



European
Commission

UDI/DEVICES USER GUIDE

Version: 2.0

Production 2.0 September 2021



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1. Introduction

The new MDR 2017/745 and IVDR 2017/746 EU regulations introduce an EU identification system for medical devices based on a Unique Device Identifier (UDI) and require that manufacturers of medical devices submit the UDI/Device information of all devices/products that they place on the market.

The UDI-DI/Device module of EUDAMED is used for this purpose.

[MDR 2017/745](#) further states that '*Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack*'. EUDAMED allows system or procedure pack producers to register their packs in a similar manner as manufacturers register their devices.

A step-by-step wizard will guide you through the respective registration processes. Please make sure that you understand all concepts and have all information at hand before starting to register a new UDI/device or a system or procedure pack.

1.1. Basic Concepts

The UDI (Unique Device Identification) system is a new feature introduced by the [MDR 2017/745](#) and [IVDR 2017/746](#) EU regulations. It will improve the traceability of medical devices, enhance post-market safety-related activities and allow for better monitoring by competent authorities.

- **BASIC UDI-DI**
This is the main access key for device-related information in the EUDAMED database. It is referenced in various other documents [e.g. certificates (including certificate of free sale), EU declaration of conformity, technical documentation and summary of safety and (clinical) performance)]. All devices with the same Basic UDI-DI share the same core characteristics such as intended purpose, risk class, essential design and manufacturing characteristics. The Basic UDI-DI information entered in EUDAMED includes this core information plus a unique Basic UDI-DI code issued by an officially designated issuing entity. It is independent/separate from the packaging/labelling of the device and does not appear on any trade item.
- **UDI-DI**
The UDI is the *main* identifier of a medical device used on its label. It identifies the specific device within a given product family. The UDI-DI is a numeric or alphanumeric code relating to a medical device.
- **(PACKAGE UDI-DI)**
If applicable, each device may have an additional, higher-level UDI-DI assigned to its higher package. Package UDI-DIs identify each package configuration, including quantities of items at each package level.

A Basic UDI-DI always references at least one UDI-DI, while multiple UDI-DIs can be referencing the same Basic UDI-DI.

Legacy Devices

Legacy devices are defined as medical devices, active implantable medical devices and in vitro diagnostic medical devices - covered by a valid Directive certificate - that will continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR). Legacy devices shall be registered in some cases in EUDAMED without a Basic UDI-DI and without a UDI-DI.

A Legacy Device has to have an assigned EUDAMED DI (instead of a Basic UDI-DI), and in some cases (when no UDI-DI was already assigned) a EUDAMED ID (instead of the UDI-DI), and has to be registered in the 'UDI/Device module' of EUDAMED, allowing EUDAMED to work as close as possible like Regulation Devices.

- **EUDAMED DI**

The EUDAMED DI corresponds to the Basic UDI-DI. It can either be entirely generated by EUDAMED if a UDI-DI has already been assigned to the legacy device, or the DI code can be partly assigned by the manufacturer (EUDAMED is the issuing entity for a EUDAMED DI)

- **EUDAMED ID**

The EUDAMED ID corresponds to the UDI-DI. In case a UDI-DI has not already been assigned, the EUDAMED ID will always be automatically and fully generated by EUDAMED from the EUDAMED DI.

2. Getting Started

Prerequisites to access EUDAMED:

[EU Login \(ECAS\) account](#)

If you do not have an EU account, please follow the instructions for creating an account and requesting access from the competent authority before attempting to use the database.

For information on how to gain access to EUDAMED, please consult the User's Guide for Economic Operators available for download on the [EUDAMED Playground](#).

Every user in EUDAMED is granted the profile "Viewer" and can search and view registered devices. In order to register a device in EUDAMED, you must request access to the Device module as:

- A "Proposer" profile may create and delete draft records in the Device module
- A "Confirmer" profile may also submit and discard records in the Device module

If you have already registered as a user in EUDAMED prior to the release of this version, in order to create and submit records you must submit a profile change request to upgrade your user profile in the Device module to "Proposer" or "Confirmer".

Important: The Local Actor Administrator (LAA) must approve your user access request before you may enter any devices for your actor. As a user cannot approve their own profile change requests, these requests must be approved by a **different** Local Actor/User Administrator.

Before you start entering details of a UDI/device in EUDAMED, please make sure that you have all requested information at hand, including the Basic UDI-DI and UDI-DI codes.

3. Registering Regulation Devices

Click on the following link to arrive to EUDAMED Playground:

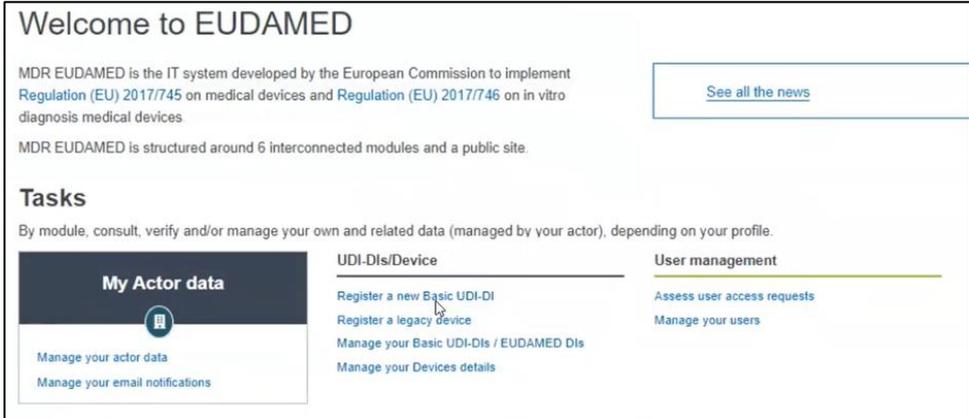
<https://webgate.training.ec.europa.eu/eudamed-play/>.

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

3.1. Registration of Basic UDI-DI together with the first UDI-DI

3.1.1 Step 1: Basic UDI-DI identification information

1. Start by clicking on “Register a new Basic UDI-DI”:



Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

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

2. On the next page, you may start entering the Basic UDI-DI information for your device. Select the applicable legislation for your Basic UDI-DI, from the two following options:

Note: For the rest of the procedure, we will assume in this quick user guide that you have selected MDR (Regulation (EU) 2017/745).



UDI-DI registration

Manufacturer identification

Organisation name:	EU_MF_IJONUT
SRN:	BE-MF-000000002
Address:	11221 BRussels
Telephone number:	-
Email:	test@test.com

* Applicable regulation

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

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

Note: Based on the selected Applicable Legislation, the set of properties (characteristics of the Device) that may be entered will vary.

An additional question appears at the bottom of the page depending on the regulation that you have selected i.e.:

REGULATION	ADDITIONAL QUESTION
MDR	Is it a System or Procedure Pack which is a Device in itself? + additional sub-questions about the device type, depending on whether you answer 'Yes' or 'No' to this first question
IVDR	Is it a kit? + additional sub-question about the device type, if you answer 'No' to this first question

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

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

Procedure Pack which is a Device in itself

System which is a Device in itself

Select the correct configuration. If you select “No”, indicating that you are entering a device, prompts for further details about the device (Special Device type) will appear:

Special device type

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

* Special device type:

Software

Standard soft contact lenses

Rigid Gas Permeable (RGP) Contact Lenses

Made to order soft contact lenses

Spectacle frames

Spectacle lenses

Ready-made reading spectacles

Orthopedic

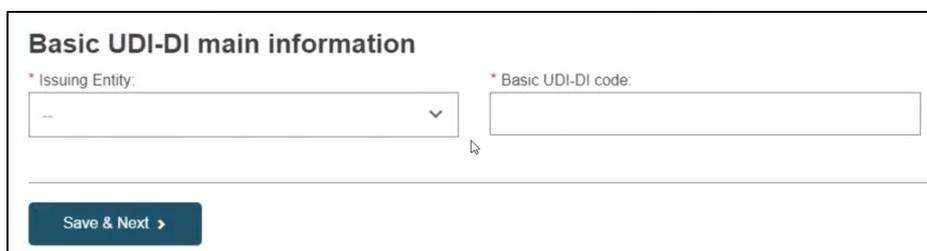
Note :

Registration of Devices having as Device one of the following Special Device types : Standard soft contact lenses, Rigid Gas Permeable (RGP) Contact Lenses, Made to order soft contact lenses, Spectacle frames, Spectacle lenses or Ready-made reading spectacles , is not possible in the current phase.

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

Important: EUDAMED will perform a validation for the Basic UDI-DI code provided based on the specific format provided by each Issuing Entity. Please ensure that you provide the correct value.

Basic UDI-DI duplicates cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value.



Basic UDI-DI main information

* Issuing Entity:

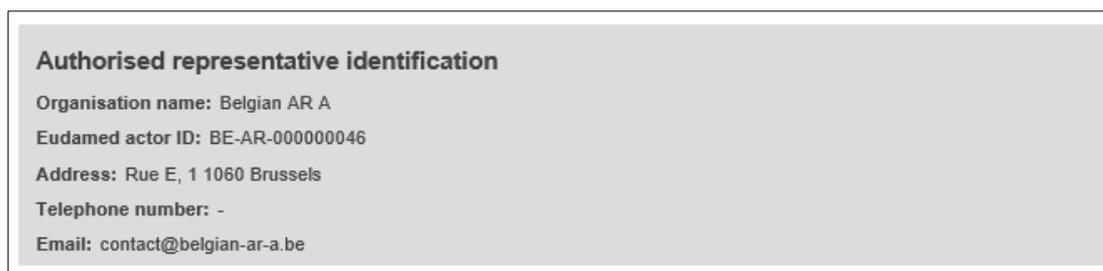
* Basic UDI-DI code:

[Save & Next >](#)

4. Select the authorised representative for the current device (Basic UDI-DI) from the options available (applicable only in case of Non EU Manufacturers).

Note: The authorised representative and the manufacturer must have an active Mandate in order to assign the authorised representative for the device.

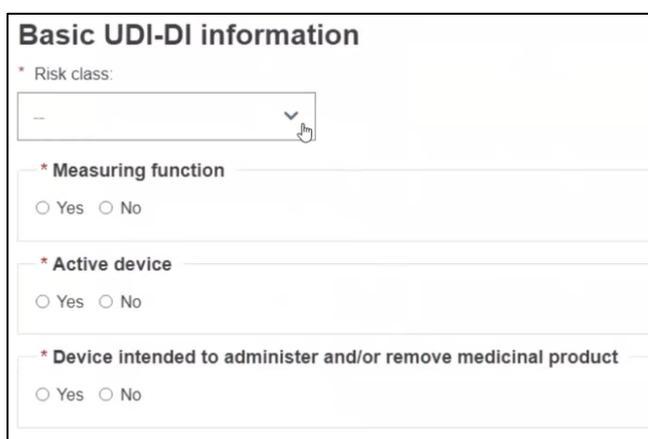
If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically selected:



Authorised representative identification

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

5. On the next page, you must choose a Risk Class and select “Yes” or “No” for each option that follows. **Note: these options change depending on your previous selections as the applicable legislation of the device can influence the properties:**



Basic UDI-DI information

* Risk class:

* Measuring function Yes No

* Active device Yes No

* Device intended to administer and/or remove medicinal product Yes No

6. Select “Yes” or “No” if a model is applicable and enter the name or number, and enter the device name if available:



The screenshot shows a form section titled "Device model applicable". It features a toggle switch for "Yes" (which is currently turned on) and a "No" option. To the right of the toggle is an information icon and the text "Device model is required by default unless you select the option - No". Below this is a text input field labeled "* Device model:" containing the text "Device Model_Test". At the bottom of the section is a text input field labeled "Device Name:" which is currently empty.

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



3.1.2 Step 2: Certificate information

Select the certificate type and enter some or all of the Notified Body name(s) or number(s). Click on “Find” and select the correct Notified Body from the new window. Optionally, provide the certificate number and revision number and click on “Save” or “Save & Next”.

Note: Certificate Information must be provided for Basic UDI-DIs which require confirmation from the Notified Body for the data provided in the UDI/Device module.

In Annex 1 to this User Guide you can find the different device cases (different device properties) in which Certificate information is required to be provided for the Device and the type of certificate that should be provided in each case apart.

This section will become active based on the selection made for Risk Class and additional properties in the Basic UDI-DI:

Certificate information

*** Certificate Type**

EU technical documentation assessment certificate (Annex IX Chapter II)

EU type-examination certificate (Annex X)

*** Enter NB number or name:**

Certificate number:

Revision number:

3.1.3 Step 3 : UDI-DI identification information

1. Select the “Issuing Entity” from the dropdown list and enter the UDI-DI code.

Important: The provided UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Note : In case of GS1 Issuing Entity, the UDI-DI code provided must have 14 characters

As an exception to this rule, the same UDI-DI can be used for different Devices if one is a Legacy Device and one is a Regulation Device, i.e. a device is initially registered under a Legacy Legislation and is later certified under a Regulation Legislation.

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 was created between the two devices (the Regulation and the Legacy Device).

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

UDI-DI identification

UDI-DI identification

* Issuing Entity:

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

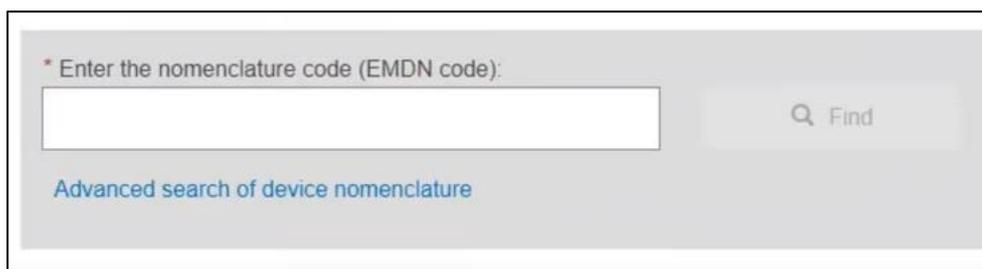
* Issuing Entity:

* Secondary UDI-DI value:

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

Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time.



* Enter the nomenclature code (EMDN code):

Find

[Advanced search of device nomenclature](#)

4. Enter the trade name (as it appears on the device label) and select the language, otherwise, select “No”:



Trade name applicable

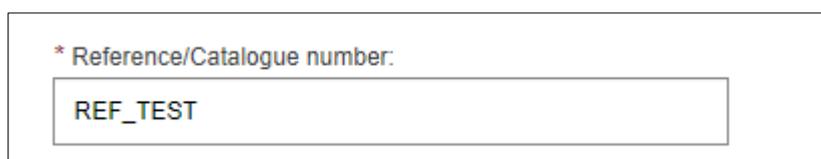
Yes No Trade name is required unless you select the option - No

* Trade name:

* Select the language:

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

5. Enter the Reference number (as found on the device label):



* Reference/Catalogue number:

6. Enter details on whether the device is directly marked or not and specify the identifier (Direct Marking DI or Unit of Use DI):

- If the device is directly marked, the Direct marking DI is required. This can be same as the UDI-DI or can be another UDI-DI.
- If the device is not directly marked and the base quantity of the device is greater than one, the Unit of Use DI should be provided. The 'Unit of Use DI' box is used to enter the actual unique DI code assigned to the lowest unit of use that is used for the patient. Issuing entity for this DI Code is the same as the UDI-DI. This can at first registration or later (e.g. when performing an update of the device).
- The same Unit of Use DI can be used for several Devices.

* Is the device directly marked?

Yes No

Same as UDI-DI

* Issuing Entity:

* Direct marking DI:

7. Provide the quantity of devices (the number of devices within a package identified by the specified UDI-DI) and select the type of UDI-PI:

Note: UDI-PI describes the manner in which production of the device is controlled.

* Quantity of device:

* Type of UDI-PI

Lot or Batch number

Serial number

Manufacturing date

Expiration date

8. Enter any additional information about the product (any additional information or details about specific features of the device), select the language and enter a URL if you have one for additional information online:

Additional product description:

Select the language:

Bulgarian

Croatian

Czech

Danish

Dutch

English

+ Add additional product description in another language

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

9. Select whether it is on the EU market or not and click on "Save" or "Save & Next":

* UDI-DI status

Not intended for the EU market

On the EU Market

Save Save & Next >

3.1.4 Step 4: UDI-DI Characteristics

1. Select if the clinical size is applicable for the UDI-DI and choose the correct values in the dropdown lists below:

Note: When the selected Clinical size type has option Other, user will be required to provide the Description of the Clinical size type and the language in which the description is given. Same behaviour applies for Measure unit.

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

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

Clinical size
Select type(s) of dimension you need

* Type:
OTHER ▾

* Description (for 'Type'):

* Select the language:
- ▾

+ [Add Type description in another language](#)

* Precision: Value ▾ * Size: * Measure unit: /litre (/L) ▾

+ [Add a type of dimension](#)

2. Select “Yes” or “No” for each option prompted:

*** Labelled as single use**

Yes No

Maximum number of reuses applicable

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

*** Need for sterilisation before use**

Yes No

*** Device labelled as sterile**

Yes No

*** Containing latex**

Yes No

*** CMR/Endocrine disruptor**

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

Yes No

3. Enter the CMR/Endocrine disruptor substances. Select the appropriate option to indicate if the device is labelled with an indication of the presence of substances. When registering CMR or Endocrine substances you may optionally provide the EC# or CAS#. If provided, only the Name of substance is required (i.e. the language is no longer required):

*** CMR/Endocrine disruptor**

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

Yes No

*** Category of CMR:**

1A 1B

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

EC#: CAS#:

[ECHA database >](#)

*** Name of the substance:**

 [Add a CMR substance](#)

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

Yes No

4. Select “Yes” or “No” for the Storage/handling conditions, if applicable, and provide the desired values by selecting from the options provided and by entering a description:

Storage/handling conditions, if applicable

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

* Storage/handling conditions type: Description:

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

5. Repeat for Critical warnings or contraindications, and click “Save” or “Save & Next”:

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](#)

3.1.5 Step 5: Device information

1. Select “Yes” or “No” for the first device information options:

Device information

* Reprocessed single use device

Yes No

* Intended purpose other than medical (Annex XVI)

Yes No

2. If you select “Yes” for the intended purpose other than medical (Annex XVI), options will appear. Select the correct purposes:

*** Intended purpose other than medical (Annex XVI)**

Yes No

Contact lenses

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

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

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

High intensity electromagnetic radiation

Brain electrostimulation

3. Select “Yes” or “No” if the device was designed by another legal or natural person. If you know the SRN, enter here:

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

Yes No

I know the SRN

* Enter SRN or name:

4. If you do not know the SRN, uncheck the box and complete the required fields:

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

PO box:

Latitude: Longitude:

Latitude format example: -15.4543 Longitude format example: 178.34354353

* City name: * Postal code:

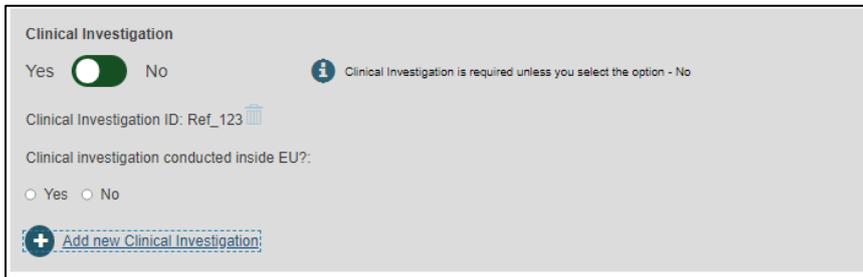
* Country:

Telephone:

Telephone format example: +32 x xxx xx xx

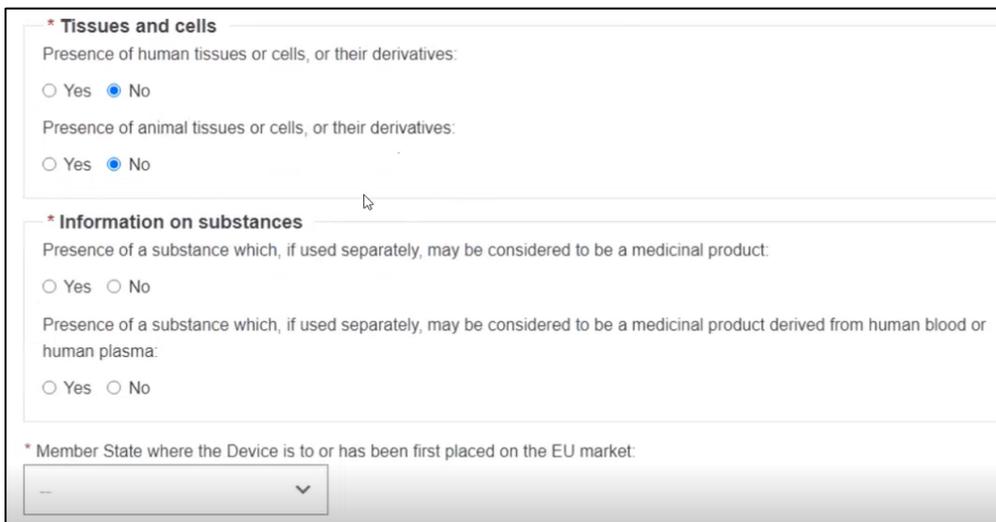
* Email:

5. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI:



The screenshot shows a form titled "Clinical Investigation". At the top, there are two radio buttons: "Yes" (which is selected) and "No". To the right of these buttons is an information icon and the text "Clinical Investigation is required unless you select the option - No". Below this, there is a text field labeled "Clinical Investigation ID:" containing the value "Ref_123". Underneath, there is a question "Clinical investigation conducted inside EU?" with two radio buttons: "Yes" and "No". At the bottom of the form, there is a button with a plus sign and the text "Add new Clinical Investigation:".

6. Select “Yes” or “No” to complete information on tissues and cells, and information on substances:



The screenshot shows two sections of a form. The first section is titled "* Tissues and cells" and contains two questions: "Presence of human tissues or cells, or their derivatives:" with radio buttons for "Yes" and "No" (where "No" is selected), and "Presence of animal tissues or cells, or their derivatives:" with radio buttons for "Yes" and "No" (where "No" is selected). The second section is titled "* Information on substances" and contains two questions: "Presence of a substance which, if used separately, may be considered to be a medicinal product:" with radio buttons for "Yes" and "No", and "Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:" with radio buttons for "Yes" and "No". At the bottom of the form, there is a question "* Member State where the Device is to or has been first placed on the EU market:" followed by a dropdown menu.

7. If you answer “Yes” to the presence of a substance which, if used separately, may be considered to be a medicinal product or a human product derived from human blood or plasma, enter details about the substance name and language in which it is provided and optionally the INN (International Non-proprietary Name):

*** 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

8. Select a Member State from the dropdown list where the device was or will be 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:

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

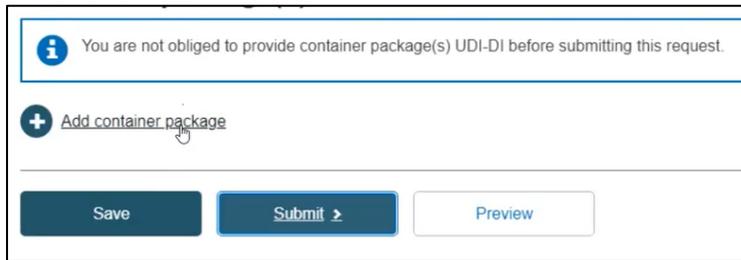
[* Select one or more countries >](#)

Note: This field may be optional or required, based on the properties selected earlier for the device (Basic UDI-DI and UDI-DI). If the device (UDI-DI) has the status “Not intended for EU Market”, this information cannot be provided.

3.1.6 Step 6: Container Package details

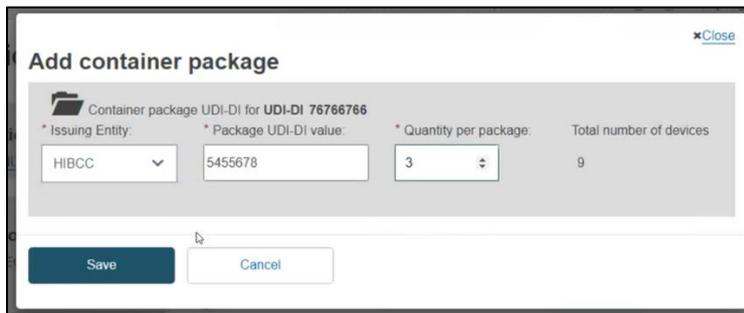
Container Package information is optional to complete. This page allows users to enter the unique UDI-DIs assigned to each package level of the device in order to distinguish between package quantities at each package level, higher level of packaging shall have their own unique UDI:

1. Click on “Add container package” (**Note: this step is not mandatory in order to submit your registration**):

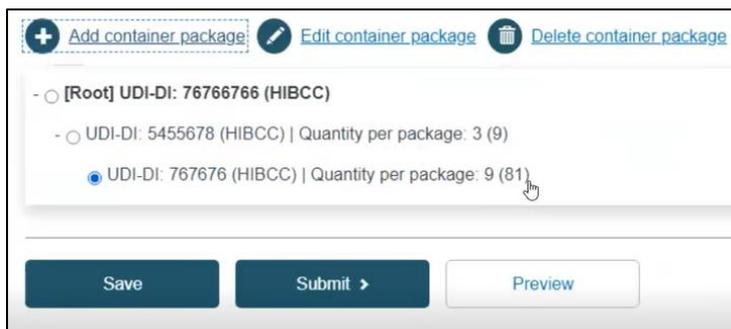


2. Add the Issuing Entity, Package UDI-DI value and the quantity per package, and click “Save”:

Note: The Package UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value.



3. Select the generated information and click on “Submit”:



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

Basic UDI-DI registration

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

What do you want to do now?

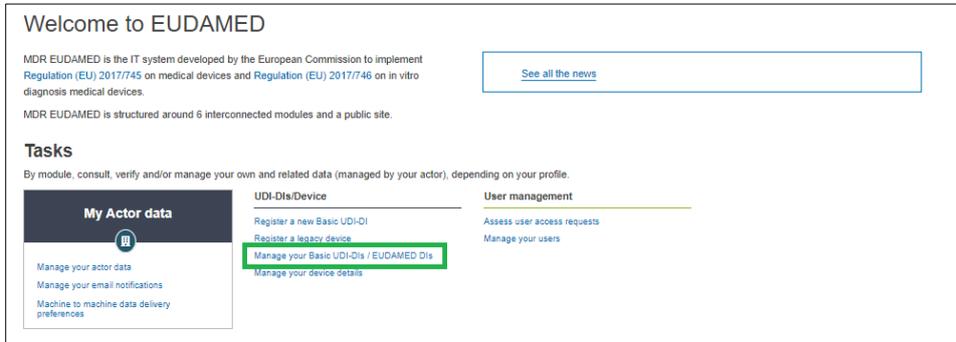
[Enter another UDI-DI associated to Basic UDI-DI 1212123333333345HG](#)
[Register new Basic UDI-DI](#)
[Go to the dashboard](#)

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

- **Registered** if the Basic UDI-DI data does not require a confirmation from the Notified Body;
- **Submitted** if the Basic UDI- DI data requires a confirmation from the Notified Body before being Registered (and being published on the Public website);

3.2. Registration of UDI-DI for an existing Basic UDI-DI

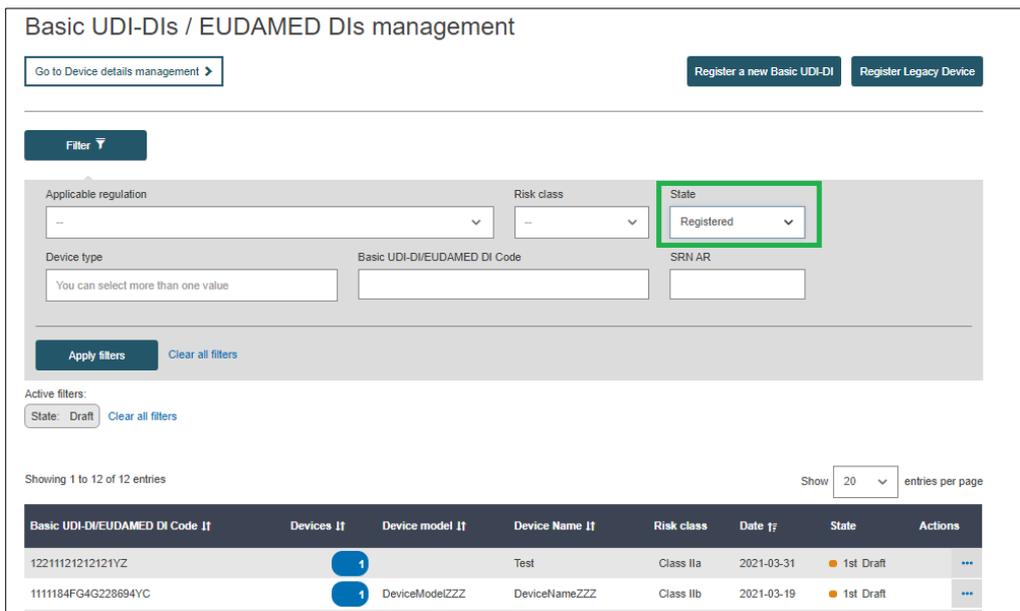
1. From your Dashboard, select “Manage your Basic UDI-DIs/ EUDAMED DIs”:



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

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

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



3. Identify the desired Basic UDI-DI for which you would like to add a new UDI-DI and use the functionality to register a new UDI-DI for this UDI-DI:

Basic UDI-DIs / EUDAMED DIs management

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

Filter ▾

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

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

Basic UDI-DI/EUDAMED DI Code ID	Devices ID	Device model ID	Device Name ID	Risk class	Date	State	Actions
1234503276	1	Model OP		Class IIb	2021-03-30	Registered	...
1234503072	1	Model 88		Class IIb	2021-03-30	Registered	View Data
1234501VP	1	Model 1	Name 1A	Class III	2021-03-30	Registered	View all UDI-DIs for this Basic UDI-DI
B-555900900698	1	MyModel111	MyDeviceName111	Class I	2021-03-30	Registered	Add a UDI-DI to this Basic UDI-DI
1234500VM	1	Model 550		Class IIa	2021-03-08	Registered	...
123450046Z	2	Model 9		Class IIb	2021-03-08	Registered	...
B-2203615490541	1	Model abc	Name abc	Class IIa	2021-03-04	Registered	...

4. Complete the fields required in the wizard for the registration of a UDI-DI for an existing Basic UDI-DI:

Add new UDI-DI to existing Basic UDI

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

Manufacturer identification
[BE-MF-00000004, Alexandru Release Manufacturer](#)

Basic UDI-DI identification
 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
 Basic UDI-DI code: 1234503276
 Issuing Entity: GS1

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

UDI-DI identification

UDI-DI identification

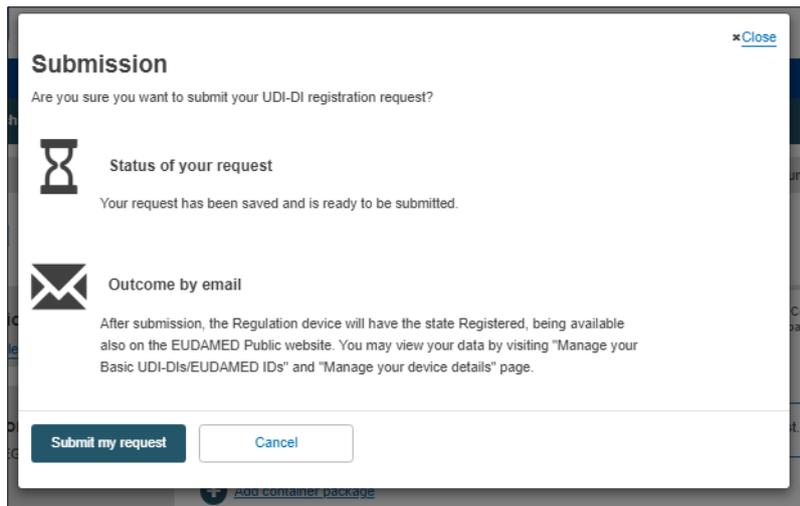
* Issuing Entity: * UDI-DI code:

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](#)

6. Submit the UDI-DI:

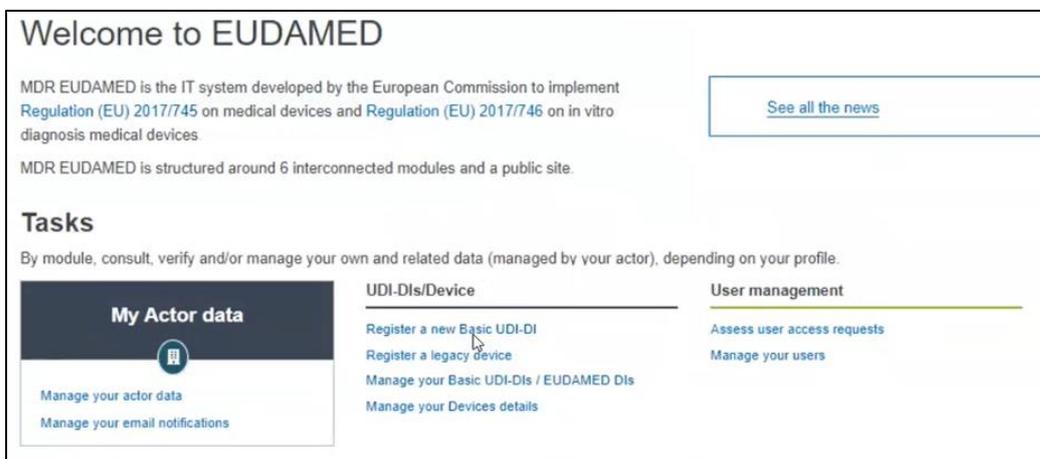


Important: After Submitting the UDI-DI, the state of the UDI-DI will be:

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

4. Registering Legacy Devices (EUDAMED DI and UDI-DI/EUDAMED ID)

On the dashboard, click on “Register a Legacy device”:



EUDAMED DIEUDAMED DI

4.1. Step 1: EUDAMED DI Identification Information

1. Select an applicable legislation:

Note: Based on the selected applicable legislation, the set of properties (characteristics of the Device) that can be provided will differ.

Note: For the rest of the procedure, we will assume in this quick user guide that you have selected IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices).

Legacy Device registration

Manufacturer identification	
Organisation name:	Belgian MF A
SRN:	BE-MF-000000041
Address:	Rue A, 1 1060 Brussels
Telephone number:	-
Email:	public-contact@belgian-mf-a.be

* Applicable Legislation

- IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)
- MDD (Directive 93/42/EEC on Medical Devices)
- AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

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

Note: In case no UDI-DI is available, the EUDAMED DI must be provided.

In case UDI-DI is provided for GS1 Issuing Entity, the UDI-DI code provided must have 14 characters.

The EUDAMED DI can be generated outside EUDAMED (using the provided algorithm for the generation of EUDAMED DI) or can be generated within the registration process by providing the manufacturer's device identifier and allowing EUDAMED to generate it.

If a UDI-DI is provided, it must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Exception: The same UDI-DI can be used for the same legacy and Regulation device, whereby a device is initially registered under a legacy legislation and is later certified under a Regulation-applicable legislation). In this case, you will be prompted that a link will be created between the two devices (the Regulation and the Legacy Device).

UDI-DI assigned for the current legacy Device?

Yes No

* Issuing Entity: * UDI-DI code:

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

Generate

3. Select whether it is a kit or not, if you select “Yes” you can move on to the next step, otherwise fill in the remaining information:

Basic UDI-DI main information

* Is it a kit?

Yes No

Special device type

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

* Special device type:

Software

4. Select the authorised representative for the current device (Basic UDI-DI) from the options available (applicable only in case of non-EU manufacturers).

Note: The authorised representative and the manufacturer must have an active Mandate in order to be able to assign the authorised representative to the Device.

If there is only one authorised representative with an active Mandate with the manufacturer, it will be automatically selected:

Authorised representative identification

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

5. On the side you will be shown a small description of the device. Select a “Risk class” from the list and select “Yes” or “No” for each of the options.

Risk Class options are dependent on the Applicable Legislation of the Device and have an influence over the properties which must be provided later.

Legacy device registration

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

Manufacturer identification
BE.MF.000000041_Belgian MFA

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

EUDAMED DI information

* Risk class:
--

* Near-patient testing
 Yes No

* Self-patient testing
 Yes No

* Companion diagnostic
 Yes No

* Reagent
 Yes No

* Instrument
 Yes No

6. Select “Yes” or “No” if the device model needs to be specified, and if available enter a Device name:

Device model applicable

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

* Device model:

Device Name:

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

4.2. Step 2: Certificate information

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

Note: Information on active certificates must be provided for Legacy Devices.

In Annex 2 to this document you may find the Certificate types that can be provided for the Legacy Devices specific for each Applicable legislation of the Device.

Several identification details for several certificates may be provided.

Certificate information

Item #1 

* Certificate Type:

[Change Notified Body](#)

Organisation name: EVPU a.s.
NB number: 1293
Address:
Telephone number: 421 42 44 03 600
Email: hudak@evpu.sk

* Certificate number: Revision number:

* Expiry date: 
YYYY-MM-DD

4.3. Step 3: Device identification information

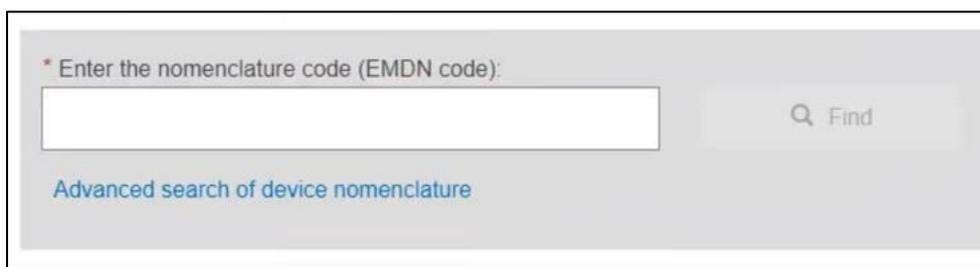
1. EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED ID generated based on the provided/generated EUDAMED DI):



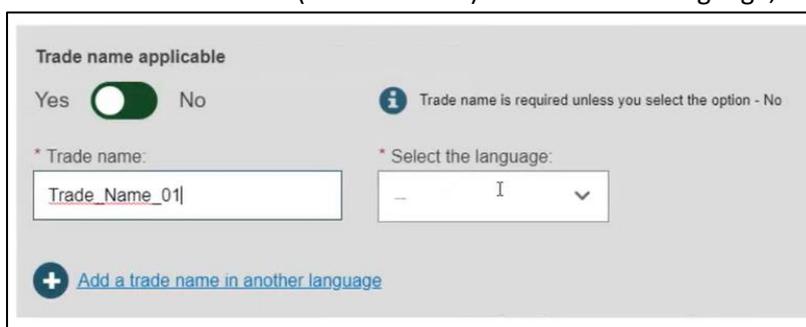
2. Enter the EMDN code. Click on “Find” and select the correct one:

Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time. (The mapping is not fully completed and not reliable and can be used only for facilitating the correct selection of EMDN code)



3. Enter the trade name (if there is one) and select the language, otherwise, select “No”:



4. Enter a reference number and any additional information you might have:

EUDAMED UDI-DI/Devices User guide

* Reference/Catalogue number:

Additional product description:

Select the language:

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

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

* Device status:

5. EUDAMED will display the status of the Device.

Note: In the case of Legacy Devices, the initial status of the Device is considered to be 'On the market'. If the device is 'No longer on the market', an update of the status can be performed on the Device (UDI-DI/EUDAMED ID):

* Device status:

4.4. Step 4: Device characteristics

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

* Labelled as single use
 Yes No

* Need for sterilisation before use
 Yes No

* Device labelled as sterile
 Yes No

Storage/handling conditions, if applicable
Yes No Storage/handling conditions are required unless you select the option - No

* Storage/handling conditions type: Description:

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

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

Storage/handling conditions, if applicable
Yes No Storage/handling conditions are required unless you select the option - No

* Storage/handling conditions type: Description:

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

3. Repeat for Critical warnings or contraindications. After completing, click on “Save” or “Save & Next”:

Critical warnings or contra-indications, if applicable
Yes No Critical warning or contra-indications are required unless you select the option - No

* Critical warning type: Description:

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

4.5. Step 5: Device information

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

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

Yes No

I know the SRN

* Enter SRN or name:

If you select “No”, enter the information manually, fill in all the fields with a red asterisk (the others are optional):

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

PO box:

Latitude:

Latitude format example: -15.4543

Longitude:

Longitude format example: 178.34354353

* City name: * Postal code:

* Country:

Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

2. Select “Yes” or “No” if you want to provide the Clinical Investigation reference for the current UDI-DI/EUDAMED ID:

Clinical Investigation

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

Clinical investigation conducted inside EU?:

Yes No

[Add new Clinical Investigation](#)

3. Select “Yes” or “No” for the three following options

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

Yes No

Presence of animal tissues or cells, or their derivatives:

Yes No

Presence of cells or substances of microbial origin:

Yes No

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

Belgium

4. Select a Member State from the dropdown list where the device was or will be placed on the EU market, and click “Submit” or “Preview”:

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

--

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

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

4. A pop-up window will appear asking you to confirm your submission. Once confirmed, you will be brought to a new page showing you succeeded in registering your Legacy device:

Legacy Device registration

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

What do you want to do now?

[Register a legacy device](#)

[Go to the dashboard](#)

5. Registering System or Procedure Packs

5.1. Registration of Basic UDI-DI together with the first UDI-DI for System or Procedure Packs

5.1.1 Step 1: Basic UDI-DI Identification information

1. On the EUDAMED dashboard, click on “Register a New System Procedure Pack”.

The screenshot shows the EUDAMED dashboard interface. At the top, there is a navigation bar with links for Home, Tasks, Search & view, Transmission, News, and Help. The user is logged in as John Smith. Below the navigation bar, the current actor is identified as 'System/Procedure Pack Producer, BE-PR-000000062, AR_SPPP [Belgium]'. The main content area includes a 'Welcome to EUDAMED' message, a 'See all the news' button, and a 'Tasks' section. Under the 'Tasks' section, the 'System or Procedure Pack' category is expanded, and the 'Register a new System Procedure Pack' button is highlighted with a red box.

2. On the next page, you may register the Basic UDI-DI information for your system or procedure pack, i.e. the Basic UDI-DI Issuing entity and code.

The screenshot shows the 'System or Procedure Pack registration' form. The 'Procedure pack producer identification' section is pre-filled with the following information:

Organisation name:	AR_SPPP
SRN:	BE-PR-000000062
Address:	8686 Brussels
Telephone number:	-
Email:	ar_sppp@abc.com

The 'Applicable regulation' section is pre-selected as 'MDR (REGULATION (EU) 2017/745 on medical devices)'. The 'Basic UDI-DI main information' section is highlighted with a red box and contains two input fields: '* Issuing Entity:' (a dropdown menu) and '* Basic UDI-DI code:' (a text input field).

Note: The applicable legislation (MDR) for system and procedure packs will be pre-selected by default.

Important: EUDAMED will perform a validation for the Basic UDI-DI code provided based on the specific format provided by each Issuing Entity. Please ensure that you provide the correct value.

Basic UDI-DI duplicates cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another value:

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

Basic UDI-DI main information

* Issuing Entity: 

* Basic UDI-DI code:

 **Duplicate device identified.**

* **System or Procedure Pack type:**

Procedure Pack
 System

3. Choose whether you are registering a system or procedure pack:

* **System or Procedure Pack type:**

Procedure Pack 
 System

4. Click on “Save & Next” to save your registration as a draft and move on to the next steps.

5.1.2 Step 2: Basic UDI-DI information

On the next page, you must provide Basic UDI-DI identification information:

System or Procedure Pack registration

Producer identification
[BE-PR-00000062_AR_SPPP](#)

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

Basic UDI-DI information

* Risk class:
--

* Indication of medical purpose:

* Select the language:
--

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

* Model:

Name:

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

[Save](#) [Save & Next >](#)

1. Choose a Risk Class from the drop-down list:

System or Procedure Pack registration

Producer identification
[BE-PR-00000062_AR_SPPP](#)

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

Basic UDI-DI information

* Risk class:
--

2. Fill in the indication of medical purpose, and select its corresponding language:

* Indication of medical purpose:

* Select the language:
--

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

You may choose to add the indication in several languages, in which case you have to click on “Add another indication of medical purpose” and select its language from the drop-down list.

3. Select “Yes” or “No” if a device model is applicable. If you selected “Yes”, enter the device model and the device name if available:

The screenshot shows a form section titled "Device model applicable". It features a toggle switch set to "Yes" and an information icon with the text "Device model is required by default unless you select the option - No". Below this is a required field labeled "* Model:" with an empty text input box. Underneath the "Model" field is a "Name:" label followed by another empty text input box.

4. Click on "Save" to save your registration as a draft, or click on "Save & Next" to save it as a draft and proceed to the next steps:

The screenshot shows two buttons: a dark teal button labeled "Save" and a dark teal button labeled "Save & Next >".

5.1.3 Step 3: UDI-DI identification information

1. Select the "Issuing Entity" from the dropdown list and enter the UDI-DI code:

The screenshot shows a form section titled "UDI-DI identification". It contains two required fields: "* Issuing Entity:" which is a dropdown menu currently showing "GS1", and "* UDI-DI code:" which is an empty text input box.

Important: The provided UDI-DI code must be unique in EUDAMED. If it already exists in EUDAMED for the selected Issuing Entity, you will be prompted to provide another.

Note : In case of GS1 Issuing Entity, the UDI-DI code provided must have 14 characters

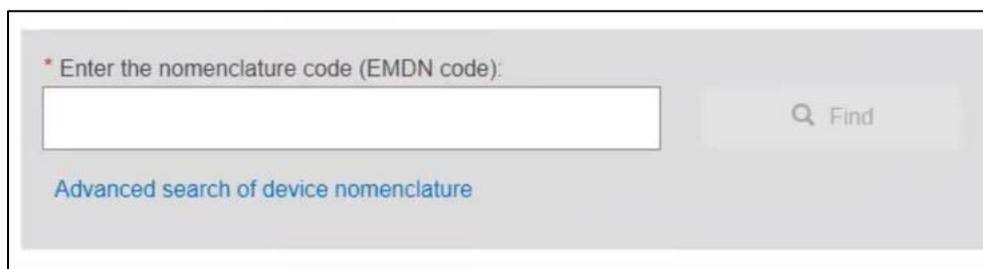
2. Enter the Secondary UDI-DI from a different Issuing Entity to the UDI-DI, if applicable:

The screenshot shows a form section titled "UDI-DI from another entity (secondary) applicable". It features a toggle switch set to "Yes" and an information icon with the text "UDI-DI from another entity is required unless you select the option - No". Below this are two required fields: "* Issuing Entity:" which is a dropdown menu currently showing "-", and "* Secondary UDI-DI value:" which is an empty text input box.

3. Enter the EMDN code (European Medical Device Nomenclature) and click on “Find”:

Note: EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.

The mapping between the EMDN and GMDN provided at this stage in the system is an initial version (draft) mapping, which can change in time. (The mapping is not fully completed and not reliable and can be used only for facilitating the correct selection of EMDN code)



Then select the correct one from the pop-up list and click on “Confirm”. You can add more than one EMDN codes.

4. If applicable, select “Yes” to enter the trade name and select its language:



You can provide trade names in several languages; in which case you have to click on “Add a trade name in another language”.

5. Enter the Reference/Catalogue number:

* Reference/Catalogue number:

REF_TEST

6. Select the type of UDI-PI, which signifies the way in which production is controlled.

You can select more than one type.

Additional product description:

Product Description

Select the language:

Bulgarian
Croatian
Czech
Danish
Dutch
English

+ Add additional product description in another language

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

* Type of UDI-PI

Lot or Batch number

Serial number

Manufacturing date

Expiration date

7. Enter any additional information about the system or procedure pack, select the language of the additional information and enter a URL if you have one for additional information online:

The screenshot shows a progress bar at the top with four steps: 1. Basic UDI-DI information (checked), 2. UDI-DI identification information (checked), 3. UDI-DI characteristics (active), and 4. Container package(s). Below the progress bar, the title "UDI-DI characteristics" is displayed. There are two form fields, each with a red asterisk indicating a required field. The first field is labeled "* Need for sterilisation before use" and contains two radio buttons: "Yes" and "No". The second field is labeled "* Device labelled as sterile" and also contains two radio buttons: "Yes" and "No". A mouse cursor is visible over the "No" radio button in the second field.

8. Select whether the system or procedure pack is intended for the EU market or not and click on “Save” to save as draft or “Save & Next” to continue to the next steps:

5.1.4 Step 4: UDI-DI Characteristics

1. Select “Yes” or “No” for each option prompted regarding sterilisation:
2. Select “Yes” or “No” if storage or handling conditions are applicable:

The screenshot shows the "UDI-DI status" section. It has a red asterisk next to the title. There are two radio buttons: "Not intended for the EU market" and "On the EU Market". The "On the EU Market" option is selected. Below the radio buttons are two buttons: "Save" and "Save & Next >". A mouse cursor is pointing at the "Save & Next >" button.

The screenshot shows the "Storage/handling conditions, if applicable" section. It features a toggle switch for "Yes" (which is turned on) and "No". An information icon and text state: "Storage/handling conditions are required unless you select the option - No". Below this, there are two fields: "* Storage/handling conditions type:" and "Description:". The "Storage/handling conditions type:" field contains a dropdown menu with a plus sign and a mouse cursor hovering over it, with a tooltip that says "open dropdown". At the bottom, there is a plus icon and a link: "Add another storage/handling condition".

If you choose “Yes”, you have to select the conditions type from a dropdown list. Some of these types require a description, which you can provide in the relevant box. You may add several storage and handling conditions types.

Note: If you select “Other” from the Storage/Handling conditions type list, the system requires the description to be provided in several languages:

Storage/handling conditions, if applicable

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

* Storage/handling conditions type:
OTHER *

* Description:
Test

* Select the language:
-

+ Add storage/handling conditions in another language

+ Add another storage/handling condition

3. Select “Yes” or “No” if any critical warnings or contra-indications are applicable (you can add several):

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:
Caution

Description:
Description

+ Add critical warnings or contra-indications

Just like for the previous section, if you choose “Other” for the critical warning type, the system requires you to provide the description in several languages:

Critical warnings or contra-indications, if applicable

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

* Critical warning type: Caution Description: Description

* Critical warning type: OTHER Description: Description

* Description: [Text Area] * Select the language: [Dropdown]

+ Add critical warnings or contra-indications in another language

+ Add critical warnings or contra-indications

4. Click on “Save” to save draft or “Save & Next” to move to the next step of the process:



5.1.5 Step 5: Container Package details

This is the last step for registering a System or Procedure Pack.

1. If you wish to provide information about packaging structures for shipping, click on “Add container package”:

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

Container package(s)

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

+ Add container package

Save Submit > Preview

A pop-up box will appear for you to make your selection:

Container package UDI-DI for UDI-DI 12121221

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

Save Cancel

2. From the drop-down list choose the issuing entity.
3. Enter the Package UDI-DI code and the quantity per package in the boxes provided.
4. Click on “Save” to return to the main page.

You can add several container packages, and also edit or delete the container package information you provided.

Note: the system calculates the total number of devices according to the quantity per package you provided:

Container package(s)

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

+ Add container package | Edit container package | Delete container package

- [Root] UDI-DI: 12121221 (ICCBBA)
 - UDI-DI: 122121 (HIBCC) | Quantity per package: 5 (5)
 - UDI-DI: 434343 (HIBCC) | Quantity per package: 3 (15)

UDI-DI: 434343 (HIBCC) | Quantity per package: 3 | Total number of devices: 15

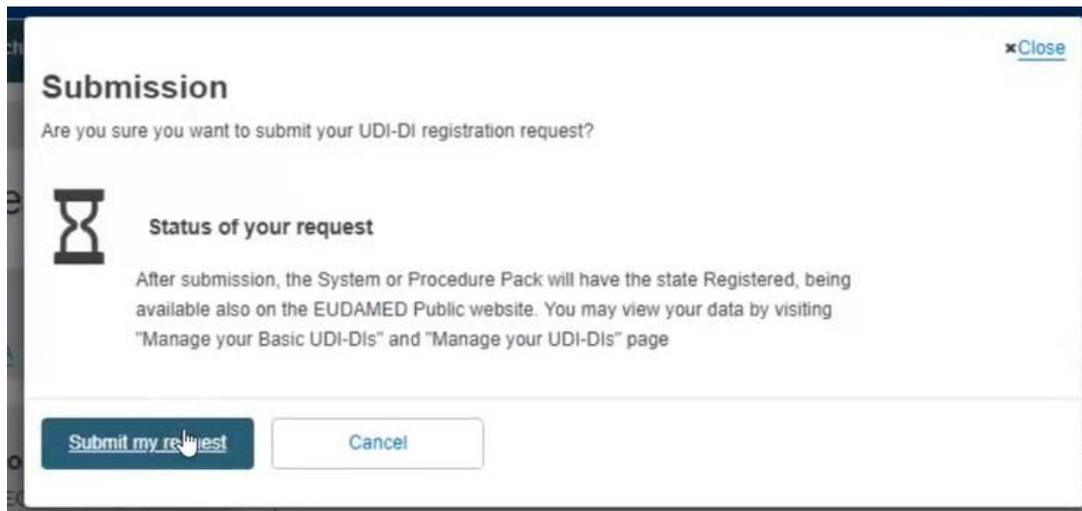
Save Submit > Preview

5. If you are ready to submit the registration, click on “Submit”:

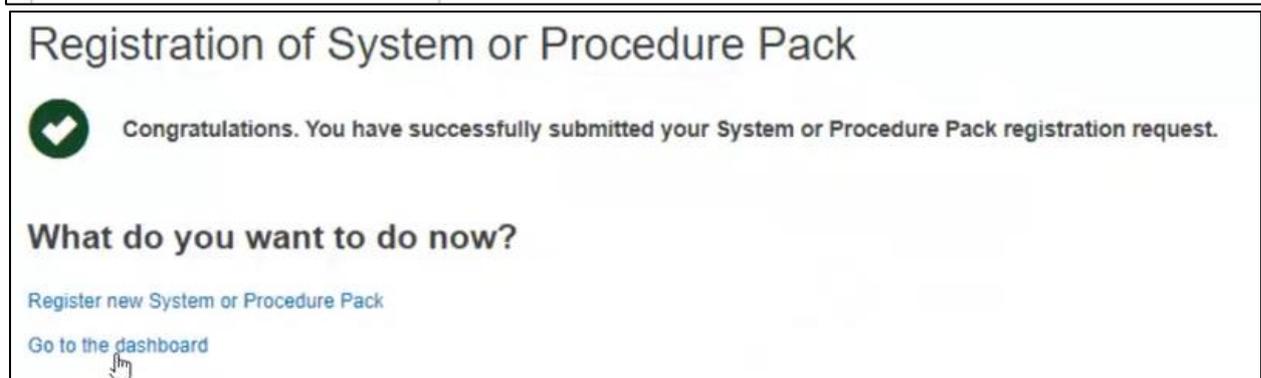
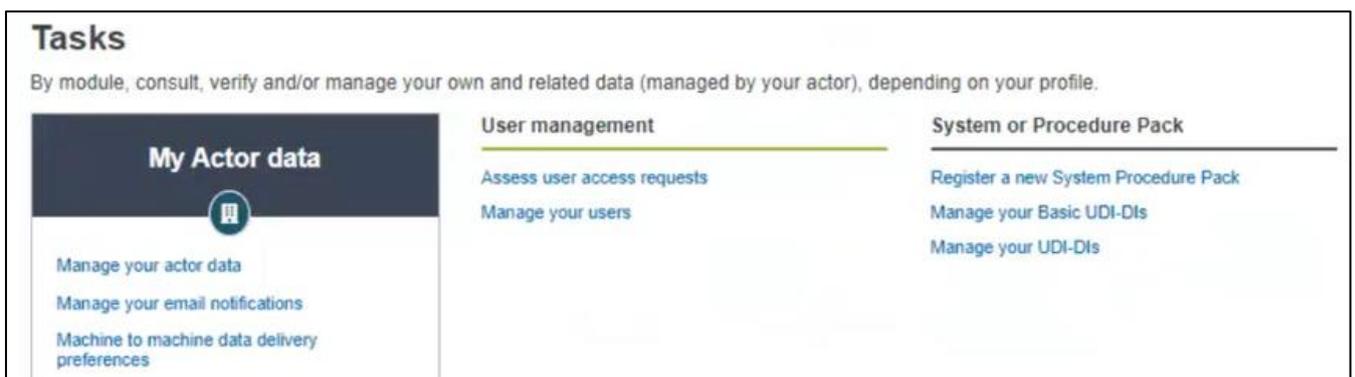
Save Submit > Preview

You also have the option to preview the information of the registration by clicking on “Preview”.

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



Upon submission, you will see a message that you have successfully submitted a System or Procedure Pack registration request:



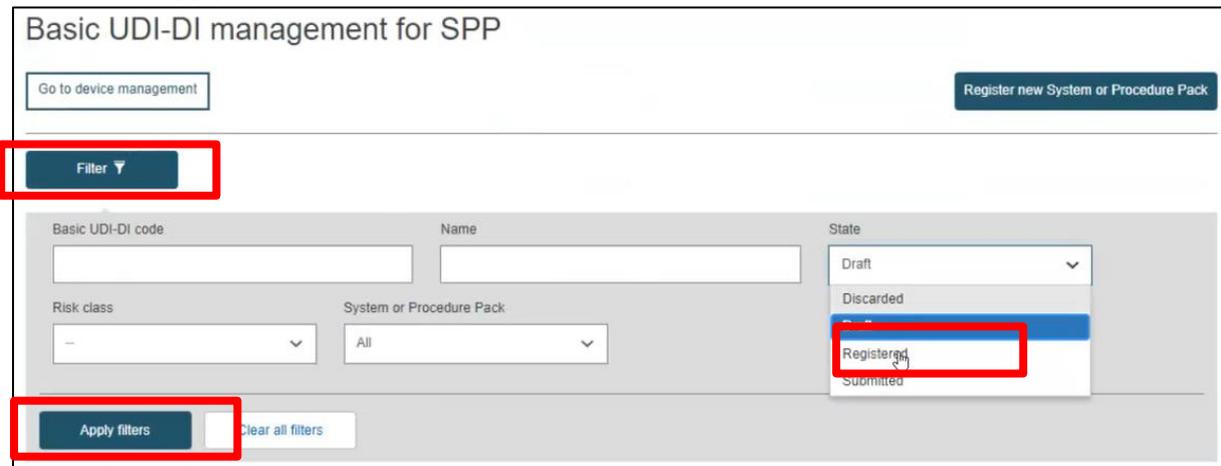
5.2. Registration of UDI-DI for an existing Basic UDI-DI of a System or Procedure Pack

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



2. Filter the Basic UDI-DIs with state “Registered”.

To do that click on the button “Filter”, then select “Registered” in the “State” box and then click on the button “Apply filter”:



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

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

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

The 'Add a UDI-DI for a Basic UDI-DI' option in the Actions menu for the first row is highlighted with a red box.

5.2.1 Step 1: UDI-DI identification information

1. Complete all the fields required in the UDI-DI identification information tab for the registration of a UDI-DI for an existing Basic UDI-DI:

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

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:

* 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):

* UDI-DI status

- Not intended for the EU market
- On the EU market

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

5.2.2 Step 2: UDI-DI Characteristics

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

UDI-DI characteristics

* Need for sterilisation before use Yes No

* Device labelled as sterile Yes No

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

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

* Critical warning type: Description:

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

2. Click on “Save & Next” to move to the next step (alternatively click on “Save” to save the details you have filled in so far as a draft).

5.2.3 Step 3: Container Package details

To complete this step, please consult Section 5.1.5. of this guide.

6. Manage your own Device Information

6.1. View own Basic UDI-DI/EUDAMED DIEUDAMED DI Details

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

The screenshot shows the EUDAMED dashboard. At the top, it says 'CURRENT ACTOR: Manufacturer, BE-MF-000000001, Belgium MF A.V3 [Belgium]'. Below this is a 'Welcome to EUDAMED' section with a 'See all the news' button. The 'Tasks' section is divided into three columns: 'My Actor data', 'User management', and 'UDI-DIs/Device'. In the 'UDI-DIs/Device' column, the option 'Manage your Basic UDIs / EUDAMED DIs' is highlighted with a red box.

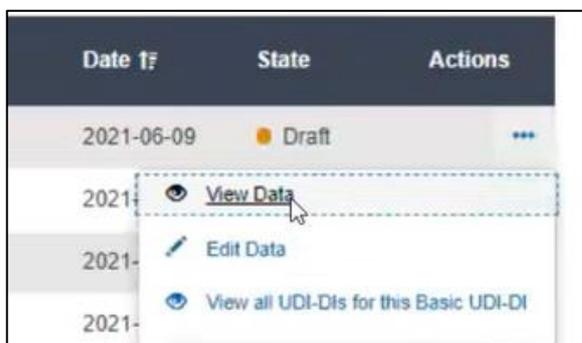
2. You will see a list with all of the Basic UDI-DIs /EUDAMED DIEUDAMED DIs registered to the current actor:

Note: By default, the Basic UDI-DIs/EUDAMED DIs listed are the ones in Draft state. In order to retrieve the desired Basic UDI-DIs/EUDAMED DIs, use the filters available:

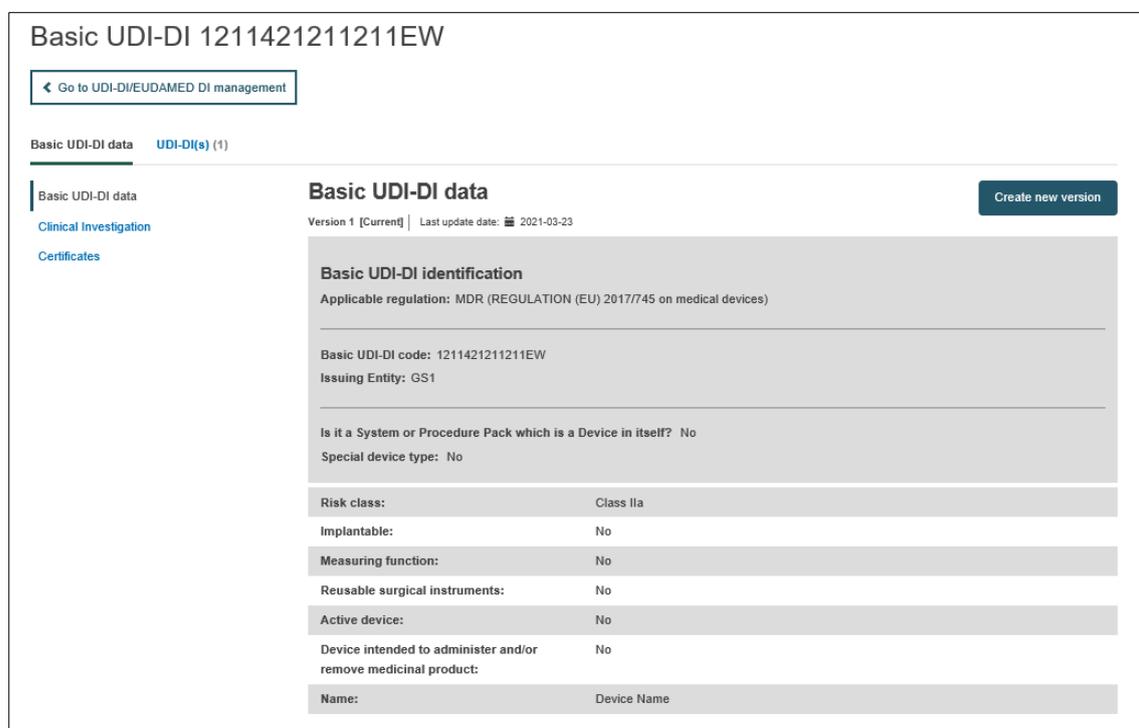
The screenshot shows the 'Basic UDI-DIs / EUDAMED DIs management' page. At the top, there are buttons for 'Go to Device details management', 'Register a new Basic UDI-DI', and 'Register Legacy Device'. A 'Filter' button is highlighted with a red box. Below the filter, there are 'Active filters' (State: Draft) and 'Clear all filters'. The page shows 'Showing 1 to 9 of 9 entries' and a 'Show 20 entries per page' dropdown. The main content is a table with the following data:

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
B-12121EL	1		Test	Class IIb	2021-04-01	1st Draft	...
1212112121U5	1		Test	Class IIa	2021-04-01	1st Draft	...
1211421211211EW	1		Device Name	Class IIa	2021-04-01	Draft	...
312121211212133383	2	Device Model_Test_CLASS IIA_v3	Device Name	Class IIa	2021-03-16	Draft	...
1212123333333343HC	1		test	Class I	2021-02-15	1st Draft	...
12345ABCBY	1		test	Class I	2021-02-05	1st Draft	...

3. Click on the ellipsis symbol (three dots) on the right of the desired item and then click on “View Data” from the menu:



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



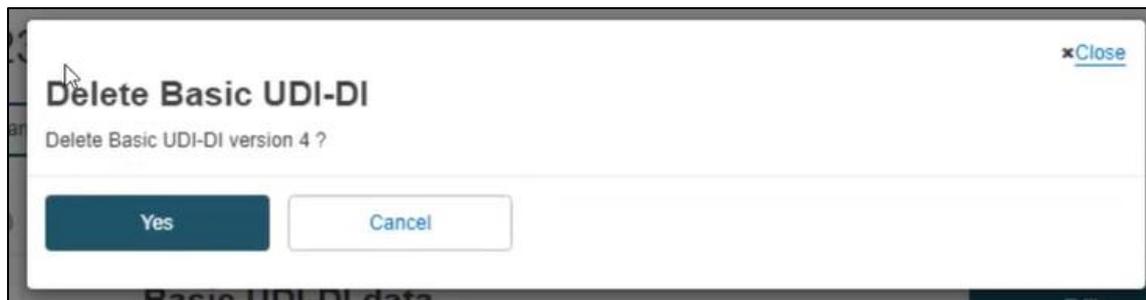
6.1.1 Delete a Draft Basic UDI-DI/EUDAMED DI

After having followed the steps in the previous section 6.1 to view a Draft Basic UDI-DI/EUDAMED DI, you have the option to delete a draft.

1. Once inside the view of the desired draft, click on “Delete”:



2. The system will prompt you to confirm your intention to delete the draft in a pop-up window. If certain, click on “Yes”:

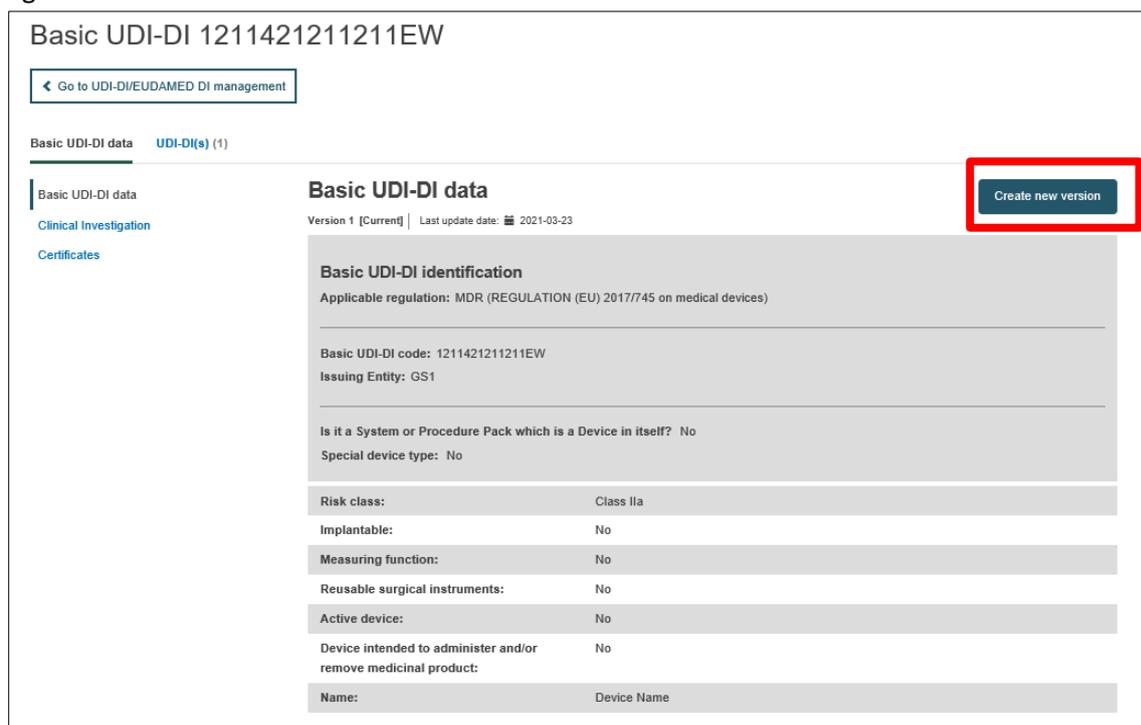


The system will revert you to the latest registered information for this Basic UDI-DI.

6.1.2 Update (Create a new version) for Basic UDI-DI/EUDAMED DI

1. Follow the steps in section 6.1 to view a Basic UDI-DI/EUDAMED DI.

2. Once inside the view mode for the desired Basic UDI-DI, click on “Create new version”, on the top right corner:



3. Update the desired details.

Note: only some details can be updated depending on the actor's specifics, such as device model and device name:

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

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

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

Device model applicable

Yes No Device model applicable

* Device Name:

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

4. To finish the action you have two options:

- Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are uncertain about the update.
- Click on “Submit new version”, if you are certain about the update and wish to finalise it.

Alternatively, you can press “Cancel” to cancel the update.



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

- Follow the steps in section 6.1 to view a Basic UDI-DI/EUDAMED DI.
- Once inside the summary of the desired Basic UDI-DI, click on “See version history” on the top of the table:

Basic UDI-DI data Create new version

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

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

3. View the list of versions for the desired Basic UDI-DI and click on the desired version to view its details:

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

[Go back to the current version](#)

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

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

4. Inside the summary of a version, note that you can browse through the different versions via the browsing function on the top right corner:

[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

6.2. View own UDI-DI/EUDAMED DI Details

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

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

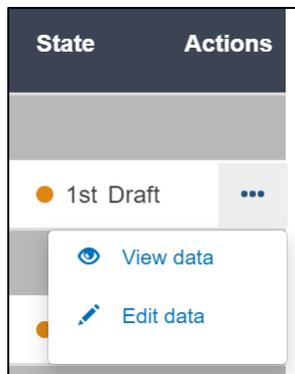
2. You will see a list with all of the devices registered to you:

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

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

Note: By default, the system lists the devices in “Draft” state. In order to retrieve the desired Devices, use the filters available by clicking on “Filter”:

3. On the right-hand side of each device there is an ellipsis symbol (three dots); click on it and then click “View data” from the menu:



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

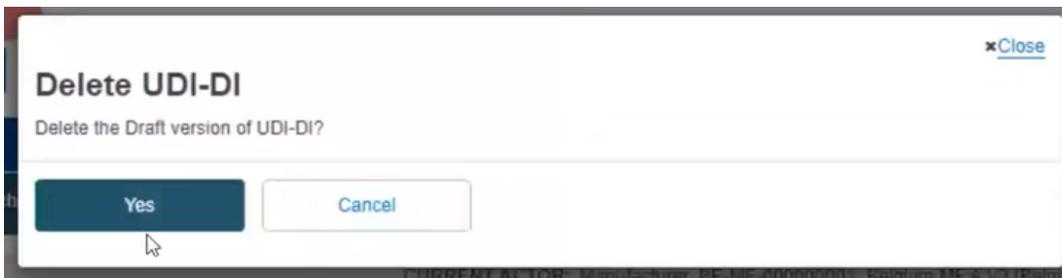
6.2.1 Delete a Draft UDI-DI/EUDAMED DI

1. Follow the steps in Section 6.2. to view a Draft UDI-DI.

2. Once inside the summary for the desired Draft UDI-DI, simply click on “Delete”, on the top right corner:



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



6.2.2 Update (Create a new version) for UDI-DI/EUDAMED DI

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.
2. Once inside the summary of the desired UDI-DI, click on “Create new version”, on the top right corner:

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

3. Update the desired details, for example:

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|

B01 clature

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

Trade name applicable

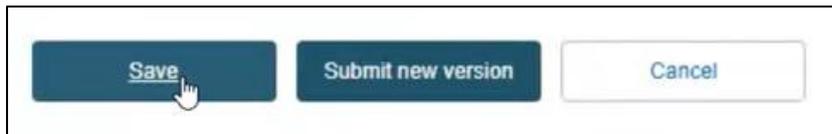
Yes No *Trade name is required unless you select the option - No*

* Trade name: * Select the language:

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

Note: only some details can be updated depending on the actor's specifics.

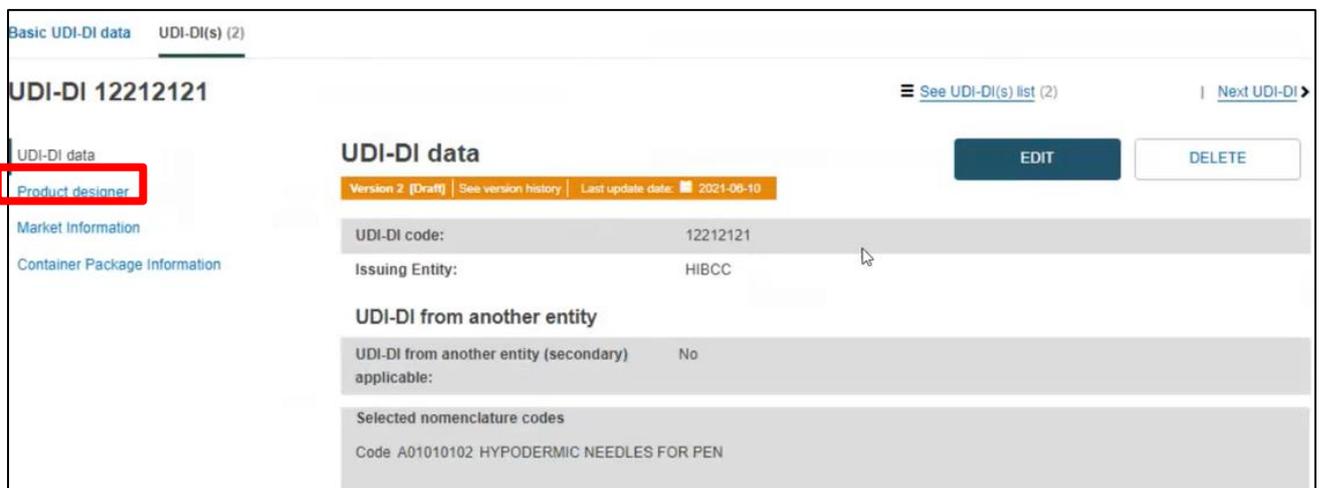
4. To finish the action you have two options:
 - a. “Save” to save the updated details without submitting the new version.
 - b. “Submit new version”, if you wish to finalise the update.



6.2.3 Update (Create new version) for Product Designer

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

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.
2. Once inside the summary of the desired UDI-DI, click on “Product Designer” from the list on the left (or scroll down to the Product Designer section):



3. Click on the “Update” button of the Product Designer section:



4. Update the fields under Product Designer:

Natural or Legal Person update

I know the SRN

* Name (Manufacturer Name):

Street information, if applicable

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

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:

* Country:

5. Click on “Submit” at the bottom of the screen to finalise the update.

You will be able to see the new version created for the “Product Designer” information.

6.2.4 Update (Create new version) for Market Information

The Market information can be updated independently of the rest of the data in a device UDI-DI.

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.
2. Once inside the summary of the desired UDI-DI, click on “Market information” from the list on the left (or scroll down to the Market information section):

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

[Product designer](#)
Market Information
[Container Package Information](#)

Product designer

[Update](#)

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

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

Original equipment manufacturer organisation:

Organisation name:	Test_v2
Street information, if applicable:	Yes
Street:	test
Street number:	-
Address line 2:	-
PO box:	-
City name:	BBBB v2
Postal code:	1111
Country:	Albania
Telephone:	-
Email:	t@t.com

Market Information

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

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

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

[Update countries](#)

3. Click on “Update countries”.

4. Update the relevant fields under “Market information”:

Market information update

Belgium	From	<input type="text"/>	To	<input type="text"/>
		YYYY-MM-DD		YYYY-MM-DD
Finland	From	<input type="text"/>	To	<input type="text"/>
		YYYY-MM-DD		YYYY-MM-DD
Greece	From	<input type="text"/>	To	<input type="text"/>
		YYYY-MM-DD		YYYY-MM-DD
Latvia	From	<input type="text"/>	To	<input type="text"/>
		YYYY-MM-DD		YYYY-MM-DD

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

[Submit](#)

5. Click on “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:	Country	From	To
	Belgium	-	-
	Finland	-	-
	Greece	-	2021-06-09
	Italy	-	-
	Latvia	-	-

6.2.5 Update (Create new version) for Container Packages

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

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.
2. Once inside the summary of the desired UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):

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

UDI-DI data Discard | Create new version

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

Left sidebar: UDI-DI data, Product designer, Market Information, **Container Package Information**

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

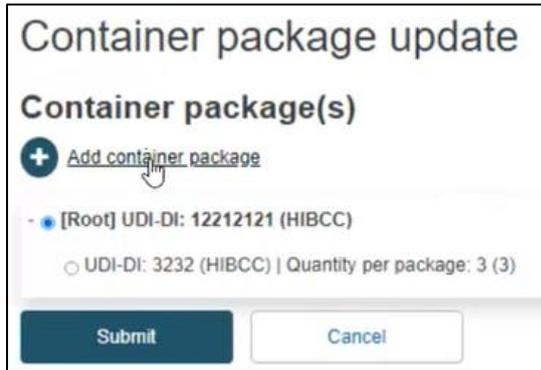
Container Package Information Create new version

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

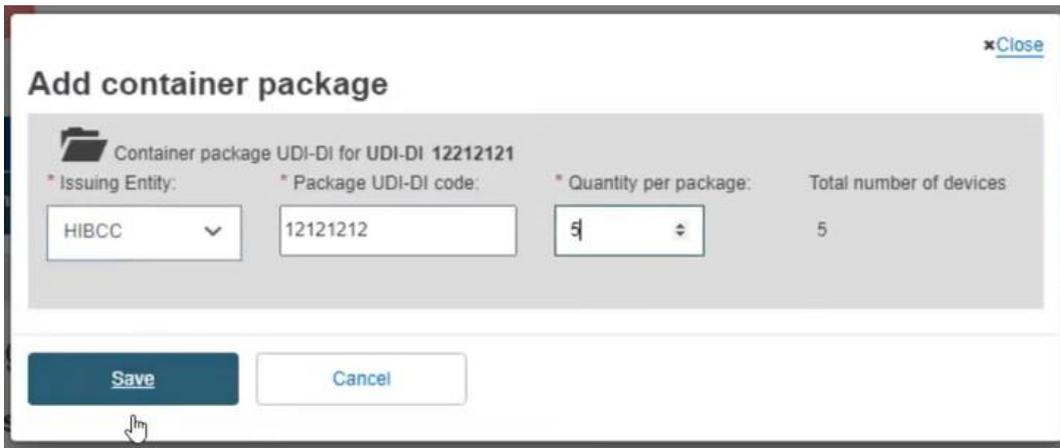
- [Root] UDI-DI: 12212121 (HIBCC)

UDI-DI: 3232 (HIBCC) | Quantity per package: 3 (3)

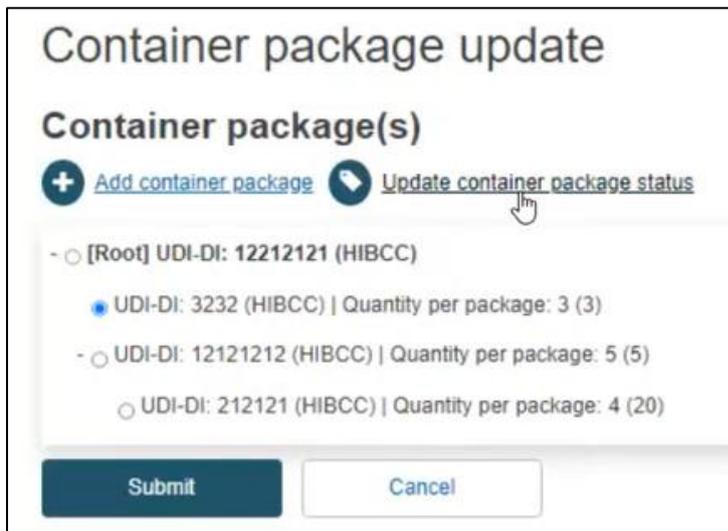
4. Click on “Add container package” to add new information about the packaging format of the device:



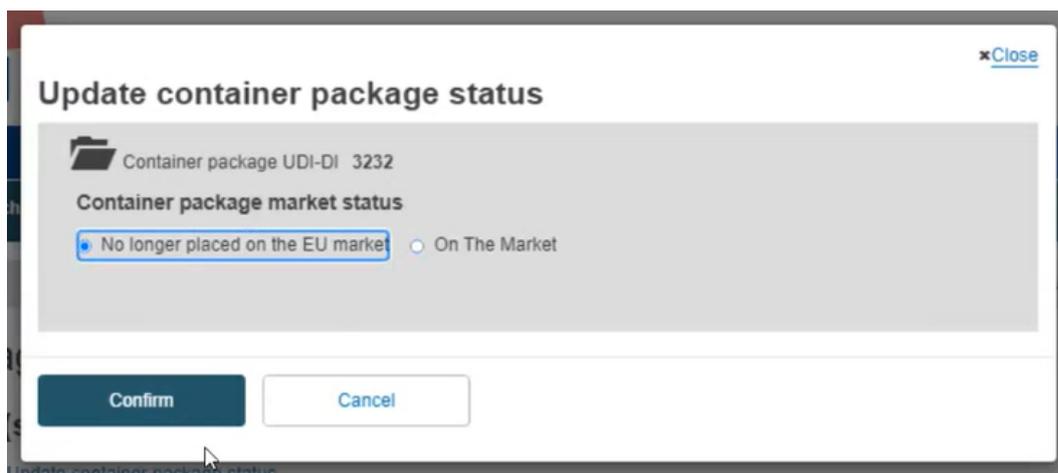
5. Insert the package details in the pop-up window and click on “Save”:



5. Once you add new package details, you also have the option to update the container package status:



6. Update the package market status if needed and click on “Confirm”:



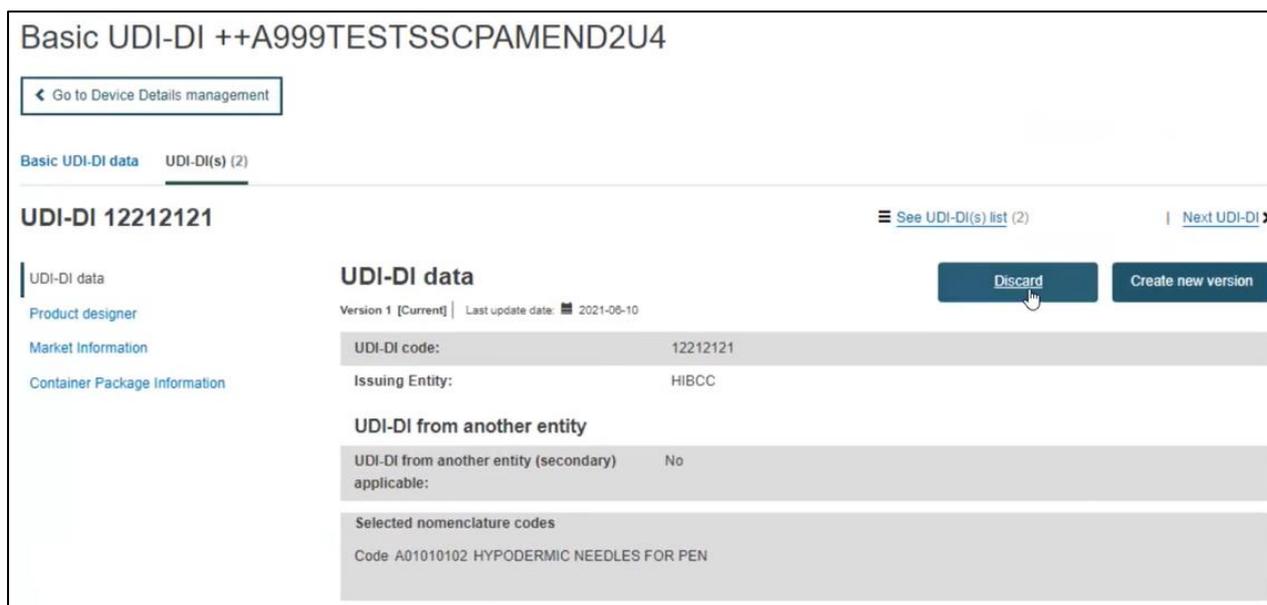
7. Click on "Submit" to finalise the container package update:



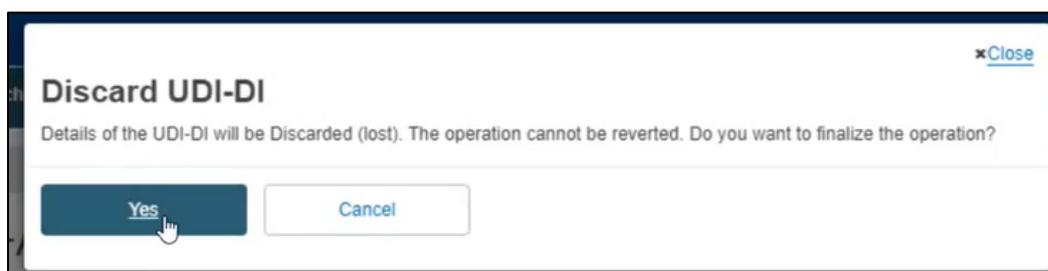
6.2.6 Discard registered UDI-DIs/EUDAMED DIs

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

1. Follow the steps in section 6.2 to view a registered UDI-DI/EUDAMED DI.
2. Once inside the summary of the desired UDI-DI, click on "Discard", on the top right corner:



3. The system will prompt you to confirm your wish to permanently discard the registered UDI-DI. Click on “Yes” to finalise the action:



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

Attention: if the UDI-DI is the only one remaining in this Basic UDI-DI category, performing the “discard” action will also discard the Basic UDI-DI. The system will inform you accordingly:



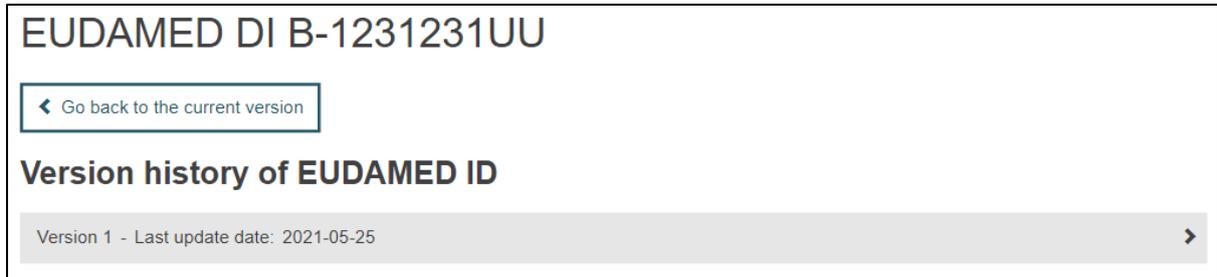
6.2.7 View historical versions of UDI-DI/EUDAMED ID and associated entities

1. Follow the steps in section 6.2 to view a UDI-DI/EUDAMED ID.
2. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:



The screenshot shows the EUDAMED-UI D-1231231UU details page. The page title is "EUDAMED-UI D-1231231UU" and there is a link "See UDI-DI(s) list (1)". The left sidebar contains "UDI-DI data", "Product designer", and "Market Information". The main content area is titled "UDI-DI data" and features a version management bar with "Version 2 [Dre 1] See version history" and "Last update date: 2021-05-25". Below this are several data fields: "EUDAMED ID code: D-1231231UU", "Issuing Entity: EUDAMED", "Selected nomenclature codes" with "Code A01010102 HYPODERMIC NEEDLES FOR PEN", "Trade name" section with "Trade name applicable: No", "Reference/Catalogue number: 44545", "URL for additional information (as electronic instructions for use): -", and "Device status: On the EU market". "EDIT" and "DELETE" buttons are visible in the top right.

3. You will see a list of all previously created versions (in the example below, there is only one version available):



The screenshot shows the "Version history of EUDAMED ID" page for EUDAMED DI B-1231231UU. It includes a "Go back to the current version" button and a list of versions. The visible entry is "Version 1 - Last update date: 2021-05-25" with a right-pointing arrow.

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

EUDAMED DI B-1231231UU

[← Go back to the current version](#)

Version history of EUDAMED ID D-1231231UU

[≡ See all version history \(1\)](#)

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

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

Trade name

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

Clinical size

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

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

7. Manage your own System or Procedure Pack information

7.1. View own 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 for SPPs:

Welcome to EUDAMED

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

[See all the news](#)

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

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”.

2. In order to retrieve the desired SPP, use the filters available by clicking on the “Filter” button and selecting the desired parameters:

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	2021-06-29	Registered	...
9970314941ShriyaHL16E	1	-	System test1	Class I	S	2021-05-14	Registered	...
9970314941ShriyaHL	1	-	Test ONE	Class I	PP	2021-05-14	Registered	...

3. On the right-hand side of each item there is an ellipsis symbol (three dots); click on it 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

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data Create new version

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

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

7.1.1 Delete a Draft Basic UDI-DI

1. Follow the steps in Section 7.1 to view a Draft Basic UDI-DI:

Basic UDI-DI management for SPP

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

Filter

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

Showing 1 to 4 of 4 entries Show entries per page

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

2. Once inside the summary for the desired Draft Basic UDI-DI, click on “Delete”, on the top right corner:

Basic UDI-DI 12344676768687687JC

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

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

Basic UDI-DI data Edit Delete

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

3. The system will prompt you to confirm your intention to delete the draft in a pop-up window. If certain, click on “Yes”:

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

The system will revert you to the latest registered information for this Basic UDI-DI.

7.1.2 Update (Create a new version) for Basic UDI-DI

1. Follow the steps in Section 7.1 to view a Basic UDI-DI:

Basic UDI-DI management for SPP

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

Filter

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

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

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

2. Once inside the summary for the desired Basic UDI-DI, click on “Create new version” on the top right corner:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data

Basic UDI-DI data Create new version

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

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

3. 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

4. To finish the action you have two options:

a. Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are uncertain about the update.

b. Click on “Submit new version”, if you are certain about the update and wish to finalise it.

Alternatively, you can click on “Cancel” to cancel the update.



5. After you have submitted the new version, you can see it has been updated under the Basic UDI-DI details:

A screenshot of the 'Basic UDI-DI 44444SSP_Shr_1VM' details page. It shows a navigation link 'Go to UDI-DI/EUDAMED DI management', tabs for 'Basic UDI-DI data' and 'UDI-DI(s) (1)', and a 'Basic UDI-DI data' section. The section includes a 'Version 2 [Current]' label with a red box around it and a 'See version history' link. Below is a table of details: Applicable regulation (MDR), Basic UDI-DI code (44444SSP_Shr_1VM), Issuing Entity (GS1), Risk class (Class I), Indication of medical purpose (SPPP test 1), Language (Greek), and Name (SPP_Shr_1). A 'Create new version' button is in the top right.

7.1.3 View historical versions for Basic UDI-DI

1. Follow the steps in Section 7.1 to view a Basic UDI-DI.
2. Once inside the summary for the desired Basic UDI-DI, click on “See version history” at the top of the table:

A screenshot of the 'Basic UDI-DI 44444SSP_Shr_1VM' details page, identical to the previous one, but with a red box highlighting the 'See version history' link in the version information area.

3. View the list of versions for the desired Basic UDI-DI and click on the desired version to view its details (in the example below, there is only one older version):

Basic UDI-DI 44444SSP_Shr_1VM

[← Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

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

4. Once inside a historical version, you can return to the versions list by clicking on “See all version history” on the top right corner:

Basic UDI-DI 44444SSP_Shr_1VM

[← Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

[≡ See all version history \(1\)](#)

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

Basic UDI-DI identification

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

Basic UDI-DI code: 44444SSP_Shr_1VM
Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

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

7.2. View own UDI-DI details

1. On the EUDAMED dashboard, click on “Manage your UDI-DIs” to see a list of all your UDI-DIs for SPPs:

Tasks

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

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)

2. In order to retrieve the desired UDI-DI, use the filters available by clicking on the blue “Filter” button and selecting the desired 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	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	...

3. On the right-hand side of each item, there is an ellipsis symbol (three dots); click on it and then click on “View data” from the menu:

Showing 1 to 3 of 3 entries Show entries per page

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

4. You will see a summary of the details concerning your chosen system or procedure pack UDI-DI:

Basic UDI-DI 44444SSP_Shr_1VM

[← Go to device management](#)

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

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

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

[Container Package Information](#)

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

UDI-DI code:	44444SSP_Shr_1VM
Issuing Entity:	HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

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

Trade name

Trade name applicable:	No
Reference/Catalogue number:	SPPP_Shr_1

Type of UDI-PI

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

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

7.2.1 Delete a Draft UDI-DI

1. Follow the steps in Section 7.2 to view a Draft UDI-DI.
2. Once inside the summary of the desired Draft UDI-DI, click on “Delete” on the top right corner:

The screenshot displays the 'Basic UDI-DI data' page for UDI-DI 34675806754T9. The page includes a navigation menu on the left with 'UDI-DI data' and 'Container Package Information'. The main content area is titled 'UDI-DI data' and shows the following information:

- Version 2 [Draft]** | See version history | Last update date: 2021-07-02
- UDI-DI code: 34675806754T9
- Issuing Entity: HIBCC
- UDI-DI from another entity**
- UDI-DI from another entity (secondary) applicable: No
- Selected nomenclature codes**
- Code A010102 BUTTERFLY NEEDLES
- Trade name**
- Trade name applicable: Yes
- Trade name: system 1All languages
- Reference/Catalogue number: 543
- Type of UDI-PI**
- Serial number: Yes
- Manufacturing date: Yes
- Additional product description: test 1 for SPPP System [BG]
- URL for additional information (as electronic instructions for use): -
- UDI-DI status: On the EU market

Buttons for 'EDIT' and 'DELETE' are located in the top right corner. The 'DELETE' button is highlighted with a red box.

3. A pop-up message will prompt you to confirm the action by clicking on “Yes”:

The screenshot shows a confirmation dialog box titled 'Delete UDI-DI'. The message asks: 'Delete the Draft version of UDI-DI?'. At the bottom, there are two buttons: 'Yes' (highlighted in dark blue) and 'Cancel' (in light blue). A 'Close' button is visible in the top right corner.

7.2.2 Update (Create a new version) for UDI-DI

1. Follow the steps in Section 7.2 to view a UDI-DI.
2. Once inside the summary for the desired UDI-DI, click on “Create new version” on the top right corner:

Basic UDI-DI 44444SSP_Shr_1VM

[← Go to device management](#)

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

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

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

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

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

UDI-DI code:	44444SSP_Shr_1VM
Issuing Entity:	HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

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

Trade name

Trade name applicable:	No
Reference/Catalogue number:	SPPP_Shr_1

Type of UDI-PI

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

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

3. Update the desired 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](#)

4. To finish the action you have two options:

a. Click on “Save” to save the updated details without submitting the new version. This option saves the update as “Draft” and allows you to go back and edit/delete if you are uncertain about the update.

b. Click on “Submit new version”, if you are certain about the update and wish to finalise it.

Alternatively, you can press “Cancel” to cancel the update.

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](#)

7.2.3 Update (Create new version) for Container Packages

The Container Packages information can be updated independently of the rest of the data in a SPP UDI-DI.

1. Follow the steps in section 7.2 to view a specific UDI-DI:

2. Once inside the summary of the desired UDI-DI, click on “Container Package information” from the list on the left (or scroll down to the relevant section):

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

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

Container package update

Container package(s)

[+ Add container package](#)

- [Root] UDI-DI: 44444SSP_Shr_1VM (HIBCC)

○ UDI-DI: 44444SSP_Shr_1VM (ICCBBA) | Quantity per package: 10 (10)

[Submit](#) [Cancel](#)

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

[✕Close](#)

Add container package

Container package UDI-DI for UDI-DI 44444SSP_Shr_1VM

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

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

7.2.4 Discard Registered UDI-DIs

1. Follow the steps in Section 7.2 to view a desired Registered UDI-DI:

UDI-DI details management for SPP

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

[Filter](#)

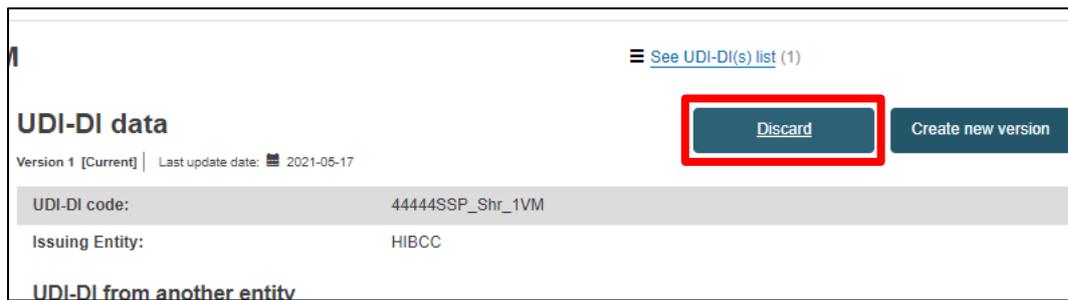
Active filters:

State: Registered [Clear all filters](#)

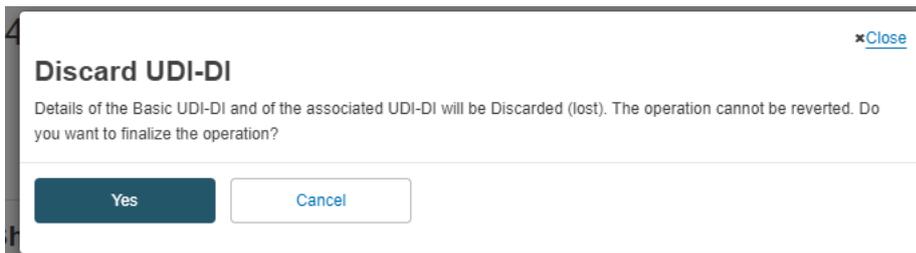
Showing 1 to 3 of 3 entries Show entries per page

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	...

2. Once inside the summary of the desired UDI-DI, click on “Discard”, on the top right corner:



3. The system will prompt you to confirm your wish to permanently discard the registered UDI-DI. Click on “Yes” to finalise the action:



7.2.5 View historical versions for UDI-DI and associated entities

1. Follow the steps in section 7.2 to view a UDI-DI for the SPP.
2. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:

Basic UDI-DI 202108201FS

[← Go to device management](#)

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

UDI-DI IFA3240032400 [See UDI-DI\(s\) list \(3\)](#) | [Next UDI-DI >](#)

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

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

Version 3 [Current] Last update date: 2021-09-24

UDI-DI code:	IFA3240032400
Issuing Entity:	IFA

UDI-DI from another entity

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

Selected nomenclature codes

Code	C0101010101 I.V. CANNULAS, WITH INJECTION VALVE
------	---

Trade name

Trade name applicable:	No
Reference/Catalogue number:	DRe223

Type of UDI-PI

Lot or Batch number:	Yes
Additional product description:	V3 [EN]

3. You will see a list of all previously created versions :

Basic UDI-DI 202108201FS

[← Go back to the current version](#)

Historical version for UDI-DI IFA3240032400

Version 2 - Last update date: 2021-09-24	>
Version 1 - Last update date: 2021-09-24	>

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

Basic UDI-DI 202108201FS

[← Go back to the current version](#)

Historical version for UDI-DI IFA3240032400

Version 2 [History] - Last update date: 2024-09-24

[≡ See all version history \(2\)](#) [← Previous version \[v1\]](#)

UDI-DI code:	IFA3240032400
Issuing Entity:	IFA

UDI-DI from another entity

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

Selected nomenclature codes

Code	C0101010101 I.V. CANNULAS, WITH INJECTION VALVE
------	---

Trade name

Trade name applicable:	No
Reference/Catalogue number:	DRe223

Type of UDI-PI

Lot or Batch number:	Yes
Additional product description:	V2 [EN]
URL for additional information (as electronic instructions for use):	-
UDI-DI status:	On the EU market

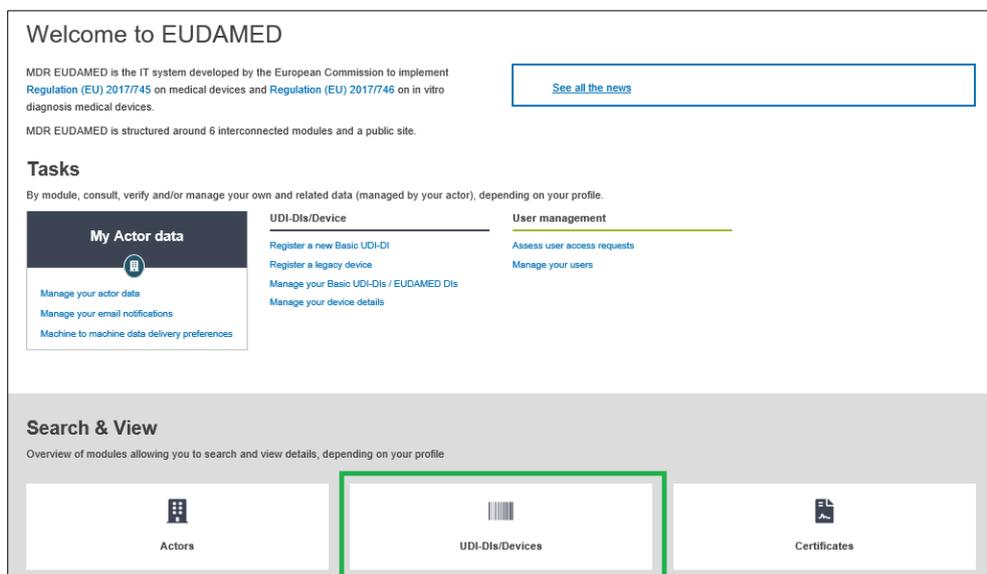
You can return to the version history list, by clicking on “See all version history” on the top right corner.

8. Search and View Devices and System or Procedure Packs on the platform

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



Alternatively, use the option available in the dashboard called ‘Search and View’:



2. EUDAMED will display the filters available for searching in the list of Devices and Systems or Procedure Packs registered in EUDAMED:

Search for UDI-DIs

Only enable search filters available for bulk XML download

UDI-DI code Basic UDI-DI code Status Model
 Name Trade name Applicable regulation
 Risk class Nomenclature code Reference/Catalogue number Country
 Scopes

MF / PR Actor ID/SRN MF / PR Name AR Actor ID/SRN AR name

Results option

Include historical version

3. Once you have entered the desired search filters, click on “Search”. A list of Devices (UDI-DIs/EUDAMED IDs) and System or Procedure Packs will appear:

Showing 1 to 20 of 150 entries Show entries per page

UDI-DI code ^{††}	Basic UDI-DI code ^{††}	MF / PR SRN	Trade name ^{††}	Risk class	Date ^{††}	UDI-DI status
12345XYZ	++B311X1Y2Z3PP	BE-PR-000000048		Class I/b	2021-03-29	On the EU market
19999QAAQ00Q2	++A999JAIMETEST12N	BE-PR-000000048		Class I/b	2021-03-26	On the EU market
12345-ivdr-class-d-ST-udi-A	12345-ivdr-class-d-ST	BE-MF-000000041		Class D	2021-03-24	On the EU market
++A999SPPVERSION2PMa	++A999SPPVERSION2PM	BE-PR-000000062		Class I	2021-03-24	On the EU market
++A999SPPVERSIONYMa	++A999SPPVERSIONNYM	BE-PR-000000062		Class I	2021-03-24	Not intended for the EU market

4. Click on the desired UDI-DI/EUDAMED ID to see a summary of the details:

Producer information

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

Basic UDI-DI details

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

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

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

System or Procedure Pack type: Procedure Pack

8.1. Search and View historical versions of Devices and System or Procedure Packs

1. Follow the steps in Section 8 to search and view a device or SPP.
2. Inside the search page, fill in the desired parameters for your search, activate the result option to include historical versions and click on “Search”:

Search for UDI-DIs

Only enable search filters available for bulk XML download

UDI-DI code:

Basic UDI-DI code:

Status:

Model:

Name:

Trade name:

Applicable regulation:

Risk class:

Nomenclature code:

Reference/Catalogue number:

Country:

State:

Scopes:

MF / PR SRN:

MF / PR Name:

AR SRN:

AR name:

Results option

Include historical version

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

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

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Next →

8.2. Download Devices and System or Procedure Packs in a structure format

Note: You can only download your own device or system/procedure pack in a structured format.

1. Follow the steps in section 8 to search and view a device or system or procedure pack.
2. On the search parameters screen, enable the top filter to enable only the search criteria that can be downloaded in an XML format, and enter your search criteria:

Search for UDI-DIs

Only enable search filters available for bulk XML download 

UDI-DI code	Basic UDI-DI code	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" value="MDR (REGULATION (EU) 2017/745 on medical devices)"/>	
Risk class	Nomenclature code	Reference/Catalogue number	Country
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
State	Scopes		
<input type="text" value="Registered"/>	<input type="text" value="You can select more than one value"/>		
MF / PR SRN	MF / PR Name	AR SRN	AR name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

3. Complete the search criteria you wish to enter, and click on “Search”, to generate results:

Only enable search filters available for bulk XML download

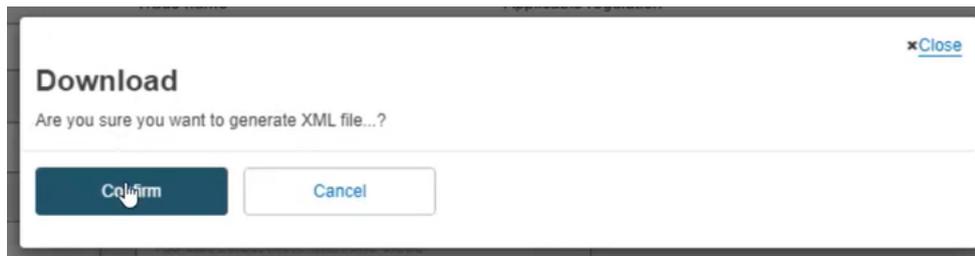
UDI-DI code	Basic UDI-DI code	Status	Model
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Name	Trade name	Applicable regulation	
<input type="text"/>	<input type="text"/>	<input type="text" value="MDR (REGULATION (EU) 2017/745 on medical devices)"/>	
Risk class	Nomenclature code	Reference/Catalogue number	Country
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
State	Scopes		
<input type="text" value="Registered"/>	<input type="text" value="You can select more than one value"/>		
MF / PR SRN	MF / PR Name	AR SRN	AR name
<input type="text" value="BE-MF-00000001"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Click on “Generate XML file”:

<input type="button" value="Search"/>	<input type="button" value="Generate XML file"/>	<input type="button" value="Clear search"/>
---------------------------------------	--	---

Note: only what is shown on the result list will be included in the generated file and not all the results of your search (in cases where these exceed the default number of results on one page).

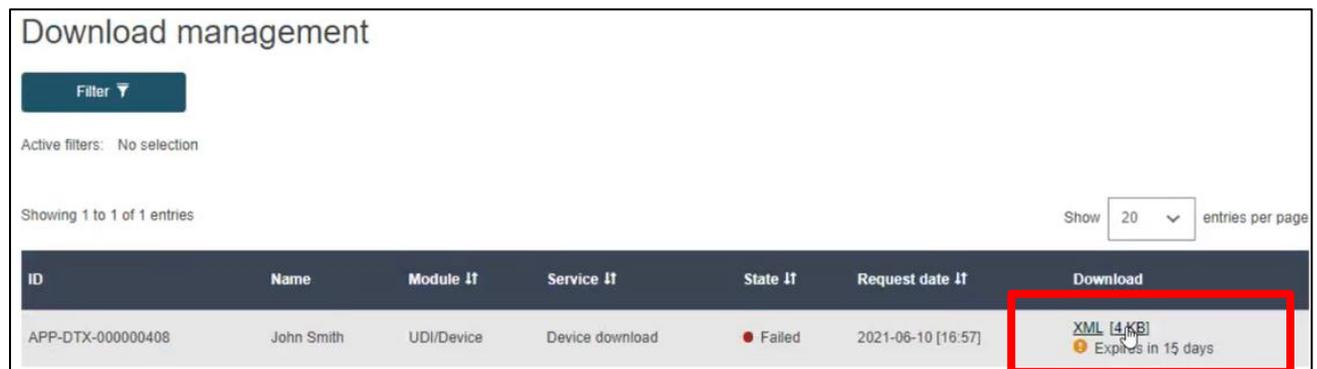
5. A pop-up window will prompt you to confirm your action:



6. The system will inform you that the action has been successful and will prompt you to take further action. Click on "Go to Download Management":



7. The generated XML response file can be downloaded by clicking on it under the "Download" column title:



8.3. View historical versions for Basic UDI, UDI-DI and associated entities

1. Follow the steps in section 8.1 to view the details of a Device or SPP.
2. Once inside the summary of the desired UDI-DI, click on "See version history" for the element for which you want preview the version history: Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID , Market Information, Product Designer or Container Package

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
--	----

3.You will see a list of all previously created versions for the selected entity (we will continue the example presenting the version history of the Basic UDI-DI):

Basic UDI-DI 22091test23_09EC

[◀ Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Basic UDI-DI 22091test23_09EC

[◀ Go back to the current version](#)

Historical version for **Basic UDI-DI 22091test23_09EC**

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

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

Manufacturer information

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

Manufacturer information

Organisation name: Japanese MF A v4
Actor ID/SRN: JP-MF-00000061
Address: 1 Main Street Tokyo
Telephone number: 213 v2
Email: public-details@japanese-mf-a.com

Authorised Representative

Organisation name: Belgium AR A v5
Eudamed actor ID: BE-AR-00000021
Address: Brussels
Telephone number: -
Email: public-contact@belgium-ar-a.com

Basic UDI-DI data

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

Basic UDI-DI identification

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

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

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

5. Inside the summary of a version, note that you can browse through the different versions via the browsing function on the top right corner:

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

Annex 1 – Device Certificate Information

Current Annex presents the cases in which the Certificate information is required to be provided when registering a Regulation Device and the Certificate type required to be provided based on the properties of the Device.

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

			EU type-examination certificate (Annex X)	EU technical documentation assessment certificate (Annex IX Chapter II)
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Color option description

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

Annex 2 – Legacy Device Certificate Types

Current Annex presents the Certificate types that can be used when registering a Legacy Device.

Certificate types are depending on the Applicable legislation of the Device.

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