ICCBBA) | Status: On the EU market
- UDI-DI: boxx-1 (HIBCC) | Quantity per package: 1 (1) | Status: Not intended for the EU market
 - UDI-DI: boxx-2 (ICCBBA) | Quantity per package: 1 (1) | Status: Not intended for the EU market
- UDI-DI: boxx-3 (ICCBBA) | Quantity per package: 1 (1) | Status: On the EU market
 - UDI-DI: bbox-3-1 (ICCBBA) | Quantity per package: 1 (1) | Status: No longer placed on the EU market

 **NOTE**
Container Package Information section for a registered Master UDI-DI:

Container Package Information Create new version

Version 1 | Last update date: 2024-06-17

- [Root] **Master** UDI-DI: 188727_00 (HIBCC) | Status: On the EU market
- Master** UDI-DI: ICC-919181 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market

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

 **VIDEO: UDI assignment and updates**



Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) 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:

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

UDI-DI data

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

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

UDI-DI code:	12212121
Issuing Entity:	HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

B01 clature

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN [Remove nomenclature code](#)

Trade name applicable

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

* Trade name:

* Select the language:

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

Playground

*** Is the device directly marked?**

Yes No

Same as UDI-DI

* Issuing Entity:

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 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.

[xClose](#)

Create new version of UDI-DI

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

i 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 >](#)



TIP
Master UDI-DI update variation

When creating a new version of a Master UDI-DI, the *Quantity of device* field is editable, whereas for the UDI-DI, it is not.

Basic UDI-DI 12345-family-015N

[Go to Device Details management](#)

Basic UDI-DI details | Master UDI-DI(s) (1)

UDI-DI 12345-master-udi-013D [See UDI-DI\(s\) list \(1\)](#)

Master UDI-DI details | **Master UDI-DI details** | [Discard](#) | [Create new version](#)

Product original manufacturer | Version 1 [Current] | Last update date: 2024-12-19

Market Information | **Master UDI-DI code:** 12345-master-udi-013D

Container Package Information

Quantity of device

Please indicate the maximum number of devices.

* Quantity of device:

10 | | |

- 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.

*** Information on substances**

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

INN:

[+ 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: No

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

Once you have submitted the new version, click on Confirm in the pop-up window to finalise the update:

Create new version of UDI-DI [xClose](#)

You are about to create a new version of UDI-DI 12345-master-udi-013D

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

5.2.4 Update (create new version) for Product original manufacturer

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



NOTE

Product original manufacturer information can be updated if it was initially provided with details of an Organisation that is not a registered Actor with an Actor ID/SRN.

It **cannot** be updated if it was initially marked as *Not applicable*, or if it was specified with an Actor ID/SRN.

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) to view a UDI-DI/EUDAMED ID.

1. Once inside the details of the selected UDI-DI, click on **Product original manufacturer** from the list on the left (or scroll down to *Product original manufacturer*):

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

2. Click on **Update** to access the *Product original manufacturer* page:

Product original manufacturer **Update**

Version 4 [Current] | [See version history](#) | Last update date: 2023-09-12

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

Original equipment manufacturer organisation:

Organisation name: PDasOrg (3)

Address: AAA, 30, AAA, Afghanistan

Telephone number: -

Email: aaa@aaa.af

- You can **either** update the details on *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 i Street information is required unless you select the option - No

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:

* Country:

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, select the *Product original manufacturer* from the list:

Playground

[xClose](#)

Select manufacturer

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

Close

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



NOTE

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

5.2.5 Update (create new version) for Market Information

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) 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 *Market Information*):

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

UDI-DI aaaa-bbb-vvv

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

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

EDIT
DELETE

UDI-DI data

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

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	-	-

3. Update the relevant fields under *Market Information*:

Market information update

Belgium From [] To []
YYYY-MM-DD YYYY-MM-DD

Finland From [] To [] []
YYYY-MM-DD YYYY-MM-DD

Greece From [] To [] []
YYYY-MM-DD YYYY-MM-DD

Latvia From [] To [] []
YYYY-MM-DD YYYY-MM-DD

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

Submit

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

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

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

5.2.6 Update (create new version) for Container Packages

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) to view a UDI-DI/EUDAMED ID.

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

The screenshot shows the 'UDI-DI existing-PD-1' details page. On the left sidebar, the 'Container Package Information' tab is highlighted with a red box. The main content area shows 'UDI-DI data' for 'Version 1 [Current]' with a last update date of '-'. The 'UDI-DI code' is 'existing-PD-1' and the 'Issuing Entity' is 'ICCBBA'. There is a 'Link to legacy device' button next to the code. Below this, it shows 'UDI-DI from another entity' with 'UDI-DI from another entity (secondary) applicable:' set to 'No'. At the top right, there are 'Discard' and 'Create new version' buttons.

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

The screenshot shows the 'Container Package Information' section for 'Version 3' with a last update date of '2023-09-15'. The 'Create new version' button is highlighted with a red box. Below the header, there is a text field containing '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'.

The screenshot shows the 'Container package update' dialog. It has a title 'Container package(s)' and a '+ Add container package' link. Below this, there is a text field containing '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'. At the bottom, there are 'Submit' and 'Cancel' buttons. The 'Submit' button is highlighted with a red box.

Playground

[*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*, will you 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.

3. 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

Playground



TIP
Master UDI-DI update variation

When creating a new version of a Master UDI-DI container package, the *Maximum quantity per package* field is editable, whereas for the UDI-DI container package, it is not:

Container package update

Container package(s)

+ Add container package

- [Root] Master UDI-DI: 12345-master-udi-013D (GS1) | Status: On the EU market
 - o Master UDI-DI: 12345-pack-mudi-01DG (GS1) | Maximum quantity per package: 10 (100) | Status: On the EU market

Submit Cancel

Container package update

Container package(s)

+ Add container package Update container package

- [Root] Master UDI-DI: 12345-master-udi-013D (GS1) | Status: On the EU market
 - o Master UDI-DI: 12345-pack-mudi-01DG (GS1) | Maximum quantity per package: 10 (100) | Status: On the EU market

Submit Cancel

Update container package *Close

Container package Master UDI-DI for 12345-pack-mudi-01DG

* Maximum quantity per package:	Total number of devices
<input type="text" value="10"/>	100

Container package market status

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

Confirm Cancel

Container package update

Container package(s)

+ Add container package Update container package

- [Root] Master UDI-DI: 12345-master-udi-013D (GS1) | Status: On the EU market
 - o Master UDI-DI: 12345-pack-mudi-01DG (GS1) | Maximum quantity per package: 5 (50) | Status: On the EU market

Submit Cancel



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



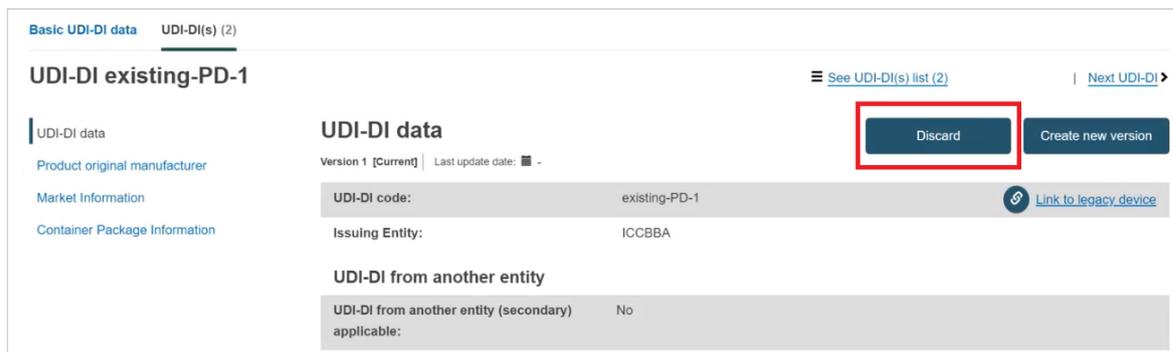
IMPORTANT

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.

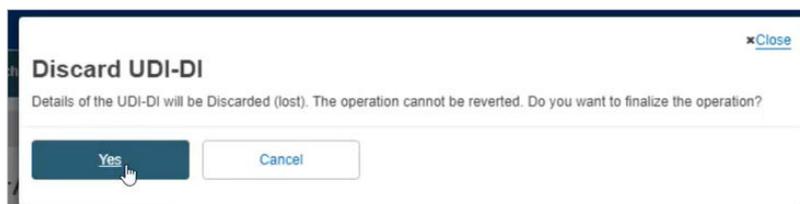
You may wish to discard a registered UDI-DI in case you discover errors that cannot be corrected.

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) to view a registered UDI-DI/EUDAMED ID.

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



2. Confirm your intention to discard the registered UDI-DI:



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



CAUTION

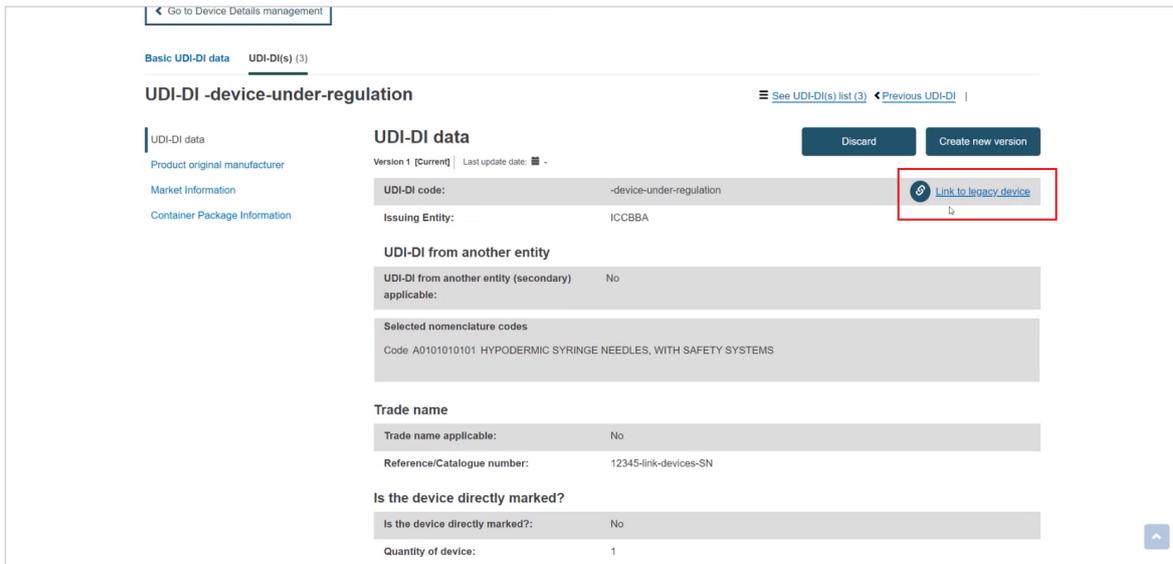
If the UDI-DI is the only one remaining in this Basic UDI-DI category, the *discard* action will also discard the Basic UDI-DI. The system will alert you accordingly:



5.2.8 Link a registered Regulation Device to a registered Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

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



2. The page next contains details on the selected registered regulation device and a list with all possible compatible legacy devices to be linked to:

Playground

EUDAMED user guide

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

- 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):	12345756984170 (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

- Click on **Confirm** in the pop-up window:

[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

 **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](#)

<p>UDI-DI data</p> <p>Product original manufacturer</p> <p>Market Information</p> <p>Container Package Information</p>	<p>UDI-DI data</p> <p>Version 1 [Current] Last update date: -</p> <p>UDI-DI code: -device-under-regulation</p> <p>Issuing Entity: ICCBBA</p> <p>UDI-DI from another entity</p> <p>UDI-DI from another entity (secondary) applicable: No</p>	<p>Discard Create new version</p>
--	---	---

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

The screenshot shows the EUDAMED interface for a device. On the left, there are navigation links: 'Product original manufacturer', 'Market Information', and 'Container Package Information'. The main content area is divided into several sections:

- medicinal product derived from human blood or human plasma:** A text field with a value of '-'. Below it, another text field with a value of '-'. A link 'Remove the link to this device' is present.
- Related Device:** A section containing a 'Related Legacy Device' field with a value of 'device-under-directives' (highlighted by a red box) and a link '(link to the Legacy Device)'. Below it, 'Devices linked on:' is shown with the date '2023-09-12' and a link 'Remove the link to this device'.
- Product original manufacturer:** A section with the question 'Is the device designed and manufactured by another legal or natural person?:' and the answer 'No'.
- Market Information:** A section with 'Version 1' and 'Last update date: 2023-09-12'. It includes a table for 'Member State of the placing on the EU market of the Device:' with columns for 'Country', 'From', and 'To'. The table shows 'Austria' in the 'Country' column and '-' in the 'From' and 'To' columns. There is an 'Update countries' button.
- Container Package Information:** A section with the text 'No container packages added' and an 'Add a container package UDI-DI for this UDI-DI' button.

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

The screenshot shows the EUDAMED interface for a device. On the left, there are navigation links: 'Product original manufacturer' and 'Market Information'. The main content area is divided into several sections:

- Presence of a substance which, if used separately, may be considered to be a medicinal product:** A text field with a value of '-'. Below it, another text field with a value of '-'. A link 'Remove the link to this device' is present.
- Related Device:** A section containing a 'Related Regulation Device' field with a value of 'device-under-regulation' (highlighted by a red box) and a link '(link to the Regulation Device)'. Below it, 'Devices linked on:' is shown with the date '2023-09-12' and a link 'Remove the link to this device'.
- Product original manufacturer:** A section with the question 'Is the device designed and manufactured by another legal or natural person?:' and the answer 'No'.
- Market Information:** A section with 'Version 1' and 'Last update date: 2023-09-12'. It includes a table for 'Member State of the placing on the EU market of the Device:' with columns for 'Country', 'From', and 'To'. The table shows 'Austria' in the 'Country' column and '-' in the 'From' and 'To' columns. There is an 'Update countries' button.
- Container Package Information:** A section with the text 'No container packages added' and an 'Add a container package UDI-DI for this UDI-DI' button.



NOTE

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

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

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) and select the *Registered* option in the *State* field.

1. Once inside the relevant registered regulation device click on *Remove the link to this device* under the *Related Device* section:

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

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

Related Device

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

Devices linked on: 2023-09-12

 [Remove the link to this device](#)

Product original manufacturer

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

Market Information [Update countries](#)

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

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

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

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

No container packages added

2. Click on **Confirm** on the pop-up window:

[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

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

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[46\]](#) to view a UDI-DI/EUDAMED ID.

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

UDI-DI data

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

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

- In the list of versions displayed, click on the version you wish to access:

EUDAMED DI B-1231231UU

[← Go back to the current version](#)

Version history of EUDAMED ID D-1231231UU

[☰ See all version history \(1\)](#)

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

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

Trade name

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

Clinical size

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

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

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

6.1 Manage your SPP Basic UDI-DI details

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

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)



NOTE

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

Basic UDI-DI management for SPP

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

[Filter](#)

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

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

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

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

Showing 1 to 3 of 3 entries Show entries per page

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

3. A details summary of your system or procedure pack is displayed:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data Create new version

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

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

6.1.1 Delete a draft Basic UDI-DI

Follow the steps in section [Manage your SPP Basic UDI-DI details \[77\]](#) 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	2021-0		View Data
1234543233234324XU	0	rferfefrefre	vddgv	Class I	PP	2021-0		Edit Data
1212112121212DL	0	-		-	PP	2021-0		View all UDI-DIs for this Basic UDI-DI

1. 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	

2. Confirm the deletion on the pop-up window:

Delete Basic UDI-DI Close

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

Yes Cancel

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

Follow the steps in section [Manage your SPP Basic UDI-DI details \[77\]](#) 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 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, 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: 2021-08-29

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

6.1.3 View historical version for Basic UDI-DI

Follow the steps in section [Manage your SPP Basic UDI-DI details \[77\]](#) 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: 2021-08-29

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	

To return, click **Go back to the current version:**

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	

6.2 Manage your SPP UDI-DI details

- 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](#)

- To find the desired UDI-DI, click on the **Filter** button and choose the right parameters:

UDI-DI details management for SPP

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

Filter ▼

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

Showing 1 to 3 of 3 entries Show 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: 44444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI								
44444SSP_Shr_1VM		SPPP_Shr_1			2021-05-17	On the EU market	Registered	...
▼ Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI								
34675806754T9	system 1	543			2021-05-14	On the EU market	Registered	...
▼ Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI								
997031494145675552	trade1	34234			2021-05-14	On the EU market	Registered	...



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 entries per page

Status	State	Actions
+ Add a new UDI-DI		
On the EU market	Registered	...
View data		
On the EU market	Registered	...
+ Add a new UDI-DI		
On the EU market	Registered	...

- A summary of the details concerning your chosen SPP UDI-DI will be displayed:

Basic UDI-DI 44444SSP_Shr_1VM

[Go to device management](#)

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

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

UDI-DI data Discard Create new version

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

UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A010204 NEEDLES AND KITS - AMNIOCENTESIS

Trade name

Trade name applicable: No

Reference/Catalogue number: SPPP_Shr_1

Type of UDI-PI

Manufacturing date: Yes

Additional product description: test [BG]

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

UDI-DI status: On the EU market

Need for sterilisation before use: No

Device labelled as sterile: No

6.2.1 Delete a draft UDI-DI

Follow the steps in section [Manage your SPP UDI-DI details \[82\]](#) to view a draft UDI-DI.

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

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

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

UDI-DI data **UDI-DI data** EDIT DELETE

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

UDI-DI code: 34675806754T9

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code: A010102 BUTTERFLY NEEDLES

Trade name

Trade name applicable: Yes

Trade name: system 1All languages

Reference/Catalogue number: 543

Type of UDI-PI

Serial number: Yes

Manufacturing date: Yes

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

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

UDI-DI status: On the EU market

2. Confirm the deletion in the pop-up window:

Delete UDI-DI Close

Delete the Draft version of UDI-DI?

Yes Cancel

6.2.2 Update (create new version) for UDI-DI

Follow the steps in [Manage your SPP UDI-DI details \[82\]](#) to view a UDI-DI:

Playground

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 entries per page

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

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data [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.

Playground

**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):

Advanced search of device nomenclature

Selected nomenclature codes
 Code A010204 NEEDLES AND KITS - AMNIOCENTESIS

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

Reference/catalogue number: SPPP_Shr_1

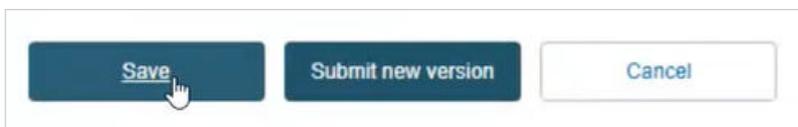
Type of UDI-PI
 * Manufacturing date: Yes

* Additional product description:

* Select the language:
 Bulgarian

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.

Otherwise press **Cancel** to cancel the update.



6.2.3 Update (create new version) for Container Packages

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

Follow the steps in section [Manage your SPP UDI-DI details \[82\]](#) to view a specific UDI-DI:

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

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

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

Playground

Container package update

Container package(s)

+ [Add container package](#)

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

Submit

Cancel

4. 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
- ▾		1	1

*** Package status**

No longer placed on the EU market

Not intended for EU market

On the EU market

Save

Cancel

6.2.4 Discard SPP registered UDI-DIs

Follow the steps in section [Manage your SPP UDI-DI details \[82\]](#) 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) Add a new UDI-DI								
44444SSP_Shr_1VM		SPPP_Shr_1			2021-05-17	On the EU market	Registered	...
Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI								
34675806754T9	system 1	543			2021-05-14	On the EU market	Registered	...
Basic UDI-DI: 9970314941ShriyaHL, Device Name: Test ONE, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices) Add a new UDI-DI								
997031494145675552	trade1	34234			2021-05-14	On the EU market	Registered	...

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to device management](#)

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

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

UDI-DI data Discard Create new version

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

Container Package Information

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

- Confirm your intention to discard the record in the pop-up window:

Discard UDI-DI

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

Yes Cancel

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

Follow the steps in section [Manage your SPP UDI-DI details \[82\]](#) to view a UDI-DI for the SPP.

- Once inside the details of the chosen UDI-DI, click on *See version history* at the top of the table to view a list of all past versions:

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

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	>

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

[Go back to the current version](#)

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

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

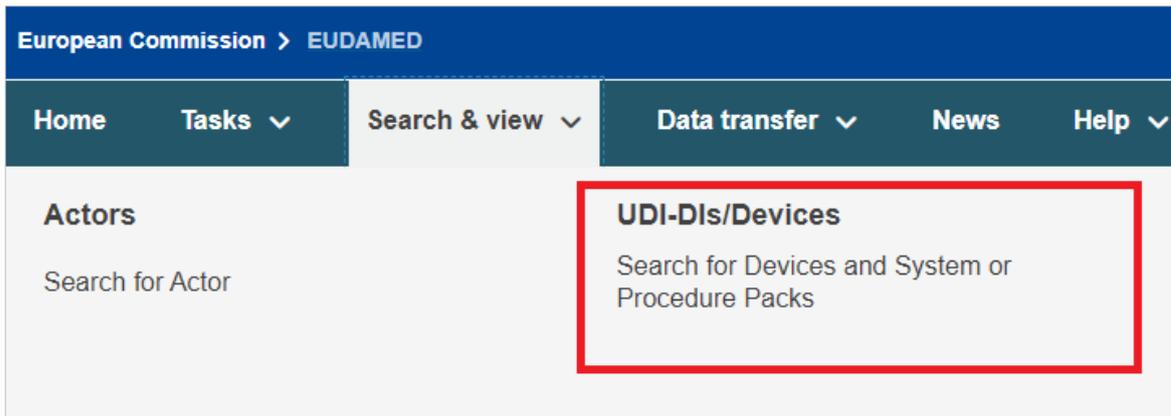
Version 2 - Last update date: 2021-06-09

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

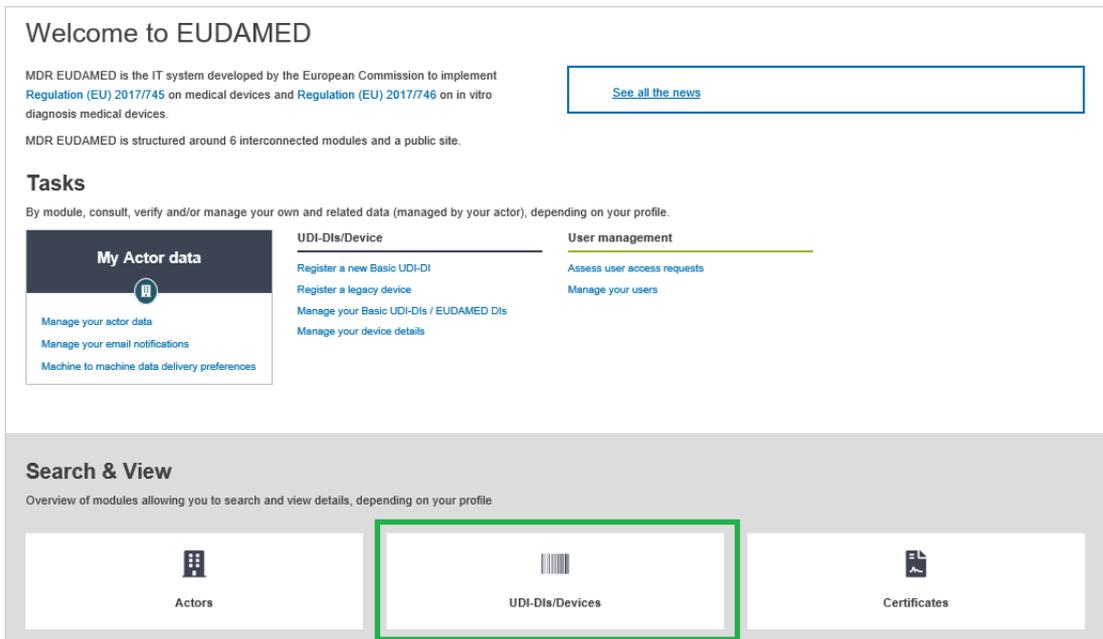
You can return to the version history list by clicking on *See all version history* at the top right corner.

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

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



Alternatively, use the option available on 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*:

Search Devices and System or Procedure Packs

Enable search filters available for bulk XML download

(Master) UDI-DI/ EUDAMED ID:

Basic UDI-DI/ EUDAMED DI:

Status: X v

Sub-status:

Model:

Name:

Trade name:

Applicable regulation: X v

Risk class: X v

Nomenclature code:

Reference/Catalogue number:

Country: X v

Scope: X v

Competent Authority: X v

NB identification: X v

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

Results option

Include historical version:

- 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 5559 entries Show entries per page

(Master) UDI-DI code I†	(Master) UDI-DI version	Basic UDI-DI / EUDAMED DI I†	MF / PR Actor ID/SRN	Trade name I†	Risk class	Date I†	UDI-DI/Device status
188727_00	1 [Current]	777777777770UZ	NL-MF-000000041	aaaaaaaaa	Class I	2024-06-17	On the EU market
555245841651036LM	1 [Current]	555245841651036LM	CA-MF-000006393		Class I	2024-06-14	On the EU market
4520363415562TP	1 [Current]	4520363415562TP	BE-MF-000006007		Class I	2024-06-14	On the EU market
4520363415561TM	1 [Current]	4520363415561TM	BE-MF-000006007		Class IIa	2024-06-14	On the EU market

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

Playground

Producer information

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

Basic UDI-DI details

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

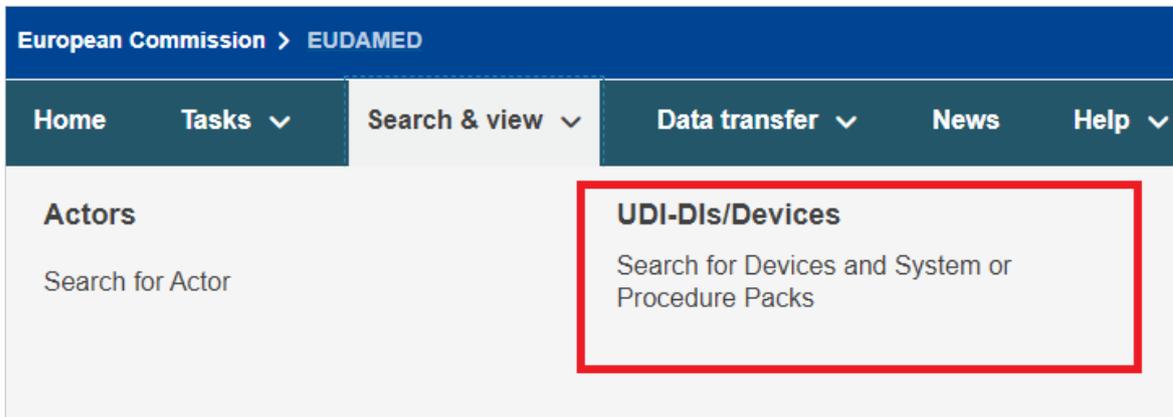
Basic UDI-DI identification
 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)

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

System or Procedure Pack type: Procedure Pack

7.1 Search & View sub-statuses of Devices, Systems and/or Procedure Packs

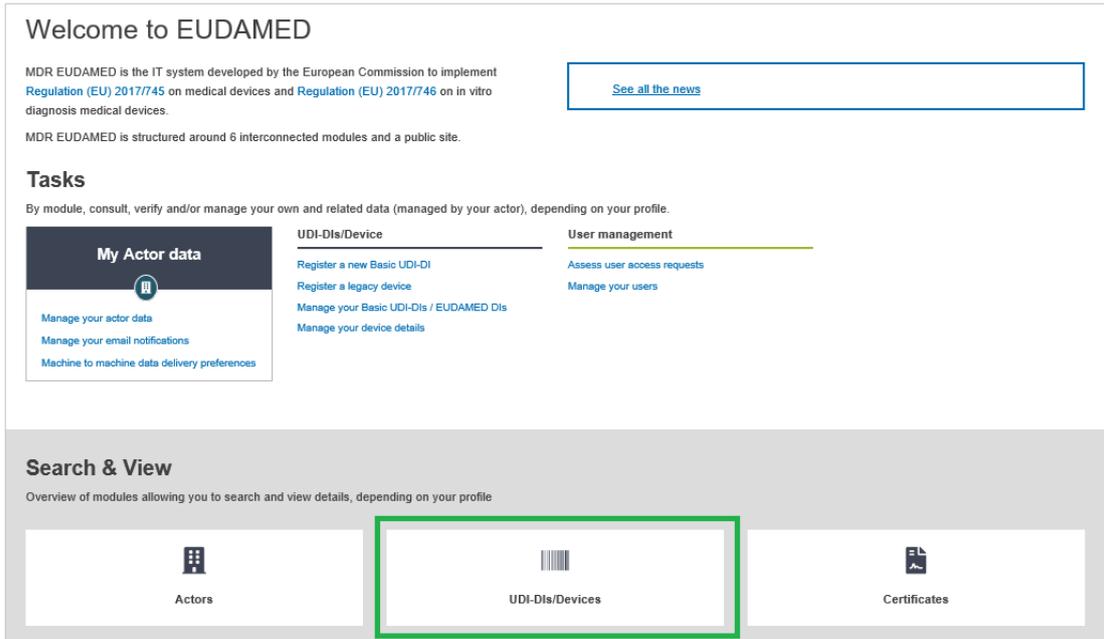
1. On the header menu, click on **Search & View**, then **UDI-DIs/Devices**:



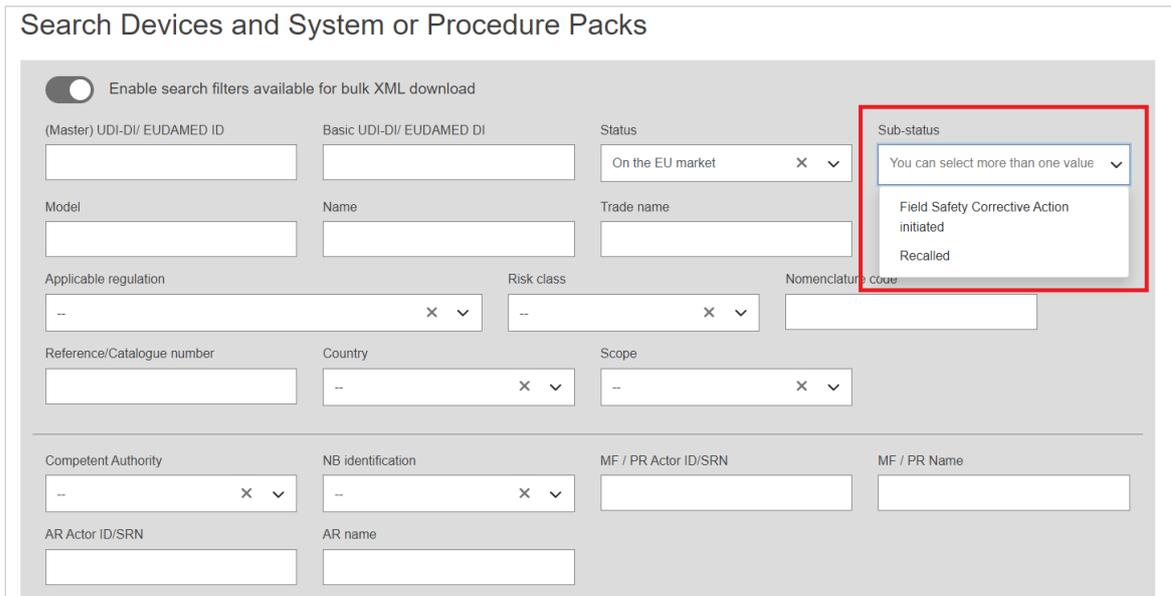
The screenshot shows the EUDAMED user interface header. At the top, it says 'European Commission > EUDAMED'. Below this is a navigation bar with several menu items: 'Home', 'Tasks' (with a dropdown arrow), 'Search & view' (with a dropdown arrow), 'Data transfer' (with a dropdown arrow), 'News', and 'Help' (with a dropdown arrow). The 'Search & view' dropdown menu is open, showing two options: 'Actors' (with a sub-link 'Search for Actor') and 'UDI-DIs/Devices' (with a sub-link 'Search for Devices and System or Procedure Packs'). The 'UDI-DIs/Devices' option is highlighted with a red rectangular border.

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

Playground



2. Select the sub-status in the dropdown list and click **Search**:



3. A list of Devices (UDI-DIs/EUDAMED IDs) and/or Systems or Procedure Packs will appear if any are found:

Playground

Showing 1 to 20 of 39 entries Show entries per page

(Master) UDI-DI It	(Master) UDI-DI code version	Basic UDI-DI / EUDAMED DI It	MF / PR Actor ID/SRN	Trade name It	Risk class	Date It	UDI-DI/Device status
BRB-cd-1	1 [Current]	109784903285972P5	NL-MF-000000041		Class IIa	2024-06-11	On the EU market (Recalled)
B09D GK9T8M	1 [Current]	7486566855F8	EL-MF-000004067		Class IIb	2024-06-10	On the EU market (Field safety corrective action initiated)
gfh12867	1 [Current]	6986201dk3N	BH-MF-000006127		Class IIb	2024-05-30	On the EU market (Field safety corrective action initiated)
300524022GT	1 [Current]	300524022GT	IN-MF-000005648		Class IIb	2024-05-30	On the EU market (Recalled)
300524021GR	1 [Current]	300524021GR	IN-MF-000005648		Class IIb	2024-05-30	On the EU market (Field safety corrective action initiated)
gudi9978	1 [Current]	6986214dk4C	BH-MF-000006127		Class D	2024-05-30	On the EU market (Field safety corrective action initiated)
280524021LS	1 [Current]	280524021LS	IN-MF-000005648		Class III	2024-05-28	On the EU market (Field safety corrective action initiated)
270524015LC	1 [Current]	270524015LC	IN-MF-000005648		Class IIa	2024-05-27	On the EU market (Recalled)
270524011L4	1 [Current]	270524011L4	IN-MF-000005648		Class IIb	2024-05-27	On the EU market (Recalled)
0000069862120	1 [Current]	6986215d01KY	BH-MF-000006127		Class C	2024-05-23	On the EU market (Recalled, Field safety corrective action initiated)
0000069862113	1 [Current]	6986213d01KJ	BH-MF-000006127		Class IIb	2024-05-23	On the EU market (Field safety corrective action initiated, Recalled)
0000069862182	1 [Current]	698621d013C	BH-MF-000006127		Class IIb	2024-05-23	On the EU market (Recalled)
0000069862137	1 [Current]	698621d003A	BH-MF-000006127		Class IIb	2024-05-23	On the EU market (Field safety corrective action initiated, Recalled)
2160524011YD	1 [Current]	2160524011YD	IN-MF-000005648		Class III	2024-05-21	On the EU market (Recalled)

- Click on the UDI-DI/EUDAMED ID row of your choice to see the details. Scroll down to the *Status of the UDI-DI/Device* subsection.
Read the [View details of a registered UDI-DI/EUDAMED ID \[49\]](#) section for more details on the sub-status of a device.

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

Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[91\]](#) to search and view a device or system or procedure pack.

- 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**:

Playground

Search Devices and System or Procedure Packs

Enable search filters available for bulk XML download

(Master) UDI-DI/ EUDAMED ID:

Basic UDI-DI/ EUDAMED DI:

Status: X v

Sub-status:

Model:

Name:

Trade name:

Applicable regulation: X v

Risk class: X v

Nomenclature code:

Reference/Catalogue number:

Country: X v

Scope: X v

Competent Authority: X v

NB identification: X v

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

Results option

Include historical version

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

UDI-DI code <i>1</i>	Version Number	Basic UDI-DI code <i>1</i>	MF / PR SRN	Trade name <i>1</i>	Risk class	Date <i>1</i>	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
vrf	1 [Current]	22222e12345665435T	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
1234_1234_57676	1 [Current]	1212112121212121214K	BE-MF-000000001	External Implant	Class I	2021-06-22	On the EU market
11223	1 [Current]	11223qqqP5	JP-MF-000000061		Class IIa	2021-06-21	On the EU market
eeee	4 [Current]	22223434444FY	BE-MF-000000001	Trade_Name_v4	Class I	2021-06-21	On the EU market
eeee	3 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v3	Class I	2021-06-21	On the EU market
eeee	2 [History]	22223434444FY	BE-MF-000000001	Trade_Name_v2	Class I	2021-06-21	On the EU market

← Previous **1** 2 3 4 5 Next →



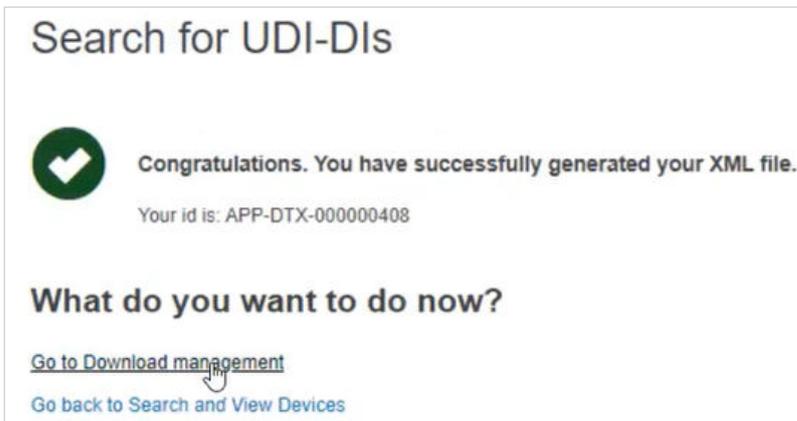
NOTE

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

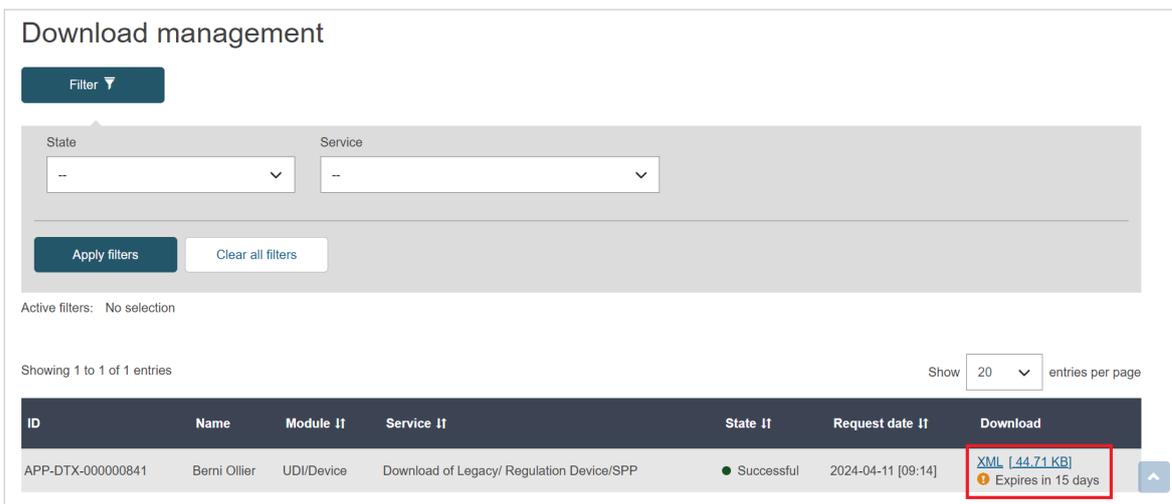
3. Confirm your action in the pop-up window:



4. The system will display a success message. Click on **Go to Download Management** under the question *What do you want to do now?*:



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



Playground

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

Follow the steps in [Search & View historical versions of Devices, System and/or Procedure Packs \[95\]](#) to view the details of a Device or System or Procedure Pack.

1. Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product original manufacturer or Container Package) and click on *See version history*:

UDI-DI 121312_Test_AR

[← Go back to the list](#)

Manufacturer information

[Basic UDI-DI details](#)

[UDI-DI details](#)

[Market information](#)

[Clinical Investigation\(s\)](#)

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI details

Version 5 [Current] See version history Last update date: 2021-06-23

Basic UDI-DI identification

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

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

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

Playground

List of UDI-DIs for the Basic UDI-DI

UDI-DI details

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

UDI-DI code: 121312_Test_AR

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010199 HYPODERMIC NEEDLES - OTHERS

Trade name

Trade name applicable: Yes

Trade name: TB_BG [BG], TN_AR1_Croatian [HR]

Reference/Catalogue number: ref

Is the device directly marked?

Is the device directly marked?: No

Market information

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

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

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

Clinical Investigation(s)

Clinical Investigation

Clinical Investigation, if applicable: No

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

Basic UDI-DI 22091test23_09EC

[◀ Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Basic UDI-DI 22091test23_09EC

[◀ Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Manufacturer information

[Basic UDI-DI data](#)

[Clinical Investigation](#)

[List of UDI-DIs for the Basic UDI-DI](#)

Manufacturer information

Organisation name: Japanese MF A v4
 Actor ID/SRN: JP-MF-00000061
 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-00000021
 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

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

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

Playground

8 Annex – device certificate information

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

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

Colour-code description.

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

