

UDI Devices - User guide

EUDAMED v2.7
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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 guide 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 (SPP).

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 and different 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 which is 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 specific medical device.

(PACKAGEUDI-DI) - If applicable, each device may have an additional, higher-level UDI-DI assigned to its higher package. Package UDI-DIs identify each package format, 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). In some cases, legacy devices shall be registered in EUDAMED without a Basic UDI-DI and without a UDI-DI.

A Legacy Device must 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). A legacy device has to be registered in the 'UDI/Device module' of EUDAMED, which allows EUDAMED to process it similarly to a Regulation Device.

EUDAMED DI - The EUDAMED DI is equivalent to the Basic UDI-DI. It can either be fully 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 is equivalent to the UDI-DI. In case a UDI-DI has not been assigned yet, the EUDAMED ID will always be automatically and fully generated by EUDAMED from the EUDAMED DI.

2. Getting started

What I need to access EUDAMED:

1. EU Login (ECAS) account

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

2. User profile registration in EUDAMED

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

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"; this profile can create and delete draft records in the Device module, or
- A "Confirmer"; this profile may also submit and discard records in the Device module

If you have already registered as a user in EUDAMED before the release of this version, in order to create and submit records you must request a profile upgrade in the Device module from "Viewer" 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. Finally, do bear in mind that any question or field marked with a red asterisk is mandatory and cannot be left blank.

3. Registering Regulation Devices

Click on the following link to arrive to EUDAMED:

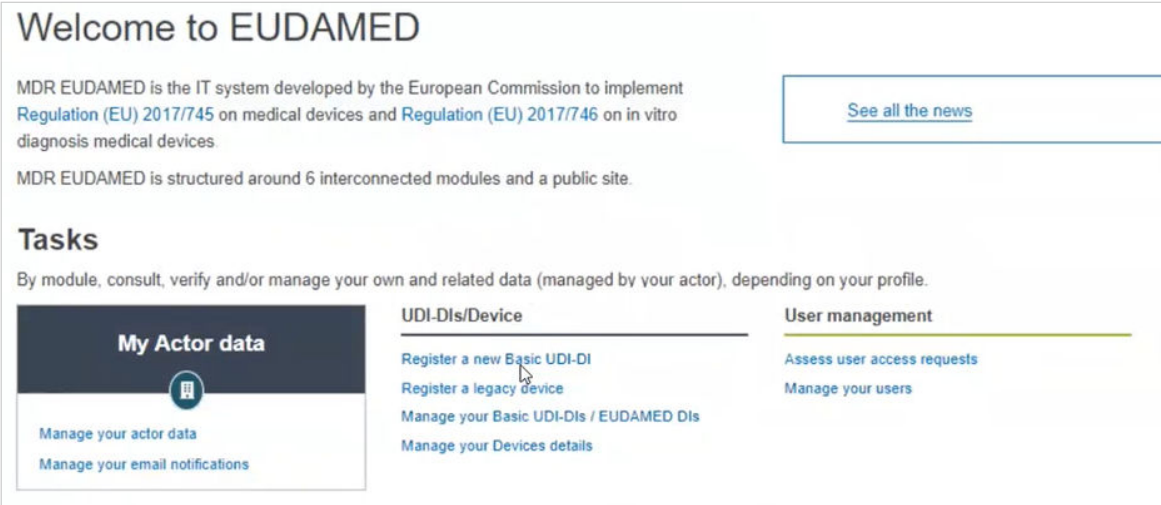
<https://webgate.ec.europa.eu/eudamed/>

You will be asked 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. Click on “Register a new Basic UDI-DI”:



The screenshot shows the 'Welcome to EUDAMED' page. At the top, it says 'Welcome to EUDAMED' and provides a brief description of the system. Below this, there is a 'Tasks' section with the instruction: 'By module, consult, verify and/or manage your own and related data (managed by your actor), depending on your profile.' There are three main columns of tasks:

- My Actor data:** Manage your actor data, Manage your email notifications.
- UDI-DIs/Device:** Register a new Basic UDI-DI (highlighted with a mouse cursor), Register a legacy device, Manage your Basic UDI-DIs / EUDAMED DIs, Manage your Devices details.
- User management:** Assess user access requests, Manage your users.

There is also a 'See all the news' button in the top right corner.

2. On the next page, enter the Basic UDI-DI information for your device. Select the applicable legislation for your Basic UDI-DI, from the two options provided:



NOTE

In this guide demonstration, we assume that you have selected MDR (Regulation (EU) 2017/745). Based on the legislation you choose, the characteristics of the Device to be entered will vary.

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)

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

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

In this example for the MDR regulation, answer the question by clicking on “Yes” or “No”:

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

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

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

If you select “No”, please choose the right information under the appearing section “Special Device type”:

Special device type

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

*** Special device type:**

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



NOTE

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

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

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

Basic UDI-DI main information

* Issuing Entity:

* Basic UDI-DI code:



IMPORTANT

EUDAMED will validate the Basic UDI-DI code you insert based on the specific format provided by each Issuing Entity. Please make sure that you provide the correct code.

Basic UDI-DI **duplicates** (two identical entries) cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, you will be asked to provide another code.

4. Select the authorised representative for the current device (Basic UDI-DI) from the options available (only for 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 chosen as shown below:

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 choices and the applicable legislation of the device:

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 model and the device name if available:

Device model applicable

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

* Device model:

Device Name:

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



3.1.2. Step 2: Certificate information

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



NOTE

You must provide Certificate Information for Basic UDI-DIs which need confirmation from the Notified Body for the information 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 needed for the Device and the type of certificate that should be given in each case apart.

This section will become active depending on the information provided 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:**

Q Find

Certificate number:

Revision number:

Save

Save & Next >

3.1.3. Step 3: UDI-DI identification information

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

IMPORTANT

The UDI-DI code you enter must be unique in EUDAMED. If it already exists in EUDAMED for the selected IssuingEntity, you will be asked to provide another.

Exception: 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 will be created between the two devices (the Regulation and the Legacy Device).

NOTE

In case of GS1 Issuing Entity, the UDI-DI code you enter must have 14 characters.

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”, and select the correct one from the list:

NOTE

EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multi-level, 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.

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

- Enter the trade name (as found on the device label) and select the language, otherwise, select “No”:

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

- 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, you should enter the Unit of Use DI. 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 be entered 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.

- Enter 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 way in which production of the device is controlled.

* Quantity of device:

3

* 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 (link) if you have one for additional information online:

Additional product description:

Product Description

Select the language:

--

Bulgarian

Croatian

Czech

Danish

Dutch

English

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

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

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 applies to the UDI-DI and choose the correct values in the drop-down lists below:



NOTE

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

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

2. Select “Yes” or “No” for each of the options below:

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

*** CMR/Endocrine disruptor**

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

Yes No

*** Category of CMR:**

1A 1B

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

EC#: CAS#:

[ECHA database >](#)

*** Name of the substance:**

+ [Add a CMR substance](#)

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

Yes No

- Select “Yes” or “No” for the Storage/handling conditions, if applicable; choose the correct information from the list and type a description:

Storage/handling conditions, if applicable

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

*** Storage/handling conditions type:** **Description:**

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

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

Critical warnings or contra-indications, if applicable

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

* Critical warning type: ▼
 Defibrillation-proof type CF applied part

* 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 below:

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:

Clinical Investigation

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

Clinical Investigation '212121' is not registered in EUDAMED

* Enter Clinical Investigation Number:

232423232

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

Yes No

Presence of animal tissues or cells, or their derivatives:

Yes No

*** Information on substances**

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

Yes No

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

Yes No

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

-- ▾

- If you answer “Yes” to 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

- Choose a Member State from the drop-down 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:

Austria ▼

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

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

Save Save & Next >



NOTE

This field may be optional or required, based on your previous answers 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

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

+ [Add container package](#)

Save Submit > Preview

2. Add the Issuing Entity, Package UDI-DI code and the quantity per package, and click on “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.

Add container package ✕Close

Container package UDI-DI for UDI-DI 76766766

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

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

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

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

Submission ✕Close


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

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

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

5. 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. On the EUDAMED Dashboard, select “Manage your Basic UDI-DIs/ EUDAMED DIs”:

Welcome to EUDAMED

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

[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.

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

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

IMPORTANT

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

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

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Basic UDI-DIs / EUDAMED DIs management

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

Filter

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

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

[Apply filters](#) [Clear all filters](#)

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

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
12211121212121Y2	1		Test	Class IIa	2021-03-31	1st Draft	...
1111184FG4G228694YC	1	DeviceModelZZZ	DeviceNameZZZ	Class IIb	2021-03-19	1st Draft	...

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter

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

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
1234503276	1	Model OP		Class IIb	2021-03-30	Registered	...
1234503072	1	Model 88		Class IIb	2021-03-30	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-555908900698	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	...

- Complete the series of steps required for the registration of a UDI-DI for an existing Basic UDI-DI:

Add new UDI-DI to existing Basic UDI

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Submission xClose

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

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

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



IMPORTANT

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

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

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

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

The screenshot shows the EUDAMED dashboard. At the top, it says "Welcome to EUDAMED" and provides information about the system's purpose and structure. A "See all the news" button is visible. Below this, a "Tasks" section explains that users can manage their own data. Three main task categories are listed: "My Actor data", "UDI-DIs/Device", and "User management". Under "UDI-DIs/Device", the option "Register a legacy device" is highlighted with a mouse cursor.

4.1. Step 1: EUDAMED DI identification information

1. Select an applicable legislation:



NOTE

Based on the applicable legislation selected, the characteristics of the Device that you can provide will differ.



NOTE

For the rest of the procedure in this user guide, we will assume 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

If no UDI-DI is available, the EUDAMED DI must be provided.



NOTE

In case of GS1 Issuing Entity, the UDI-DI code you enter 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 during the registration process by providing the manufacturer’s device identifier and allowing EUDAMED to generate it.



IMPORTANT

When 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 asked 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 asked to create a link 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 if it is a kit or not. If you choose “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. Choose 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 as shown below:

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 left you will see a summary of the device characteristics. Choose a “Risk class” from the list and select “Yes” or “No” for each of the options. Risk Class options depend on the Applicable Legislation of the Device and influence the properties which must be entered later.

Legacy device registration

Manufacturer identification
BE-MF-000000041, Belgian MF A

EUDAMED DI identification
Applicable legislation: IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)

EUDAMED DI code: B-56909
Issuing Entity: EUDAMED

Kit: No
Special device type: Software

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

EUDAMED DI information

* Risk class:

* Near-patient testing
 Yes No

* Self-patient testing
 Yes No

* Companion diagnostic
 Yes No

* Reagent
 Yes No

* Instrument
 Yes No

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

Device model applicable

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

* Device model:

Device Name:

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

Save
Save & Next >

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 can be entered:

Certificate information

Item #1
▼

* Certificate Type:

EC Certificate Full Quality Assurance System ▼

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

NB number: 1293

Address:

Telephone number: 421 42 44 03 600

Email: hudak@evpu.sk

* Certificate number: Revision number:

* Expiry date:
YYYY-MM-DD

4.3. Step 3: Device identification information

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):

Device identification information

* Issuing Entity: ▼ * UDI-DI code:

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.

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

3. Enter the trade name (if there is one) 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](#)

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

* Reference/Catalogue number:

Additional product description:


Select the language:

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


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

* Device status:

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:

On the EU market 

4.4. Step 4: Device Characteristics


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

* Labelled as single use Yes No


* Need for sterilisation before use Yes No

* Device labelled as sterile Yes No

Storage/handling conditions, if applicable

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

* Storage/handling conditions type:

 [Add another storage/handling condition](#)

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

Storage/handling conditions, if applicable

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

* Storage/handling conditions type: Description:

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

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

Critical warnings or contra-indications, if applicable

Yes No ⓘ Critical warning or contra-indications are required unless 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, and enter the SRN number if you know it:

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

Yes No

I know the SRN

* Enter SRN or name:

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

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

PO box:

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

* City name: * Postal code:

* Country:

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

* Email:

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

Clinical investigation conducted inside EU?:
 Yes No

[+ Add new Clinical Investigation](#)

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

*** Tissues and cells**

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

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

Presence of cells or substances of microbial origin:
 Yes No

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

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


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

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

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

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

Legacy Device registration

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

What do you want to do now?

[Register a legacy device](#)

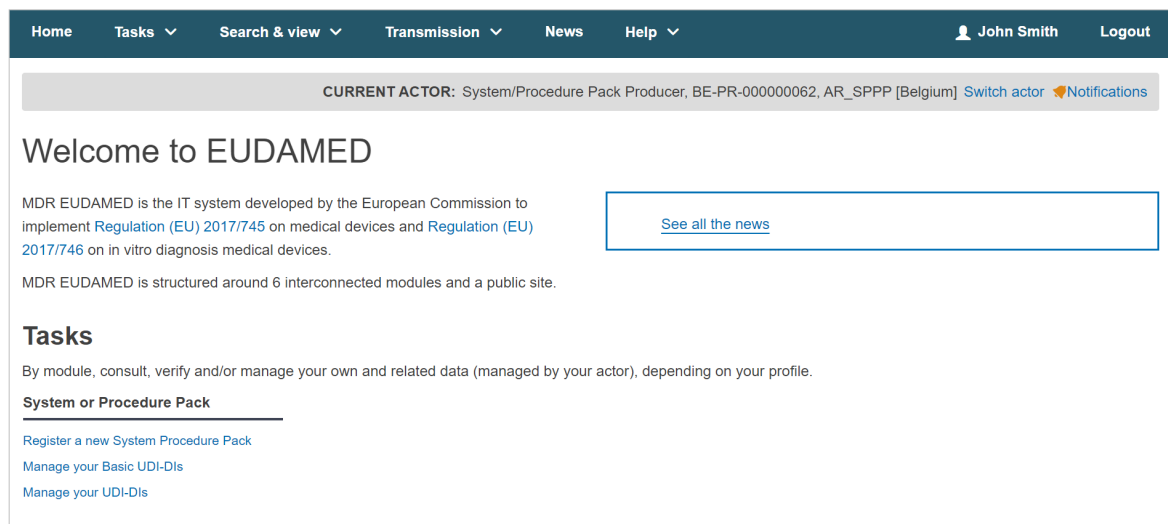
[Go to the dashboard](#)

5. Registering System or Procedure Packs

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

5.1.1. Step 1: Basic UDI-DI main information

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



2. On the next page, register the Basic UDI-DI main information for your system or procedure pack, meaning the Basic UDI-DI Issuing entity and code.

System or Procedure Pack registration

Procedure pack producer identification

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

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


Basic UDI-DI main information


* Issuing Entity: * Basic UDI-DI code:

* System or Procedure Pack type:

Procedure Pack
 System

[Save & Next >](#)

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

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

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 asked to provide another value:

System or Procedure Pack registration

Procedure pack producer identification

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

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

✘ Duplicate device identified.

* System or Procedure Pack type:

Procedure Pack
 System

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

*** System or Procedure Pack type:**

Procedure Pack

System

Save & Next >

5.1.2. Step 2: Basic UDI-DI information

On the next page, enter the Basic UDI-DI information:

System or Procedure Pack registration

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

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

Basic UDI-DI code: 1212112121212DL
Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

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

Basic UDI-DI information

* Risk class:

* Indication of medical purpose:

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

* Select the language:

Device model applicable

Yes No [i](#) Device model is required by default unless you select the option - No

* Model:

Name:

Save
Save & Next >

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

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

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

Basic UDI-DI code: 1212112121212DL

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

Basic UDI-DI information

* Risk class:

* Indication of medical purpose:

* Select the language:

- Fill in the indication of medical purpose, and choose its corresponding language.

2017745 on medical devices)

Basic UDI-DI code: 1212112121212DL
Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

* Indication of medical purpose:

* Select the language:

+ Add another indication of medical purpose

You can 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”, it is mandatory to provide the ‘Device model’ and the ‘Device name’ is optional. If you select “No”, providing the ‘Device name’ becomes mandatory.

Device model applicable

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

* Model:

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

Save Save & Next >

5.1.3. Step 3: UDI-DI identification information

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: GS1

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity:

* Secondary UDI-DI value:



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 you enter must have 14 characters.

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity: * Secondary UDI-DI value:

3. Enter the EMDN code (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.

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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; just click on “Add a trade name in another language”.

5. Enter the Reference/Catalogue number:

6. Select the type of UDI-PI, which shows the way in which production is controlled. You can select more than one type.

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

Additional product description:

Product Description

Select the language:

--

Bulgarian

Croatian

Czech

Danish

Dutch

English

+ Add additional product description in another language

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

- Choose if the system or procedure pack is intended for the EU market or not and click on “Save” to save as draft and finish later or “Save & Next” to continue directly to the next steps:

* UDI-DI status

Not intended for the EU market

On the EU Market

Save

Save & Next

5.1.4. Step 4: UDI-DI Characteristics

- Select “Yes” or “No” for each option regarding sterilisation:

Basic UDI-DI information

UDI-DI identification information

3 UDI-DI characteristics

4 Container package(s)

UDI-DI characteristics

* Need for sterilisation before use

Yes No

* Device labelled as sterile

Yes No

- Select “Yes” or “No” if storage or handling conditions are applicable:

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



NOTE

If you select “Other” from the Storage/Handling conditions type list, you need to provide the description in several languages:

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

Just like for the previous section, if you choose “Other” for the critical warning type, the system asks 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 unless you select the option - No

* Critical warning type: Description

Caution

* Critical warning type: OTHER

* Description: * Select the language:

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

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

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

Save Save & Next >

5.1.5. Step 5: Container Package Details

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

- If you wish to enter information about packaging structures for shipping, click on “Add container package”:

Basic UDI-DI information
UDI-DI identification information
UDI-DI characteristics
4 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:

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 entered.



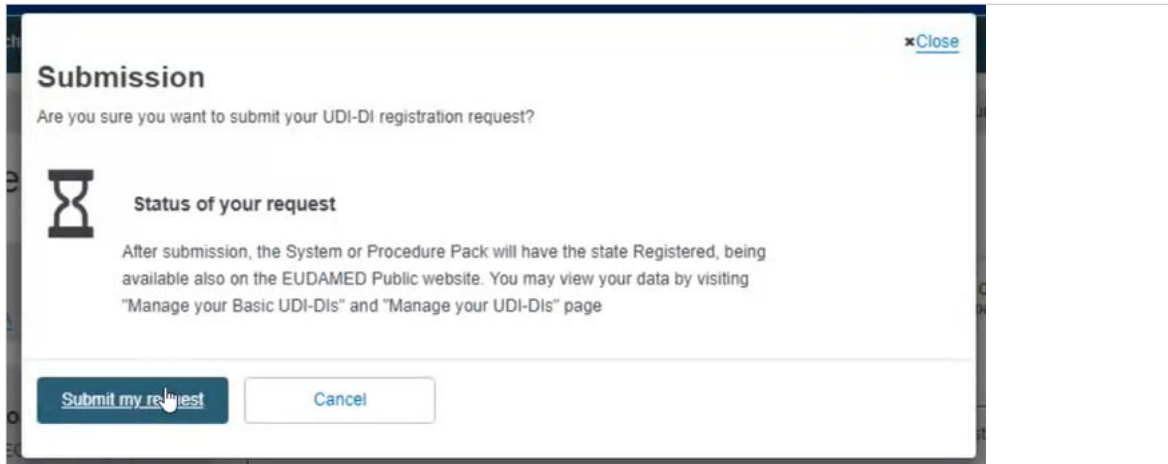
NOTE

The system calculates the total number of devices according to the quantity per package you entered:

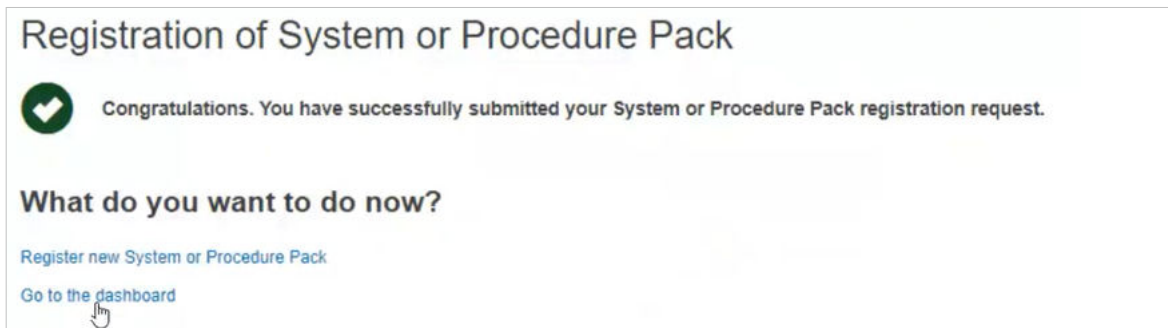
5. If you are ready to submit the registration, click on “Submit”:

You can also preview the information of the registration by clicking on “Preview”.

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

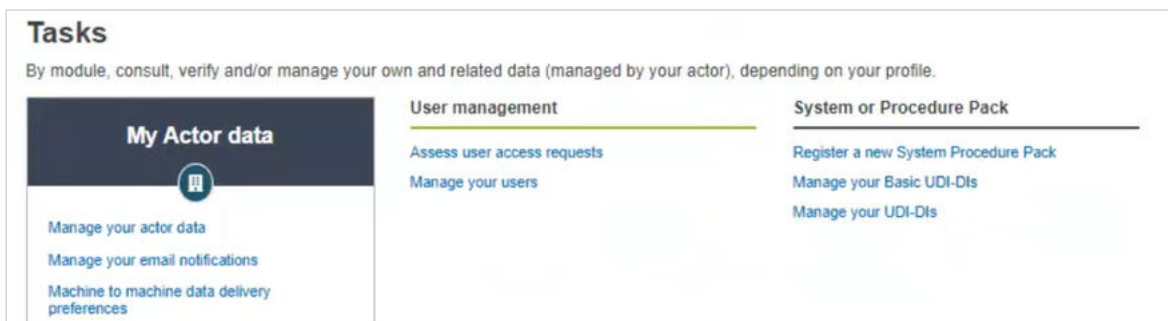


Upon submission, you will see a message that you have successfully submitted a System or Procedure Pack registration request:



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

Basic UDI-DI management for SPP

Go to device management Register new System or Procedure Pack

Filter ▾

Basic UDI-DI code: Name: State: Draft ▾
Discarded
Draft
Registered
Submitted

Risk class: -- ▾ System or Procedure Pack: All ▾

Apply filters Clear all filters

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

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

Basic UDI-DI code	UDI-DI(s)	Device model	Device Name	Risk class	Type	Date	State	Actions
1212112121212DL	1	-	Device Name	Class IIIa	PP	2021-06-10	Registered	⋮
12345KT-Devices-3BY	1	-	test	Class I	PP	2021-05-2		View Data
223311445578899583F	1	SPP_Model		Class I	S	2021-04-0		View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI

5.2.1. Step 1: UDI-DI identification information

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: HIBCC ▾ * UDI-DI code: 121212

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code): Find

[Advanced search of device nomenclature](#)

Selected nomenclature codes

Code **A01010101** HYPODERMIC NEEDLES FOR SYRINGE Remove nomenclature code

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

* Trade name: * Select the language:

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

* Reference/Catalogue number:

 REF_TEST

Manufacturing date
 Expiration date

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

5.2.2. Step 2: UDI-DI Characteristics

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

UDI-DI characteristics

* Need for sterilisation before use
 Yes No

* Device labelled as sterile
 Yes No

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

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

* Critical warning type: Description:

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

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

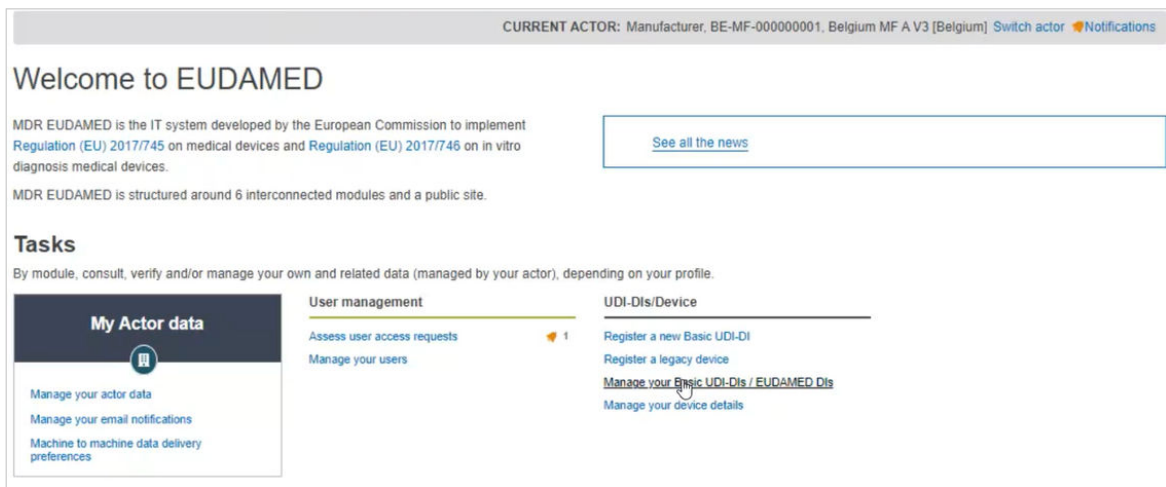
5.2.3. Step 3: Container Package Details

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

6. Manage your own Device Information

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

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



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



NOTE

By default, the 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 filter button.

Basic UDI-DIs / EUDAMED DIs management

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

Filter ▼

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

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
B-12121EL	1		Test	Class IIb	2021-04-01	1st Draft	...
1212112121U5	1		Test	Class IIa	2021-04-01	1st Draft	...
1211421211211EW	1		Device Name	Class IIa	2021-04-01	Draft	...
31212121121212133383	2	Device Model_Test_CLASS IIA_v3	Device Name	Class IIa	2021-03-16	Draft	...
1212123333333343HC	1		test	Class I	2021-02-15	1st Draft	...
12345ABCBY	1		test	Class I	2021-02-05	1st Draft	...

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

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

Basic UDI-DI 1211421211211EW

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

Basic UDI-DI data [UDI-DI\(s\) \(1\)](#)

Basic UDI-DI data [Clinical Investigation](#) [Certificates](#)

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

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

Basic UDI-DI identification

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

Basic UDI-DI code: 1211421211211EW
Issuing Entity: GS1

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

Risk class: Class IIa

Implantable: No

Measuring function: No

Reusable surgical instruments: No

Active device: No

Device intended to administer and/or remove medicinal product: No

Name: Device Name

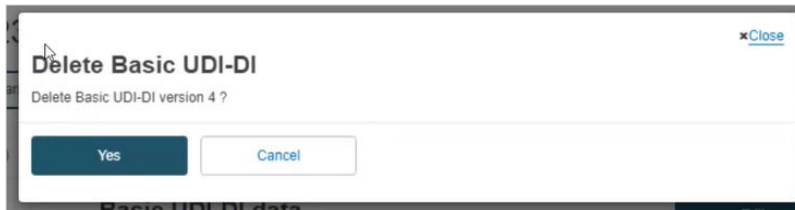
6.1.1. Delete a Draft Basic UDI-DI/EUDAMED DI

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

1. When you are inside the summary of the desired draft, click on “Delete”:



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



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

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

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

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

Basic UDI-DI 1211421211211EW

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

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

Basic UDI-DI data
[Clinical Investigation](#)
[Certificates](#)

Basic UDI-DI data Create new version

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

Basic UDI-DI identification

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

Basic UDI-DI code: 1211421211211EW
 Issuing Entity: GS1

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

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

2. Update the desired details:



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:

version 3

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

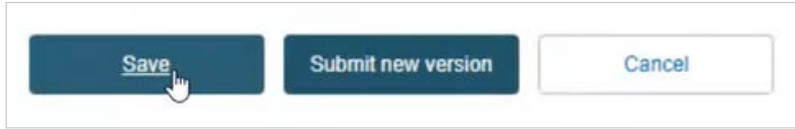
Save Submit new version Cancel

3. To 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.



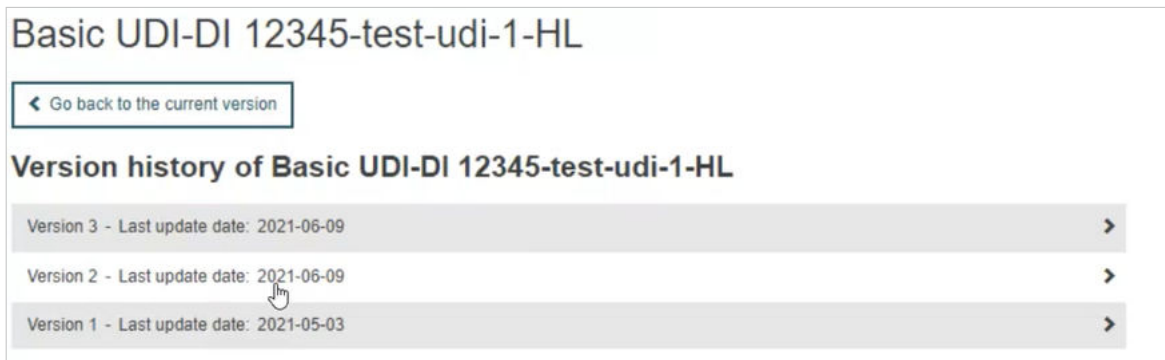
6.1.3. View historical versions for Basic UDI-DI/ EUDAMED DI

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

1. Once inside the summary of the desired Basic UDI-DI, click on “See version history”:



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



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

[← Go back to the current version](#)

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

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”:

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

My Actor data

[Manage your actor data](#)

[Manage your email notifications](#)

[Machine to machine data delivery preferences](#)

UDI-DIs/Device

[Register a new Basic UDI-DI](#)

[Register a legacy device](#)

[Manage your Basic UDI-DIs / EUDAMED DIs](#)

[Manage your device details](#)


User management

[Assess user access requests](#)


[Manage your users](#)

Search & View


Overview of modules allowing you to search and view details, depending on your profile



Actors



UDI-DIs/Devices



Certificates

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

UDI Devices - User guide

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



NOTE

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

Filter

Applicable regulation: [Dropdown]

Risk class: [Dropdown]

Trade name: [Text]

Nomenclature code: [Text]

Properties: You can select more than one value [Text]

Status: [Dropdown]

UDI-DI/EUDAMED ID Code: [Text]

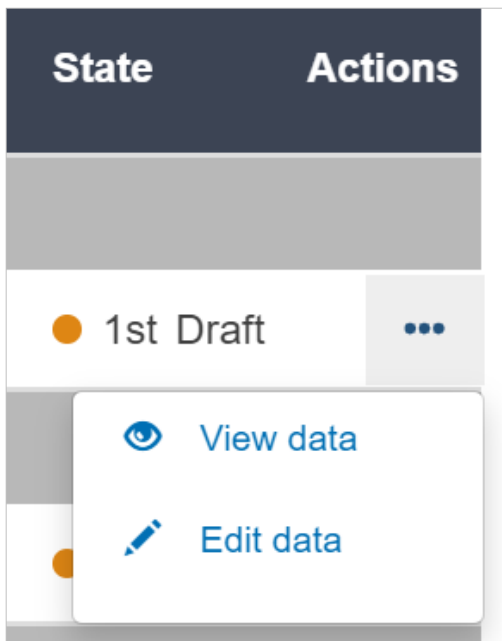
Reference/Catalogue number: [Text]

State: [Dropdown] (Registered, Draft, Registered, Submitted)

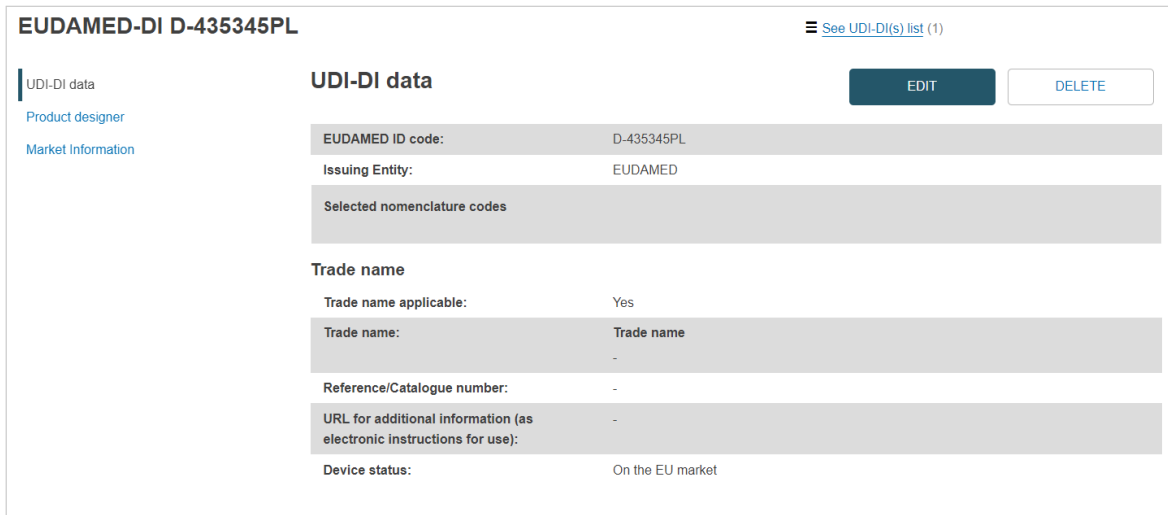
Apply filters Clear all filters

Active filters: State: Draft Clear all filters

- 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:



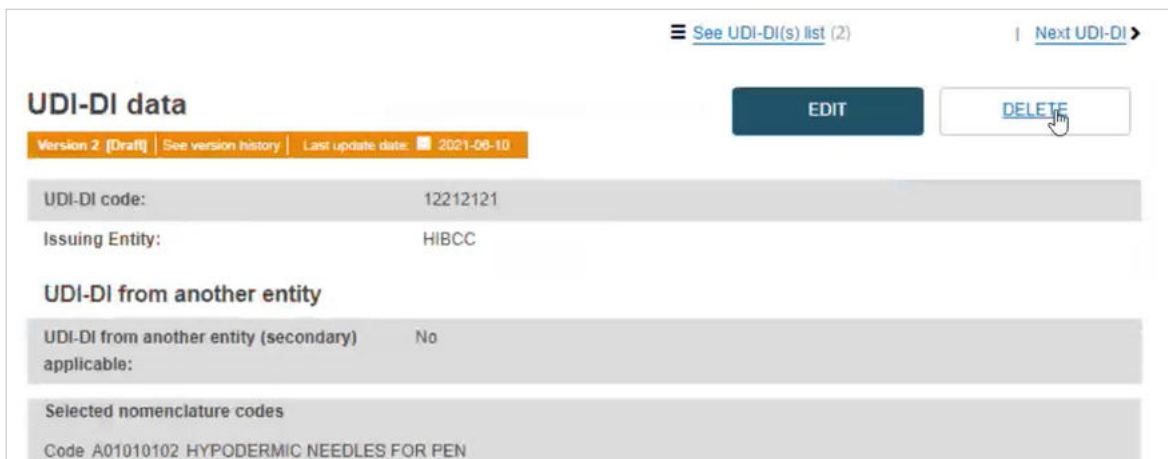
- You will see a summary of the details of your device:



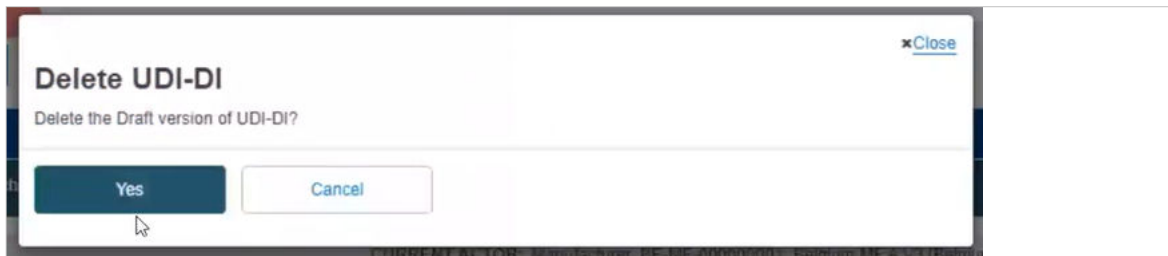
6.2.1. Delete a draft UDI-DI/EUDAMED-DI

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

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



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



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

Follow the steps in section 6.2 to view a UDI-DI/EUDAMED DI.

1. Once inside the summary of the desired UDI-DI, click on “Create new version”:

[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

2. Update the desired details, for example:

UDI-DI from another entity (secondary) applicable

Yes No

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

* Enter a nomenclature code (EMDN code):

clature

Selected nomenclature codes

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

Trade name applicable

Yes No

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

* Trade name:

* Select the language:

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



NOTE

Only some details can be updated depending on the actor's specifics.

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

6.2.3. Update (Create new version) for Product Designer

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

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):

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

UDI-DI 12212121 [See UDI-DI\(s\) list \(2\)](#) | [Next UDI-DI >](#)

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

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

UDI-DI code: 12212121

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

3. Click on “Update”:

Product designer **Update**

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

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

Original equipment manufacturer organisation:

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

4. Update the information under Product Designer:

Natural or Legal Person update

I know the SRN

* Name (Manufacturer Name):

Street information, if applicable

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

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:

* Country:

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

6.2.4. Update (Create new version) for Market information

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

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 Devices - User guide

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

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

Product designer

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

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 [Update countries](#)

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	-	-

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"/>	<input type="button" value="🗑️"/>
		YYYY-MM-DD		YYYY-MM-DD	
Greece	From	<input type="text"/>	To	<input type="text"/>	<input type="button" value="🗑️"/>
		YYYY-MM-DD		YYYY-MM-DD	
Latvia	From	<input type="text"/>	To	<input type="text"/>	<input type="button" value="🗑️"/>
		YYYY-MM-DD		YYYY-MM-DD	

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

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

6.2.5. Update (Create new version) for Container Packages

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

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

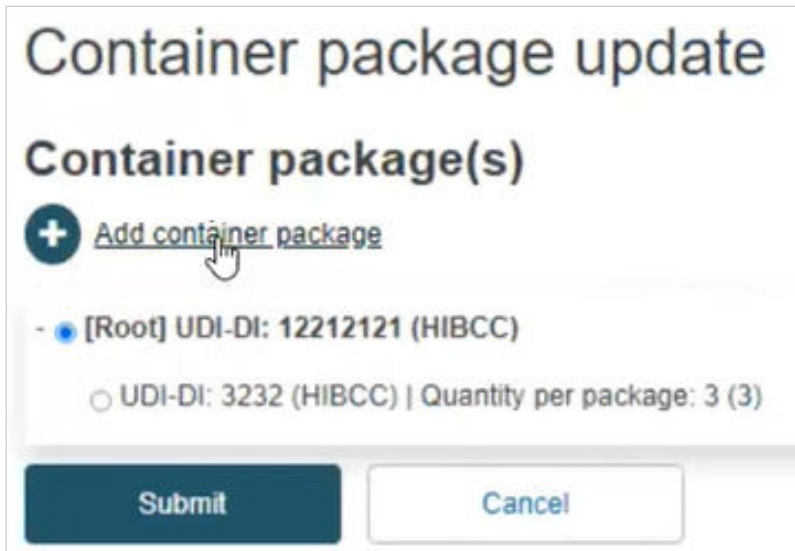
3. Click on “Create new version” in the Container Package section:

Container Package Information Create new version

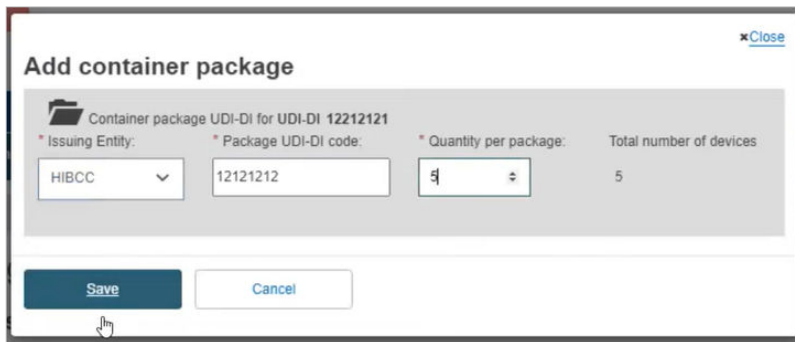
Version 1 | Last update date: 2021-06-10

- [Root] UDI-DI: 12212121 (HIBCC)
 - UDI-DI: 3232 (HIBCC) | Quantity per package: 3 (3)

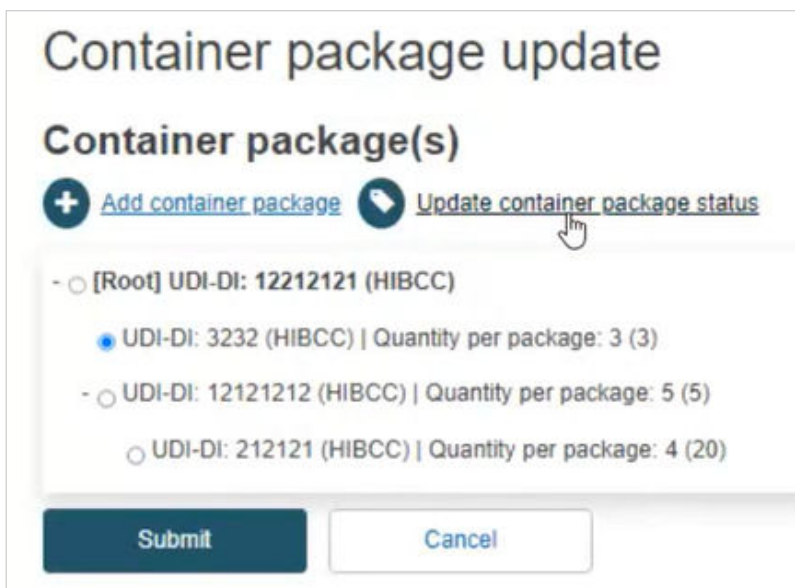
4. Click on “Add container package” to add new information about the packaging format of the device:



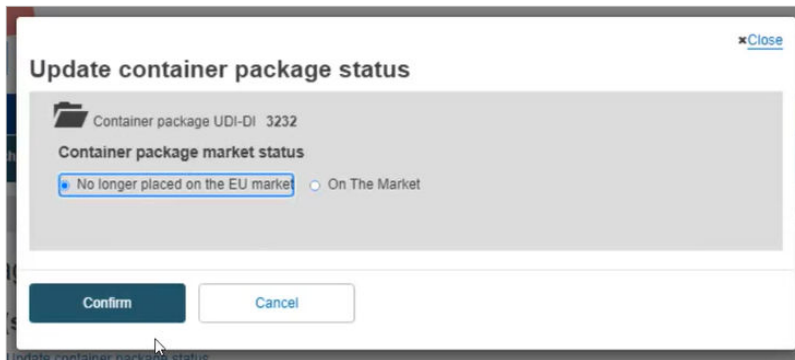
5. Enter the package details in the pop-up window and click on “Save”:



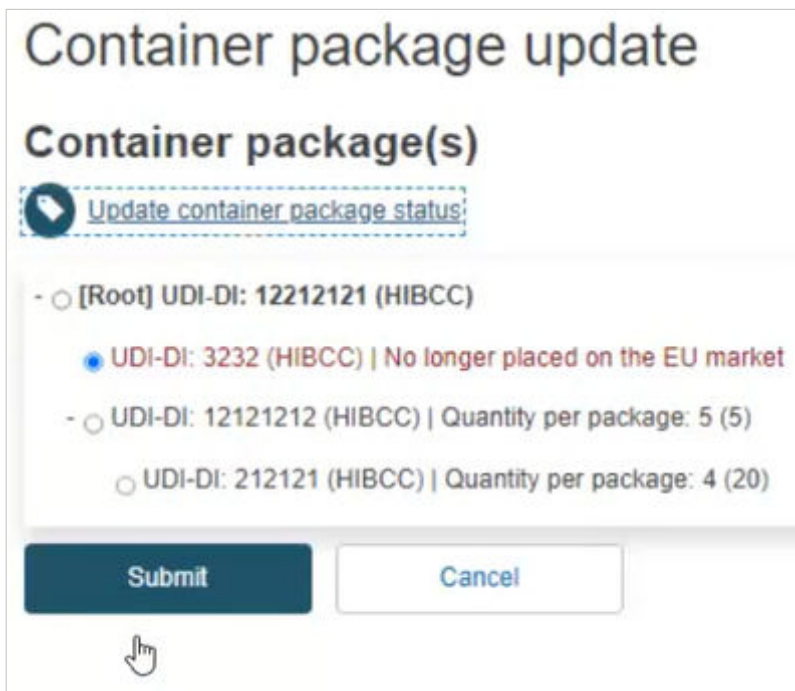
6. Once you add new package details, you can also update the container package status:



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



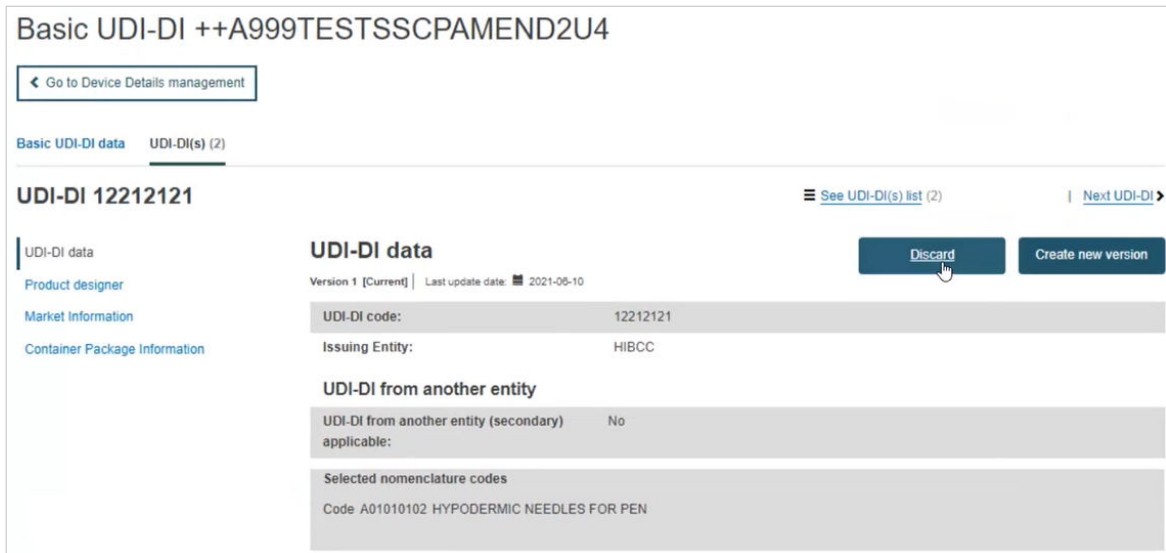
8. Click on “Submit” to finalise the container package update:



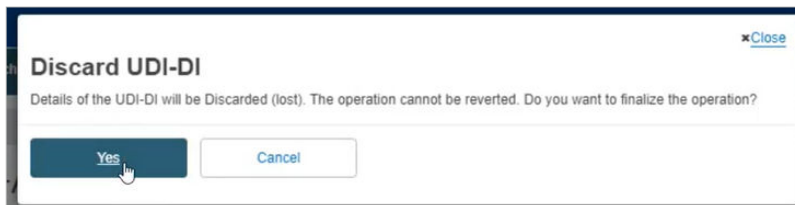
6.2.6. Discard registered UDI-DIs/EUDAMED DIs

You may 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 ask you to confirm your wish to permanently discard (delete) the registered UDI-DI. Click on “Yes” to finalise the action:

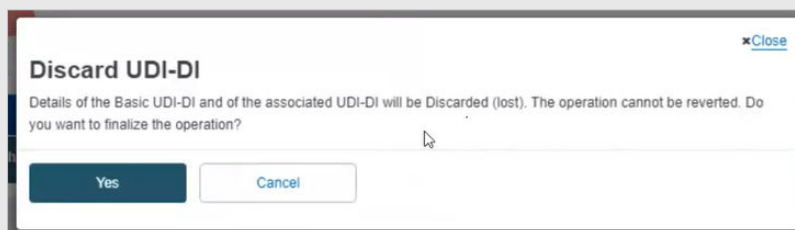


The UDI-DI will be discarded and as a result it will no longer be visible on the public EUDAMED platform.



CAUTION

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



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

Follow the steps in section 6.2 to view a UDI-DI/EUDAMED ID.

1. Once inside the summary of the desired UDI-DI, click on “See version history” on the top of the table:

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

UDI-DI data

Product designer

Market Information

UDI-DI data [EDIT](#) [DELETE](#)

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

EUDAMED ID code: D-1231231UU

Issuing Entity: EUDAMED

Selected nomenclature codes

Code A01010102 HYPODERMIC NEEDLES FOR PEN

Trade name

Trade name applicable: No

Reference/Catalogue number: 44545

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

Device status: On the EU market

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

EUDAMED DI B-1231231UU

[← Go back to the current version](#)

Version history of EUDAMED ID

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

3. 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 see the desired SPP, click on the “Filter” button and choose the correct 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 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	2021-06-29	Registered	...
9970314941ShriyaHL16E	1	-	System test1	Class I	S	2021-05-14	Registered	...
9970314941ShriyaHL	1	-	Test ONE	Class I	PP	2021-05-14	Registered	...

- Click on the three dots of the desired entry and then click on “View data” from the menu:

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	2021-06-29	Registered	...
9970314941ShriyaHL16E	1	-	System test1	Class I	S	2021-05-14	Registered	View Data
9970314941ShriyaHL	1	-	Test ONE	Class I	PP	2021-05-14	Registered	View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI

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

Basic UDI-DI 4444SSP_Shr_1VM

Go to UDI-DI/EUDAMED DI management

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

Basic UDI-DI data Create new version

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

Applicable regulation:	MDR (REGULATION (EU) 2017/745 on medical devices)	
Basic UDI-DI code:	4444SSP_Shr_1VM	
Issuing Entity:	GS1	
Risk class:	Class I	
Indication of medical purpose:	Indication of medical purpose	Language
	SPPP test 1	Croatian
Name:	SPP_Shr_1	

7.1.1. Delete a Draft Basic UDI-DI

- Follow the steps in Section 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	2021-06-22		View Data
1234543233234324XU	0	rferfefrefre	vddgv	Class I	PP	2021-06-22		Edit Data
1212112121212DL	0	-		-	PP	2021-06-22		View all UDI-DIs for this Basic UDI-DI

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

Basic UDI-DI 44444SSP_Shr_1VM

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

Basic UDI-DI data [UDI-DI\(s\) \(1\)](#)

[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	

- The system will ask you to confirm your intention to delete the draft in a pop-up window. If you are sure, 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?

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

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

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 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 View all UDI-DIs for this Basic UDI-DI Add a UDI-DI for a Basic UDI-DI
9970314941ShriyaHL	1	-	Test ONE	Class I	PP	2021-05-		

- Once inside the summary for the relevant Basic UDI-DI, click on “Create new version”:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

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

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

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

- 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: * Select the language:

SPPP test 1 Greek x v

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

* Device Name:

SPP_Shr_1

3. 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.



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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data

Version 2 [Current] | [See version history](#) | Last update date: 2021-08-29

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

7.1.3. View historical version 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:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data

Basic UDI-DI data Create new version

Version 2 [Current] | [See version history](#) | Last update date: 2021-09-29

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	

3. View the list of versions for the desired Basic UDI-DI and click on the chosen 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 find the desired UDI-DI, click on the “Filter” button and choose the right parameters:

UDI-DI details management for SPP

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

Filter ▾

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

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

UDI-DI code ID	Trade name ID	Reference/Catalogue number ID	Nomenclature code ID	Sterile ID	Date ID	Status	State	Actions
Basic UDI-DI: 4444SSP_Shr_1VM, Device Name: SPP_Shr_1, Class I, Type PP, MDR (REGULATION (EU) 2017/745 on medical devices)								+ Add a new UDI-DI
4444SSP_Shr_1VM		SPPP_Shr_1			2021-05-17	On the EU market	Registered	⋮
Basic UDI-DI: 9970314941ShriyaHL16E, Device Name: System test1, Class I, Type S, MDR (REGULATION (EU) 2017/745 on medical devices)								+ 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	⋮

- Click on the three dots of the desired entry and then click on “View data” from the menu:

Show 20 entries per page

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

Note: A context menu is shown over the second entry with the option "View data".

- 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 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 chosen Draft UDI-DI, click on “Delete” on the top right corner:

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

UDI-DI 34675806754T9

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

UDI-DI data EDIT DELETE

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

UDI-DI code: 34675806754T9

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A010102 BUTTERFLY NEEDLES

Trade name

Trade name applicable: Yes

Trade name: system 1All languages

Reference/Catalogue number: 543

Type of UDI-PI

Serial number: Yes

Manufacturing date: Yes

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

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

UDI-DI status: On the EU market

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

[Close](#)

Delete UDI-DI

Delete the Draft version of UDI-DI?

Yes Cancel

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

- Follow the steps in Section 7.2 to view a UDI-DI.

Basic UDI-DI management for SPP

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

[Filter](#)

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

Showing 1 to 3 of 3 entries Show entries per page

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

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data

Basic UDI-DI data Create new version

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

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

3. Update the necessary details.

NOTE

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

Create a new version of UDI-DI 44444SSP_Shr_1VM [version: 2]

UDI-DI: 44444SSP_Shr_1VM

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

Advanced search of device nomenclature

Selected nomenclature codes

Code A010204 NEEDLES AND KITS - AMNIOCENTESIS Remove nomenclature code

Trade name applicable

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

Reference/catalogue number: SPPP_Shr_1

Type of UDI-PI

* Manufacturing date: Yes

* Additional product description:

test

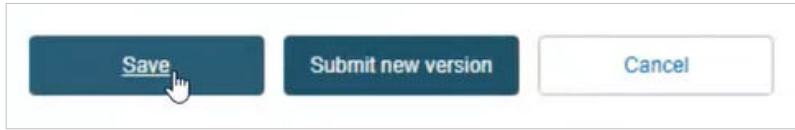
+ Add additional product description in another language

* Select the language:

Bulgarian
x
v

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 unsure about the update.

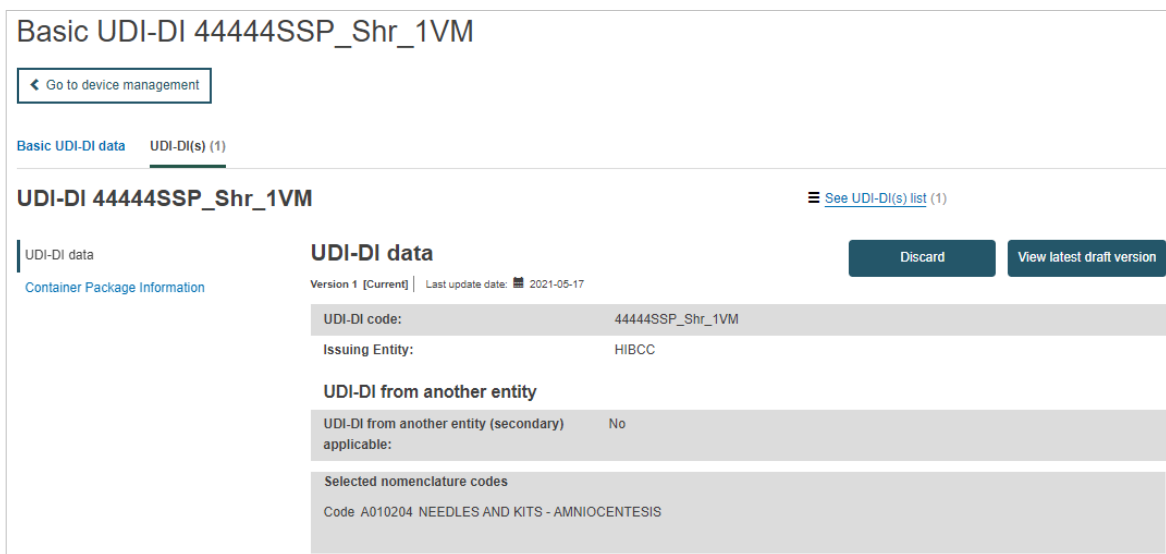
- b. Click on “Submit new version”, if you are sure about the update and wish to finalise it.
Otherwise, you can press “Cancel” to cancel the update.



7.2.3. Update (create new version) for Container Packages

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

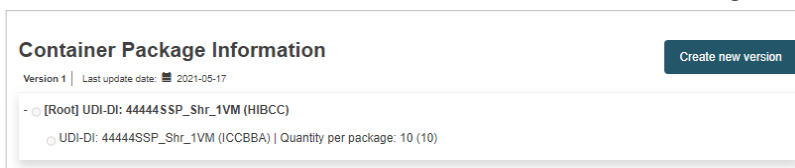
1. Follow the steps in section 7.2 to view a specific UDI-DI:



2. Once inside the summary of the chosen 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)

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

[*Close](#)

Add container package

Container package UDI-DI for UDI-DI 44444SSP_Shr_1VM

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

7.2.4. Discard Registered UDI-DIs

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

UDI-DI details management for SPP

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

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 chosen UDI-DI, click on “Discard” on the top right corner:

Basic UDI-DI 44444SSP_Shr_1VM

[← Go to device management](#)

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

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

UDI-DI data 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

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

UDI-DI data Discard Create new version

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

UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: HIBCC

UDI-DI from another entity

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

Discard UDI-DI ✕Close

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

Yes Cancel

7.2.5. View historical versions for UDI-DI and associated entities

- Follow the steps in section 7.2 to view a UDI-DI for the SPP.

- Once inside the summary of the chosen UDI-DI, click on “See version history” on the top of the table:

Basic UDI-DI data Create new version

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

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

- You will see a list of all old versions:

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

[Go back to the current version](#)

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

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

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

[Go back to the current version](#)

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

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

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

Basic UDI-DI identification

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

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

Issuing Entity: GS1

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

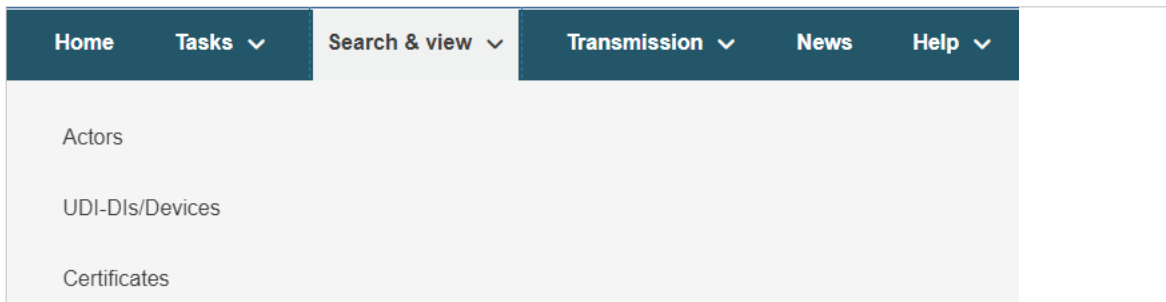
Risk class: Class IIb

Implantable: No

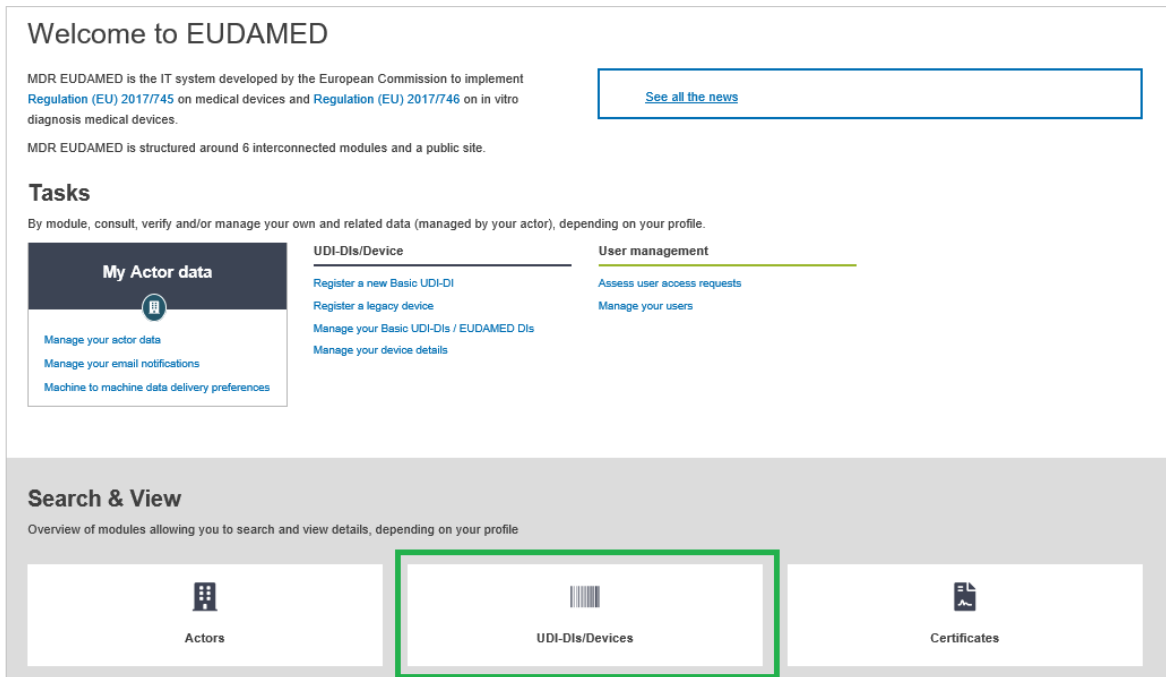
You can return to the version history list by clicking on “See all version history” on the top right corner.

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 show the filters available for searching in the list of Devices and Systems or Procedure Packs registered in EUDAMED:

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

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

- Click on the UDI-DI/EUDAMED ID of your choice 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 right parameters for your search, activate the result option to include old versions and click on “Search”:

Search for UDI-DIs

Only enable search filters available for bulk XML download

<small>UDI-DI code</small> <input type="text"/>	<small>Basic UDI-DI code</small> <input type="text"/>	<small>Status</small> -- <input type="button" value="v"/>	<small>Model</small> <input type="text"/>
<small>Name</small> <input type="text"/>	<small>Trade name</small> <input type="text"/>	<small>Applicable regulation</small> -- <input type="button" value="v"/>	
<small>Risk class</small> -- <input type="button" value="v"/>	<small>Nomenclature code</small> <input type="text"/>	<small>Reference/Catalogue number</small> <input type="text"/>	<small>Country</small> -- <input type="button" value="v"/>
<small>State</small> Registered <input type="button" value="x"/> <input type="button" value="v"/>	<small>Scopes</small> You can select more than one value <input type="text"/>		

<small>MF / PR SRN</small> <input type="text"/>	<small>MF / PR Name</small> <input type="text"/>	<small>AR SRN</small> <input type="text"/>	<small>AR name</small> <input type="text"/>
--	---	---	--

Results option

Include historical version

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

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

← Previous
1
2
3
4
5
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 structure format.

1. Follow the steps in section 8 to search and view a device or system or procedure pack.
2. On the search page, activate the top filter so that you only include the search results 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"/>	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		
Registered	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. Enter the search criteria of your choice, 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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Name	Trade name	Applicable regulation	
<input type="text"/>	<input type="text"/>	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		
Registered	You can select more than one value		
MF / PR SRN	MF / PR Name	AR SRN	AR name
BE-MF-000000001	<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Click on “Generate XML file”:



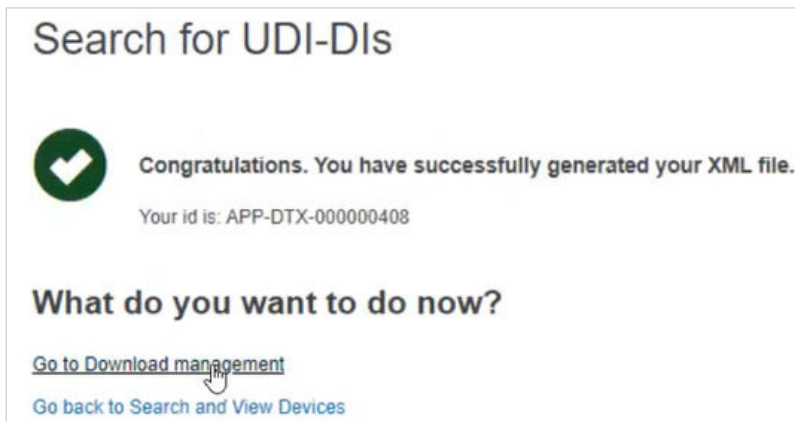
NOTE

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

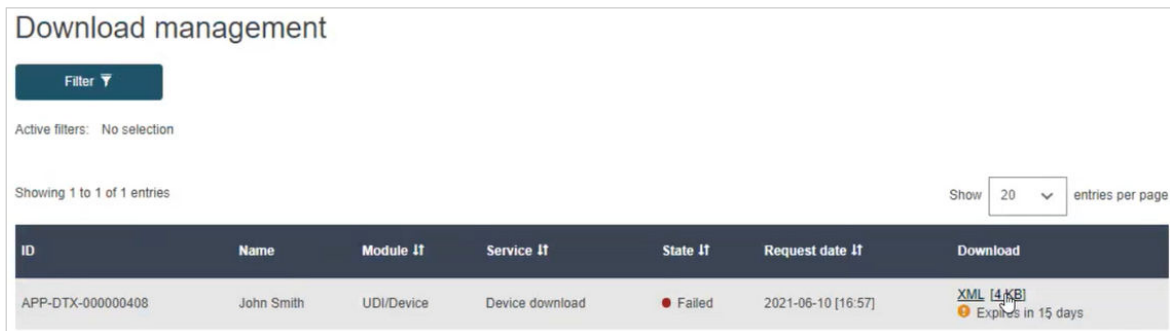
5. A pop-up window will ask you to confirm your action:



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



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



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

- Follow the steps in section 8.1 to view the details of a Device or SPP.
- Once inside the summary of the chosen UDI-DI, go to the section in which you wish to check old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product Designer or Container Package) and click on “See version history”:

UDI-DI 121312_Test_AR

[← Go back to the list](#)

Manufacturer information

[Basic UDI-DI details](#)
[UDI-DI details](#)
[Market information](#)
[Clinical Investigation\(s\)](#)

Manufacturer information

Organisation name: Japanese MF A v4
 Actor ID/SRN: JP-MF-00000061
 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-00000021
 Address: Brussels
 Telephone number: -
 Email: public-contact@belgium-ar-a.com

Basic UDI-DI details

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

Basic UDI-DI identification

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

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

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

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

UDI-DI details

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

UDI-DI code: 121312_Test_AR
 Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010199 HYPODERMIC NEEDLES - OTHERS

Trade name

Trade name applicable: Yes
 Trade name: TB_BG [BG], TN_AR1_Croatian [HR]
 Reference/Catalogue number: ref

Is the device directly marked?

Is the device directly marked?: No

Market information

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

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

Clinical Investigation(s)

Clinical Investigation

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

- You will see a list of all old 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	>

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI data

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

Basic UDI-DI identification

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

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

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

5. Inside a version, you can browse through the different versions by clicking on the arrows 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

9. Annex 1 – Device Certificate Information

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

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

Colour code description

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

10. Annex 2 – Legacy Device Certificate Types

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

