



EUDAMED user guide

UDI Devices

Production v 2.14
2024



Table of Contents

1. Introduction	1
2. Getting started	3
3. Registering Regulation Devices	5
3.1. Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device	6
3.1.1. Step 1: Basic UDI-DI identification information	7
3.1.2. Step 2: Certificate information (when applicable)	10
3.1.3. Step 3: UDI-DI identification information	12
3.1.4. Step 4: UDI-DI characteristics	15
3.1.5. Step 5: Device information	18
3.1.6. Step 6: Container package details	23
3.2. Registration of a UDI-DI for an existing Basic UDI-DI of a Regulation Device	26
4. Registering System or Procedure Packs (SPP)	29
4.1. Registration of a Basic UDI-DI together with a UDI-DI for a System or Procedure Pack	29
4.1.1. Step 1: Basic UDI-DI main information	29
4.1.2. Step 2: Basic UDI-DI information	31
4.1.3. Step 3: UDI-DI identification information	32
4.1.4. Step 4: UDI-DI characteristics	35
4.1.5. Step 5: Container package details	36
4.2. Registration of a UDI-DI for an existing Basic UDI-DI of a System or Procedure Pack	38
4.2.1. Step 1: UDI-DI identification information	39
4.2.2. Step 2: UDI-DI characteristics	41
4.2.3. Step 3: Container package details	41
5. Manage your own device information	42
5.1. Manage your device Basic UDI-DI/EUDAMED DI details	42
5.1.1. Delete a draft Basic UDI-DI/EUDAMED DI	43
5.1.2. Update (create new version) for Basic UDI-DI/ EUDAMED DI	44

5.1.3. View historical versions for Basic UDI-DI/ EUDAMED DI	46
5.2. Manage your device UDI-DI/EUDAMED ID details	47
5.2.1. Delete a draft UDI-DI/EUDAMED ID	49
5.2.2. Update (create a new version) for UDI-DI/ EUDAMED ID	49
5.2.3. Update (create new version) for Product original manufacturer	53
5.2.4. Update (create new version) for Market Information	55
5.2.5. Update (create new version) for Container Packages	56
5.2.6. Discard registered UDI-DIs/EUDAMED IDs (and their Basic UDI-DI/EUDAMED DI)	59
5.2.7. Link a registered Regulation Device to a registered Legacy Device	60
5.2.8. Delete the link between a Regulation Device and a Legacy Device	64
5.2.9. View historical versions of UDI-DI/EUDAMED ID and associated entities	65
6. Manage your own System or Procedure Pack (SPP) information	67
6.1. Manage your SPP Basic UDI-DI details	67
6.1.1. Delete a draft Basic UDI-DI	68
6.1.2. Update (create new version) for Basic UDI-DI	69
6.1.3. View historical version for Basic UDI-DI	71
6.2. Manage your SPP UDI-DI details	72
6.2.1. Delete a draft UDI-DI	74
6.2.2. Update (create new version) for UDI-DI	75
6.2.3. Update (create new version) for Container Packages	77
6.2.4. Discard SPP registered UDI-DIs	78
6.2.5. View SPP historical versions for UDI-DI and associated entities	80
7. Search & View Devices, Systems and/or Procedure Packs .	81

7.1. Search & View historical versions of Devices, Systems and Procedure Packs	83
7.2. Download Devices or Systems or Procedure Packs data in a structured format (XML)	84
7.3. View historical versions for Basic UDI-DI/EUDAMED DI, UDI-DI/EUDAMED ID and associated entities	86
8. Annex 1 – device certificate information	90

1 Introduction

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

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

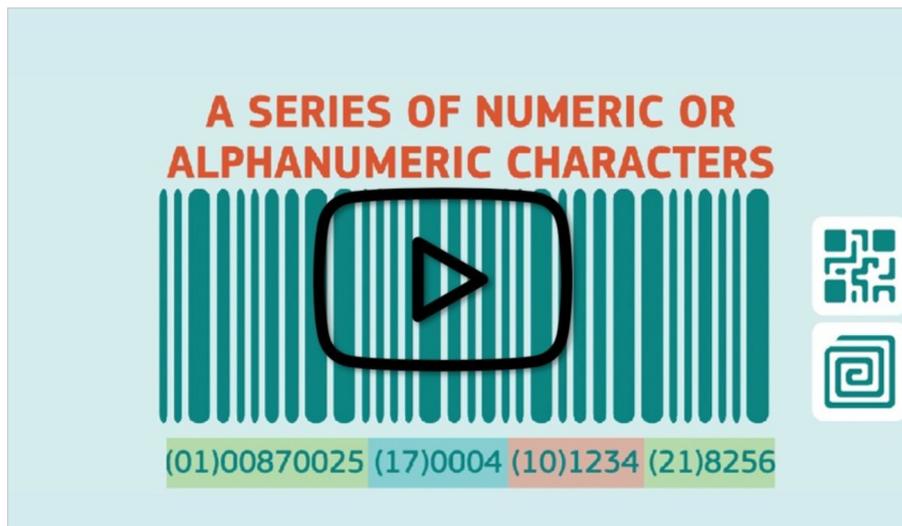


WARNING

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



VIDEO: What is a UDI?



INFOGRAPHIC: Basic UDI-DI/UDI-ID concept

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

IDENTIFIERS

What are the different identifiers?

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

Basic UDI-DI

UDI-DI

Package UDI-DI
(If applicable)

2 Getting started

What I need to access EUDAMED:

1. EU Login (ECAS) account

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

2. User profile registration in EUDAMED

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



NOTE

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



Every user in EUDAMED is granted by default the profile *Viewer* for the UDI/Device module, and can search and view registered devices. However, to enter UDI/Device data in EUDAMED, you must request access for the UDI/Device module with a higher profile² as either:

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



NOTE

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

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



IMPORTANT

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

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

3 Registering Regulation Devices

VIDEO: Registering Regulation Devices



Each Regulation Device must have a unique Basic UDI-DI and a unique UDI-DI assigned to it. Both are always required – you cannot register a Basic UDI without a UDI-DI.

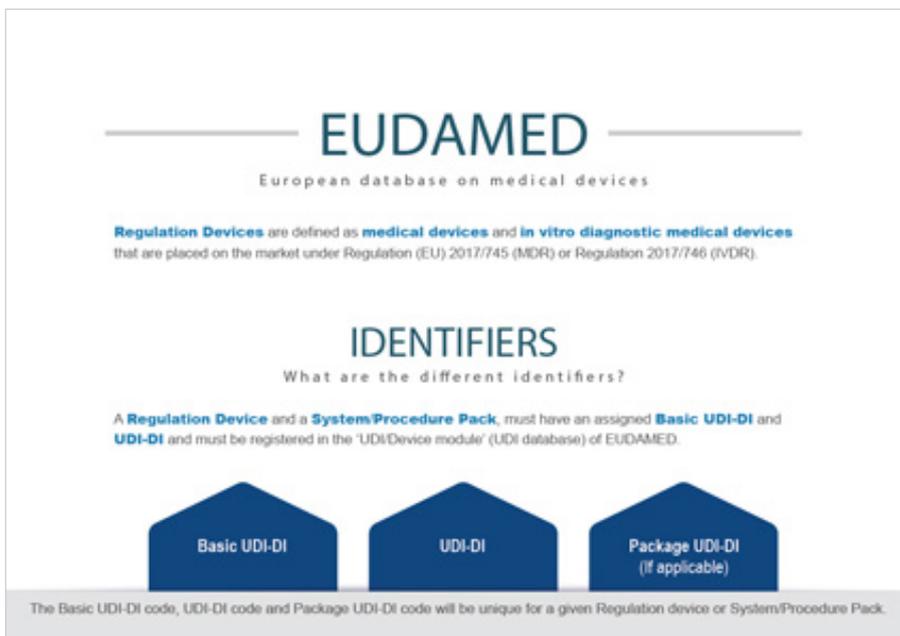
You will be asked to enter EUDAMED via your EU Login account.

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



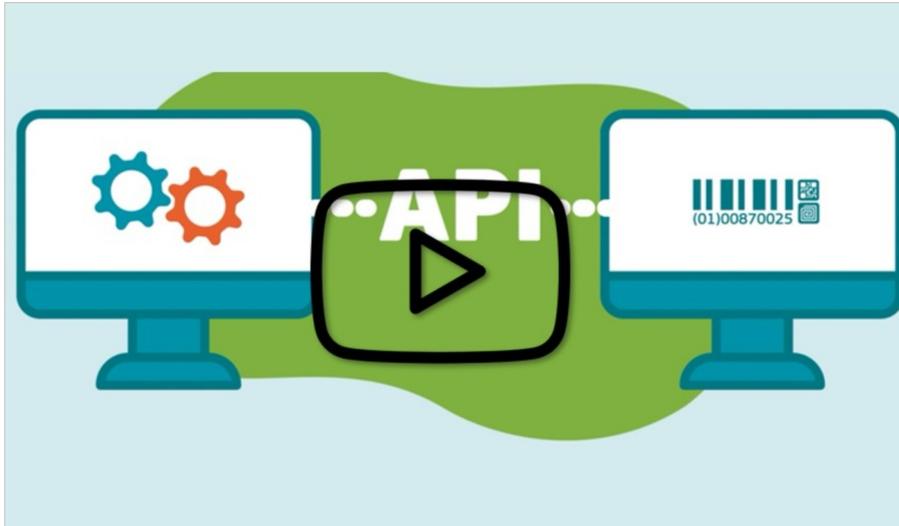
3.1 Registration of a Basic UDI-DI together with a UDI-DI of a Regulation Device

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



3.1.1 Step 1: Basic UDI-DI identification information

 **VIDEO: UDI and medical software devices**



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

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

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

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



NOTE

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

UDI-DI registration

Manufacturer identification

Organisation name: Test MF
 Actor ID/SRN: LI-MF-00000104
 Address: Oak St, 101 8088 Vaduz
 Telephone number: +343 8987 65 13
 Email: eudamed@manufacturer.com

*** Applicable regulation**

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

Depending on the regulation 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 <i>Yes</i> or <i>No</i> 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 <i>No</i> to this first question</p>

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

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

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

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

Special device type

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

*** Special device type:**

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

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



NOTE

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

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

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:



IMPORTANT

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

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

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

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

Authorised representative identification

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

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

Basic UDI-DI information

* Risk class:

--

* Measuring function

Yes No

* Active device

Yes No

* Device intended to administer and/or remove medicinal product

Yes No

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

Device model applicable

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

* Device model:

Device Model_Test

Device Name:

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

3.1.2 Step 2: Certificate information (when applicable)

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

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

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

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

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

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



NOTE

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

In [Annex 1 – Device Certificate Information \[90\]](#) you can find the different cases in which Certificate information is needed and the type of certificate. (In summary, it is applicable for MDR risk class III and IIb and IVDR risk class B with self-patient testing/ near-patient testing, risk class D and C).

Certificate information

EU type-examination certificate if applicable

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

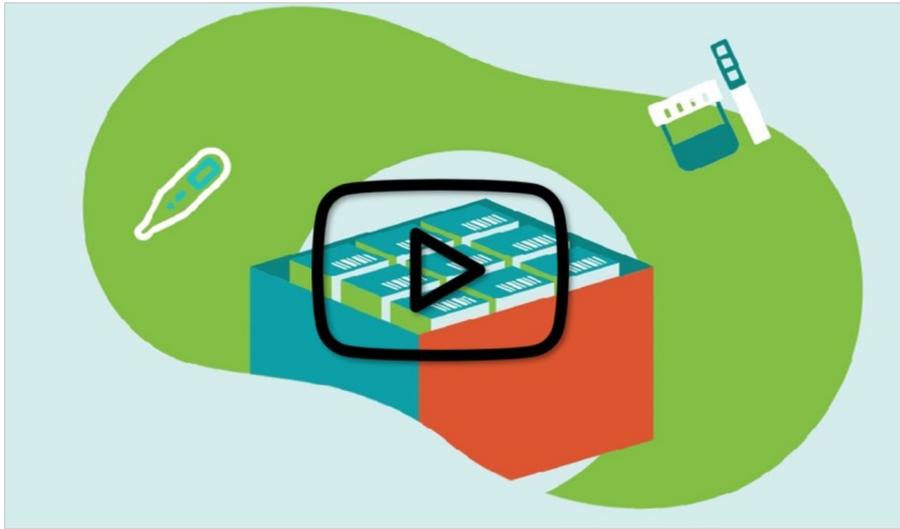
* Enter NB number or name:

Certificate number:

Revision number:

3.1.3 Step 3: UDI-DI identification information

VIDEO: UDI carrier and display formats



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



IMPORTANT

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

Exception: the same UDI-DI can be used for a Legacy Device and its Regulation Device equivalent.

If the same UDI-DI code was already provided for a Legacy Device (i.e. Applicable Legislation MDD, AIMDD or IVDD), you will be prompted that a link will be created between the two devices (the Regulation and the Legacy Device) on the condition there is no conflict between some of the Basic UDI-DI properties and the related legacy device EUDAMED DI properties. In case of conflict, the system will prevent you from using the same UDI-DI.



NOTE

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

For example:

000000nnnnnnnn (GTIN-8)

00nnnnnnnnnnnn (GTIN-12)

0nnnnnnnnnnnnnn (GTIN-13)

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

UDI-DI identification

UDI-DI identification

* Issuing Entity:

* UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity:

* Secondary UDI-DI value:

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

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Trade name applicable

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

* Trade name:

* Select the language:

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

- Enter the *Reference/Catalogue number*.

* Reference/Catalogue number:

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

* Is the device directly marked?

Yes No

Same as UDI-DI

* Issuing Entity:

* Direct marking DI:

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

* Is the device directly marked?

Yes No

* Quantity of device:

Issuing Entity:

Unit of Use DI:

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

* Is the device directly marked?

Yes No

* Quantity of device:

* Type of UDI-PI

Lot or Batch number

Serial number

Manufacturing date

Expiration date

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

* Quantity of device:

* Type of UDI-PI

Lot or Batch number

Serial number

Manufacturing date

Expiration date

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

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

3.1.4 Step 4: UDI-DI characteristics

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



NOTE

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

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

You shall provide one of the following precision type:

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

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

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

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

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

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

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

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

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

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

*** CMR/Endocrine disruptor**

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

Yes No

*** Category of CMR:**

1A 1B

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

EC#: CAS#:

[ECHA database >](#)

*** Name of the substance:**

 [Add a CMR substance](#)

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

Yes No

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

Storage/handling conditions, if applicable

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

*** Storage/handling conditions type:**

*** Description:**

*** Select the language:**

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

 [Add another storage/handling condition](#)



NOTE

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

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

Critical warnings or contra-indications, if applicable

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

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

* Description:

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



NOTE

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

3.1.5 Step 5: Device information

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

Device information

* Reprocessed single use device

Yes No

* Intended purpose other than medical (Annex XVI)

Yes No

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

* Intended purpose other than medical (Annex XVI)

Yes No

Contact lenses

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

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

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

High intensity electromagnetic radiation

Brain electrostimulation

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

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

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

Yes No

I know the Actor ID/SRN

* Enter Actor ID/SRN or name:



NOTE

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

Select the Actor from the list:

[*Close](#)

Select manufacturer

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

← Previous 1 2 ... 19 Next →

Close

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

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

Yes No

I know the Actor ID/SRN

* Product original manufacturer organisation name:

Select the Organisation name from the list:

[Close](#)

Select manufacturer

Organisation name ↓↑

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

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

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

[Change manufacturer](#)

* Name (Manufacturer Name):

Street information, if applicable

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

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:

* Country:

Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

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

Clinical Investigation

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

✘ Clinical Investigation '212121' is not registered in EUDAMED

* Enter Clinical Investigation Number:

5. When registering under MDR, select **Yes** or **No** to 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 Information on substances, enter the details:

*** Information on substances**

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

Yes No

INN:

* Name of the substance:

* Select the language: -- ▾

[+ Add another language](#)

[+ Add a substance](#)

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

Yes No

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

Yes No

Presence of animal tissues or cells, or their derivatives:

Yes No

Presence of cells or substances of microbial origin:

Yes No

*** 'New' Device**

Yes No [?](#)



NOTE

A device shall be considered *new* if:

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

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

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

France

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

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

[Select one or more countries >](#)



NOTE

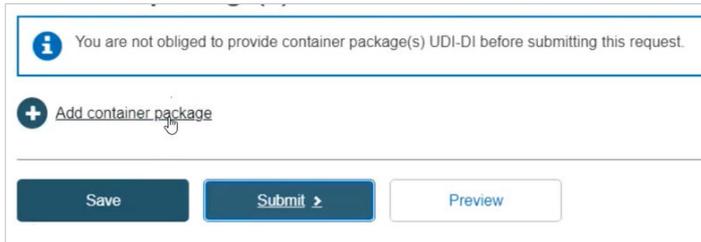
The countries where the device is or is to be made available on the market are mandatory, to be provided when the device's status is *On the EU market* and device's risk class is **not risk class I (MDR) and not risk class A (IVDR)**.

3.1.6 Step 6: Container package details

 **VIDEO: UDI carrier placing**



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



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

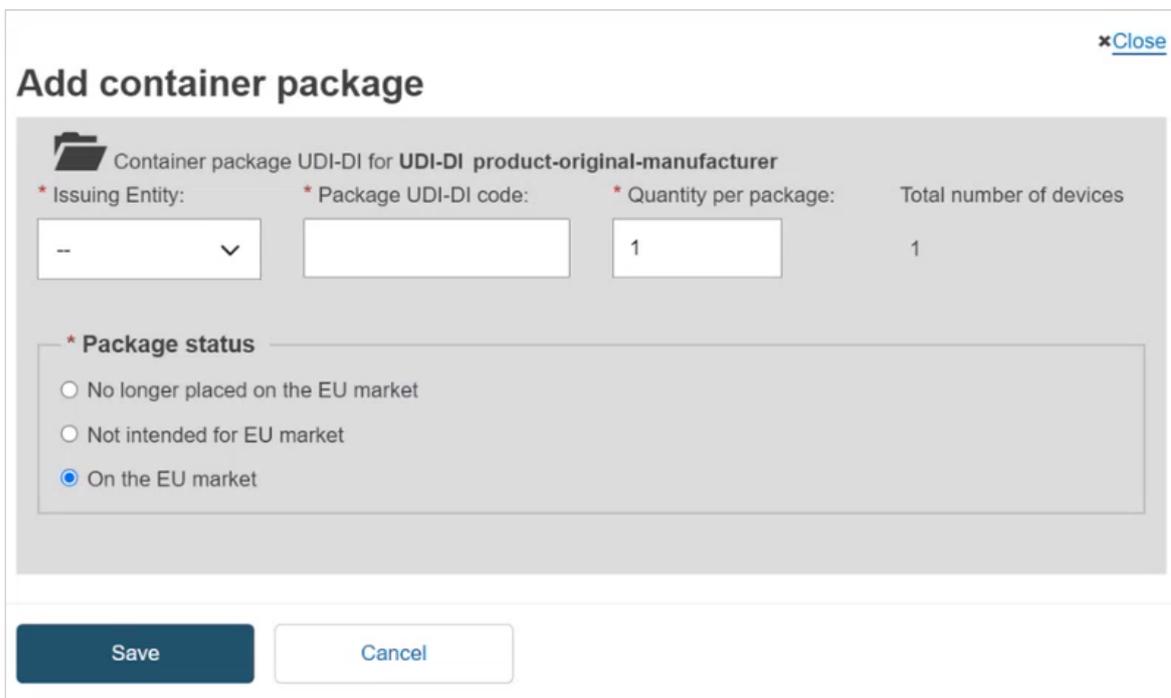
+ Add container package

Save Submit Preview

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

**NOTE**

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



[*Close](#)

Add container package

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

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

* Package status

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

Save Cancel

**NOTE**

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

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

Container package(s)

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

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

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

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

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

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

Submission

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

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

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

[Submit my request](#) [Cancel](#)

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

Basic UDI-DI registration

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

What do you want to do now?

[Enter another UDI-DI associated to Basic UDI-DI 1212123333333345HG](#)

[Register new Basic UDI-DI](#)

[Go to the dashboard](#)

**IMPORTANT**

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

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

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

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

Welcome to EUDAMED

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

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

[See all the news](#)

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

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

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

**IMPORTANT**

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

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

Basic UDI-DIs / EUDAMED DIs management

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

Filter

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

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

Apply filters Clear all filters

Active filters: State: Draft Clear all filters

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

Basic UDI-DI/EUDAMED DI Code	Devices	Device model	Device Name	Risk class	Date	State	Actions
122111212121YZ	1		Test	Class IIa	2021-03-31	1st Draft	...
1111184FG228694YC	1	DeviceModelZZZ	DeviceNameZZZ	Class IIb	2021-03-19	1st Draft	...

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

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

Add new UDI-DI to existing Basic UDI

Manufacturer identification
BE-MF-000000004, Alexandru Release Manufacturer

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

Basic UDI-DI code: 1234503276
Issuing Entity: GS1

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

Yes No 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](#)

5. 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*.

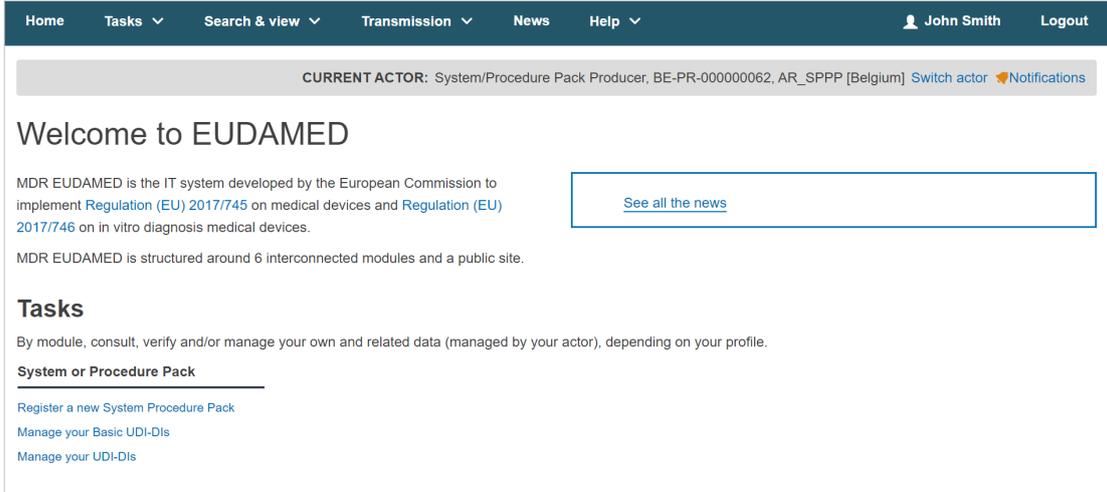
4 Registering System or Procedure Packs (SPP)

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

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

4.1.1 Step 1: Basic UDI-DI main information

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



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

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

System or Procedure Pack registration

Procedure pack producer identification

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

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

* System or Procedure Pack type:

Procedure Pack
 System

[Save & Next >](#)

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

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

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

System or Procedure Pack registration

Procedure pack producer identification

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

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

Basic UDI-DI main information

* Issuing Entity: * Basic UDI-DI code:

Duplicate device identified.

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

*** System or Procedure Pack type:**

Procedure Pack

System

Save & Next >

4.1.2 Step 2: Basic UDI-DI information

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

System or Procedure Pack registration

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

Producer identification
BE-PR-000000062_AR_SPPP

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

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

System or Procedure Pack type: Procedure Pack

Basic UDI-DI information

* Risk class:
--

* Indication of medical purpose:

* Select the language:
--

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

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

* Model:

Name:

Save **Save & Next >**

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

Producer identification: BE-PR-000000062_AR_SPPP

Basic UDI-DI identification: UDI-DI identification information

UDI-DI characteristics: UDI-DI characteristics

Container package(s): Container package(s)

Basic UDI-DI information

* Risk class:
--

* Indication of medical purpose:

* Select the language:

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

2017745 on medical devices)

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

System or Procedure Pack type: Procedure Pack

* Indication of medical purpose: [Text area]

* Select the language: [Dropdown menu]

+ Add another indication of medical purpose

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

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

Device model applicable

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

* Model: [Text input field]

3. 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 >

4.1.3 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: [Dropdown menu with GS1 selected]

* UDI-DI code: [Text input field]



IMPORTANT

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



NOTE

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

For example:

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

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

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Issuing Entity: * Secondary UDI-DI value:

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

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

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

Trade name applicable

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

* Trade name: * Select the language:

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

5. Enter the *Reference/Catalogue number*:

* Reference/Catalogue number:

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

*** Type of UDI-PI**

Lot or Batch number

Serial number

Manufacturing date

Expiration date

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

Additional product description:

Select the language:

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

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

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

*** UDI-DI status**

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

4.1.4 Step 4: UDI-DI characteristics

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

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

UDI-DI characteristics

*** Need for sterilisation before use**

Yes No

*** Device labelled as sterile**

Yes No

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

Storage/handling conditions, if applicable

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

*** Storage/handling conditions type:**

OTHER *

*** Description:**

Test

*** Select the language:**

-

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



NOTE

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

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

* Description: Test

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

Save Save & Next >



NOTE

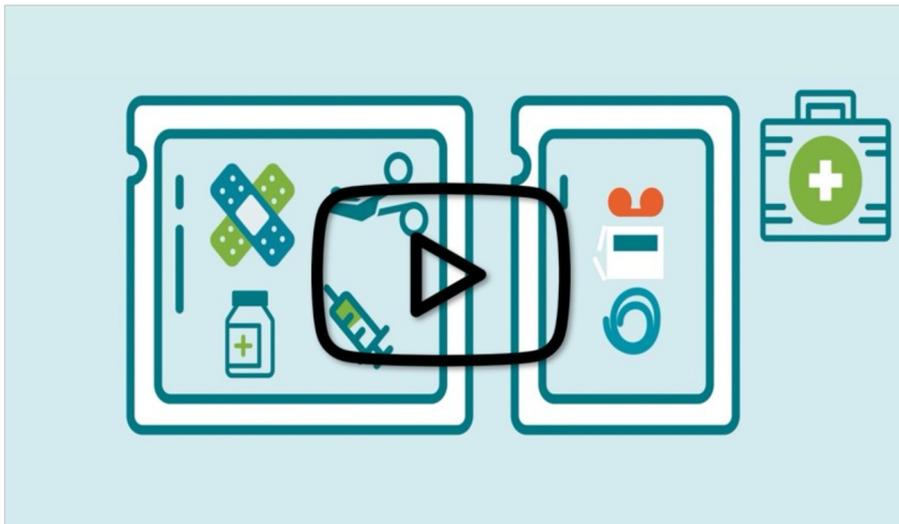
When the selected Critical warning or contra-indications type has the option *Other*, users will be required to enter the Description of the Critical warning or contra-indications type and the language in which the description is given.

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

Save Save & Next >

4.1.5 Step 5: Container package details

VIDEO: UDI and Systems and Procedure Packs



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

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

+ [Add container package](#)

Save

Submit >

Preview

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



NOTE

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

[xClose](#)

Add container package

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

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

*** Package status**

No longer placed on the EU market

Not intended for EU market

On the EU market

Save

Cancel



NOTE

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

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

Container package(s)

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

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

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

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

Save

Submit >

Preview

3. 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**:

✕Close

Submission

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

⌚ **Status of your request**

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

Submit my request

Cancel

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

Registration of System or Procedure Pack

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

What do you want to do now?

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

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

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

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

My Actor data

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

User management

- Assess user access requests
- Manage your users

System or Procedure Pack

- Register a new System Procedure Pack
- Manage your Basic UDI-DIs
- Manage your UDI-DIs

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

Basic UDI-DI management for SPP

Go to device management Register new System or Procedure Pack

Filter ▼

Basic UDI-DI code: Name: State:

Risk class: System or Procedure Pack:

Apply filters Clear all filters

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

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

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

4.2.1 Step 1: UDI-DI identification information

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

1

UDI-DI
identification
information

2

UDI-DI
characteristics

3

Container
package(s)

UDI-DI identification

UDI-DI identification

* Issuing Entity: * UDI-DI code:

UDI-DI from another entity (secondary) applicable

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

* Enter a nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

Selected nomenclature codes

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

Trade name applicable

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

* Trade name: * Select the language:

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

* Reference/Catalogue number:

Ref_12134

REF_TEST

Ref_12134

Manufacturing date

Expiration date

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

Save

Save & Next

4.2.2 Step 2: UDI-DI characteristics

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

UDI-DI characteristics

* Need for sterilisation before use

Yes No

* Device labelled as sterile

Yes No

Storage/handling conditions, if applicable

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

Critical warnings or contra-indications, if applicable

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

* Critical warning type:

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

Save **Save & Next >**

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

4.2.3 Step 3: Container package details

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

5 Manage your own device information

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

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

The screenshot shows the EUDAMED dashboard for a manufacturer. At the top, it says 'CURRENT ACTOR: Manufacturer, BE-MF-00000001, Belgium MF A V3 [Belgium]'. Below this is a 'Welcome to EUDAMED' message and a 'See all the news' button. The 'Tasks' section is divided into three main areas: 'My Actor data', 'User management', and 'UDI-DIs/Device'. Under 'UDI-DIs/Device', there are several options: 'Register a new Basic UDI-DI', 'Register a legacy device', 'Manage your Basic UDI-DIs / EUDAMED DIs' (highlighted with a red box), and 'Manage your device details'.

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



NOTE

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

Basic UDI-DIs / EUDAMED DIs management

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

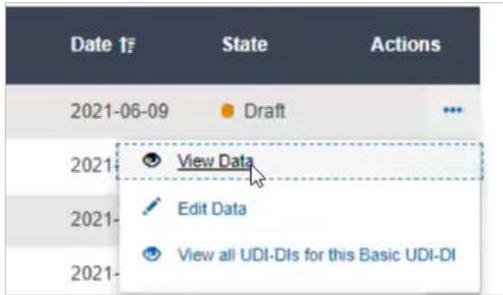
Filter ▾

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

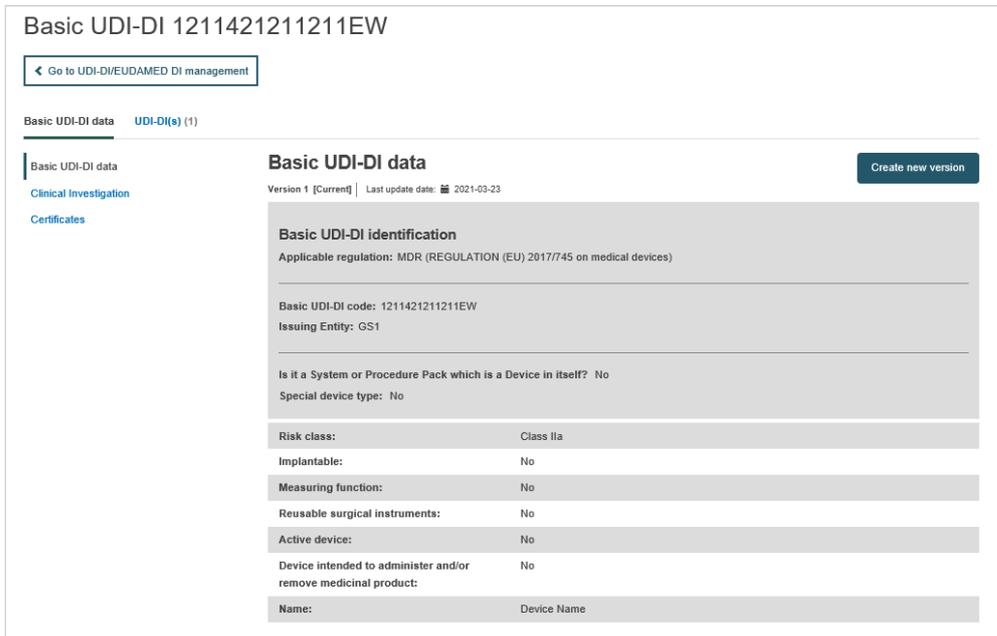
Showing 1 to 9 of 9 entries Show 20 entries per page

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

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



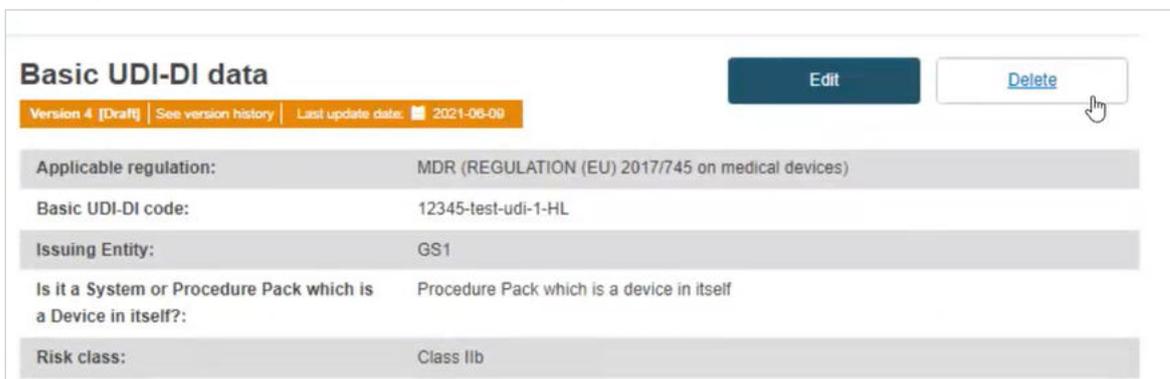
- You will see a summary of the details concerning your Basic UDI-DI/EUDAMED DI:



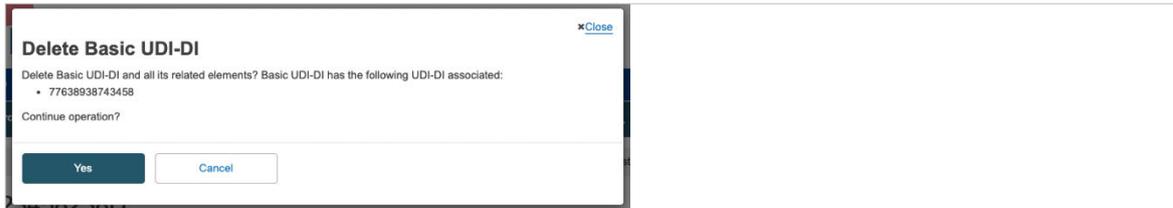
5.1.1 Delete a draft Basic UDI-DI/EUDAMED DI

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

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

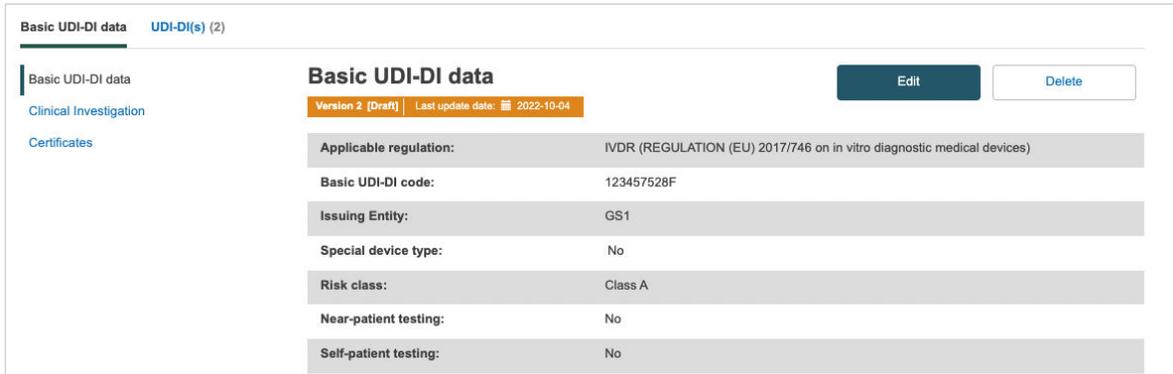


A pop-up will ask you to confirm the *delete* action:

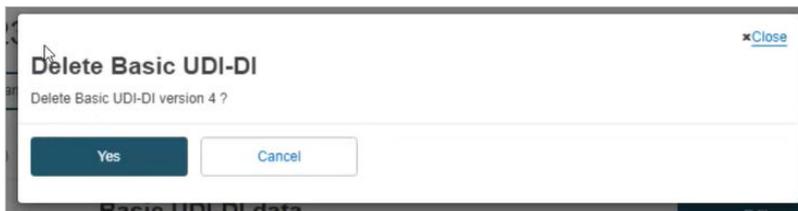


The system also warns about deletion of the UDIs under the *1st draft* device.

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



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



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

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

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

Basic UDI-DI 1211421211211EW

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

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

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

Basic UDI-DI data Create new version

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

Basic UDI-DI identification

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

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

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

Risk class: Class IIa

Implantable: No

Measuring function: No

Reusable surgical instruments: No

Active device: No

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

Name: Device Name

2. Update the desired details:

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

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

Risk class: Class IIb

Implantable: No

Measuring function: Yes

Reusable surgical instruments: No

Active device: No

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

Device model applicable

Yes No Device model applicable

* Device Name:

version 3

Presence of human tissues or cells, or their derivatives: Yes

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

Save Submit new version Cancel

3. To complete the action:

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

Save Submit new version Cancel

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

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

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

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

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

Basic UDI-DI data Create new version

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

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

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

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

[Go back to the current version](#)

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

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

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

[Go back to the current version](#)

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

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

5.2 Manage your device UDI-DI/EUDAMED ID details

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

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

My Actor data

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

UDI-DIs/Device

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

User management

- Assess user access requests
- Manage your users

Search & View

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

Actors

UDI-DIs/Devices

Certificates

2. You will see a list:

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

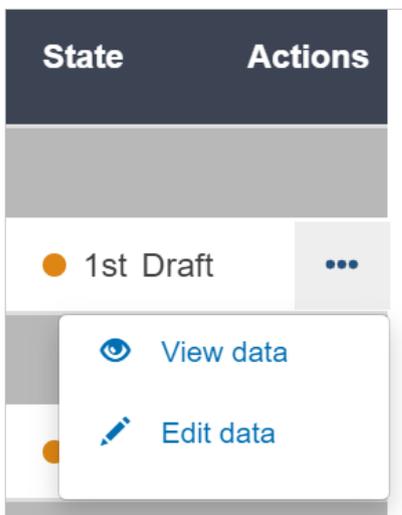
UDI-DI/EUDAMED ID Code II	Trade name II	Reference/Catalogue number II	Nomenclature code II	Date f†	Status	State	Actions
▼ EUDAMED DI code: B-435345PL , Device Name: dsfdafd, Class IIb, MDD (Directive 93/42/EEC on Medical Devices)							
D-435345PL				2021-03-29	On the EU market	● 1st Draft	...
▼ EUDAMED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



NOTE

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

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



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

5.2.1 Delete a draft UDI-DI/EUDAMED ID

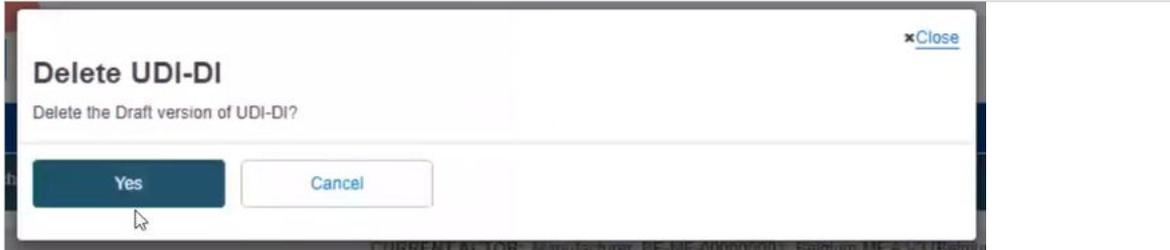
Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a draft UDI-DI.

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



The screenshot shows the 'UDI-DI data' page. At the top right, there are links for 'See UDI-DI(s) list (2)' and 'Next UDI-DI >'. Below the title, there are 'EDIT' and 'DELETE' buttons. A status bar indicates 'Version 2 [Draft]', 'See version history', and 'Last update date: 2021-06-10'. The main data fields are: 'UDI-DI code: 12212121', 'Issuing Entity: HIBCC', 'UDI-DI from another entity' section with 'UDI-DI from another entity (secondary) applicable: No', and 'Selected nomenclature codes' with 'Code A01010102 HYPODERMIC NEEDLES FOR PEN'.

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



The screenshot shows a 'Delete UDI-DI' confirmation dialog box. The title is 'Delete UDI-DI' and the message is 'Delete the Draft version of UDI-DI?'. There are 'Yes' and 'Cancel' buttons at the bottom. A 'Close' button is in the top right corner.

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

 **VIDEO: UDI assignment and updates**



Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

1. Once inside the details of the selected UDI-DI, click on **Create new version** and proceed to update:

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

- Version 1 [Current] | Last update date: 2021-06-10
- UDI-DI code: 12212121
- Issuing Entity: HIBCC
- Section: UDI-DI from another entity
- UDI-DI from another entity (secondary) applicable: No
- Section: Selected nomenclature codes
- Code: A01010102 HYPODERMIC NEEDLES FOR PEN

This screenshot shows the configuration options for the UDI-DI.

- UDI-DI from another entity (secondary) applicable:** A toggle switch is set to 'No'. An information icon indicates that 'UDI-DI from another entity is required unless you select the option - No'.
- Nomenclature code search:** A search box contains 'B|' and a 'Find' button. A dropdown menu shows 'B01' with a 'clature' label. Below the search, the 'selected nomenclature codes' section shows 'Code: A01010102 HYPODERMIC NEEDLES FOR PEN' and a 'Remove nomenclature code' button.
- Trade name applicable:** A toggle switch is set to 'Yes'. An information icon indicates that 'Trade name is required unless you select the option - No'.
- Trade name fields:** A 'Trade name' input field contains 'Trade_Name'. A 'Select the language' dropdown menu is set to 'All languages'.
- Additional options:** A plus icon and a link 'Add a trade name in another language' are visible at the bottom.

*** Is the device directly marked?**

Yes No

Same as UDI-DI

* Issuing Entity:

* Direct marking DI:

Quantity of device: 1

*** Type of UDI-PI**

Lot or Batch number
 Serial number
 Manufacturing date
 Expiration date

Additional product description:

Select the language:

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

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

Clinical size

Clinical size applicable: No

Labelled as single use

* Labelled as single use: No

Maximum number of reuses applicable: No

* Need for sterilisation before use: No

* Device labelled as sterile: No

* Containing latex: No

*** CMR/Endocrine disruptor**

Labelled for presence of Carcinogenic, Mutagenic and toxic to Reproduction (CMR) substances of category 1A or 1B:
 Yes No

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

Storage/handling conditions, if applicable

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

Critical warnings or contra-indications, if applicable

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

*** UDI-DI status**

On the EU market No longer placed on the EU market

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

**NOTE**

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

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

**NOTE**

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

Create new version of UDI-DI xClose

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

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

Confirm **Cancel**

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

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

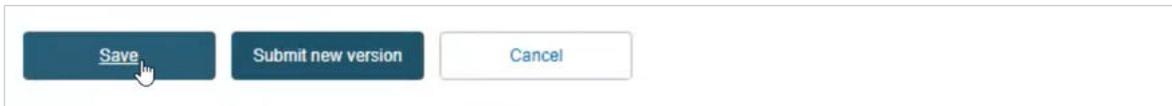
Austria ▼

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

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

2. To finish the action you have two options:
 - **Save** to save the updated details without submitting the new version.

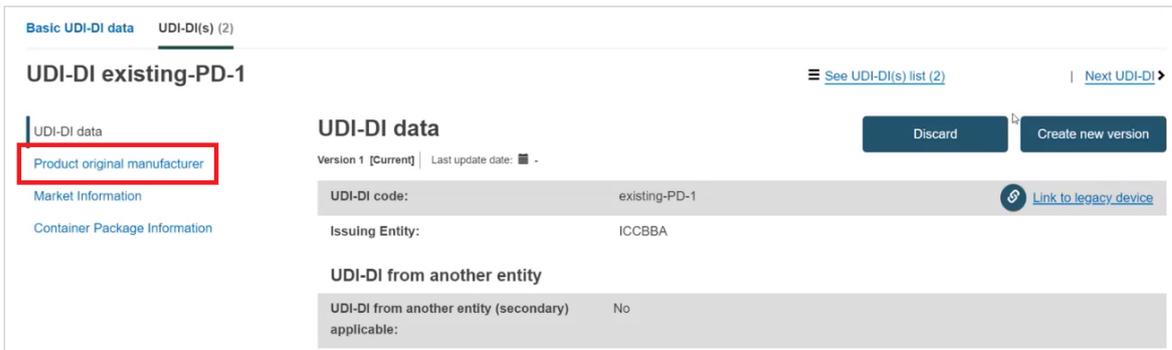
- **Submit new version**, if you wish to finalise the update.



5.2.3 Update (create new version) for Product original manufacturer

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

1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.
2. Once inside the details of the selected UDI-DI, click on **Product original manufacturer** from the list on the left (or scroll down to the *Product original manufacturer* section):



3. Click on **Update**:



The *Product original manufacturer* page will appear.

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

Natural or Legal Person update

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

* Name (Manufacturer Name):

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

* Street: Street number:
 Address line 2:

PO box:

* City name: * Postal code:

* Country:

Telephone:

- Or you can update the *Product original manufacturer* to an actor that is already registered in EUDAMED.
 Check the box *I know the Actor ID/SRN*, enter the Actor ID/SRN or name of the *Product original manufacturer* of the device and click on **Check registry**:

Natural or Legal Person update

I know the Actor ID/SRN

* Enter Actor ID/SRN or name:

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

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

Close

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



NOTE

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

5.2.4 Update (create new version) for Market Information

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.
- Once inside the details of the selected UDI-DI, click on **Market Information** from the list on the left (or scroll down to the *Market Information* section):

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

UDI-DI aaaa-bbb-vvv

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

UDI-DI data

Product original manufacturer

Market Information

Container Package Information

UDI-DI data

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

EDIT | DELETE

UDI-DI code: aaaa-bbb-vvv

Issuing Entity: ICCBBA

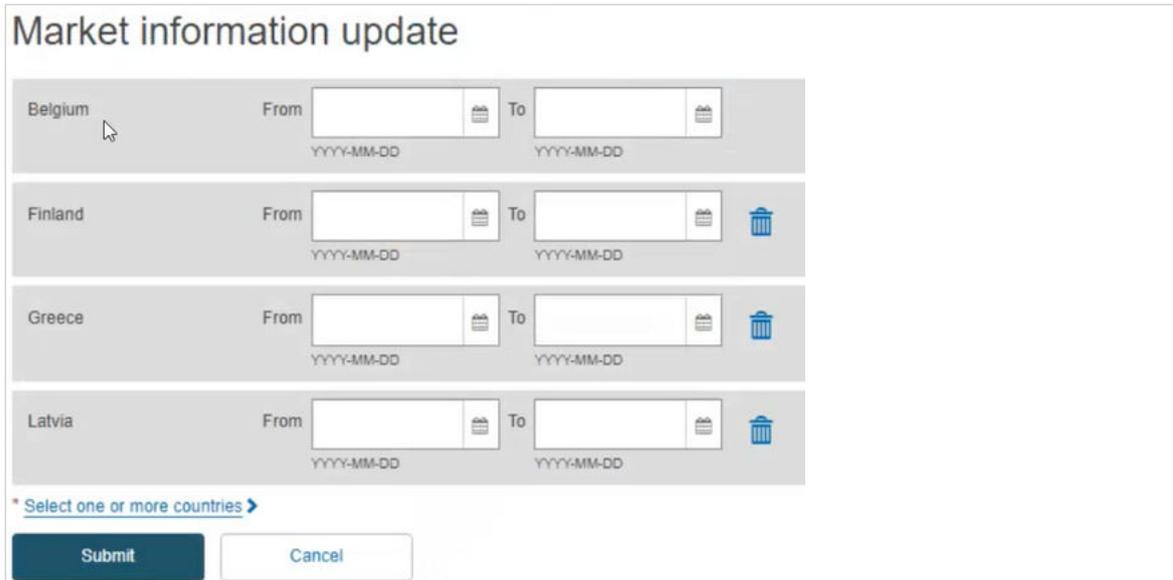
UDI-DI from another entity

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

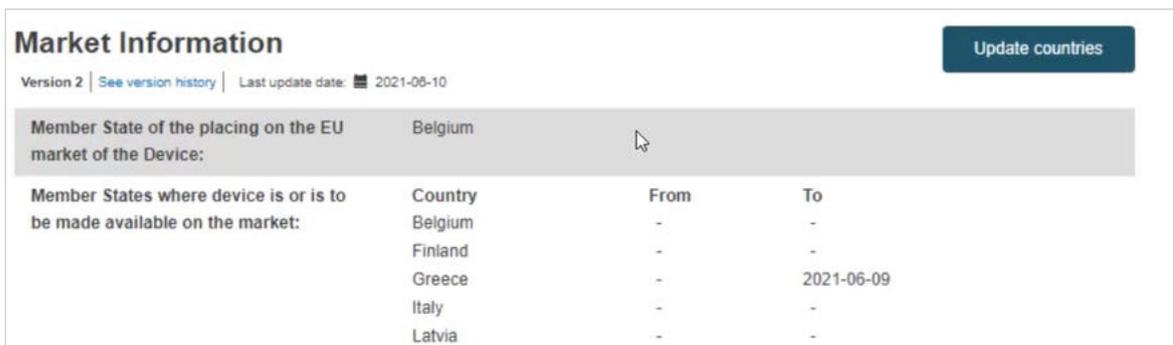
- Click on **Update countries**:



- Update the relevant fields under *Market Information*:



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



5.2.5 Update (create new version) for Container Packages

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

- Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

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

The screenshot displays the 'UDI-DI existing-PD-1' page. On the left sidebar, the 'Container Package Information' link is highlighted with a red box. The main content area shows 'UDI-DI data' with the following details:

- Version 1 [Current] | Last update date: -
- UDI-DI code: existing-PD-1
- Issuing Entity: ICCBBA
- UDI-DI from another entity applicable: No

Buttons for 'Discard' and 'Create new version' are located in the top right corner.

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

The top screenshot shows the 'Container Package Information' section for Version 3, with the 'Create new version' button highlighted by a red box. Below it, a list shows the selected UDI-DI: '[Root] UDI-DI: u-122323CiibPAY (HIBCC) | Status: On the EU market'.

The bottom screenshot shows the 'Container package update' dialog box. It features a title 'Container package update', a sub-header 'Container package(s)', and a '+ Add container package' link. The same UDI-DI is selected in the list below. At the bottom, there are 'Submit' and 'Cancel' buttons.

[✕Close](#)

Add container package

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

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

* **Package status**

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

Container package update

Container package(s)

[Add container package](#)
 [Update container package status](#)

- [Root] UDI-DI: u-123123MI9N (HIBCC) | Status: On the EU market
 - UDI-DI: Cp-1-1-1 (ICCBBA) | Quantity per package: 10 (10) | Status: On the EU market
 - UDI-DI: CP-1-1-2 (ICCBBA) | Quantity per package: 5 (50) | Status: On the EU market

[✕Close](#)

Update container package status

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

Container package market status

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

**NOTE**

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

4. Click on **Submit** to finalise the container package update:

Container package update

Container package(s)

 [Add container package](#)
 [Update container package status](#)

- [Root] UDI-DI: u-123123MI9N (HIBCC) | Status: On the EU market
- UDI-DI: Cp-1-1-1 (ICCBBA) | Quantity per package: 10 (10) | Status: No longer placed on the EU market
- UDI-DI: CP-1-1-2 (ICCBBA) | Quantity per package: 5 (50) | Status: No longer placed on the EU market

Submit

Cancel

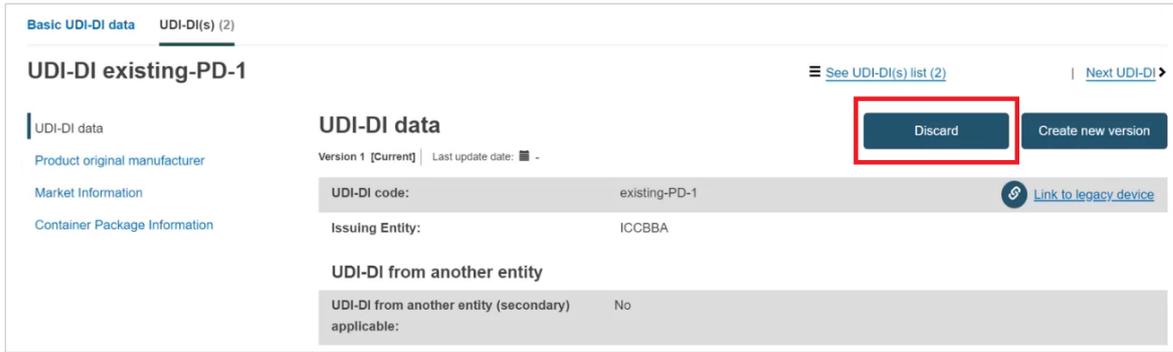
5.2.6 Discard registered UDI-DIs/EUDAMED IDs (and their Basic UDI-DI/EUDAMED DI)

**IMPORTANT**

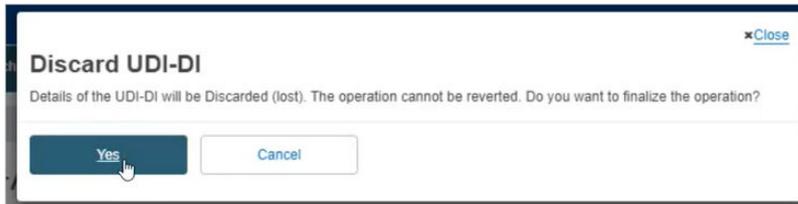
The *discard* operation acts as a final deactivation. A device in state *discarded* is therefore not listed and cannot be viewed in the public site of EUDAMED. However, it can be viewed by the MF (owner of the discarded device), CA and NB actors.

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

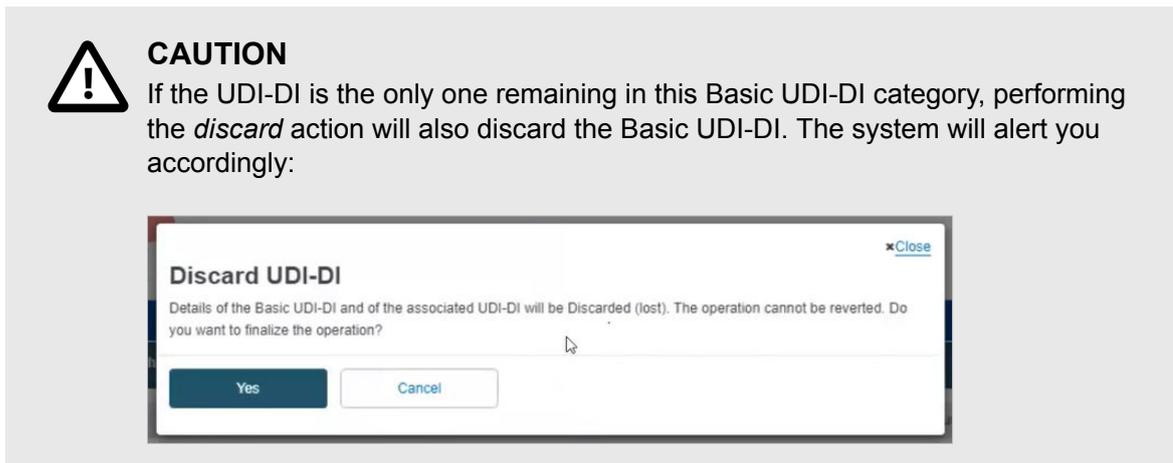
1. Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a registered UDI-DI/EUDAMED ID.
2. Once inside the details page of the selected UDI-DI, click on **Discard** at the top right corner:



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



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

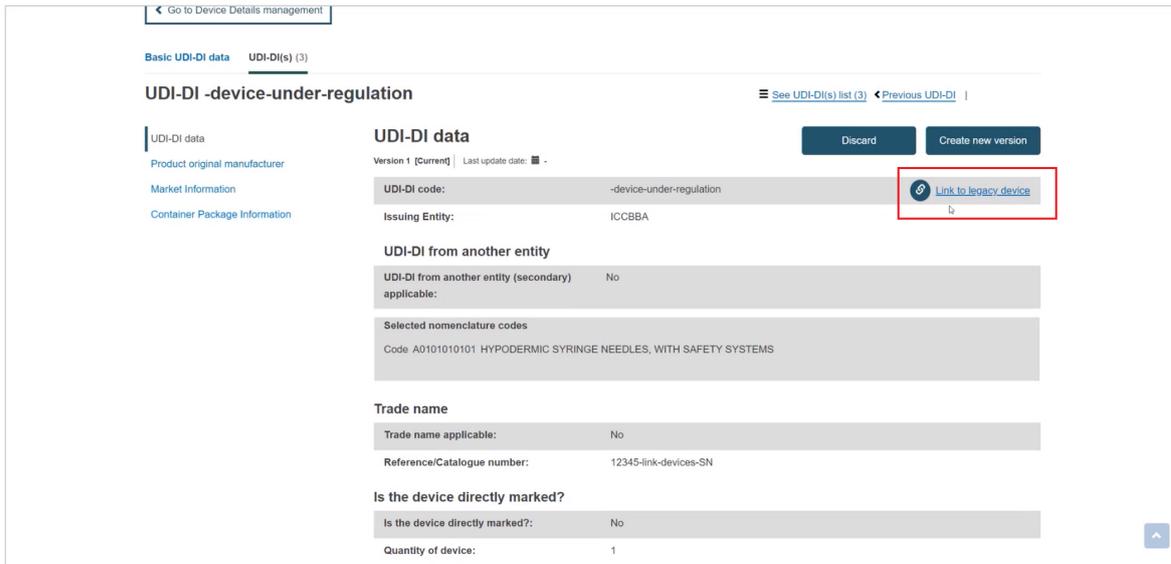


5.2.7 Link a registered Regulation Device to a registered Legacy Device

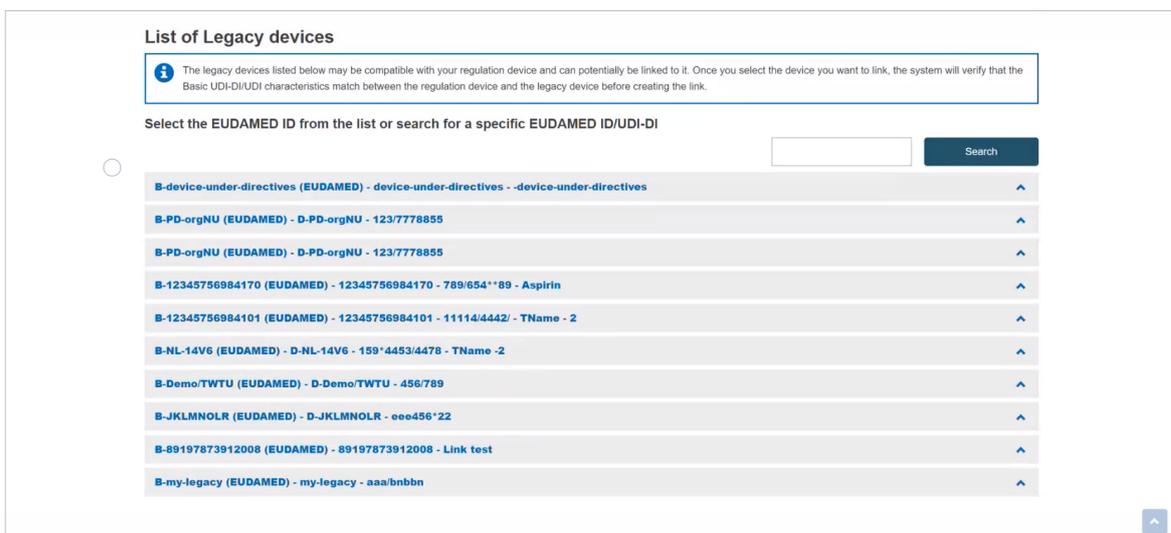
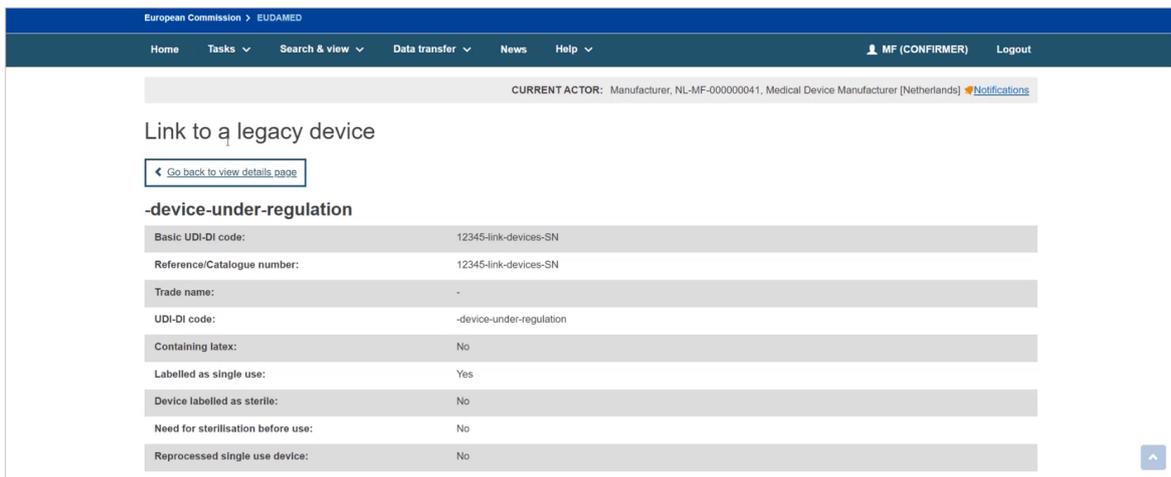
Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) and select the *Registered* option in the *State* field to manually link a registered regulation device to a registered legacy device.

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

EUDAMED user guide



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



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

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

Select this device

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

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

xClose

Link to a legacy device

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

Confirm

 **NOTE**

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

xClose

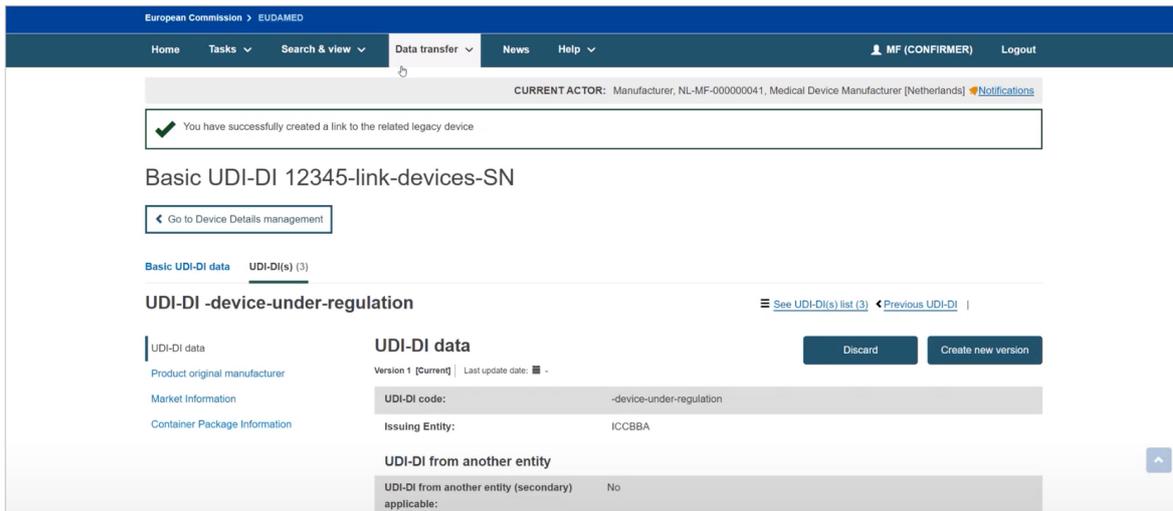
Link to a legacy device

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

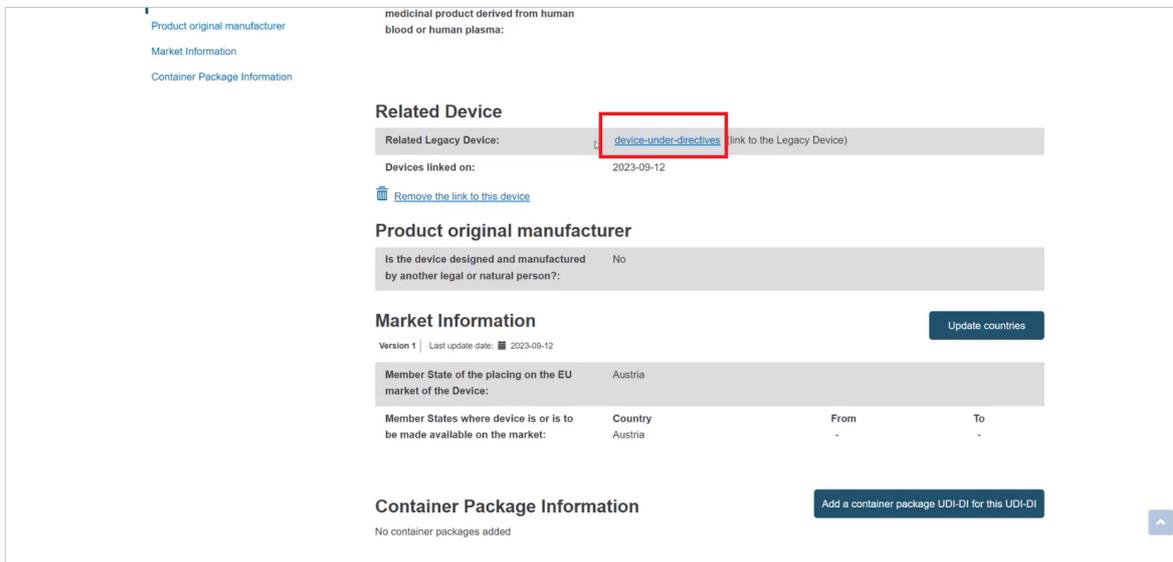
 The following characteristics do not match

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

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



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



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

The screenshot shows the EUDAMED interface with the following sections:

- Product original manufacturer**
- Market Information**
- Related Device** (highlighted with a red box):
 - Related Regulation Device: [-device-under-regulation](#) (link to the Regulation Device)
 - Devices linked on: 2023-09-12
- Product original manufacturer**
- Market Information** (with an **Update countries** button):
 - Version 1 | Last update date: 2023-09-12
 - Member State of the placing on the EU market of the Device: Austria
 - Member States where device is or is to be made available on the market:

Country	From	To
Austria	-	-



NOTE

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

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

Follow the steps in [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) and select the *Registered* option in the *State* field.

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

The screenshot shows the EUDAMED interface with the following sections:

- UDI-DI data**
- Product original manufacturer**
- Market Information**
- Container Package Information**
- Related Device** (highlighted with a red box):
 - Related Legacy Device: [device-under-directives](#) (link to the Legacy Device)
 - Devices linked on: 2023-09-12
 - [Remove the link to this device](#) (highlighted with a red box)
- Product original manufacturer**
- Market Information** (with an **Update countries** button):
 - Version 1 | Last update date: 2023-09-12
 - Member State of the placing on the EU market of the Device: Austria
 - Member States where device is or is to be made available on the market:

Country	From	To
Austria	-	-
- Container Package Information** (with an **Add a container package UDI-DI for this UDI-DI** button):
 - No container packages added

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

[xClose](#)

Link to a legacy device

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

Confirm

Cancel

**NOTE**

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

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

Follow the steps in section [Manage your device UDI-DI/EUDAMED ID details \[47\]](#) to view a UDI-DI/EUDAMED ID.

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

UDI-DI data

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

EDIT

DELETE

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

You will see a list of all versions:

EUDAMED DI B-1231231UU

[← Go back to the current version](#)

Version history of EUDAMED ID

Version 1 - Last update date: 2021-05-25 [▶](#)

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

EUDAMED DI B-1231231UU

[← Go back to the current version](#)

Version history of EUDAMED ID D-1231231UU

[≡ See all version history \(1\)](#)

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

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

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

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

6.1 Manage your SPP Basic UDI-DI details

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

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*. To see other states, use the filters.

Basic UDI-DI management for SPP

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

[Filter](#)

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

Showing 1 to 3 of 3 entries Show entries per page

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

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

Showing 1 to 3 of 3 entries Show entries per page

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

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data Create new version

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

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

6.1.1 Delete a draft Basic UDI-DI

- Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Draft Basic UDI-DI:

Basic UDI-DI management for SPP

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

Filter

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

Showing 1 to 4 of 4 entries Show entries per page

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

- Once inside the draft, click on **Delete**:

Basic UDI-DI 12344676768687687JC

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

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

Basic UDI-DI data Edit Delete

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

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

Delete Basic UDI-DI ✕Close

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

Yes Cancel

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

Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Basic UDI-DI:

Basic UDI-DI management for SPP

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

Filter

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

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

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

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data Create new version

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

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

2. Update the desired details.

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

44444SSP_Shr_1VM [version: 2]

Create a new version of 44444SSP_Shr_1VM

Risk class: Class I

* Indication of medical purpose: SPPP test 1

* Select the language: Greek

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

* Device Name: SPP_Shr_1

Save Submit new version Cancel

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

Save Submit new version Cancel

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

Basic UDI-DI 44444SSP_Shr_1VM

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

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

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

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

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

6.1.3 View historical version for Basic UDI-DI

1. Follow the steps in section [Manage your SPP Basic UDI-DI details \[67\]](#) to view a Basic UDI-DI.
2. Once inside the details page for the selected Basic UDI-DI, click on *See version history* at the top of the table:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

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

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

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

Basic UDI-DI 44444SSP_Shr_1VM

[← Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

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

Basic UDI-DI 44444SSP_Shr_1VM

[← Go back to the current version](#)

Version history of Basic UDI-DI 44444SSP_Shr_1VM

[≡ See all version history \(1\)](#)

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

Basic UDI-DI identification

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

Basic UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: GS1

System or Procedure Pack type: Procedure Pack

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

6.2 Manage your SPP UDI-DI details

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

Tasks

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

System or Procedure Pack

[Register a new System Procedure Pack](#)

[Manage your Basic UDI-DIs](#)

[Manage your UDI-DIs](#)

2. In order to find the desired UDI-DI, click on the **Filter** button and choose the right parameters:

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	...



NOTE

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

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

Showing 20 entries per page

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

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

Basic UDI-DI 44444SSP_Shr_1VM

[← Go to device management](#)

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

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

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

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

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

UDI-DI code:	44444SSP_Shr_1VM
Issuing Entity:	HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

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

Trade name

Trade name applicable:	No
Reference/Catalogue number:	SPPP_Shr_1

Type of UDI-PI

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

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

6.2.1 Delete a draft UDI-DI

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a Draft UDI-DI.
2. Once inside the draft, click on **Delete**:

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

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

UDI-DI data **EDIT** DELETE

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

UDI-DI code: 34675806754T9

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A010102 BUTTERFLY NEEDLES

Trade name

Trade name applicable: Yes

Trade name: system 1All languages

Reference/Catalogue number: 543

Type of UDI-PI

Serial number: Yes

Manufacturing date: Yes

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

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

UDI-DI status: On the EU market

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

[Close](#)

Delete UDI-DI

Delete the Draft version of UDI-DI?

Yes
Cancel

6.2.2 Update (create new version) for UDI-DI

1. Follow the steps in [Manage your SPP UDI-DI details \[72\]](#) to view a UDI-DI.

Basic UDI-DI management for SPP

Go to device management **Register new System or Procedure Pack**

Filter ▼

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

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

Basic UDI-DI code	UDI-DI(s)	Device model	Device Name	Risk class	Type	Date	State	Actions
44444SSP_Shr_1VM	1	-	SPP_Shr_1	Class I	PP	2021-05-17	Registered	...
9970314941ShriyaHL16E	1	-	System test1	Class I	S	2021-05-		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 details of the chosen UDI-DI, click on **Create new version** at the top right corner:

Basic UDI-DI 44444SSP_Shr_1VM

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

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

Basic UDI-DI data

Basic UDI-DI data

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	

Create new version

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:

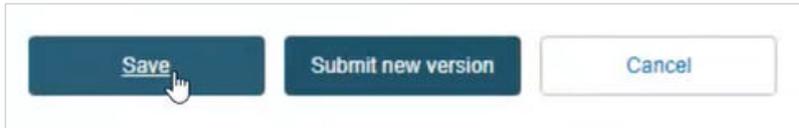
test

+ Add additional product description in another language

* Select the language:

Bulgarian x v

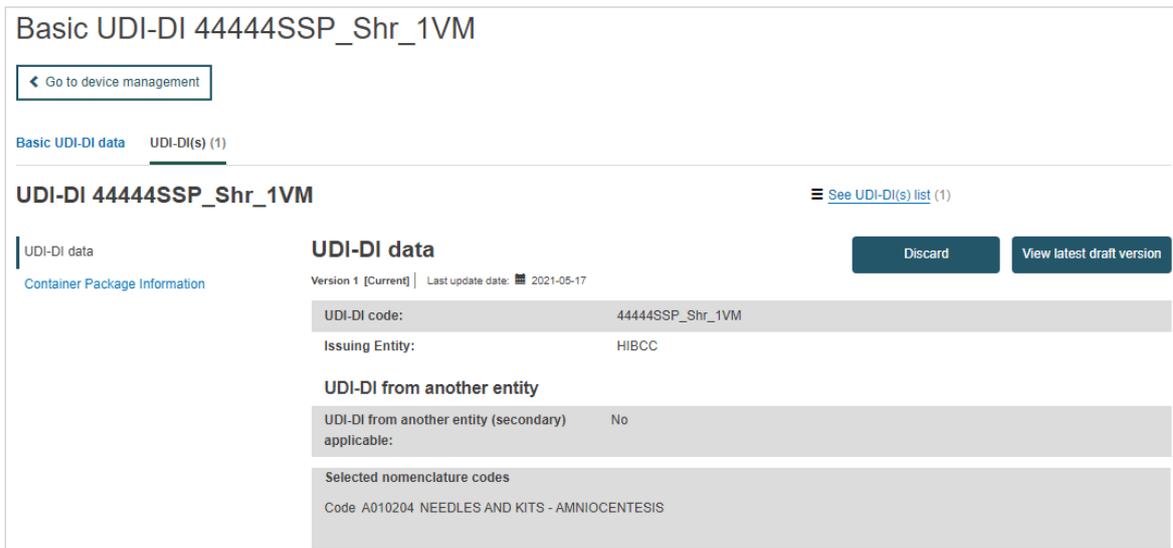
4. To finish the action you have two options:
 - a. Click on **Save** to save the updated details without submitting the new version.
 - b. Click on **Submit new version**, if you wish to submit it.
 Otherwise, you can press **Cancel** to cancel the update.



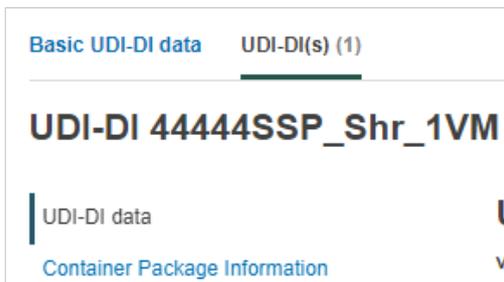
6.2.3 Update (create new version) for Container Packages

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

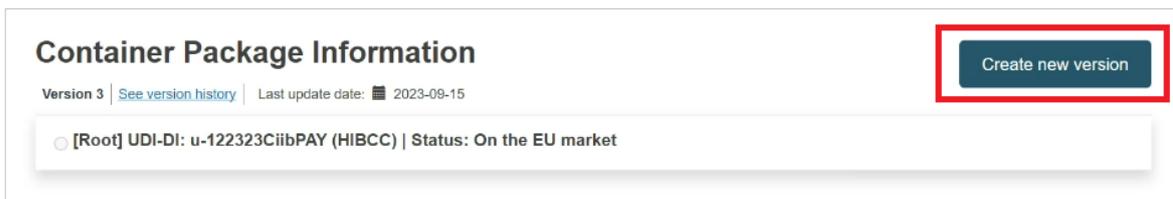
1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a specific UDI-DI:



2. 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: u-122323CiiibPAY (HIBCC) | Status: On the EU market

Submit

Cancel

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

✕Close

Add container package

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

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

*** Package status**

No longer placed on the EU market

Not intended for EU market

On the EU market

Save

Cancel

6.2.4 Discard SPP registered UDI-DIs

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a chosen Registered UDI-DI:

UDI-DI details management for SPP

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

Filter

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

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

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

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

Basic UDI-DI 44444SSP_Shr_1VM

[Go to device management](#)

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

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

UDI-DI data Discard Create new version

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

Container Package Information

UDI-DI code: 44444SSP_Shr_1VM

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A010204 NEEDLES AND KITS - AMNIOCENTESIS

Trade name

Trade name applicable: No

Reference/Catalogue number: SPPP_Shr_1

Type of UDI-PI

Manufacturing date: Yes

Additional product description: test [BG]

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

UDI-DI status: On the EU market

Need for sterilisation before use: No

Device labelled as sterile: No

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 if you wish to discard the record:

Discard UDI-DI Close

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

Yes Cancel

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

1. Follow the steps in section [Manage your SPP UDI-DI details \[72\]](#) to view a UDI-DI for the SPP.
2. Once inside the details of the chosen UDI-DI, click on *See version history* at the top of the table:

Basic UDI-DI data Create new version

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

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

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

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

[Go back to the current version](#)

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

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

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

[Go back to the current version](#)

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

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

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

Basic UDI-DI identification

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

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

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

Risk class: Class IIb

Implantable: No

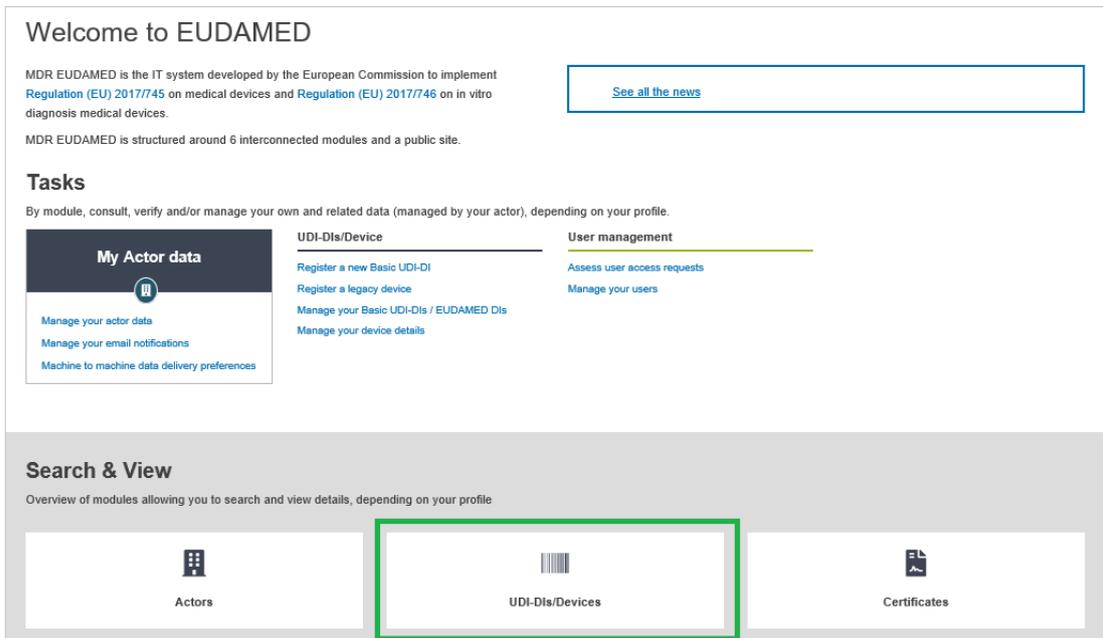
You can return to the version history list by clicking on *See all version history* at the top right corner.

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

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



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



2. You can use the filters to search for *Devices*, *Systems* and/or *Procedure Packs (SPP)* registered in EUDAMED, or, in the case of Competent Authorities and Notified Bodies, those *submitted* or *discarded*:

Only enable search filters available for bulk XML download

Scopes
You can select more than one value

Results option

Include historical version

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

Showing 1 to 20 of 150 entries Show entries per page

UDI-DI code ^{††}	Basic UDI-DI code ^{††}	MF / PR SRN	Trade name ^{††}	Risk class	Date ^{††}	UDI-DI status
12345XYZ	++B311X1Y2Z3PP	BE-PR-000000048		Class 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 row of your choice to see the details:

Producer information

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

Basic UDI-DI details

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

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

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

System or Procedure Pack type: Procedure Pack

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

1. Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[81\]](#) to search and view a device or system or procedure pack.
2. Inside the search page, select the filters for your search, activate the option to include historical versions (toggle just above the **Search** button) and click on **Search**:

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED DI:

Basic UDI-DI/ EUDAMED DI:

Status: --

Model:

Name:

Trade name:

Applicable regulation: --

Risk class: --

Nomenclature code:

Reference/Catalogue number:

Country: --

Scopes

Competent Authority: --

NB identification: --

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

Results option

Include historical version

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

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

7.2 Download Devices or Systems or Procedure Packs data in a structured format (XML)



NOTE

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

- Follow the steps in [Search & View Devices, Systems and/or Procedure Packs \[81\]](#) to search and view a device or a system or procedure pack. On the search page, activate the top filter (**Only enable search filters available for bulk XML download**) so that you can only enter search criteria that can be used for search results that can be downloaded in an XML format, and enter your search criteria. Enter the search criteria of your choice, and click on **Search**:

Only enable search filters available for bulk XML download

UDI-DI/ EUDAMED DI:

Basic UDI-DI/ EUDAMED DI:

Status:

Model:

Name:

Trade name:

Applicable regulation:

Risk class:

Nomenclature code:

Reference/Catalogue number:

Country:

Scopes:

MF / PR Actor ID/SRN:

MF / PR Name:

AR Actor ID/SRN:

AR name:

Results option

Include historical version

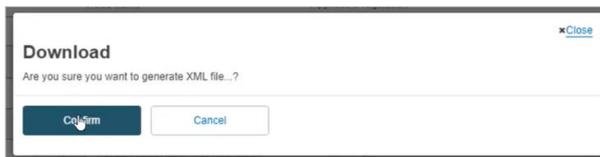
2. Click on **Generate XML file**:



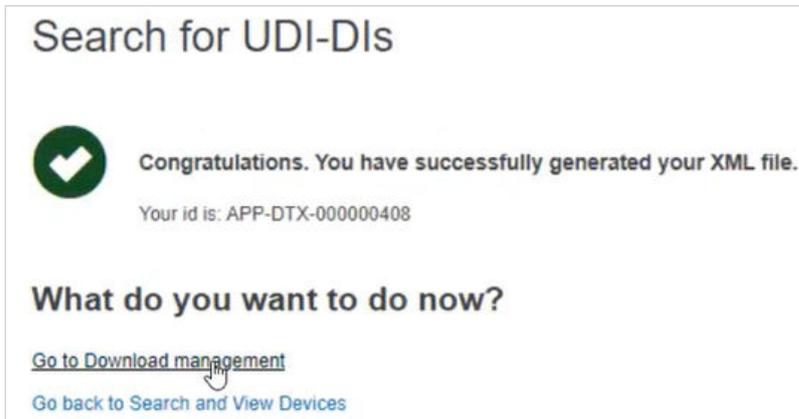
NOTE

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

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



4. 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:

Download management

Filter 

Active filters: No selection

Showing 1 to 1 of 1 entries

Show entries per page

ID	Name	Module 	Service 	State 	Request date 	Download
APP-DTX-000000408	John Smith	UDI/Device	Device download	 Failed	2021-06-10 [16:57]	XML [4 KB]  Expires in 15 days

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

- Follow the steps in [Search & View historical versions of Devices, System and/or Procedure Packs \[83\]](#) to view the details of a Device or System or Procedure Pack.
- Once inside the details of the chosen UDI-DI, go to the section in which you wish to view old versions (e.g. Basic UDI-DI/ EUDAMED DI, UDI-DI/EUDAMED ID, Market Information, Product original manufacturer or Container Package) and click on *See version history*:

UDI-DI 121312_Test_AR

[Go back to the list](#)

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI details

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

Basic UDI-DI identification

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

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

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

List of UDI-DIs for the Basic UDI-DI

UDI-DI details

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

UDI-DI code: 121312_Test_AR

Issuing Entity: HIBCC

UDI-DI from another entity

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

Selected nomenclature codes

Code A01010199 HYPODERMIC NEEDLES - OTHERS

Trade name

Trade name applicable: Yes

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

Reference/Catalogue number: ref

Is the device directly marked?

Is the device directly marked?: No

Market information

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

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

Clinical Investigation(s)

Clinical Investigation

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

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Manufacturer information

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI data

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

Basic UDI-DI identification

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

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

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

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

Basic UDI-DI 22091test23_09EC

[← Go back to the current version](#)

Historical version for Basic UDI-DI 22091test23_09EC

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

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

Manufacturer information

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

Manufacturer information

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

Authorised Representative

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

Basic UDI-DI data

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

Basic UDI-DI identification

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

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

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

8 Annex 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 <i>EU technical documentation assessment certificate (Annex IX Chapter II)</i>
MDR	III	Any	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided <i>EU technical documentation assessment certificate (Annex IX Chapter II)</i>
IVDR	B	Self-patient testing= Yes or Near Patient Testing = Yes		<i>EU technical documentation assessment certificate (Annex IX Chapter II)</i>
IVDR	C	Self-patient testing= No, Near Patient Testing = No	EU type-examination certificate (Annex X)	
IVDR	C	Self-patient testing= Yes or Near Patient Testing = Yes	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided <i>EU technical documentation assessment certificate (Annex IX Chapter II)</i>
IVDR	D	Any	Either TE or TD required to be provided EU type-examination certificate (Annex X)	Either TE or TD required to be provided <i>EU technical documentation assessment certificate (Annex IX Chapter II)</i>

Colour-code description.

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

