



EUDAMED user guide

UDI Devices

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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 /Device module of EUDAMED is used for the manufacturers to provide their s/ Devices information and ensure its availability to everyone. Moreover, it is used to manage the registration of devices and systems and procedure packs (SPPs) across the EU/EEA.

It falls within the responsibilities of manufacturers (MFs) of devices and system and procedure pack producers (SPPPs) to ensure product registration in the UDI/Device Module. Authorised Representatives and Importers cannot register devices or SPPs. The devices to be registered are defined by Article 2 in MDR and IVDR. UDI-DI/Device module of EUDAMED is used for the manufacturers to provide information on the devices and the corresponding UDIs and to make it available to everyone.



TIP

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



NOTE

This user guide outlines the registration of medical devices, IVD medical devices, SPPs, the device data, including the corresponding Basic UDI-DI and UDI-DI.

Economic Operators (EOs) must register their organisation in the Actor (ACT) module before they are given access to EUDAMED and become able to register their devices and SPPs in the UDI/Devices module. See the [EOs User Guide](#). Devices and SPPs must be registered in the UDI/Devices module before they are placed on the union market (see [Q&A on EUDAMED gradual roll out](#)). Device registration does not involve any assessment, review or approval by a Competent Authority (CA). Some of the information in EUDAMED is publicly available for searching and viewing.



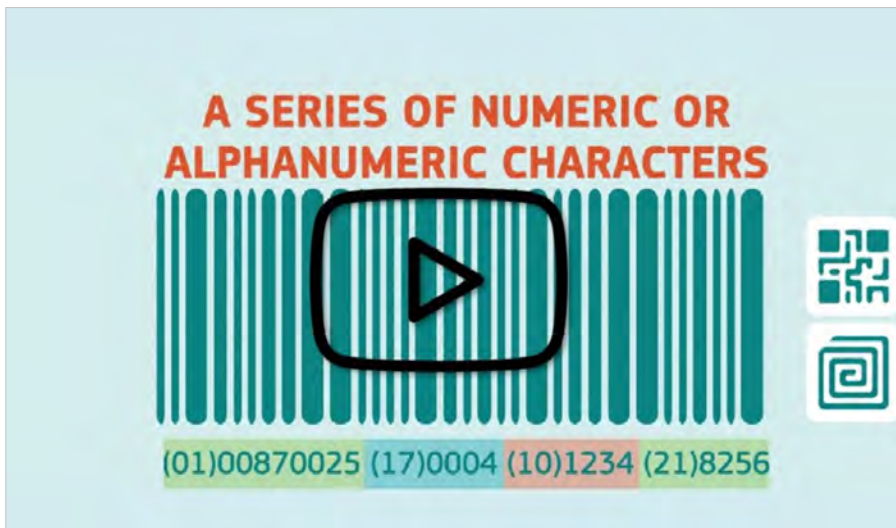
WARNING

- The requirements for device registration differ, depending on when the device is placed on the market and depending on which legislation it is compliant with ("regulation devices", "legacy devices", "old devices" – see [Q&A on EUDAMED gradual roll out](#)).
- In EUDAMED, device/SPP registration in the UDI/Devices module means registering a device/SPP at the level of the device identifier. Production identifiers are not required.
- 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.

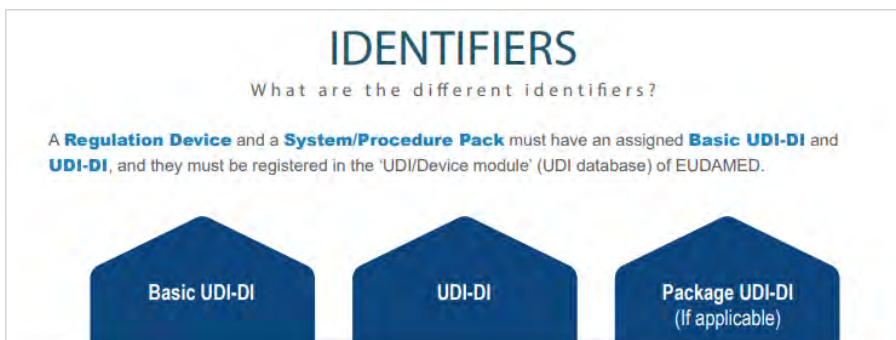


VIDEO: What is a UDI?

Please note that this video contains sound.



INFOGRAPHIC: Basic UDI-DI/UDI-ID concept



2 Getting started

What I need to access EUDAMED

1. [EU Login \(ECAS\) account](#):

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

2. User profile registration in EUDAMED:

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



NOTE

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



Every user in EUDAMED is granted by default the profile *Viewer* for the /Device module, and can search and view registered devices. However, to enter data on the devices and their UDIs in EUDAMED, your profile for the UDI/Device module ¹ must be either:

- A *Proposer* – this profile allows you to create and delete draft records related to your manufacturer, but not to submit a device, or
- A *Confirmer* – this profile includes the *Proposer* rights and additionally, allows you to submit and discard records. Moreover, it allows you to directly register a device.



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*.

¹See the [Economic Operators user guide](#), Section *User rights and profiles*, for more information on user rights and profiles.



IMPORTANT

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

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

Once you enter information into EUDAMED, it may not be possible to change it, if entered incorrectly. Certain fields are not editable after submission of the record.



NOTE

EUDAMED user interface is available in all EU languages and the information can be entered in any official language within the EU.

3 Register Regulation Devices

VIDEO: Registering Regulation Devices

Please note that this video does not contain sound.



NOTE

- Devices or SPPs to be placed on the market according to MDR/IVDR (“regulation devices”) must first be registered in the UDI/Devices module together with their UDI and other device data;
- Each Regulation Device must have a unique and a unique assigned to it. Both are always required – you cannot register a without a .

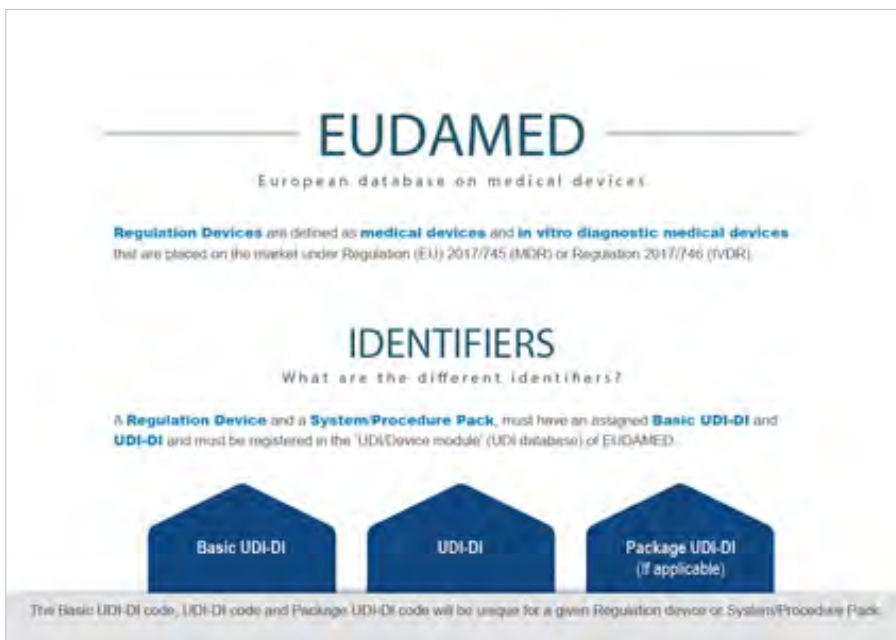
You will be asked to log into EUDAMED via your EU Login account. This will take you to the actor (manufacturer, system/procedure pack producer) to which you are connected through your user account. If you have user accounts for more than one actor, your options will be available on the screen. Choose the appropriate one by clicking on the actor name.

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



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

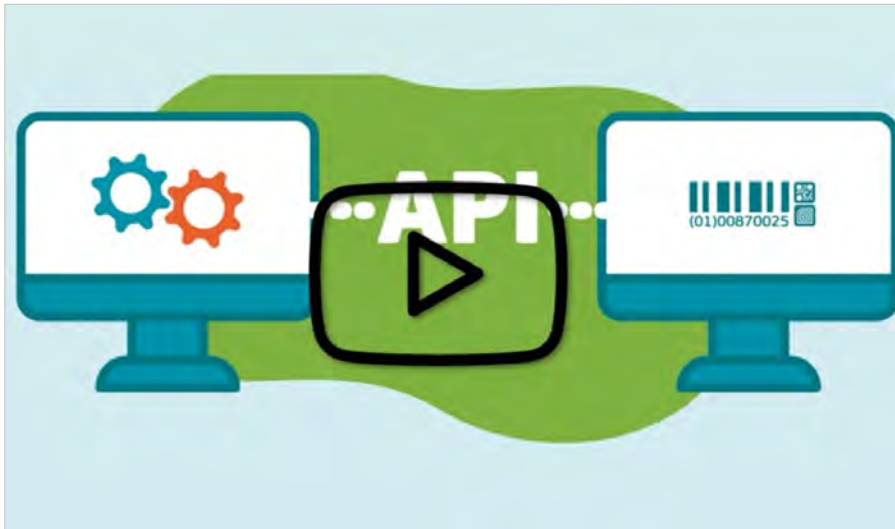
INFOGRAPHIC: [Basic UDI-DI/UDI-ID concept](#)



3.1.1 Step 1: Enter the device and its Basic UDI-DI information

VIDEO: [UDI and medical software devices](#)

Please note that this video contains sound.



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

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: #2c3e50; 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"> <li style="margin-bottom: 5px;">Manage your actor data <li style="margin-bottom: 5px;">Manage your email notifications 	<p>UDI-DIs/Device</p> <ul style="list-style-type: none"> <li style="border: 2px solid red; padding: 2px; margin-bottom: 5px;">Register a new Basic UDI-DI <li style="margin-bottom: 5px;">Register a legacy device <li style="margin-bottom: 5px;">Manage your Basic UDI-DIs / EUDAMED DIs <li style="margin-bottom: 5px;">Manage your Devices details 	<p>User management</p> <ul style="list-style-type: none"> <li style="margin-bottom: 5px;">Assess user access requests <li style="margin-bottom: 5px;">Manage your users
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2. Enter the Basic UDI-DI information and select the applicable regulation for your device:



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.

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

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*² (See video above):



NOTE

For certain MDR device types, the registration of a UDI-DI is not appropriate. If one of the following Special Device types is selected, the Master UDI-DI applies instead:

- 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;
- Spectacle readers.

²For more information, visit the EUDAMED Information Centre, or the [UDI Assignment to Medical Device Software](#) webpage.

- Fill in the Basic UDI-DI identification details and click **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. However, EUDAMED cannot verify that the code is correct beyond the format.

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. Once you save your changes, you will not be able to amend the information at a later stage.

- 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:

- Choose a corresponding Risk Class and select **Yes** or **No** for each option that follows:

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

3.1.2 Step 2: Enter certificate information (if applicable)

This section only becomes accessible depending on the Risk Class information provided and additional properties in the and applies to certificates issued by the Notified Bodies (s).



NOTE

Certificate Information for registration of a device and its 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 \[109\]](#) you can find the different cases in which Certificate information is required and the type of certificate.

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 . For the , enter some or all of the name or number, click **Find** and choose the correct from the new window. EUDAMED does not verify whether the is the right one for your device.

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

Certificate information

EU type-examination certificate if applicable

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

* Enter NB number or name:

Certificate number: Revision number:

**NOTE****Notifications to MFs and ARs**

When a new Product Certificate has been registered in EUDAMED both the MF and, if applicable, the AR are notified.

3.1.3 Step 3: Enter UDI-DI identification information

VIDEO: UDI carrier and display formats

Please note that this video does not contain sound.



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 from the same manufacturer.

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 your chosen Issuing Entity is GS1, 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  UDI-DI from another entity is required unless you select the option - No

* Issuing Entity: * Secondary UDI-DI value:



NOTE


Secondary UDI-DI may exist due to the fact that the manufacturer changed issuing entity. The UDI-DI assigned to the device being registered from the previous issuing entity can be referenced in EUDAMED together with the new one.

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

Selected nomenclature codes

[Code A0101010101](#) HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS  [Remove nomenclature code](#)



NOTE

MDR and IVDR require that an internationally recognised medical devices nomenclature is used when registering devices in EUDAMED. The nomenclature to be used according to MDR/IVDR is EMDN.

**NOTE****Search for Nomenclature codes (EMDN)**

Click on **Advanced search of device nomenclature** to search by partial code name and view the list of codes alphabetically:

Find the code ✕ Close

EMDN Code: EMDN Description:

A DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION

A01 NEEDLES

A0101 NEEDLES FOR INFUSION AND SAMPLING

A010101 HYPODERMIC NEEDLES

A01010101 HYPODERMIC SYRINGE NEEDLES

A0101010101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS

A0101010102 HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS

A01010102 HYPODERMIC PEN NEEDLES

A0101010201 HYPODERMIC PEN NEEDLES, WITH SAFETY SYSTEMS

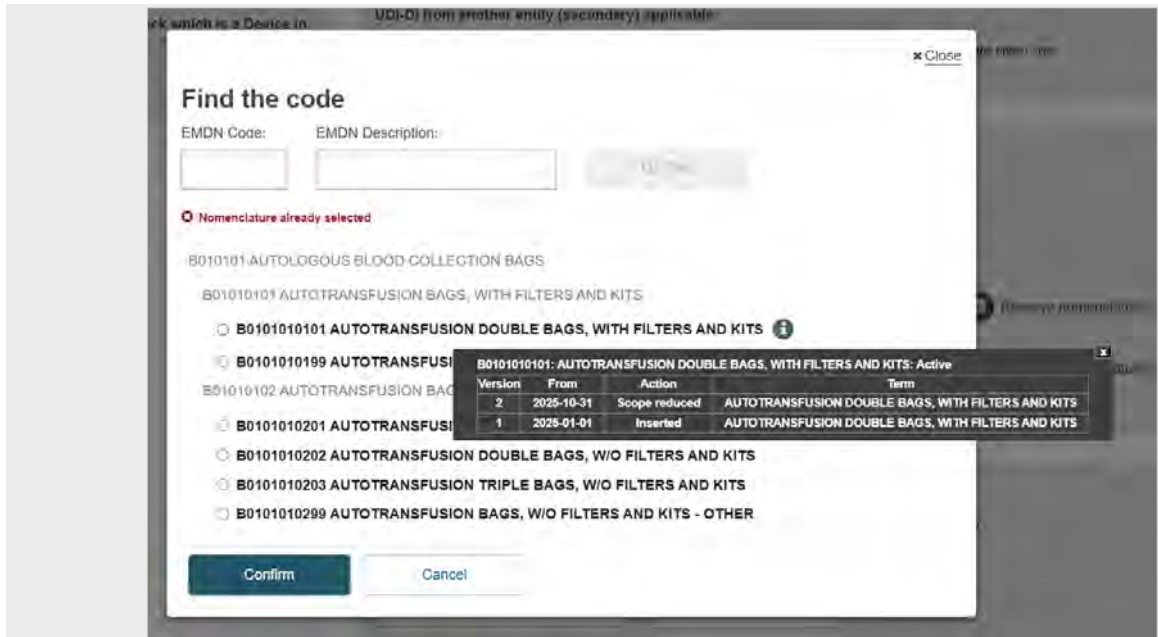
A0101010202 HYPODERMIC PEN NEEDLES, W/O SAFETY SYSTEMS

A01010199 HYPODERMIC NEEDLES - OTHER

EMDN Code updates

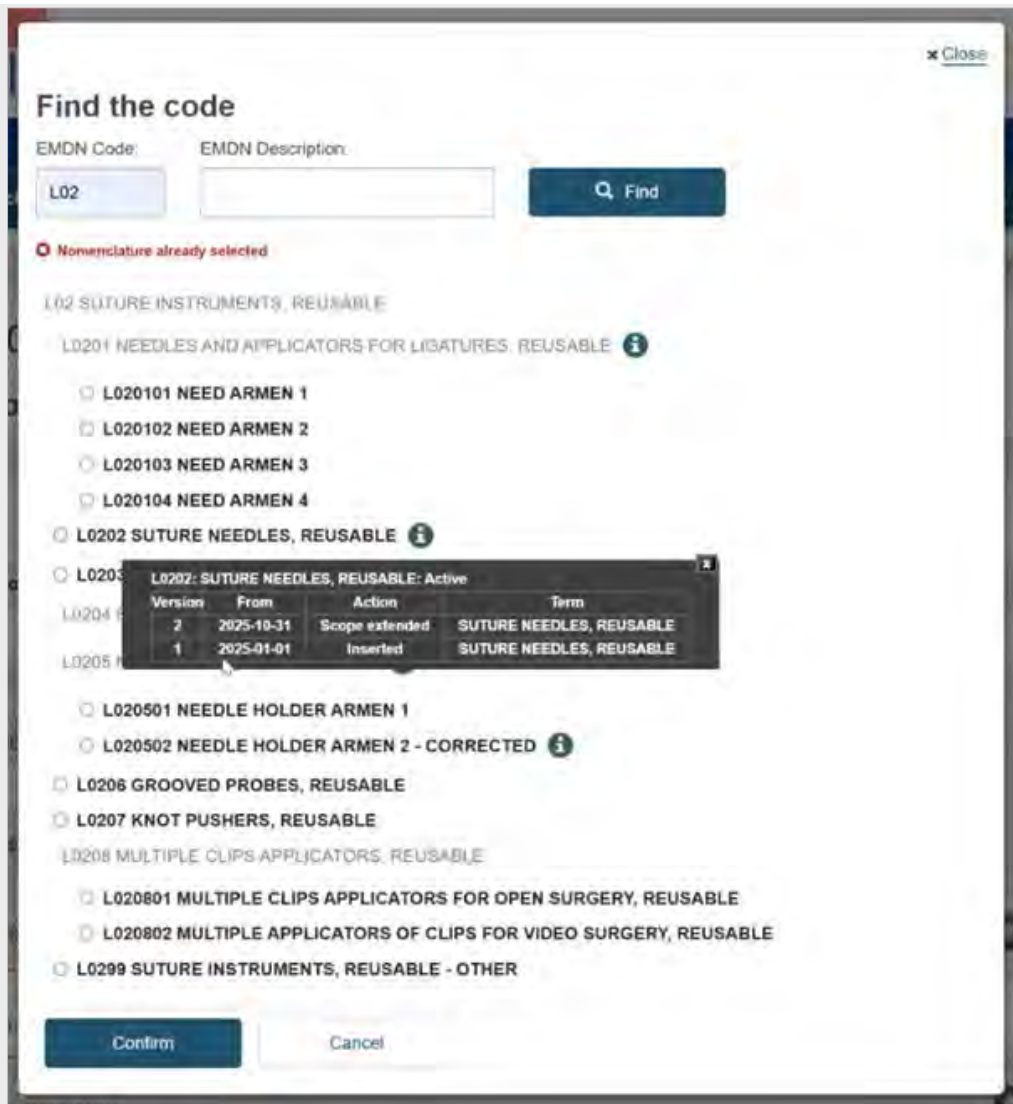
EMDN codes may get updated and therefore have a version history, which is indicated by an *information* icon.

Click on the *information* icon to view details about a code's versions and status:

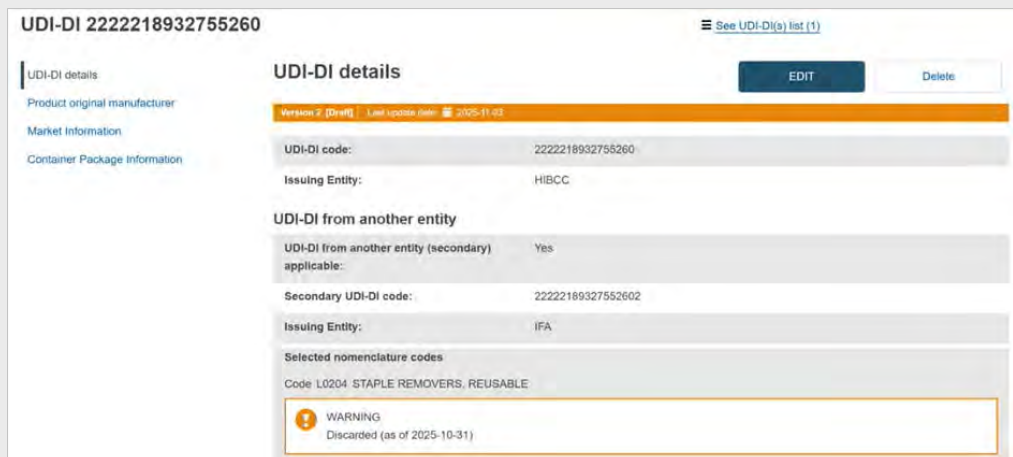


How does an EMDN code update affect my device?

1. If an EMDN code gets *scope-extended* or *corrected*, the device entry is not affected and no action is necessary.

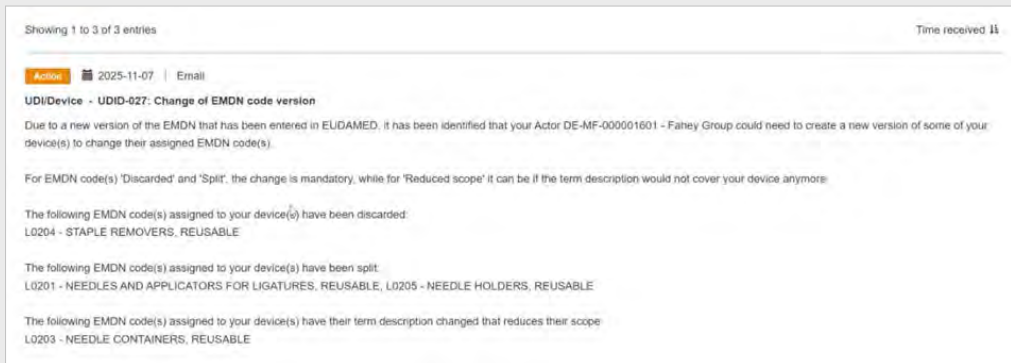


2. If an EMDN code gets *discarded* (inactive status), *split* or *scope-reduced*, the system will issue a warning (UDI details section):

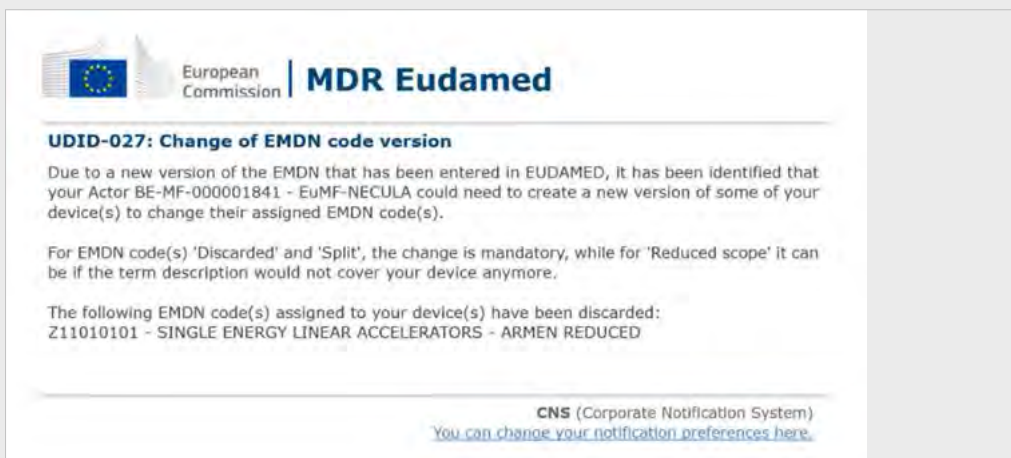


Depending on the specific case, the system may prompt the user to remove the obsolete EMDN code before creating a new device version with the correct EMDN code. In such cases, the user will receive EUDAMED and email notifications.

EUDAMED Notification



Email Notification



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

Trade name applicable

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

* Trade name:

* Select the language:

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

5. Enter the *Reference/Catalogue number*.

* Reference/Catalogue number:



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

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

* Is the device directly marked?

Yes No

Same as UDI-DI

* Issuing Entity:

* Direct marking DI:



NOTE

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

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

* Is the device directly marked?

Yes No

* Quantity of device:

Issuing Entity:

Unit of Use DI:



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* . The UDI-PI is the production identifier for each unit. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date, depending on how the device is produced.
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

+ Add additional product description in another language

Select the language:
 -
 Bulgarian
 Croatian
 Czech
 Danish
 Dutch
 English

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

11. Specify the status of the device by selecting whether it is *On the EU market*, *Not intended for the EU market* or *No longer placed on the EU market* and click **Save** or **Save & Next**:

* UDI-DI status

No longer placed on the EU market

Not intended for the EU market

On the EU market

Save Save & Next >

**NOTE**

A device *not intended for the EU market* may be registered in EUDAMED.

3.1.4 Step 4: Enter UDI-DI characteristics

- Specify clinical size for the device 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:

Frequency

* Precision: Range * Minimum: 50 * Maximum: 60 * Measure unit: hertz (Hz)

[+ 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.

2. 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)

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

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

The screenshot shows three separate form sections, each with a title and a radio button group for 'Yes' and 'No' options. The first section is titled '* Need for sterilisation before use' and has 'No' selected. The second section is titled '* Device labelled as sterile' and has 'No' selected. The third section is titled '* Containing latex' and has 'No' selected.



NOTE

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

4. For devices, enter the information on whether the device contains any substance which could be CMR (carcinogenic, mutagenic, or toxic for reproduction) and/or Endocrine disruptor substances if applicable. When specifying CMR and/or Endocrine disruptor 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):

*** 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:**

+ 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:**

Defibrillation-proof type CF applied part

+ 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: Enter additional 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):

2. If you select *Yes* for the *Intended purpose*, select the relevant purpose(s):

**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. The (legal) manufacturer may use another natural or legal person(s) for design and manufacturing activities. However, the (legal) manufacturer, as defined by MDR and IVDR always bears the sole responsibility for device compliance.

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	BeI_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-000004087	VIANEX S.A
AI-MF-000004047	AR Aguilla Ionut 2nd

1 2 ... 19

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

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

Yes No

I know the Actor ID/SRN

* Product original manufacturer organisation name:

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'

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:

[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/Performance study reference for the current device:

Clinical Investigation / Performance Study

Yes No i The information is required unless you select 'No'

Clinical Investigation / Performance Study conducted inside EU?:
 Yes No

[+ Add new Clinical Investigation / Performance Study](#)

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

Yes No


Presence of animal tissues or cells, or their derivatives:

Yes No

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.



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"/>	<input type="button" value="calendar"/>	To	<input type="text"/>	<input type="button" value="calendar"/>	<input type="button" value="trash"/>
		YYYY-MM-DD			YYYY-MM-DD		
France	From	<input type="text"/>	<input type="button" value="calendar"/>	To	<input type="text"/>	<input type="button" value="calendar"/>	
		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)**.



NOTE

It is possible to enter this information for all risk classes and this may be helpful for users searching for information on devices available in a particular MS.

3.1.6 Step 6: Enter container package details

 **VIDEO: UDI carrier placing**

Please note that this video does not contain sound.





NOTE

Some devices may have more than one packaging level. In that case, each higher level of packaging shall have its own unique . MDR and IVDR define packaging levels as the various levels of device packaging that contain a defined quantity of devices, such as a carton or case.

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

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

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**:

The screenshot shows the "Add container package" form. At the top right is a "Close" button. The form title is "Add container package". Below the title is a folder icon and the text "Container package UDI-DI for UDI-DI product-original-manufacturer". The form contains the following fields:

- * Issuing Entity: A dropdown menu with a downward arrow.
- * Package UDI-DI code: A text input field.
- * Quantity per package: A text input field containing the number "1".
- Total number of devices: A text input field containing the number "1".
- * Package status: A group of three radio buttons:
 - No longer placed on the EU market
 - Not intended for EU market
 - On the EU market

At the bottom of the form are two buttons: "Save" and "Cancel".



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 **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

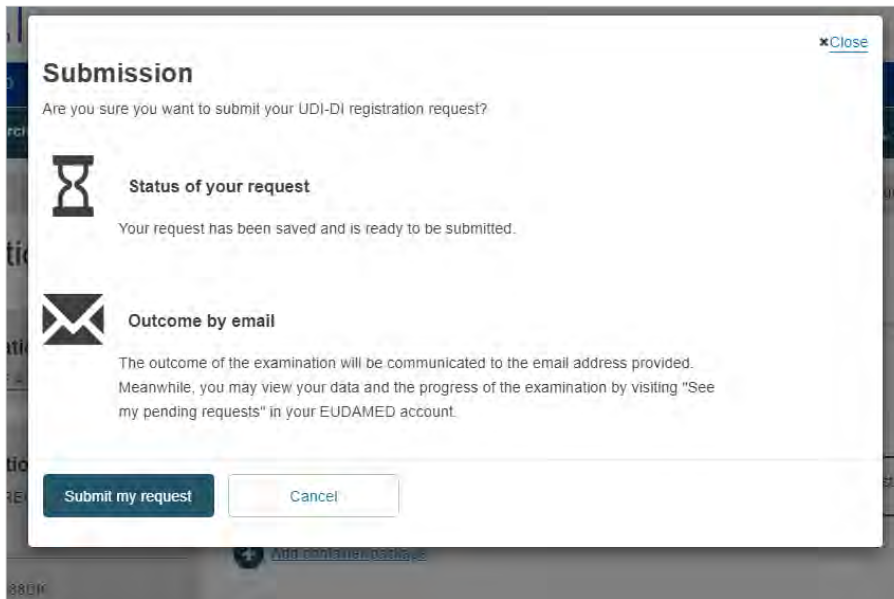
UDI-DI: boxxx-6 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market

Save

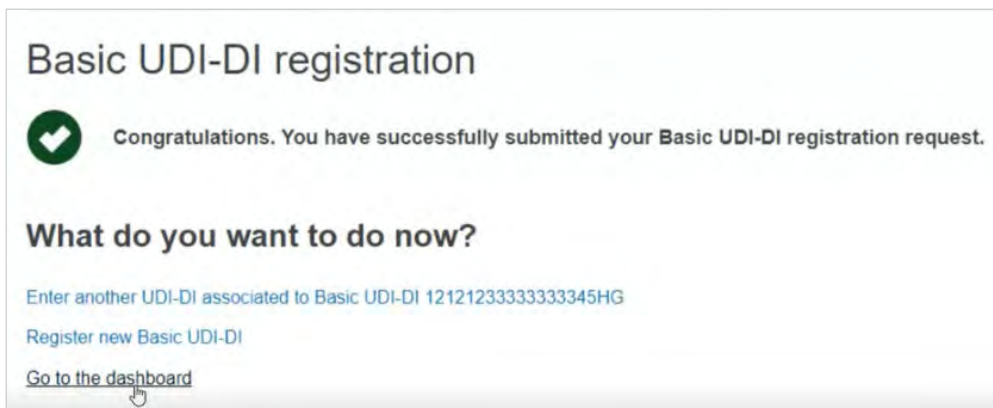
Submit >

Preview

3. Users with *Confirmer* profile can submit the device registration in the pop-up window. The device will be then registered and publicly available:



4. The screen will display a success message:



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 Register a regulation device and its UDI-DI for an existing Basic UDI-DI

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

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

NOTE

If you wish to register a regulation device, belonging to already registered, the registration process is simplified, since some device details are already available in EUDAMED. Therefore, the registration starts by selecting the .

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter ▾

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

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

Apply filters Clear all filters

Active filters: State: Draft Clear all filters

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
12211121212121YZ	1		Test	Class IIa	2021-03-31	1st Draft	...
1111184FG228694YC	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 device and its 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 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	MModel 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 [20], Step 5: Device information [23], Step 6: Container Package Details [28]*):

Add new UDI-DI to existing Basic UDI

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

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

Basic UDI-DI code: 1234503276
 Issuing Entity: GS1

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

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

UDI-DI identification

UDI-DI identification

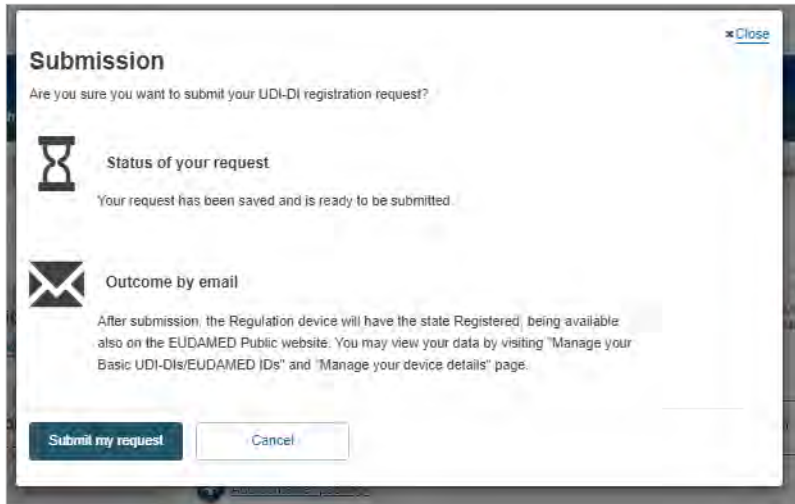
* Issuing Entity: * UDI-DI code:

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

- When you have completed all steps, click **Submit my request** to submit the new device registration request:



IMPORTANT

After Submitting the device registration request, its state will be:

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

4 Register System or Procedure Packs (SPP)

4.1 Register 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: Enter SPP and Basic UDI-DI main information

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

Tasks

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

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)

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

System or Procedure Pack registration

Procedure pack producer identification

Organisation name: AR_SPPP
 SRN: BE-PR-000000002
 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. However, EUDAMED cannot verify that the code is correct beyond the format.

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



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

* 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:
[Text area]
[+ Add another indication of medical purpose](#)

* Select the language:
--

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

* Model:
[Text input]

Name:
[Text input]

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

Basic UDI-DI code: 1212112121212DL

Basic UDI-DI information: * Risk class: --

* Indication of medical purpose: [Text area] * Select the language: --

+ Add another indication of medical purpose

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

2017/745 on medical devices)

Basic UDI-DI code: 1212112121212DL
Issuing Entity: GS1
System or Procedure Pack type: Procedure Pack

* Risk class: --

* Indication of medical purpose: [Text area] * Select the language: --

+ 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]

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

A screenshot of a form with two buttons: a dark blue button labeled 'Save' and a lighter blue button labeled 'Save & Next >'.

4.1.3 Step 3: UDI-DI identification information

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

A screenshot of the 'UDI-DI identification' form. It has a title 'UDI-DI identification' and two fields: '* Issuing Entity:' with a dropdown menu showing 'GS1' and '* UDI-DI code:' with an empty text input field.



IMPORTANT

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



NOTE

In case your chosen Issuing Entity is GS1, 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)**

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


A screenshot of the 'UDI-DI identification' form. The top section is the same as in the previous screenshot. Below it is a grey-shaded section titled 'UDI-DI from another entity (secondary) applicable'. It contains a toggle switch for 'Yes' (which is turned on) and 'No'. An information icon and text state: 'UDI-DI from another entity is required unless you select the option - No'. Below this are two fields: '* Issuing Entity:' with a dropdown menu showing '-' and '* Secondary UDI-DI value:' with an empty text input field.

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

Selected nomenclature codes

[Code A0101010101](#) HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS  [Remove nomenclature code](#)

**NOTE****Search for Nomenclature codes (EMDN)**

Click on **Advanced search of device nomenclature** to search by partial code name and view the list of codes alphabetically:

Find the code ✕ Close

EMDN Code: EMDN Description:

A DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION

A01 NEEDLES

A0101 NEEDLES FOR INFUSION AND SAMPLING

A010101 HYPODERMIC NEEDLES

A01010101 HYPODERMIC SYRINGE NEEDLES

A0101010101 HYPODERMIC SYRINGE NEEDLES, WITH SAFETY SYSTEMS

A0101010102 HYPODERMIC SYRINGE NEEDLES, W/O SAFETY SYSTEMS

A01010102 HYPODERMIC PEN NEEDLES

A0101010201 HYPODERMIC PEN NEEDLES, WITH SAFETY SYSTEMS

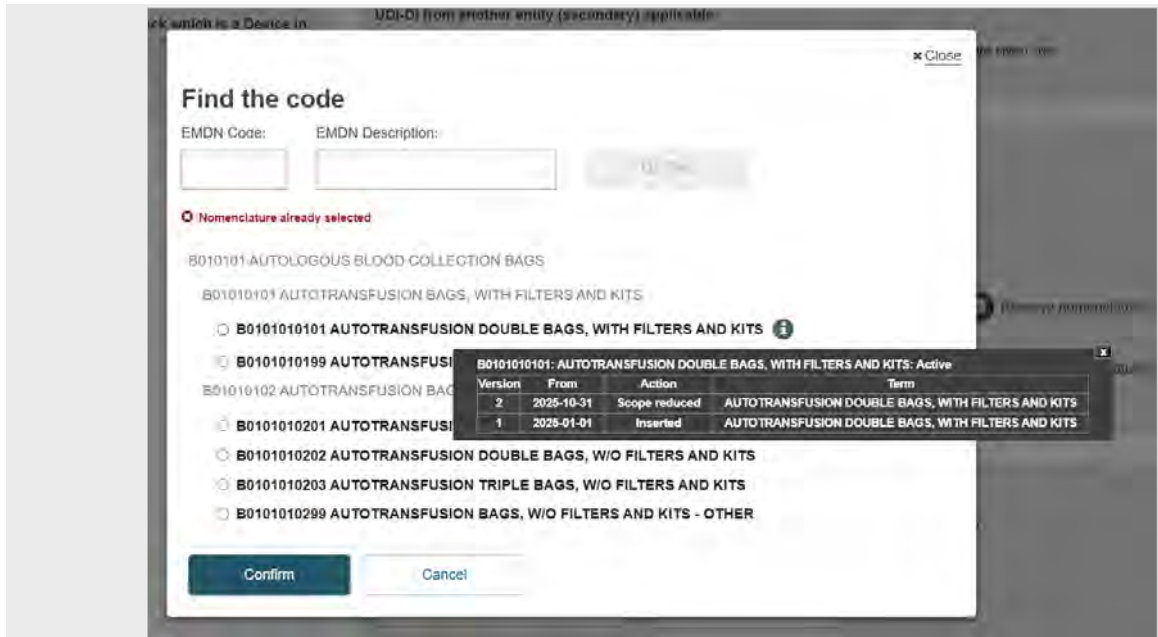
A0101010202 HYPODERMIC PEN NEEDLES, W/O SAFETY SYSTEMS

A01010199 HYPODERMIC NEEDLES - OTHER

EMDN Code updates

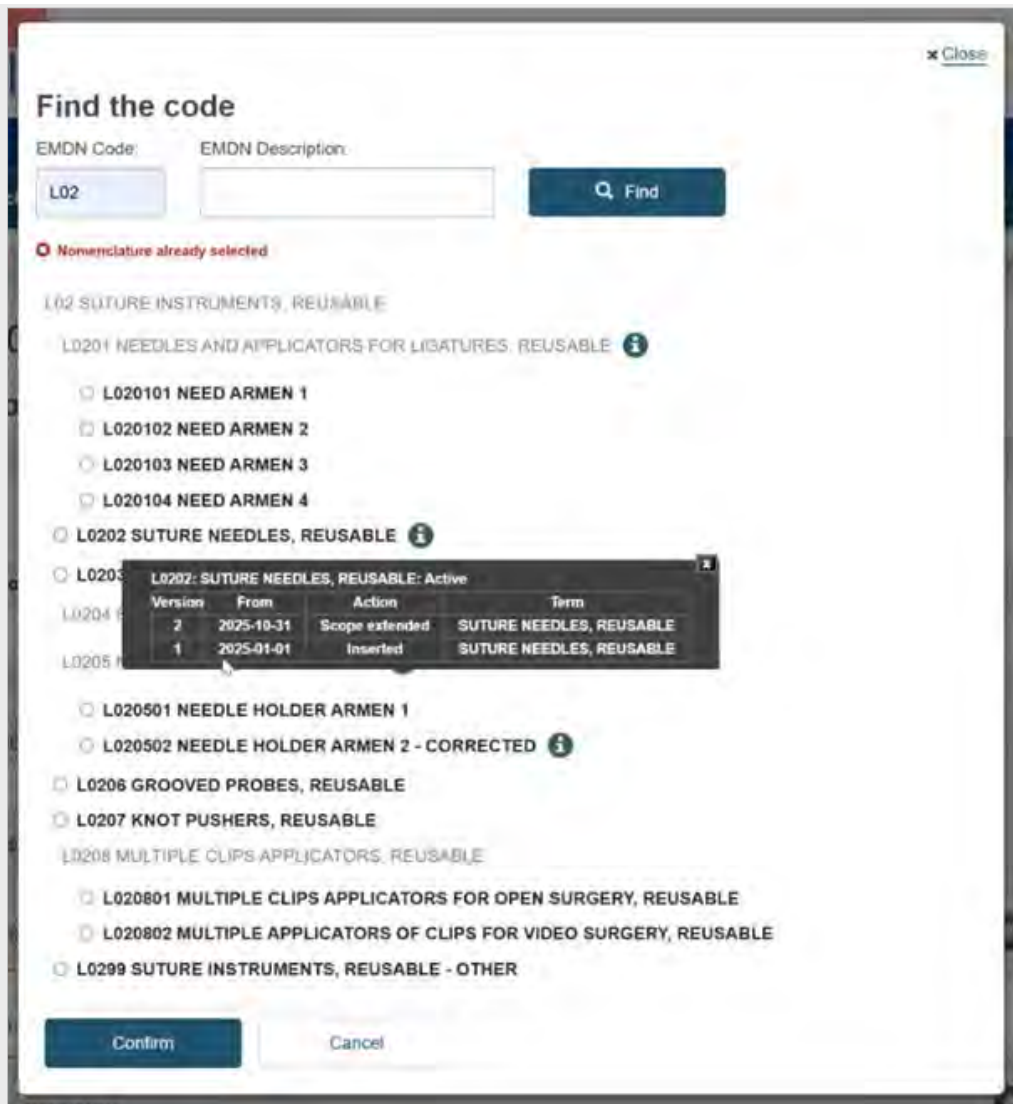
EMDN codes may get updated and therefore have a version history, which is indicated by an *information* icon.

Click on the *information* icon to view details about a code's versions and status:

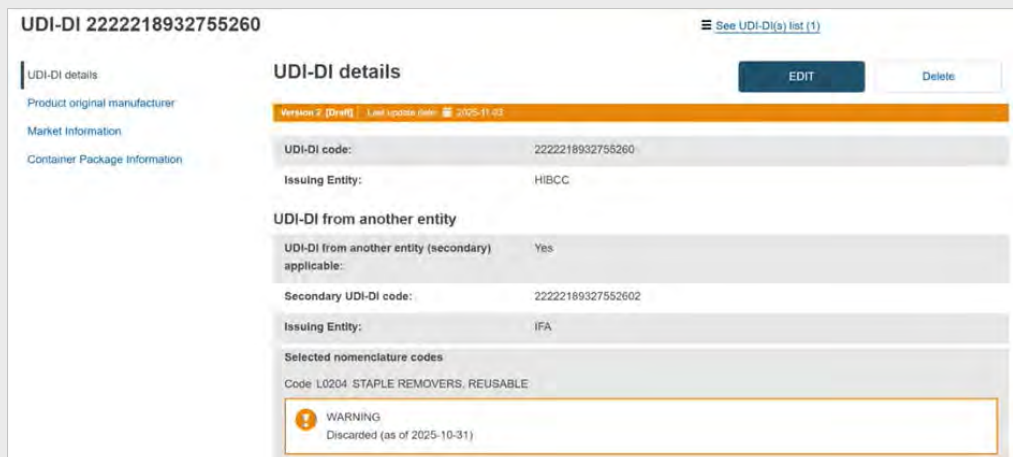


How does an EMDN code update affect my device?

1. If an EMDN code gets *scope-extended* or *corrected*, the device entry is not affected and no action is necessary.

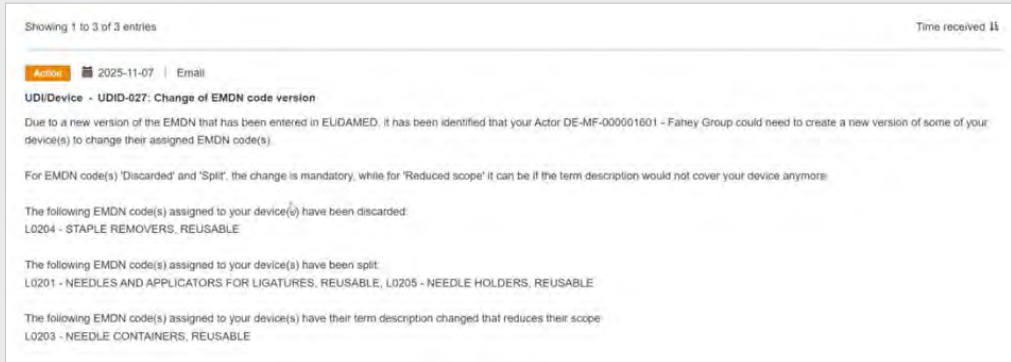


2. If an EMDN code gets *discarded* (inactive status), *split* or *scope-reduced*, the system will issue a warning (UDI details section):

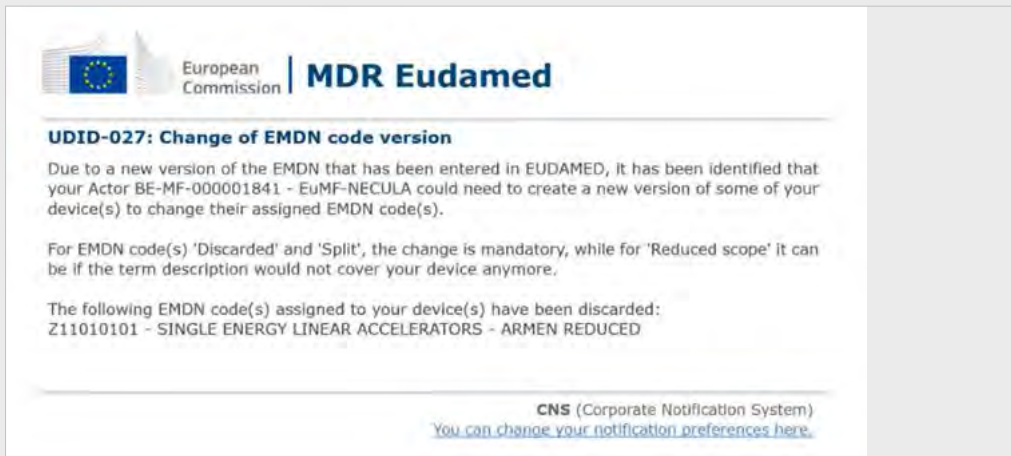


Depending on the specific case, the system may prompt the user to remove the obsolete EMDN code before creating a new device version with the correct EMDN code. In such cases, the user will receive EUDAMED and email notifications.

EUDAMED Notification



Email Notification



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):

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:

- 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 **Save** or **Save & Next**:

4.1.4 Step 4: UDI-DI characteristics

- Select **Yes** or **No** for each option regarding sterilisation:

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



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 description's language.

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



NOTE

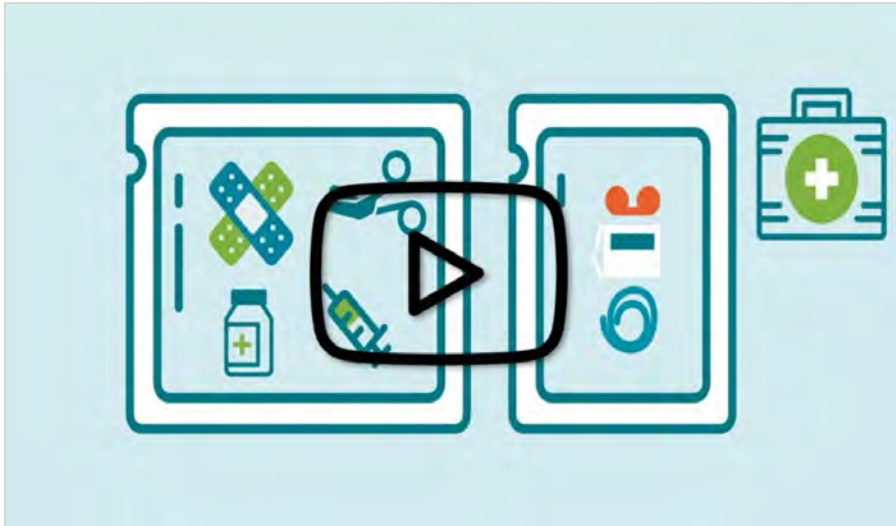
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the description's language.

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

4.1.5 Step 5: Container package details

VIDEO: UDI and Systems and Procedure Packs

Please note that this video contains sound.



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

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

+ [Add container package](#)

Save **Submit >** **Preview**

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



NOTE

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

*Close

Add container package

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

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

* Package status

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



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.

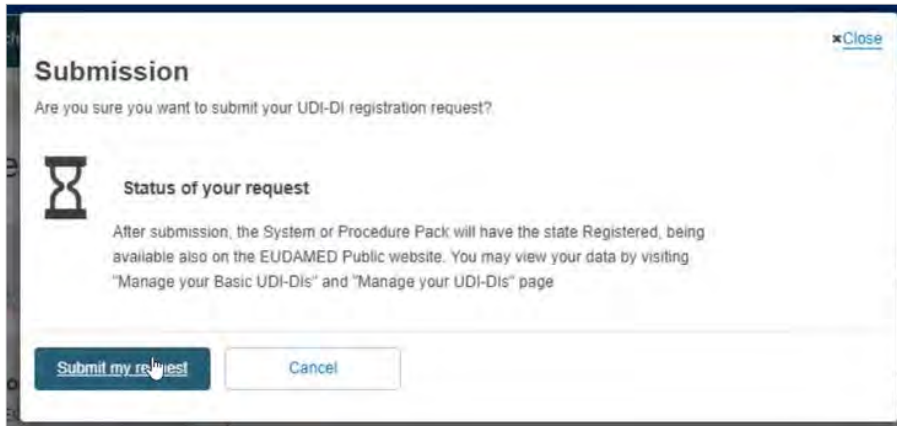
- Select the generated information and click on **Submit**:

Container package(s)

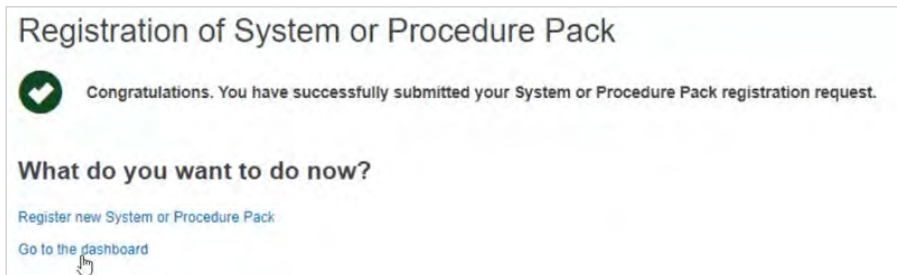
i You are not obliged to provide container package(s) UDI-DI before submitting this request.

- [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

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

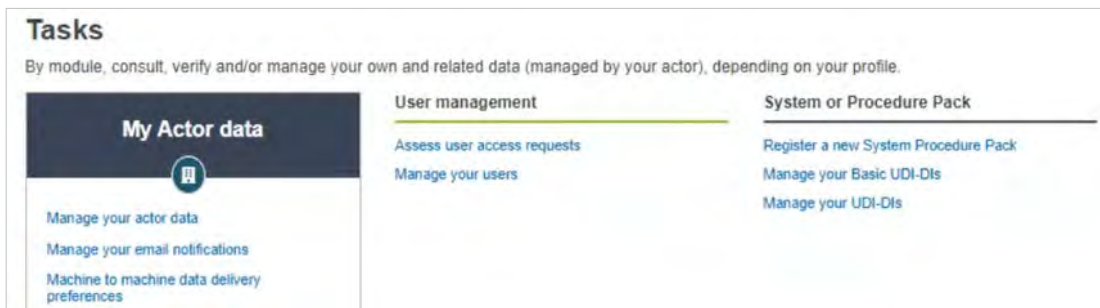


Upon submission, a success message will be displayed on the screen:

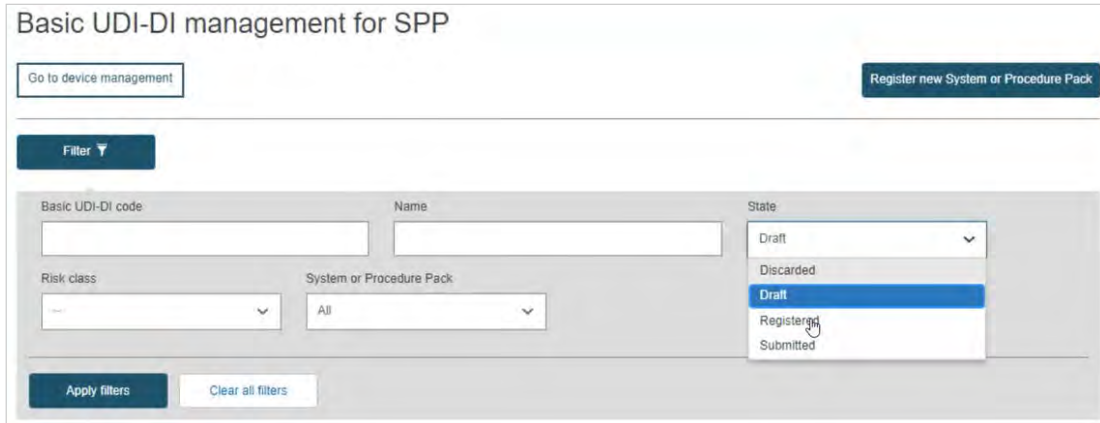


4.2 Register a new System or Procedure Pack for an existing

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



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



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

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

Basic UDI-DI code ID	UDI-DI(s) ID	Device model ID	Device Name ID	Risk class ID	Type ID	Date ID	State	Actions
1212112121212DL	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

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

Yes No ⓘ 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 🗑️ [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](#)

* Reference/Catalogue number:

REF_TEST

Manufacturing date

Expiration date

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

4.2.2 Step 2: UDI-DI characteristics

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

UDI-DI characteristics

* Need for sterilisation before use

Yes No

* Device labelled as sterile

Yes No

Storage/handling conditions, if applicable

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

Critical warnings or contra-indications, if applicable

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

* Critical warning type: Description:

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

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

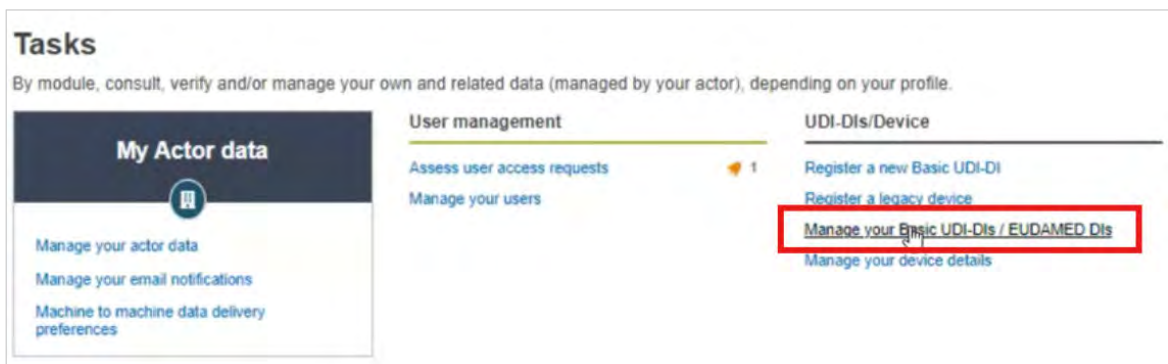
4.2.3 Step 3: Container package details

To complete this step, please consult [Container Package Details \[46\]](#) of this guide.

5 Manage your own Device information

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

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



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



NOTE

By default, the devices listed are the ones in *draft* state (not yet *submitted*, nor *registered*). To retrieve devices 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

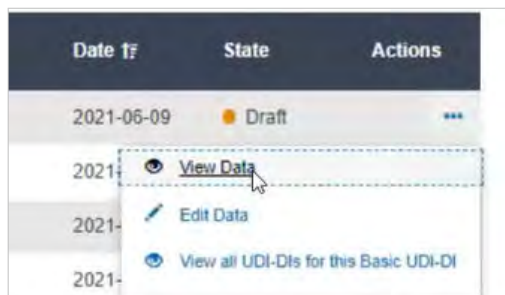
Filter ▾

Active filters: State: Draft Clear all filters

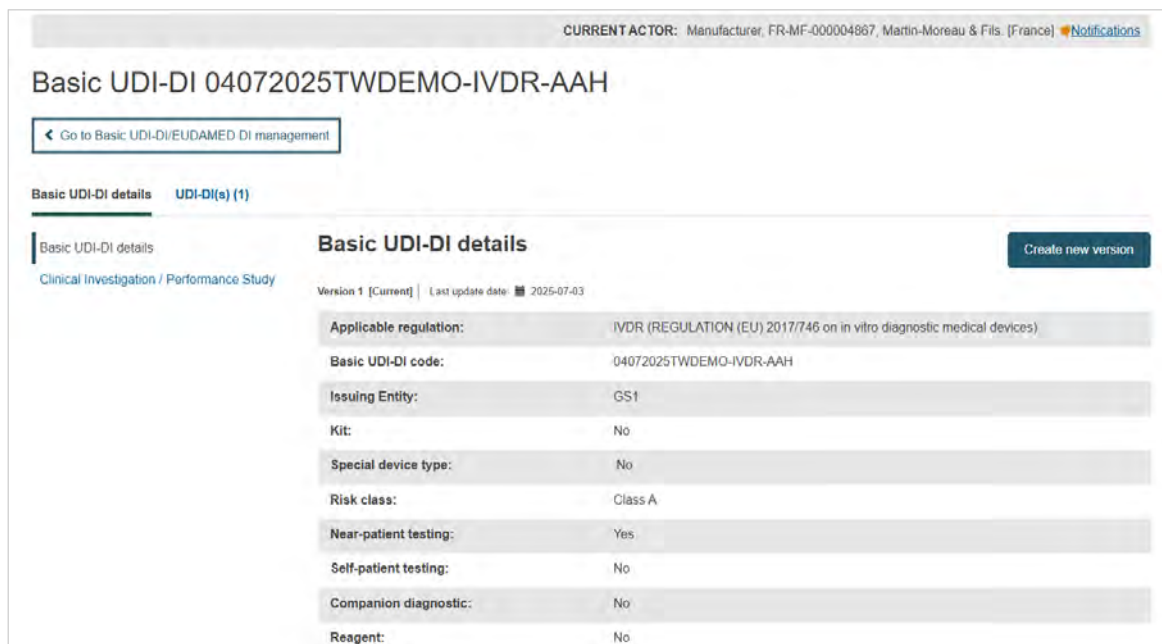
Showing 1 to 9 of 9 entries Show 20 entries per page

Basic UDI-DI/EUDAMED DI Code IT	Devices IT	Device model IT	Device Name IT	Risk class	Date IT	State	Actions
B-12121EL	1		Test	Class IIb	2021-04-01	1st Draft	...
121212121U5	1		Test	Class IIa	2021-04-01	1st Draft	...
1211421211211EW	1		Device Name	Class IIa	2021-04-01	Draft	...
3121212121212133383	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	...

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



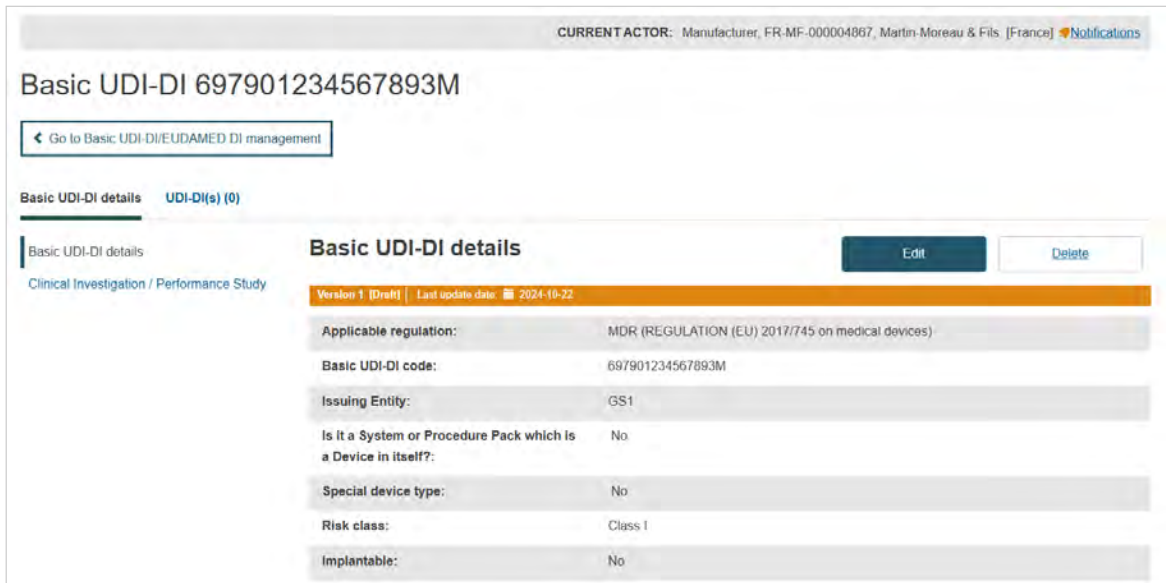
- You will see a summary of the details concerning your device and its Basic UDI-DI/EUDAMED DI:



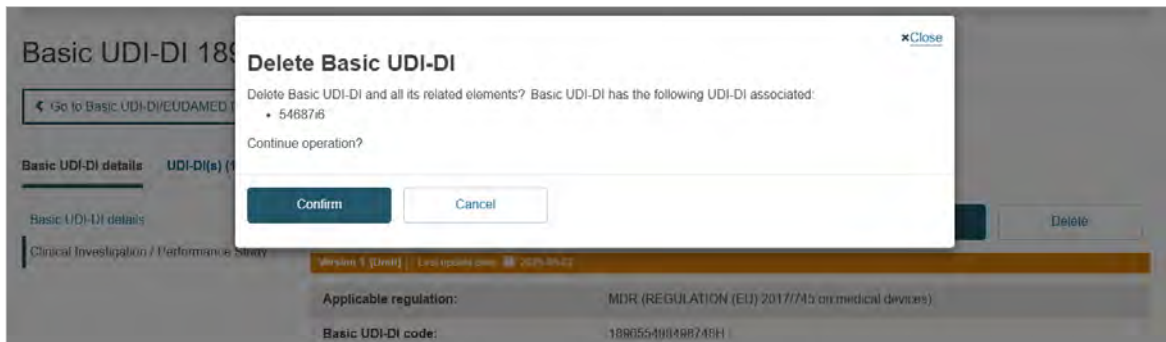
5.1.1 Delete draft Basic UDI-DI/EUDAMED DI

After following steps 1, 2 and 3 from [Manage your device Basic UDI-DI/EUDAMED DI details \[52\]](#) 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 **Delete**:



2. A pop-up window will ask you to confirm the deletion. The system also warns about simultaneous deletion of any associated device *1st draft* UDIs:



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

Follow the steps in section [Manage your device Basic UDI-DI/EUDAMED DI details \[52\]](#) to view a device and its Basic UDI-DI/EUDAMED DI.

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

CURRENT ACTOR: Manufacturer, FR-MF-000004887, Martin-Moreau & Fils. [France] [Notifications](#)

Basic UDI-DI 04072025TWDEMO-IVDR-AAH

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

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

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

[Clinical Investigation / Performance Study](#)

Version 1 [Current] | Last update date: 2025-07-03

Applicable regulation:	IVDR (REGULATION (EU) 2017/745 on in vitro diagnostic medical devices)
Basic UDI-DI code:	04072025TWDEMO-IVDR-AAH
Issuing Entity:	GS1
Kit:	No
Special device type:	No
Risk class:	Class A
Near-patient testing:	Yes
Self-patient testing:	No
Companion diagnostic:	No
Reagent:	No

2. Update the desired details:

04072025TWDEMO-IVDR-AAH [version: 2]

Create a new version of 04072025TWDEMO-IVDR-AAH

Basic UDI-DI code:	04072025TWDEMO-IVDR-AAH
Issuing Agency:	GS1
Special device type:	No
Risk class:	Class A
Near-patient testing:	Yes
Self-patient testing:	No
Companion diagnostic:	No
Reagent:	No
Instrument:	No
Professional Testing:	No
Device model applicable	<input checked="" type="radio"/> Yes <input type="radio"/> No i Device model applicable
* Device Name:	<input type="text" value="TW DEMO - IVDR Class A"/>
Presence of human tissues or cells, or their derivatives:	No
Presence of animal tissues or cells, or their derivatives:	No
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:	-
Presence of cells or substances of microbial origin:	No

3. To complete the action:

- Click **Save** to save to your registration as a draft and continue later.
- Click **Submit new version** if you are certain about the update and wish to submit it.

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

5.1.3 View historical versions of device data and its /

Follow the steps in section [Manage your device Basic UDI-DI/EUDAMED DI details \[52\]](#) to view data on a device and its Basic UDI-DI/EUDAMED DI.

1. Once inside the details of the selected device and its Basic UDI-DI, click *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*:

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

My Actor data

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

UDI-DIs/Device

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

User management

- Assess user access requests
- Manage your users

2. You will see a list:

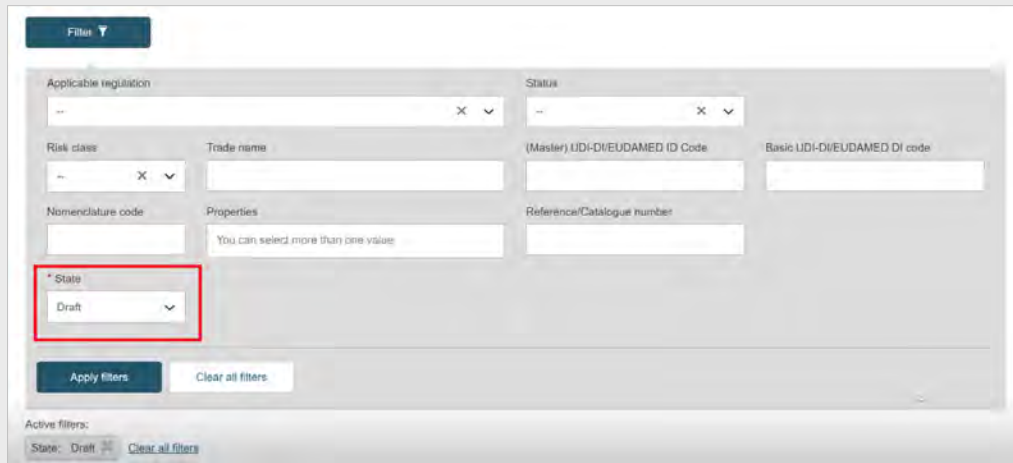
Showing 1 to 20 of 50 entries Show 20 entries per page

(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-nikoIVD, Device Name: odjcouwbfk, Class I, MDD (Directive 93/42/EEC on Medical Devices)							
D-nikoIVD				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)							
opo-81910	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: 77777777770UZ, Device Name: aaaaaaaaaa, Class I, MDR (REGULATION (EU) 2017/745 on medical devices)							
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)							
12345756984101	sdsdfcd	as23r43x		2024-06-18	On the EU market	1st Draft	...

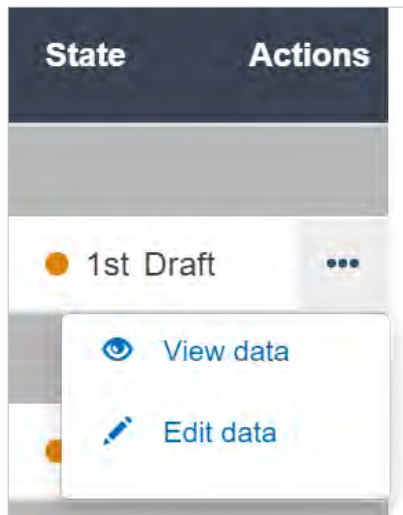


NOTE

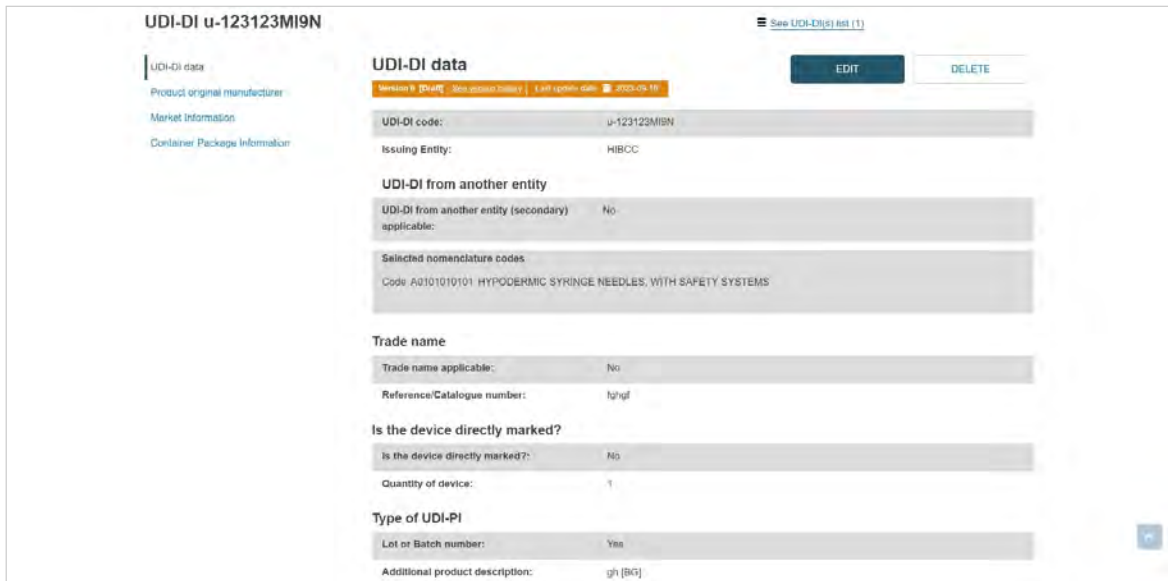
By default, the system lists the devices in *draft* state. To retrieve other states use the filters:



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



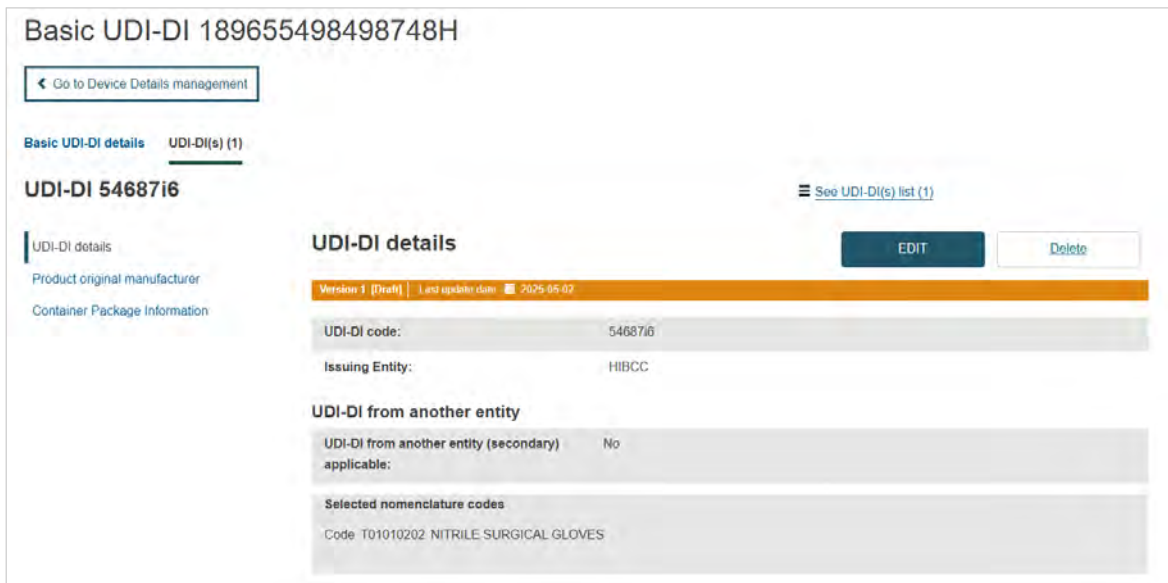
4. You will see a summary of the details of your device:



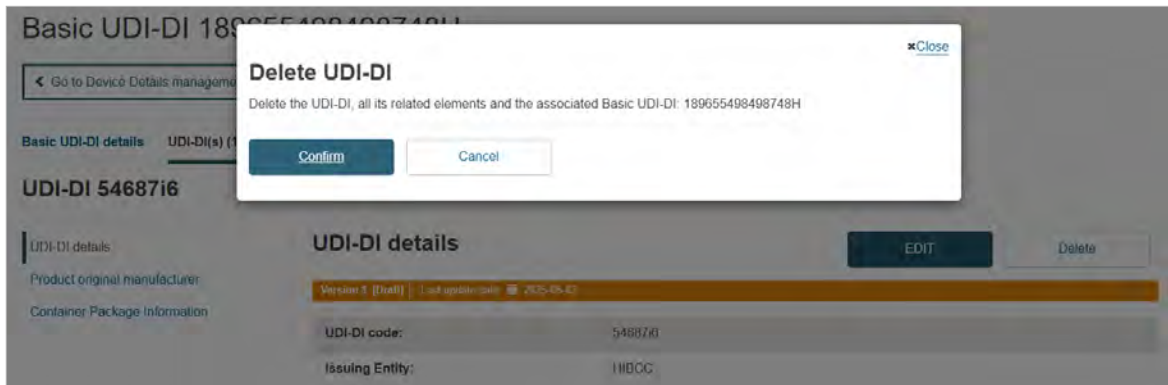
5.2.1 Delete draft UDI-DI/EUDAMED ID

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) to view a draft UDI-DI.

1. Once inside the desired device's Draft UDI-DI, click **Delete**:

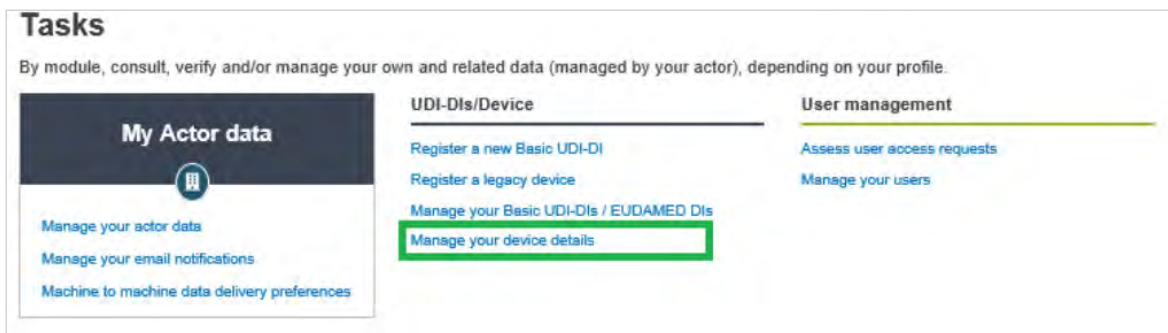


2. A pop-up message will ask you to confirm the deletion. The system will also warn about simultaneous deletion of the associated Basic UDI-DI, in case there is only this single device under it:

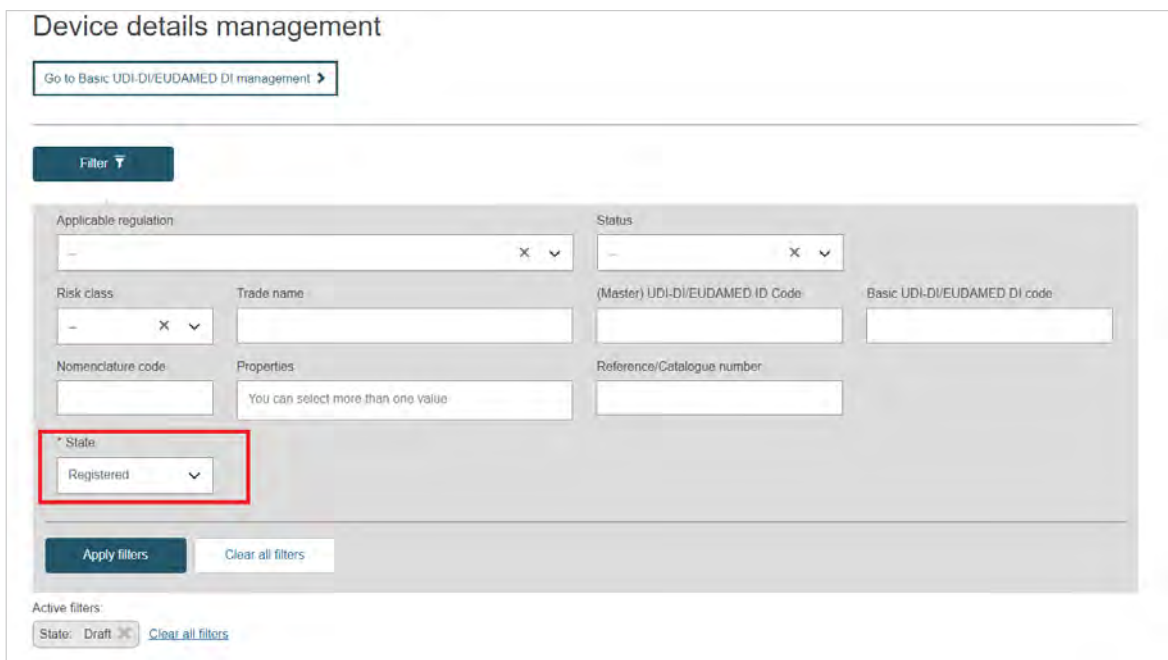


5.2.2 View details of a registered device and its UDI-DI/ EUDAMED ID details

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



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



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

Showing 1 to 20 of 454 entries Show entries per page

UDI-DI/EUDAMED ID Code	Trade name II	Reference/Catalogue number II	Nomenclature code II	Date II	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: 109784903286972P5, 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



NOTE

See below for the devices where Master replaces , the *Details* section for a registered device and its Master :

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:	aaaaaaaa v2
Reference/Catalogue number:	0101912

Is the device directly marked?

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

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

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
 - o 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
 - o 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 a device and its UDI-DI/EUDAMED ID

VIDEO: UDI assignment and updates

Please note that this video does not contain sound.



Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) to view a device and its UDI-DI/EUDAMED ID.

1. Once inside the details of the selected UDI-DI, click **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

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

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

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

B| [Find](#)

B01 [Nomenclature](#)

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](#)

*** 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 device 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.

The screenshot shows the 'Master UDI-DI details' page for 'UDI-DI 12345-master-udi-013D'. At the top, there is a breadcrumb trail: 'Basic UDI-DI 12345-family-015N' > 'Go to Device Details management' > 'Basic UDI-DI details' > 'Master UDI-DI(s) (1)'. Below this, the 'Master UDI-DI details' section is visible, showing 'Version 1 [Current]' and 'Last update date: 2024-12-19'. The 'Master UDI-DI code' is '12345-master-udi-013D'. At the bottom of this section, there are 'Discard' and 'Create new version' buttons. A separate callout box highlights the 'Quantity of device' field, which contains the value '10' and is accompanied by the instruction: 'Please indicate the maximum number of devices.'

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

The screenshot shows the 'Information on substances' form. It has a title '* Information on substances' and a question: 'Presence of a substance which, if used separately, may be considered to be a medicinal product:'. The answer is 'Yes'. Below this, there is an 'INN:' field with the value 'abc-358'. There is a '+ Add a substance' button. Below that, another question: 'Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:'. The answer is 'No'. At the bottom, there are three buttons: 'Save', 'Submit new version', and 'Cancel'.

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

The screenshot shows a pop-up window titled 'Create new version of UDI-DI'. It contains the text: 'You are about to create a new version of UDI-DI 12345-master-udi-013D'. At the bottom, there are two buttons: 'Confirm' and 'Cancel'. There is also a 'Close' button in the top right corner.

5.2.4 Update 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 \[57\]](#) to view a UDI-DI/EUDAMED ID.

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

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

- Click **Update** to access the *Product original manufacturer* page:

The screenshot shows the 'Product original manufacturer' page for 'Version 4 [Current]' with a last update date of '2023-09-12'. The 'Update' button in the top right corner is highlighted with a red box. The page contains a form with the following fields:

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 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:

- Click **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 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 \[57\]](#) to view a UDI-DI/EUDAMED ID.

- Once inside the details of the selected UDI-DI, click **Market Information** from the list on the left (or scroll down to *Market Information*):

- Click **Update countries**:

Market Information Update countries

Version 1 | Last update date: 2025-07-01

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

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

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](#)

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

Market Information Update countries

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

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

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

5.2.6 Update 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 \[57\]](#) to view a UDI-DI/EUDAMED ID.

1. 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 'Basic UDI-DI data' page for 'UDI-DI(s) (2)'. The main heading is 'UDI-DI existing-PD-1'. On the left, a sidebar menu includes 'UDI-DI data', 'Product original manufacturer', 'Market Information', and 'Container Package Information', which is highlighted with a red box. The main content area shows 'UDI-DI data' for 'Version 1 [Current]' with a last update date of '-'. It lists 'UDI-DI code: existing-PD-1' and 'Issuing Entity: ICGBBA'. Below this, it asks 'UDI-DI from another entity' and shows 'No' for 'applicable:'. There are 'Discard' and 'Create new version' buttons at the top right.

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

This screenshot shows the 'Container Package Information' section for 'Version 3' with a last update date of '2023-08-15'. A red box highlights the 'Create new version' button. Below the button, there is a text field containing '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'.

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

[*Close](#)

Add container package

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

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

Container package update

Container package(s)

- [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

[*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



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 **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



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
 - 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
 - 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
 - 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 devices and their s/s (and their /)



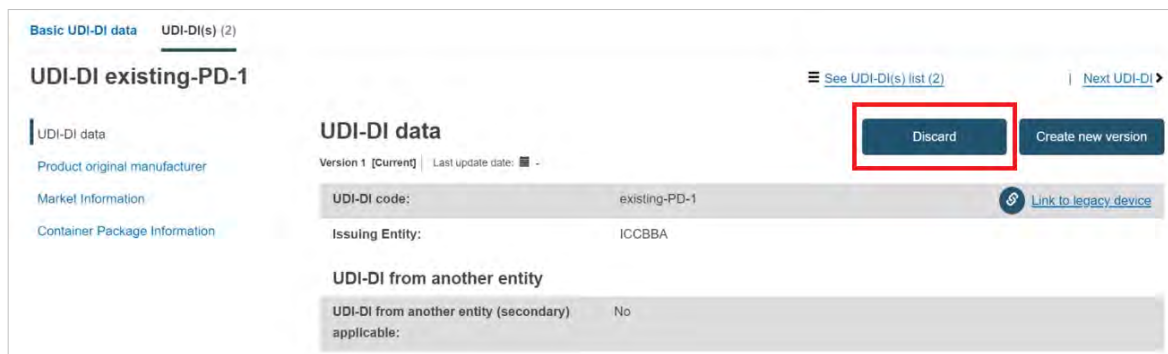
IMPORTANT

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.

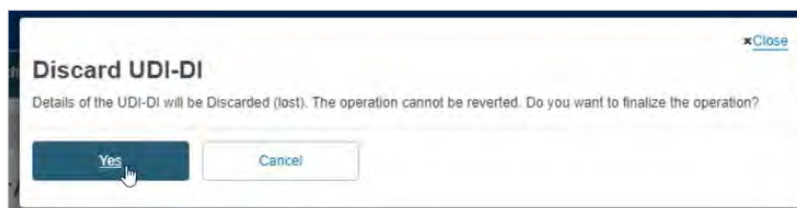
You may wish to discard a registered device and its UDI-DI in case you discover errors that cannot be corrected.

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) to view a registered UDI-DI/EUDAMED ID.

1. Only a user with *Confirmer* profile can discard. Once inside the details page of the selected UDI-DI, click **Discard** at the top right corner:



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

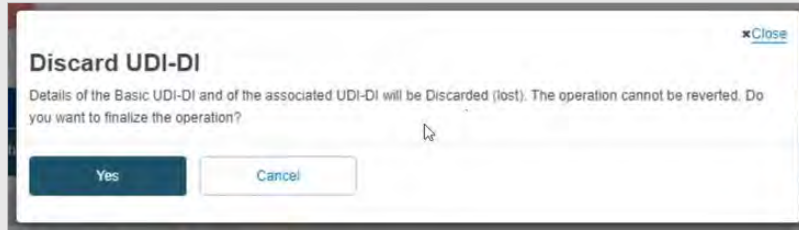


The UDI-DI will be discarded and will no longer be visible on the public EUDAMED website.



CAUTION

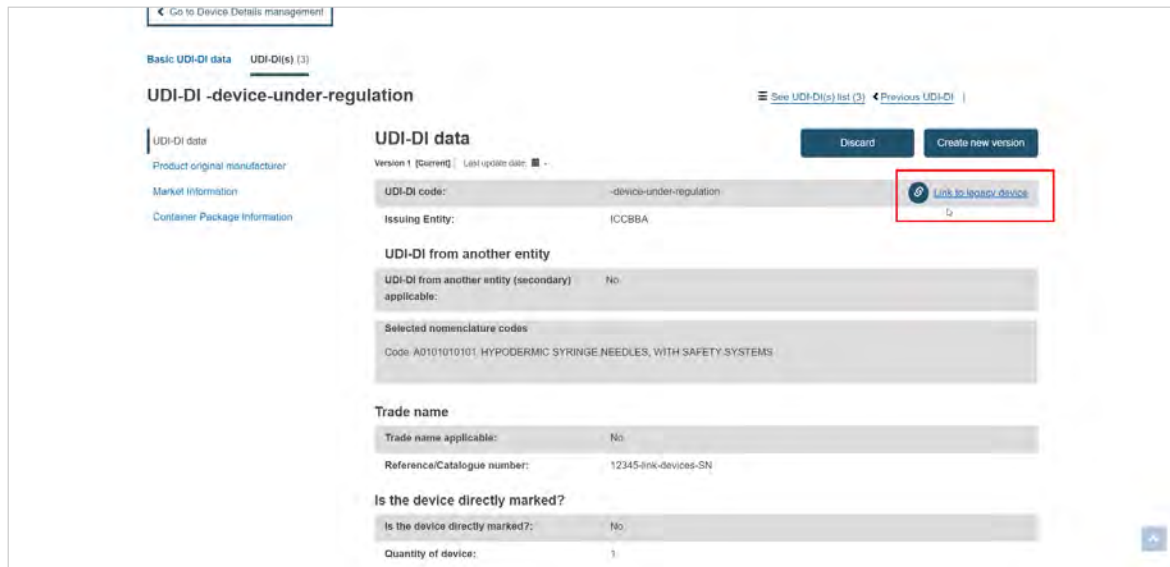
If the UDI-DI is the only one in this Basic UDI-DI category, the *discard* action will also discard the Basic UDI-DI. The system will alert you accordingly:



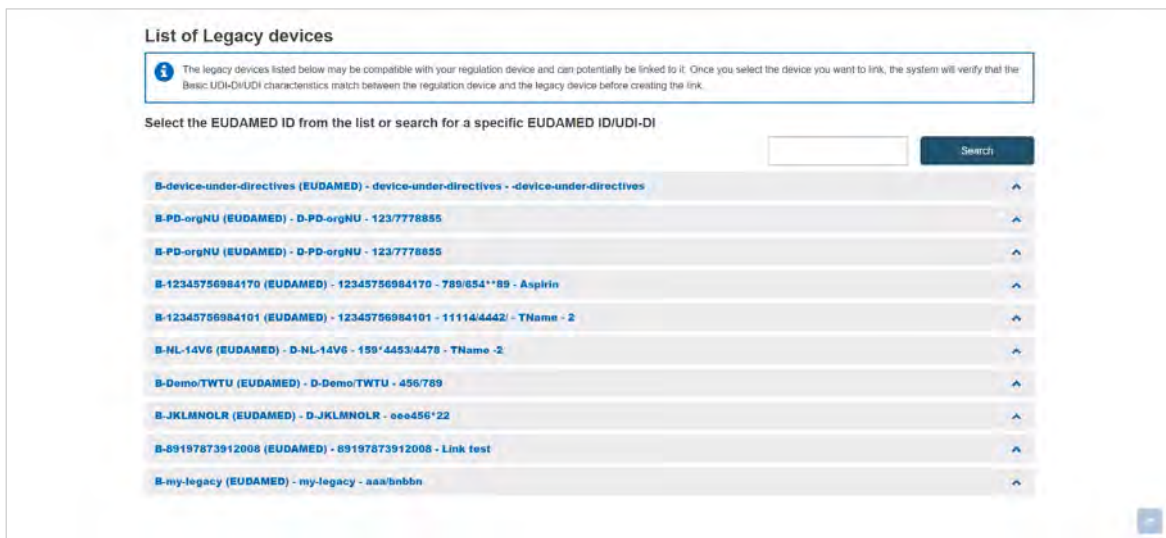
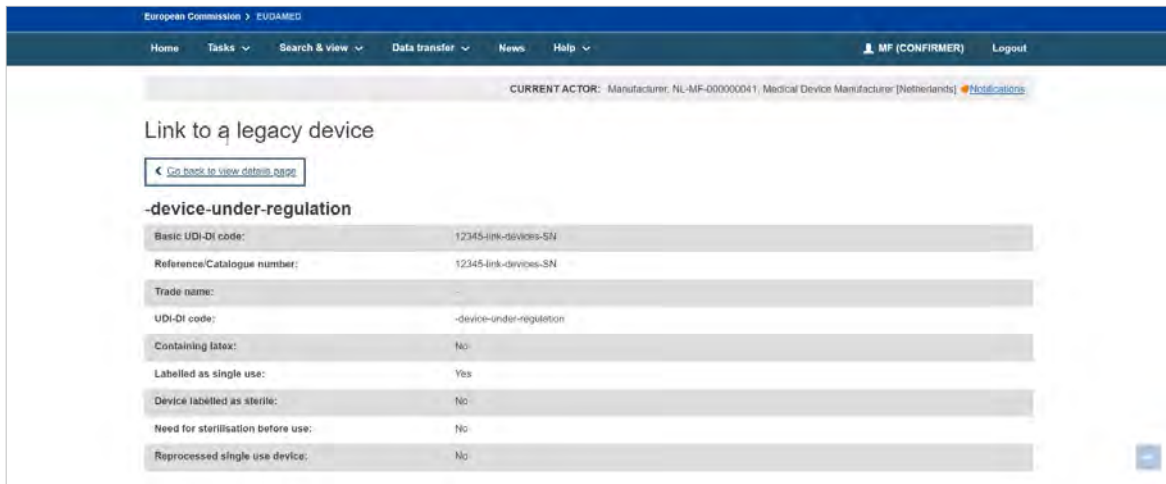
5.2.8 Link registered Regulation Device to registered Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

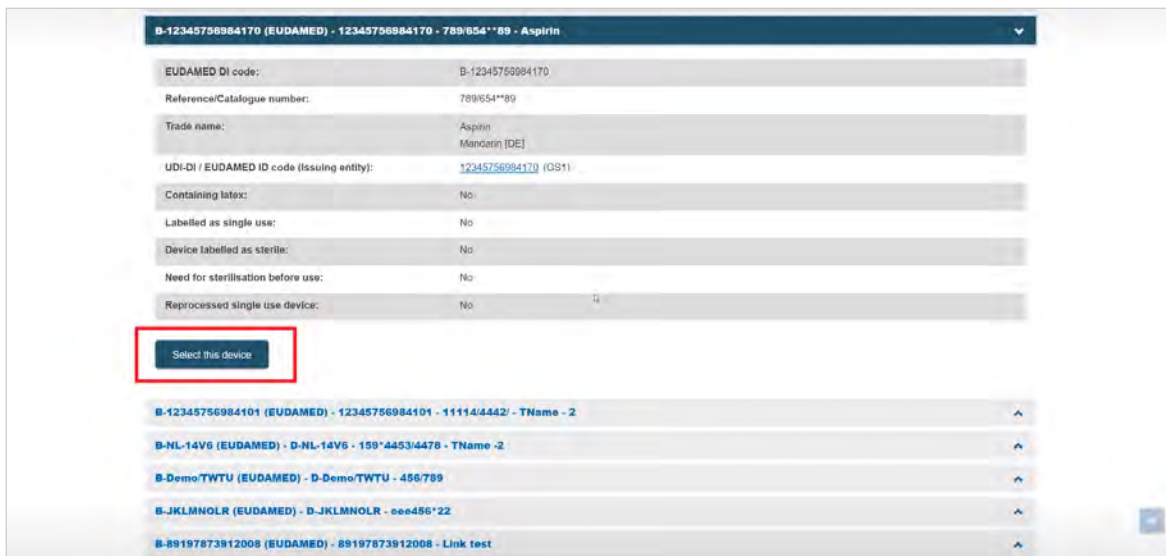
1. Once inside the relevant registered regulation device click on *Link to legacy device*:



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:



- 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 **Select this device**:

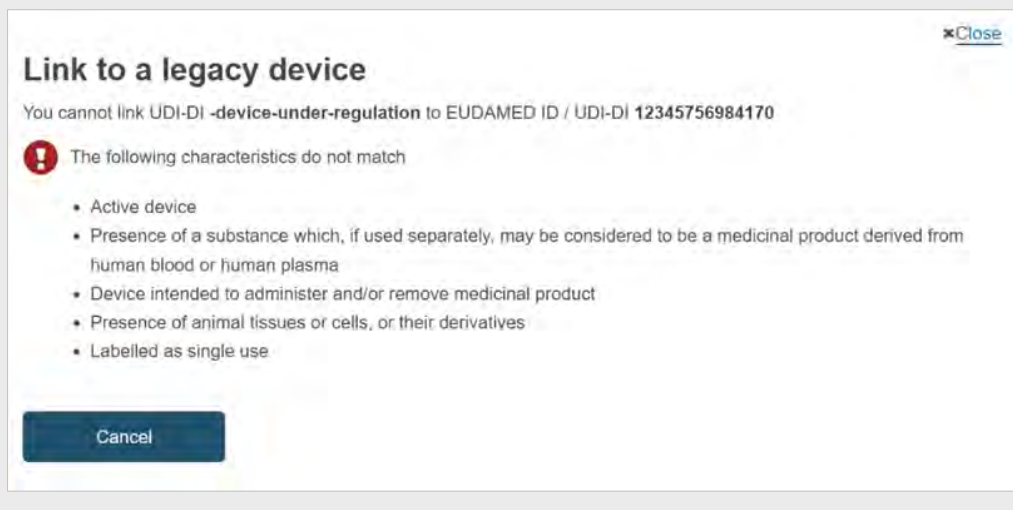


- Click **Confirm** in the pop-up window:

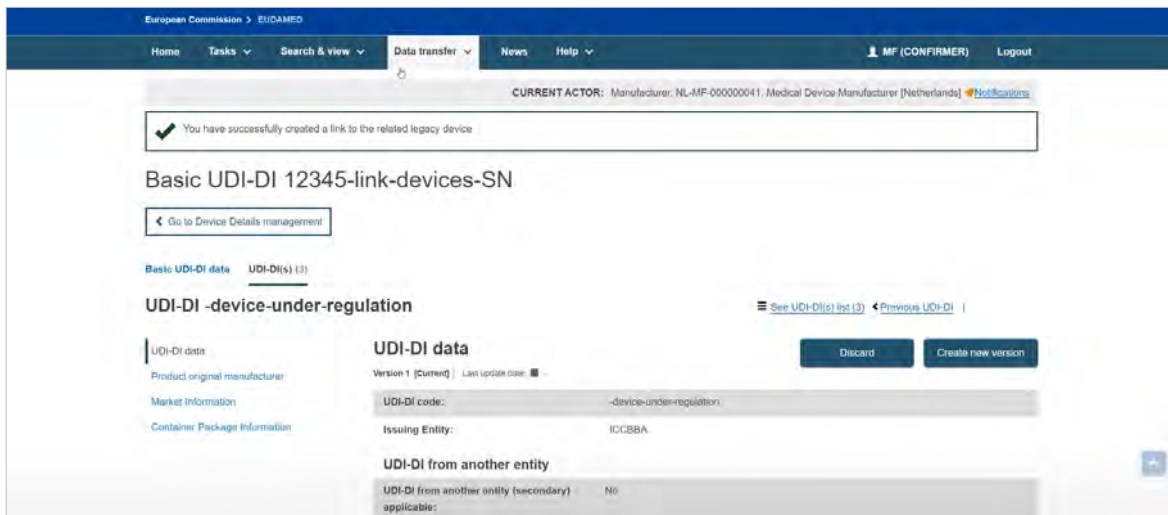


NOTE

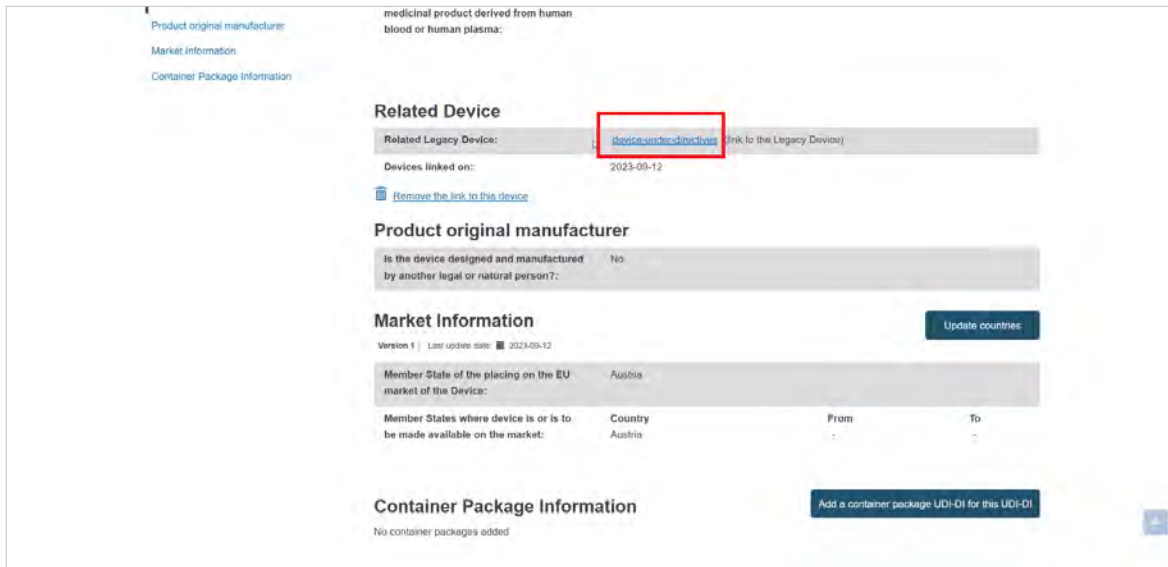
If some characteristics don't match, then you will not be able to link the registered regulation device to the selected legacy device:



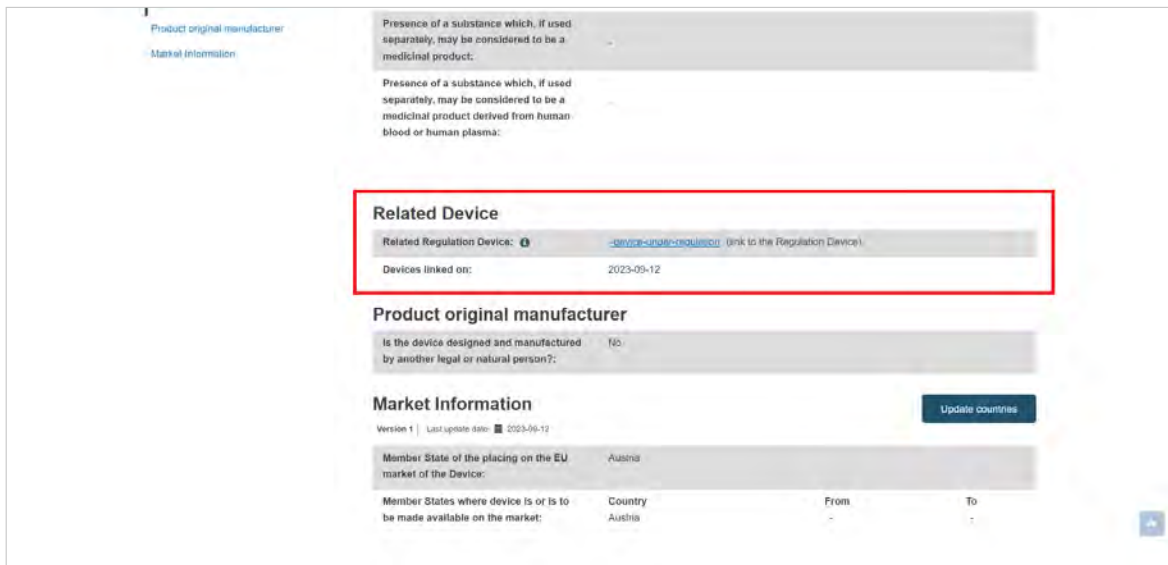
5. The system will redirect you back to the regulation device's page:



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



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



NOTE

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

5.2.9 Delete link between Regulation Device and Legacy Device

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) 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:

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



NOTE

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

5.2.10 View historical versions of a device and its / and associated entities

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[57\]](#) 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

EDIT
DELETE

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

2. 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

3. 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:

Tasks

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

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)



NOTE

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

Basic UDI-DI management for SPP

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

Filter ▼

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

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

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

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

Showing 1 to 3 of 3 entries Show entries per page

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

3. 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 SPP draft Basic UDI-DI

Follow the steps in section [Manage your SPP Basic UDI-DI details \[86\]](#) 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
123454323234324XU	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 **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 in 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 SPP Basic UDI-DI

Follow the steps in section [Manage your SPP Basic UDI-DI details \[86\]](#) 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
4444SPP_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 **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 **Save** to save the updated details without submitting the new version.
 - Click **Submit new version** if you wish to submit it.

Alternatively, click **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 SPP Basic UDI-DI historical versions

Follow the steps in section [Manage your SPP Basic UDI-DI details \[86\]](#) to view a Basic UDI-DI.

Once inside the *Details* page for the selected Basic UDI-DI, click *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:**

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 *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 relevant UDI-DI, click 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 SPP draft UDI-DI

Follow the steps in section [Manage your SPP UDI-DI details \[91\]](#) to view a draft UDI-DI.

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

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

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

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

Container Package Information

UDI-DI data

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 SPP UDI-DI

Follow the steps in [Manage your SPP UDI-DI details \[91\]](#) to view a UDI-DI:

Basic UDI-DI management for SPP

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

Filter ▼

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

Showing 1 to 3 of 3 entries Show 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

- Once inside the details of the chosen UDI-DI, click **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.

**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 Remove nomenclature code

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

Reference/catalogue number: SPPP_Shr_1

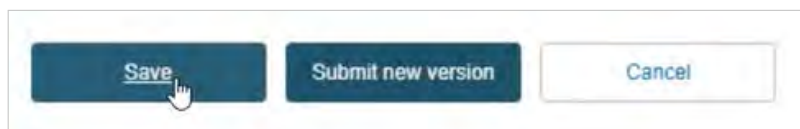
Type of UDI-PI
 * Manufacturing date: Yes

* Additional product description:
 Select the language: Bulgarian

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

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

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



6.2.3 Update SPP 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 \[91\]](#) to view a specific UDI-DI:

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

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

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

Container package update

Container package(s)

[+ Add container package](#)

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

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

Add container package ✕Close

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

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

* Package status

No longer placed on the EU market

Not intended for EU market

On the EU market

6.2.4 Discard SPP registered UDI-DIs

Follow the steps in section [Manage your SPP UDI-DI details \[91\]](#) to view a chosen Registered UDI-DI:

UDI-DI details management for SPP

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

Filter

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

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

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

- Once inside the *Details* page of the chosen UDI-DI, click **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 **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:



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

Follow the steps in section [Manage your SPP UDI-DI details \[91\]](#) to view a UDI-DI for the SPP.

1. Once inside the details of the chosen UDI-DI, click *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	>

2. 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

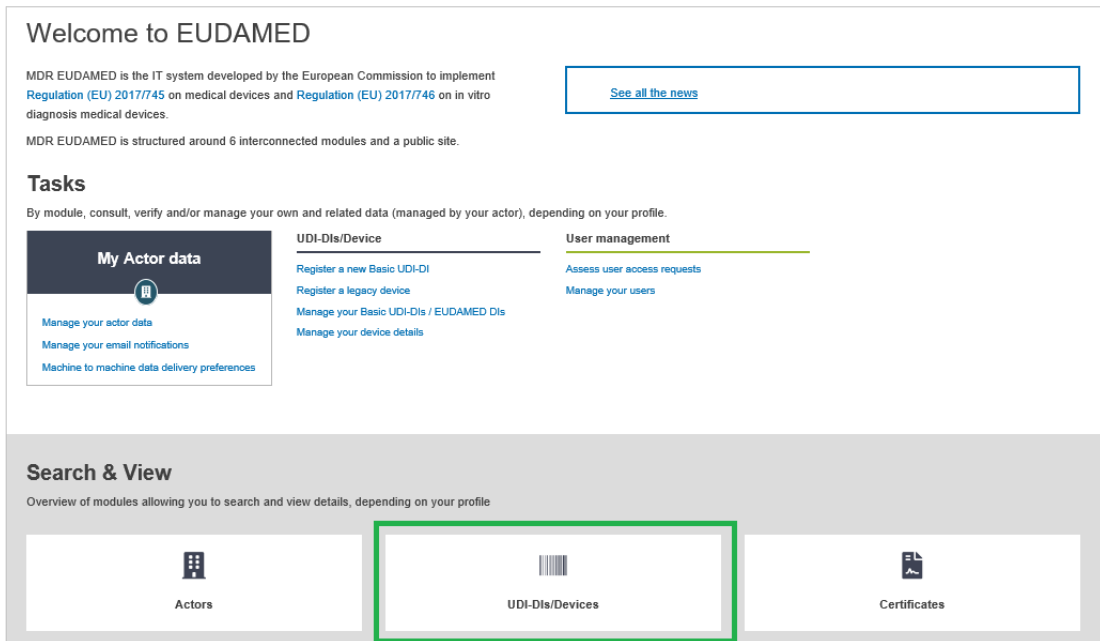
You can return to the version history list by clicking on *See all version history* at the top right corner.

7 Search & View Devices and Systems or Procedure Packs

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



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



NOTE

Search and view can be accessed by all users, regardless of profile. It is possible to search and view device and data from all actors in EUDAMED.

- 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*:

- Once you have entered your search filters, click **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 II	(Master) UDI-DI version	Basic UDI-DI / EUDAMED DI II	MF / PR Actor ID/SRN	Trade name II	Risk class	Date II	UDI-DI/Device status
188727_00	1 [Current]	77777777770UZ	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:

Producer information

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

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

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

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

System or Procedure Pack type: Procedure Pack

7.1 Search & View historical versions of Devices or SPPs

Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[100\]](#) to search and view a Device or System or Procedure Pack.

1. 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 **Search**:

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED ID:

Basic UDI-DI/ EUDAMED DI:

Status:

Model:

Name:

Trade name:

Applicable regulation:

Risk class:

Nomenclature code:

Reference/Catalogue number:

Country:

Scopes:

Competent Authority:

NB identification:

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

Results option

Include historical version

- 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 #	Version Number	Basic UDI-DI code #	MF / PR SRN	Trade name #	Risk class	Date #	UDI-DI status
232121122132	2 [Current]	223311445578899583F	BE-PR-000000022	Trade_Name	Class I	2021-07-07	On the EU market
D-12345-bug-testFF	1 [Current]	B-12345-bug-testFF	BE-MF-000000001		Class I	2021-07-05	On the EU market
IFA0705	2 [Current]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
0705HIBCC	2 [Current]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
0705HIBCC	1 [History]	202107051FQ	BE-MF-000000001		Class IIb	2021-07-05	On the EU market
IFA0705	1 [History]	202107052FS	BE-MF-000000001		Class III	2021-07-05	On the EU market
udid-36	1 [Current]	12345test-empty-langTC	BE-MF-000000001		Class I	2021-07-05	Not intended for the EU market
test-empty-lang1	1 [Current]	12345test-empty-langTC	BE-MF-000000001	trade name1	Class I	2021-07-05	Not intended for the EU market
udid-37	1 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	2 [Current]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
UDID-1	1 [History]	12345empty-MLT-1NH	BE-MF-000000001		Class I	2021-07-02	Not intended for the EU market
12123	1 [Current]	12123qqP9	BE-MF-000000001		Class IIb	2021-07-01	On the EU market
cdc	1 [Current]	22222e1234566543e5L5	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
cdc	1 [Current]	22222e1234566543eEG	BE-MF-000000001		Class IIa	2021-06-28	On the EU market
vfvf	1 [Current]	22222e12345665435T	BE-MF-000000001		Class IIb	2021-06-28	On the EU market
1234_1234_57676	1 [Current]	1212112121212121214K	BE-MF-000000001	External Implant	Class I	2021-06-22	On the EU market
11223	1 [Current]	11223qqP5	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

7.2 Download Devices or SPPs data in a structured format (XML)



NOTE

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

Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[100\]](#) to search and view a device or a system or procedure pack.

- On the *Search* page, activate the top filter (**Only enable search filters available for bulk XML download**) and enter your search criteria.
Enter the search criteria of your choice, and click **Search**:

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED ID	Basic UDI-DI/ EUDAMED DI	Status	Model
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Name	Trade name	Applicable regulation	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Risk class	Nomenclature code	Reference/Catalogue number	Country
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Scopes <input type="text"/>			
Competent Authority	NB identification	MF / PR Actor ID/SRN	MF / PR Name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
AR Actor ID/SRN	AR name		
<input type="text"/>	<input type="text"/>		

Results option

Include historical version

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



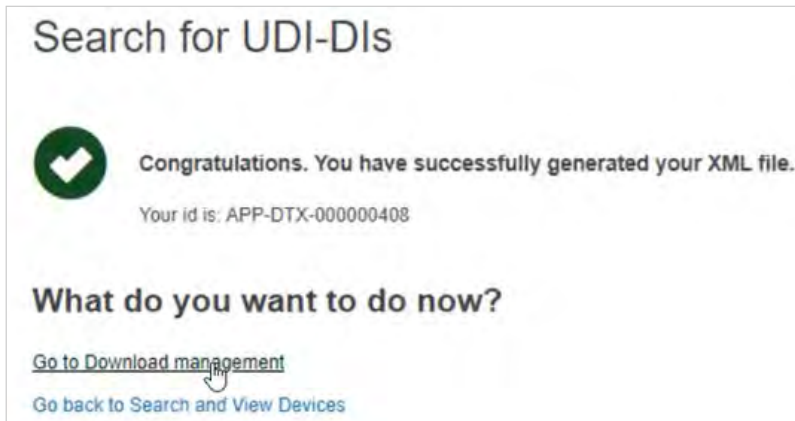
NOTE

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

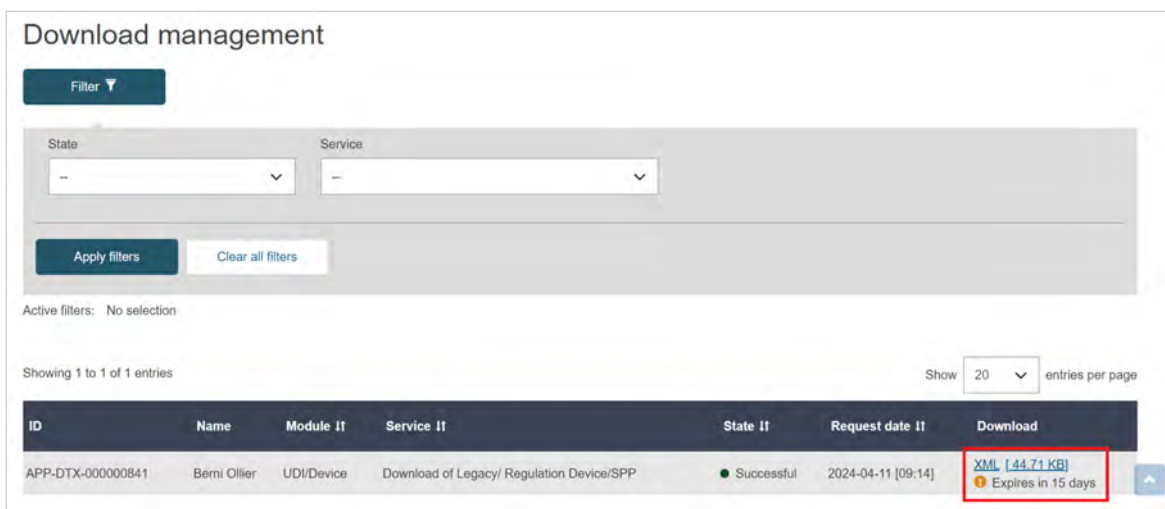
3. Confirm your action in the pop-up window:



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



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



7.3 View historical versions of 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 \[102\]](#) to view the details of a Device or System or Procedure Pack.

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

UDI-DI 121312_Test_AR

[Go back to the list](#)

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI details

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

Basic UDI-DI identification

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

Basic UDI-DI code: 22091test23_09EC
 Issuing Entity: GS1

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

List of UDI-DIs for the Basic UDI-DI

UDI-DI details

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

UDI-DI code: 121312_Test_AR

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010199 HYPODERMIC NEEDLES - OTHERS

Trade name

Trade name applicable: Yes

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

Reference/Catalogue number: ref

Is the device directly marked?

Is the device directly marked?: No

Market information

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

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

Clinical Investigation(s)

Clinical Investigation

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

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

Basic UDI-DI 22091test23_09EC

[Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Manufacturer information

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI data

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

Basic UDI-DI identification

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

Basic UDI-DI code: 22091test23_09EC
Issuing Entity: GS1

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

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Manufacturer information

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI data

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

Basic UDI-DI identification

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

Basic UDI-DI code: 22091test23_09EC
Issuing Entity: GS1

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

8 Annex – 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 to be provided based on the properties of the device.

The updated versions of the tables below can also be consulted here: [Notified Bodies and Certificates module - Documentation](#)

IVDR Conformity assessments table

[Regulation \(EU\) 2017/746 on in vitro diagnostic medical devices](#) (IVDR) Applicable conformity assessments per device class

IVD: Device class & Certificate type		EU QMS Device or Group	EU TDA Device	EU TE Device	EU PQA Device or Group
Class D		✓ (NB)	✓ (NB, SSP, scrutiny)		
Class C	Self/near patient testing devices	✓ (NB)	✓ (NB, SSP)	✓ (SSP, scrutiny)	✓
	Companion diagnostics	✓ (NB)	✓ (NB, SSP)	✓ (SSP)	✓
	All other class C devices	✓ (SSP)		✓ (SSP)	✓
Class B	Self/near patient testing devices	✓ (NB)	✓ (NB)	✓ (SSP)	✓
	All other class B devices	✓			
A sterile		✓			✓

29.3 par #1: MF assigns a Basic UDI-DI before it applies to a NB
 29.3 par #2: NB confirms the concerned device data in registering the certificate in Eudamed.
 As a pre-requisite the MF provides the NB identification and certificate type information with submission of Basic UDI-DI data in Eudamed.
 (NB) = Same NB carries the conformity assessments.

MDR Conformity assessments table

Regulation (EU) 2017/745 on medical devices (MDR) Applicable conformity assessments per device class

MDR: Applicable conformity assessments per device class (and characteristics of the device class)			EU QMS (scope is defined using devices and/or device groups)	EU TDA (certificate scope is defined using devices)	EU TE (certificate scope is defined using devices)	EU QA (scope is defined using devices and/or device groups)	EU PV (certificate scope is defined using devices)
Each line represents a different path for assessing the conformity of a device.							
IIb non implantable	Active devices intended to administer and/or remove a medicinal product		CECP	sample/generic device group	✓ (SSCP)		
					✓ (SSCP)		
IIa	Implantable	Non active devices	✓	sample/generic device group	✓ CECP	✓	
		Active devices NOT intended to administer and/or remove a medicinal product			✓ CECP		
IIa	Non-implantable		✓ (SSCP)	sample/device category		✓ (SSCP)	
			✓	sample/device category		✓	✓ (SSCP)
I sterile condition/measuring function/reusable surgical instrument)			✓			✓	
III custom-made implantable (a certificate is needed only for implantable devices)			✓				
System/Procedure pack (SPP: sterilisation)			✓			✓	

29.3 par #1: MF assigns a Basic UDI-DI before it applies to a NB

29.3 par #2: NB confirms the concerned device data in registering the certificate in Eudamed. As a pre-requisite the MF provides the certificate identification information with submission of Basic UDI-DI data in Eudamed.

Reminder that only Class III CECP or a QMS certificate (in case there is no EU TDA certificate or EU Type examination certificate)

CECP could apply from MDR but it was agreed that CECP is never to be applied for custom-made devices

(NB) = Same NB carries the conformity assessments.

(CECP) = Should requires a CECP

SSCP is required for implantable and class III devices. If the device needs both a product and a quality certificate then the SSCP is only uploaded with the product certificate.

