European Commission
GROWTH
Internal Market, Industry, Entrepreneurship and SMEs

Guide to Using

EUDAMED

UDI Device Management for Manufacturers

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Contents

Introduction

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

EUDAMED is structured around 6 interconnected modules and has a public site. The 6 modules include:

- Actors registration
- UDI database and registration of devices
- Certificates and Notified Bodies
- Clinical Investigation and performance studies
- Vigilance and post-market surveillance
- Market Surveillance

This manual covers the second module i.e. UDI database and registration of devices. It is intended for Manufacturers who are supposed to have validly registered in EUDAMED (i.e. obtained an 'SRN' (Single Registration Number)).

Further guidance

Please be aware that this manual does not provide guidance, clarifications or recommendations for complying with the legislation. For more specific information regarding the correct interpretation of the medical device legislation, please refer to the following websites:

- *The web section about Medical Devices on the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs website: http://ec.europa.eu/growth/sectors/medical-devices_en*
- *The Medical Devices Coordination Group (MDCG) MDCG Guidance web section on the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs website: http://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en*
- *The online documents available on the CAMD (Competent Authorities for Medical Devices CAMD) website: https://www.camd-europe.eu/regulatory/medical-devices-regulation-vitro-diagnostics-regulation-mdr-ivdr-roadmap/*

Managing UDI Devices

IN THIS SECTION

The new MDR 2017/745 and IVDR 2017/746 EU regulations require that manufacturers of medical devices submit the UDI/Device information of all devices/products that they place on the market.

The Device module of EUDAMED is used for this purpose.

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

Basic Concepts

The UDI (Unique Device Identification) system is one of the main novelties brought by the MDR 2017/745 and IVDR 2017/746 EU regulations. It is intended to improve the traceability of medical devices throughout the supply chain by connecting all the information about every single medical device.

Upon production of a medical device, manufacturers will have to register their devices in EUDAMED. Every UDI device will be uniquely identified and characterised by 2 main device identifiers i.e. a ***Basic* UDI-Di** and a **UDI-DI**.

In addition to these, for devices with a higher level of packaging, a *Package UDI-DI* will be used if applicable, to identify a package in a unique way.

- **BASIC UDI-DI**
  In EUDAMED, the Basic UDI Device Identifier, or 'Basic UDI-DI', is the *primary* identifier of a device model/family/group (e.g. insulin syringes, hip prosthesis, etc.) in a manufacturer's portfolio, regardless of any specific any variations in minor characteristics or packaging levels. All devices with the same Basic UDI-DI shall share the same core characteristics, like intended purpose, risk class, essential design and manufacturing characteristics. The Basic UDI-DI information to be provided for a device in EUDAMED includes this core information, plus a unique Basic UDI-DI *code* issued by an officially designated issuing entity. It is not referenced on labels, only in some documents like Certificates, Declarations of Conformity and Technical documentation

- **UDI-DI**
  The UDI is the *main* identifier of a medical device used on its label. It identifies the specific device within a given product family. The UDI-DI (Device Identifier is a unique *code* created through/received from an officially designated issuing entity.

  (PACKAGE UDI-DI)
  If applicable, each device may have an additional, higher-level UDI-DI assigned to its higher package. Package UDI-DIs are used to identify each package configuration, with its quantities of items at each package level.

  While a UDI-DI can have only one Basic UDI-DI, multiple UDI-DIs can be referencing the same Basic UDI-DI to reflect the different devices that a manufacturer has under the same intended purpose and essential design and manufacturing characteristics.

Registering Devices

Before you start entering details of a device in EUDAMED, please make sure that you have all requested information at hand, including the Basic UDI-DI and UDI-DI codes that you have assigned from the list of codes that were allocated by the selected UDI issuing entity/entities.

STEP 1 Entering **Basic UDI-DI** Identification Information

♦ **To enter Basic UDI-DI**

1. Log in to EUDAMED with your Manufacturer account.
2. Select the **Register a new Basic UDI-DI** hyperlink in the *UDI-DIs/Device* section on the homepage.

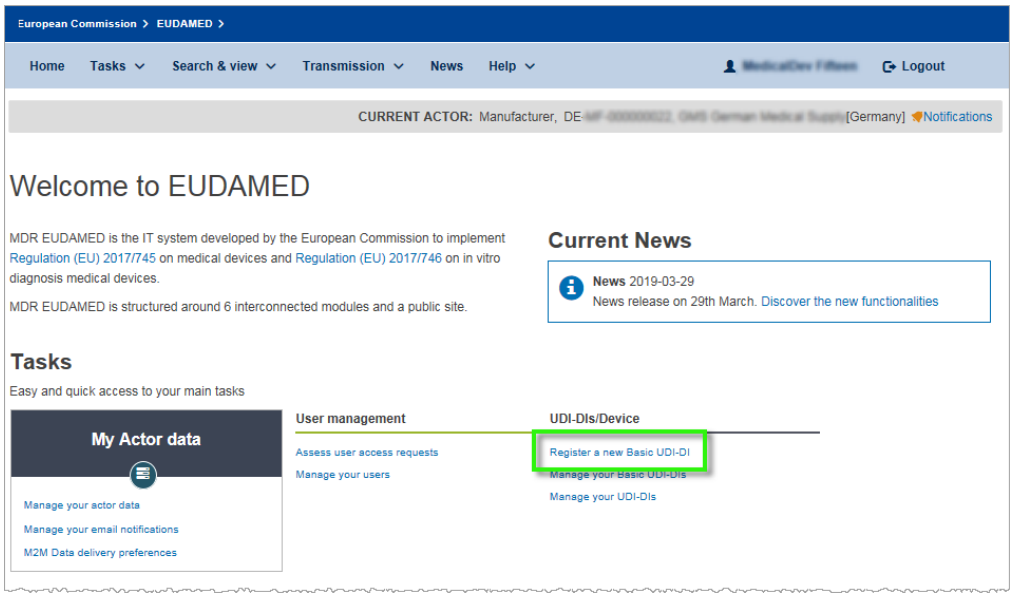


Figure 1 – 'Register a new Basic UDI-DI' hyperlink on the homepage

Result: The device registration start page prompts you to enter some basic identifying information about the device family, including the applicable regulation and the assigned Basic UDI-DI code received from the issuing entity:

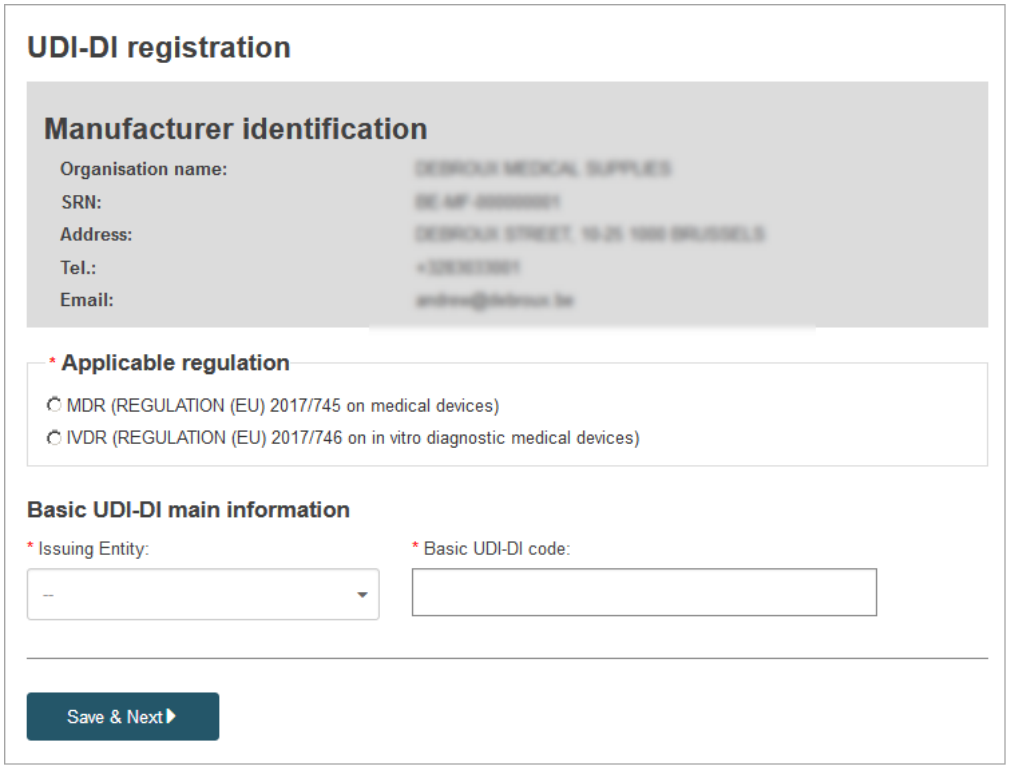


Figure 2 – UDI-DI registration: start page

3. On the device registration start page, select/enter the following information:

   i) the **Applicable regulation**,

   ii) the name of the official **Issuing entity** that provided the Basic UDI-DI code, and

   iii) the actual **Basic UDI-DI code**.

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

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

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

4. Answer all questions on the page, and then click **Save & Next**.

Result: Page ❶ of the Basic UDI-DI registration wizard appears. The content of this page will be different depending on the underlying regulation.

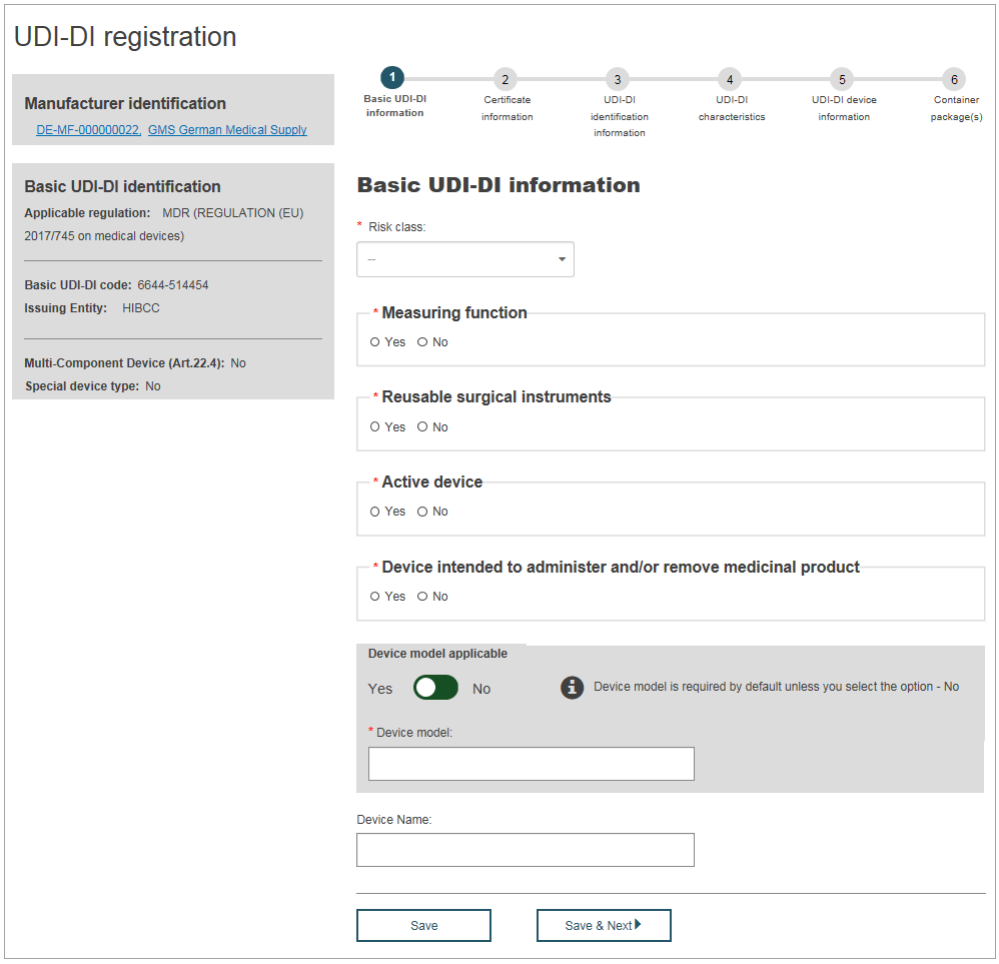


Figure 3 – UDI-DI registration wizard: page 1, 'Basic UDI-DI information' (MDR)

5. Complete the page with all mandatory information:

Select the authorised representative

This field appears only if you are a non-EU manufacturer. It is used to select the European Authorised Representative that you have mandated for the device in question. The Authorised Representative must have been validly registered in EUDAMED first (i.e. obtained an SRN), and the manufacturer's mandate must have been validated, and it must be active at the time of registration of the device (otherwise the Authorised Representative will not be available for selection in the list).

Risk class

Select the risk class assigned to the medical device, resulting from the classification rules applicable to the selected Directive/Regulation.

For MDR, the following classes are available.

`Class I`	(Low)	`Class IIb`	(Medium-High)
`Class IIa`	(Medium-Low)	`Class III`	(High)

The content of the page will change based on the risk class that you have selected.

Implantable

`[Available only in connection with risk class IIa/IIb/III devices]`

Select the appropriate option button to indicate whether the device is an implantable device in the meaning of the regulation i.e.,

'Any device which is intended:
- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,
by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.'

Is the device a suture, staple, dental filing, dental brace (…)?

`[Available only in connection with risk class IIb implantable devices]`

Select the appropriate option button to indicate whether the device is a suture, staple, dental filling, dental brace, tooth crown, screw, wedge plate, wire, pin, clip or connector.

Measuring function

Specify whether the device has a primary analytical measuring function.

Reusable surgical instruments

`[Available only in connection with non-implantable device models]`

Select the appropriate option button to indicate whether the device is a reusable surgical instrument in the meaning of the regulation i.e.,

'Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out).'

Active device

Specify whether the device is an active device in the meaning of the regulation i.e.,

'*Any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices*'.

Device intended to administer and/or remove medicinal product

Select the appropriate option button to indicate whether the device is intended to administer and/or remove medicines, body liquids or other substances to or from the body.

Device model applicable

Free-text box identifying the device model/family e.g. hip prosthesis.

Device name

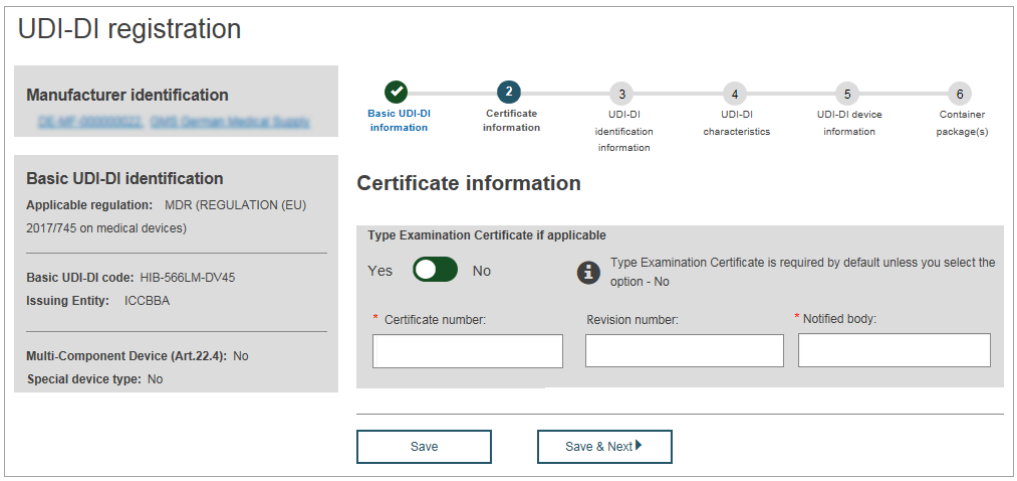
Free-text box used to enter the (generic) name of the device model/family.
Please note that either the model or the name is mandatory.

6. Click **Save & Next** to move to the next page of the wizard.

   Result: Page ❷ of the UDI-DI registration wizard is enabled in certain cases only; and its content differs based on different parameters, including selected directive/regulation, risk class, etc.

   For example:

   If the device requires confirmation by a Notified Body, then the corresponding certificate must have been issued before you may submit your device data. In some cases, you will then be prompted to enter some extra information about the certificate in question. This is for example the case for Class IIb implantable devices being Sutures or Staples. In such cases, page 2 of the device registration wizard would look like this:



7. Enter the requested information about the certificate on the *Certificate information* page:

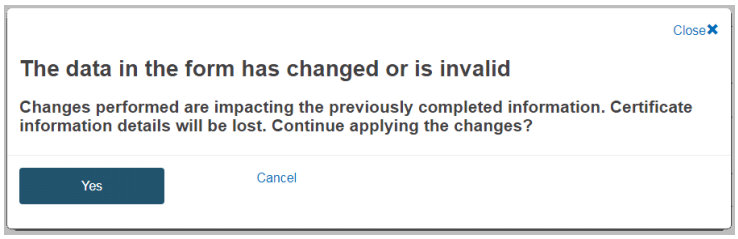
Type Examination Certificate if applicable	If this field is available and you select 'Yes', then you will be prompted to provide the Certificate Number and Revision number (optional), and to identify the Notified body.
Certificate Type	If this field is available, please enter here the type of certificate that you have received for the device.
Certificate Number	If this field is available, please enter here the unique certificate number received for the device.
Revision Number	If available and applicable, please enter here the revision number of the certificate that you have received for the device.
Notified Body	If this field is available, please enter here the code of the Notified Body that issued the certificate.

8. Click **Save & Next** when finished, to move on to the next page of the wizard.

   ↳ *Result:* Page 3 of the UDI-DI registration wizard appears (see next page). This is used to enter the identification information relating to the specific variation/version of the device.

Impact of changes to the saved information

Please be aware that if, at some point after saving the device registration form, you decide to modify any information from the Step 1 pages of the wizard, EUDAMED *will then recalculate the type of Certificate Information to be collected. Previously completed information will be lost.* EUDAMED *would then warn you before you decide to perform this operation:*



STEP 2 Entering **UDI-DI Identification** Information

Pages 3-5 of the UDI-DI registration wizard are used for entering the UDI-DI identification information relating to the specific variation/version of the medical device under the Basic UDI-DI that you specified on the previous pages of the wizard.

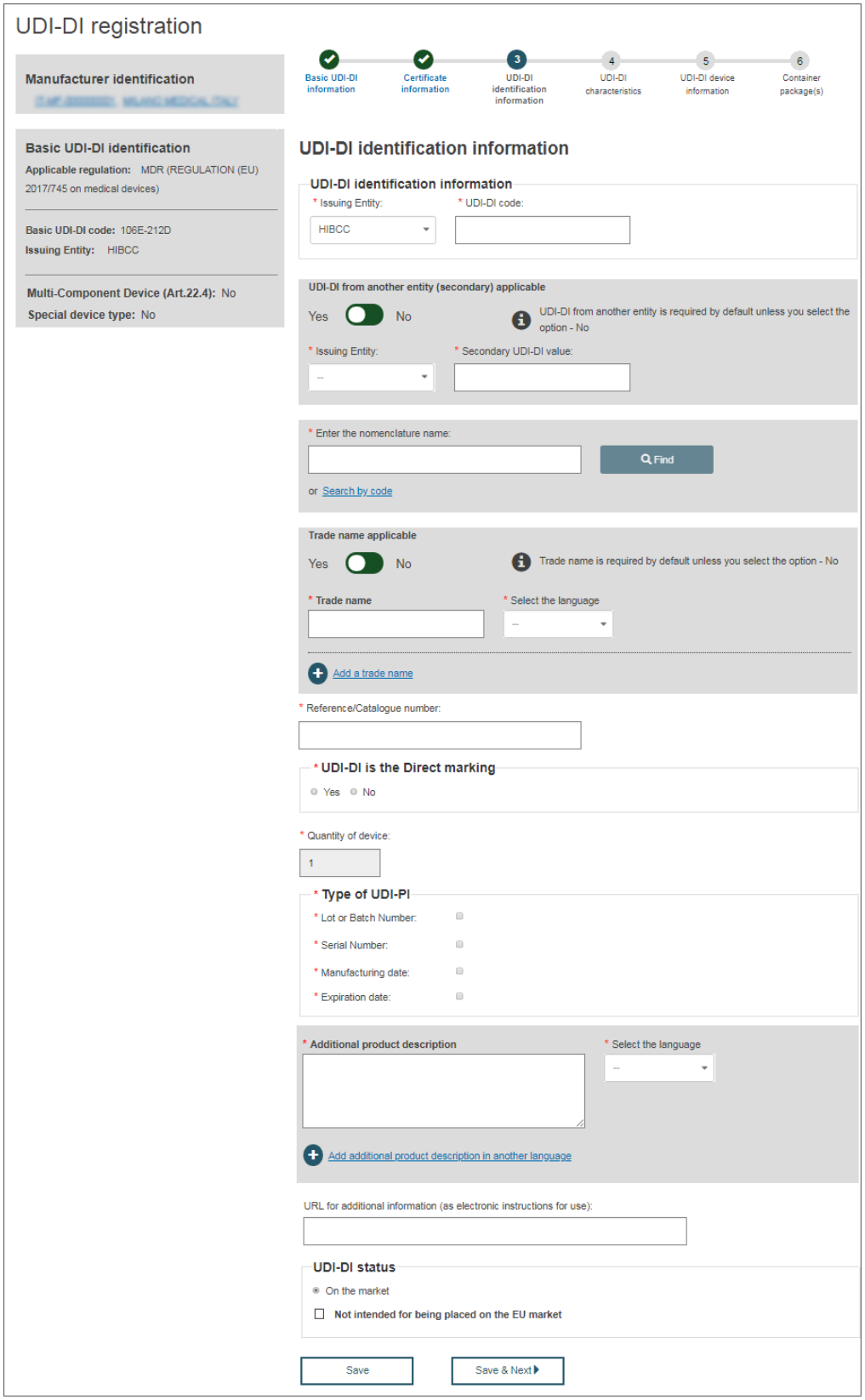


Figure 4 – UDI-DI registration wizard: page 3, 'UDI-DI identification information'

♦ **To enter UDI-DI identification information**

1. Complete page ❸ of the UDI-DI registration wizard as follows:

Issuing Entity	Please select here the official agency that issued the UDI-DI code for the specific device. By default, this will be the same entity as the one that issued the Basic UDI-DI for the device family, but it can be different.
UDI-DI code	The actual unique UDI-DI code that you received from the issuing entity for this specific device.
UDI-DI from another entity (secondary) applicable	If a second UDI-DI code was received from another issuing entity, please select 'Yes', select the issuing entity in question, and the secondary UDI-DI code in question.
Enter the nomenclature code	Please look for and select the unique code associated with the nomenclature term that describes the device. Can be searched by code or by name.
Trade name applicable	The trade/brand/proprietary name of the medical device in the selected language(s), as it appears on the device label.
Reference/ Catalogue number	The reference, catalogue or product number as found on the device label or accompanying the packaging.
UDI-DI is the Direct marking	Select the appropriate option button to indicate whether the device is directly marked with a DI Code or not (is not labelled individually).
Quantity of device	The number of devices within a package identified by the specified UDI-DI.
Unit of Use DI	This field appears only if you have select 'No' for '*UDI-DI is the Direct marking*' above, and a value greater than 1 to '*Quantity of Device*'. It is used to enter the actual unique DI code assigned to the lowest unit of use that is used for the patient. Issuing entity for this DI Code is the same as the UDI-DI.
Type of UDI-PI	The options in this section describe the manner in which production of the device is controlled i.e.
Lot or Batch Number	The number assigned to the group of devices with the same UDI-DI which have been produced in the same process or series of processes.
Serial Number	The number that allows for the identification of an individual device, indicating its position within a series.
Expiry date	The upper limit of the time interval during which the performance characteristics of the device conditions can be assured when stored under specified conditions.
Manufacturing date	The date on which the device was manufactured.
Additional product description	Any additional information or details about specific features of the device in the selected language(s).
URL for additional information (as electronic instructions for use)	A web address (URL) where additional official information on the device can be found on the Internet.
UDI-DI status	Indication of the device status on the market.

2. Click **Save & Next** to move to the next page of the wizard.

Result: Page 4 of the UDI-DI registration wizard appears:

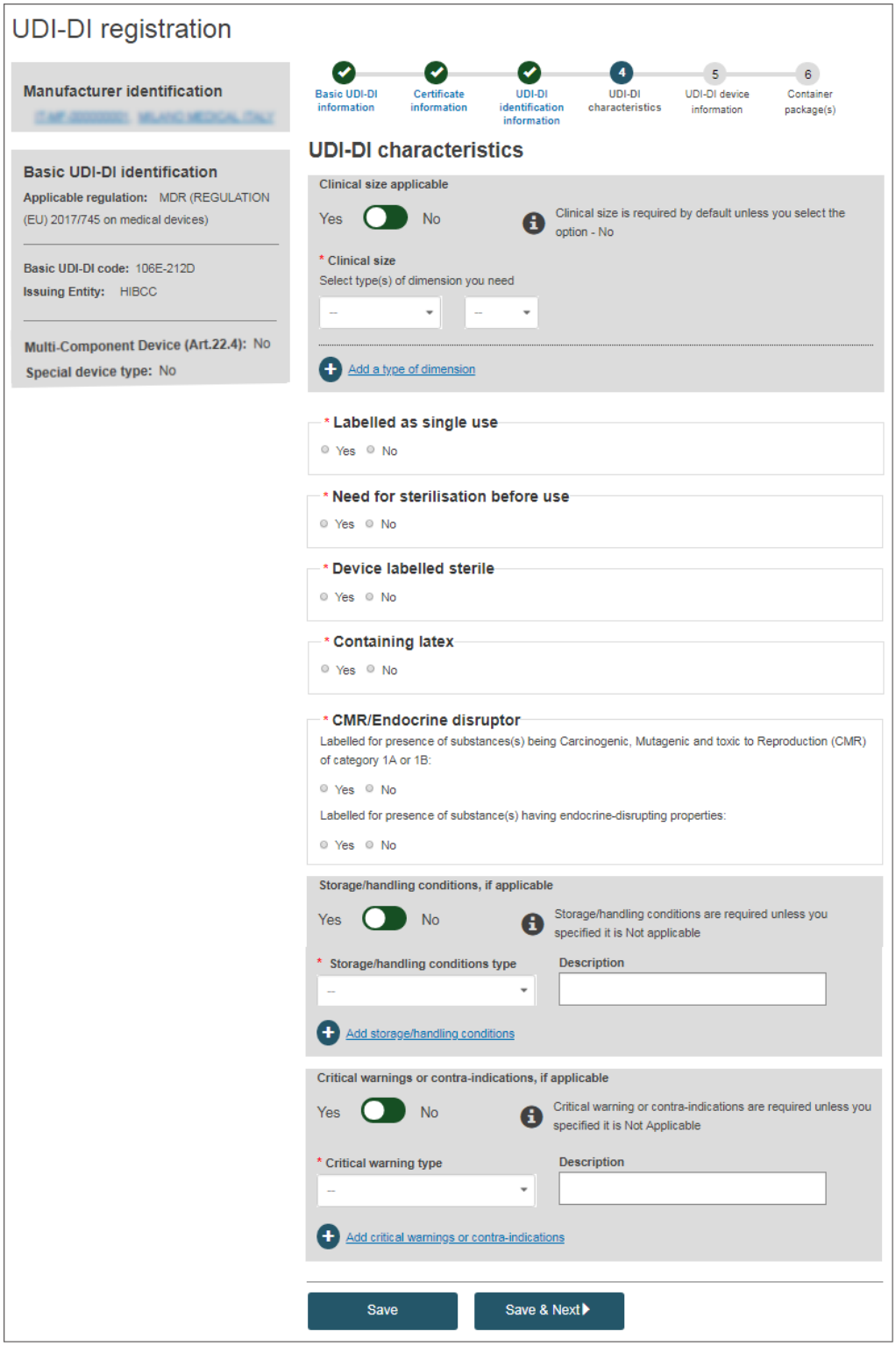


Figure 5 – UDI-DI registration wizard: page 4, 'UDI-DI characteristics'

3. Complete page 4 of the UDI-DI registration wizard as follows:

Clinical size applicable	Select the appropriate option button to indicate whether a numeric value for the clinically relevant size measurement of the medical device is indicated on the label.
Labelled as single use	Select the appropriate option button to indicate whether the device is labelled as a 'single use device', i.e. a device intended for one use, or on a single patient during a single procedure.

Need for sterilisation before use	Select the appropriate option button to indicate whether the device requires sterilization prior to use.
Device labelled sterile	Select the appropriate option button to indicate whether the device is labelled as 'sterile' (i.e. sterile and in a sterilised packaging).
Containing latex	Select the appropriate option button to indicate whether the device or its packaging is labelled as containing natural rubber that comes in contact with humans.
CMR/Endocrine disruptor	Select the appropriate option buttons to indicate whether the device is labelled with an indication of the presence of substances • which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of either category 1A or 1B. If you select 'Yes', please identify the substance(s) in question by their name and possibly CAS and/or EC number from the ECHA database. and/or • having endocrine-disrupting properties, for which there is scientific evidence of probable serious effects to human health. If you select 'Yes', please identify the substance(s) in question by their name in the selected language(s) and possibly CAS and/or EC number from the ECHA database.
Storage/handling conditions, if applicable	Select the appropriate option button to indicate whether storage and/or handling requirements are required for the device in accordance with Annex I, 23.2 (k) of the MDR. If you select 'Yes', please specify the type(s) of storage/handling conditions in question, and describe those conditions.
Critical warnings or contra-indications, if applicable	Select the appropriate option button to indicate whether warnings, contra-indications, precautions need to be brought to the immediate attention of the user of the device, and/or to any other person. If you select 'Yes', please specify the critical warning type(s) in question, and describe these briefly.

Please note that if the desired storage/ handling condition, or the desired critical warning or contra-indication is not available in the list, you can select '**Other**' and enter a detailed custom description in different languages.

4. Click **Save & Next** to move on to the next page of the wizard.

Result: Page 5 of the UDI-DI registration wizard appears:

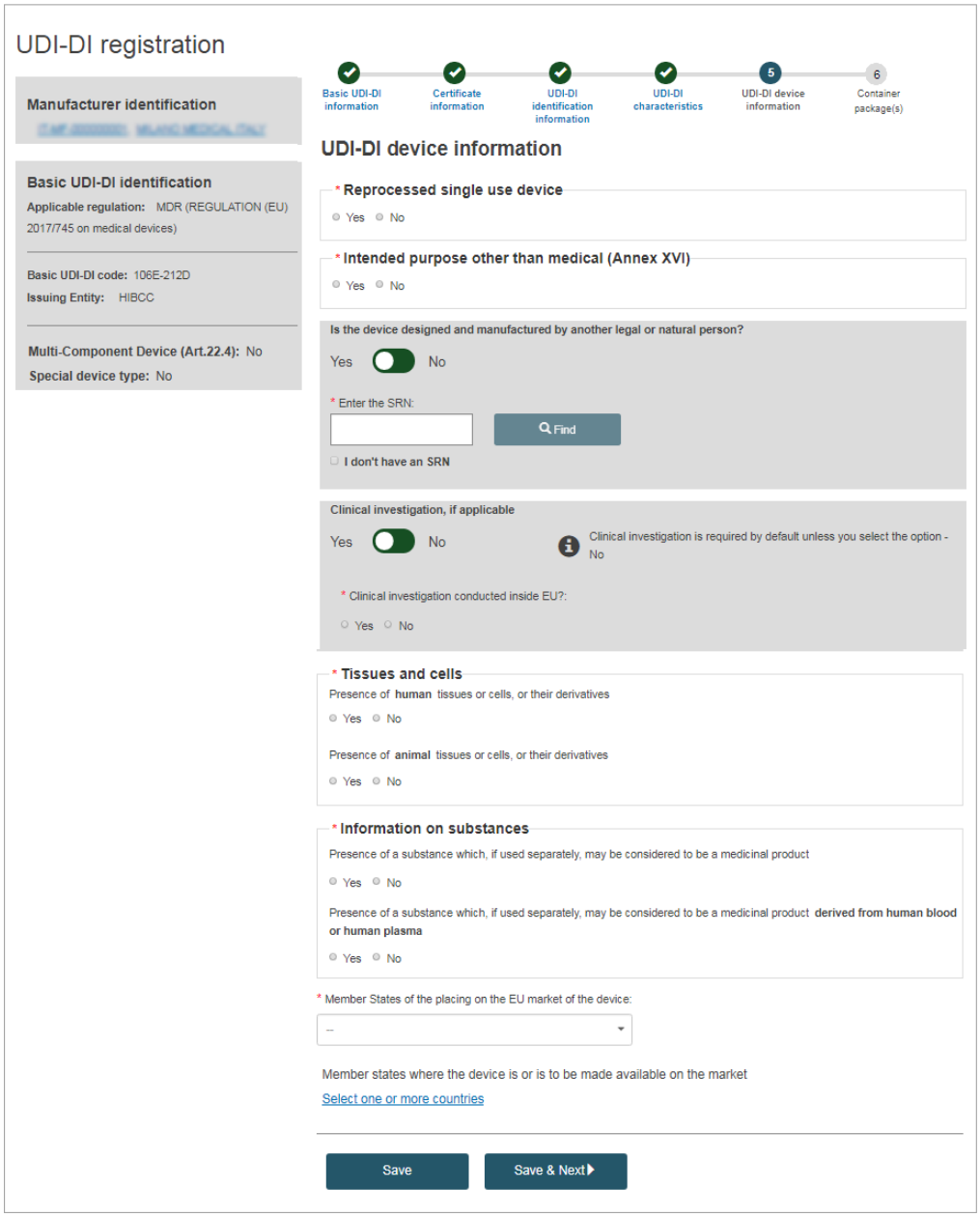


Figure 6 – UDI-DI registration wizard: page 5, 'UDI-DI device information'

5. Complete page 5 of the UDI-DI registration wizard as follows:

Reprocessed single use device

Select the appropriate option button to indicate whether the device is a reprocessed single-use device in the meaning given in the legislation.

Intended purpose other than medical (Annex XVI)

If the device is listed in Annex XVI of the Medical Device Regulation, select the appropriate option button to indicate whether the intended purpose of the device is other than a medical purpose. If you select 'Yes', please select the check box(es) corresponding to the purpose(s) in question.

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

Select the appropriate option button to indicate whether the device is designed and manufactured by another legal or natural person as referred in Article 10(15) of the MDR. If you select 'Yes', look for and select the SRN of the legal or natural person in question if it is already registered in EUDAMED, or select 'I don't have an SRN and provide the name, address and contact details of the legal or natural person in question.

Clinical investigation, if applicable	Select the appropriate option button to indicate whether a clinical investigation was performed on the medical device. If you answer 'Yes' to the subsequent question about the clinical investigation being conducted inside the EU, click the **Check registry** button and select its reference from the EUDAMED registry.
Tissues and cells	Select the appropriate option buttons to indicate whether the device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives.
Information on substances	Select the appropriate option buttons to indicate whether the device incorporates, as an integral part, any substances which, if used separately, may be considered to be medicinal products and/or medicinal products derived from human blood or human plasma. If you select 'Yes' to any question, you will have to enter the name of these substances in the selected language, and possibly their INN (International Non-proprietary Name of an ingredient as recommended by the World Health Organisation).
Member States of the placing on the EU market of the device	Use the selection box to select the EU Member States (i.e. at least 2) in which the device is placed on the market. You will then be prompted to specify the From and To dates of availability on the market (if applicable).

6. Click **Save & Next** to proceed to the last page of the wizard.

STEP 3 Entering **Container Package** Information

Page 6 of the UDI-DI registration wizard is optional to complete. It is used to enter the unique UDI-DIs assigned to each package level of the device in order to distinguish between package quantities at each package level:

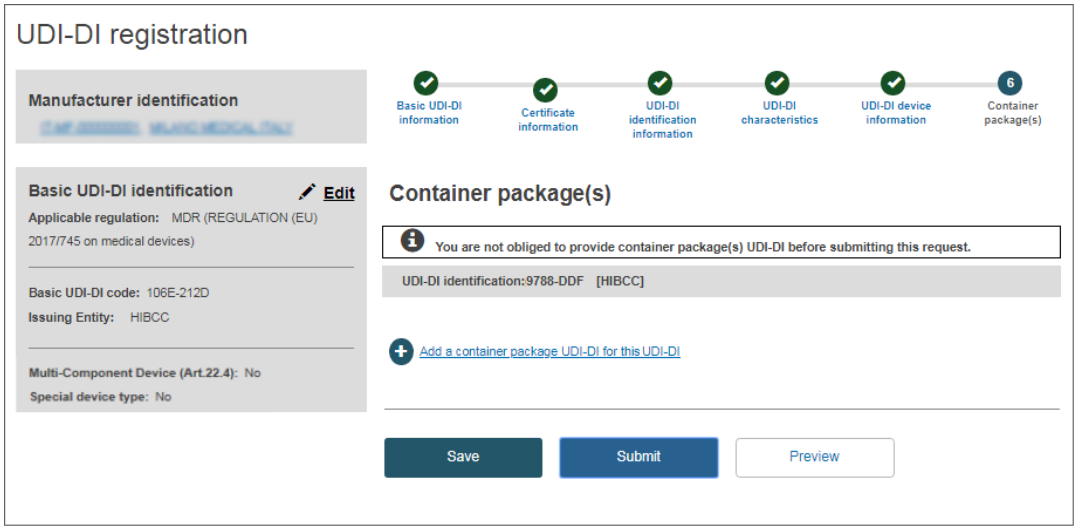


Figure 7 – UDI-DI registration wizard: page 6, 'Container package(s)'

♦ To enter Package UI-DI information

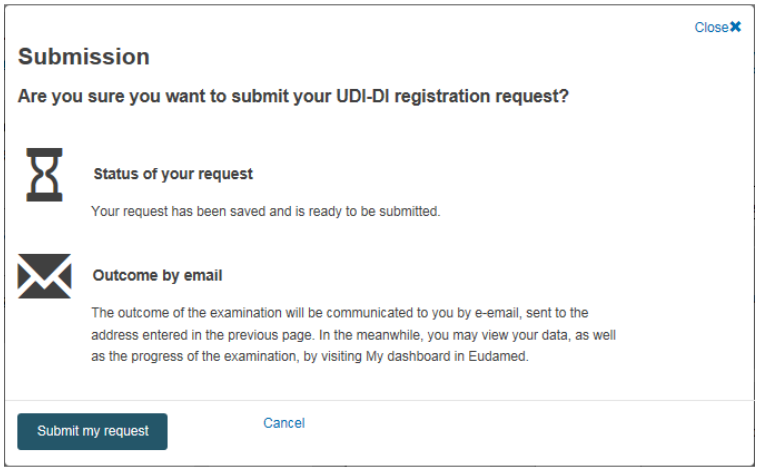
1. If you wish to complete page 6 of the UDI-DI registration wizard, proceed as follows: select the **Add a container package UI-DI for this UDI-DI** hyperlink for each package level of the device, and provide the following corresponding information:

Issuing Entity	The name of the official Issuing agency that provided the Package UDI-DI for the package level that you are describing.
Package UDI-DI value	The unique Package UDI-DI code corresponding to the package level that you are describing.
Quantity per package	The number of items in the package level that you are describing.

   The calculated total number of devices for all specified containers is displayed on the right hand-side.

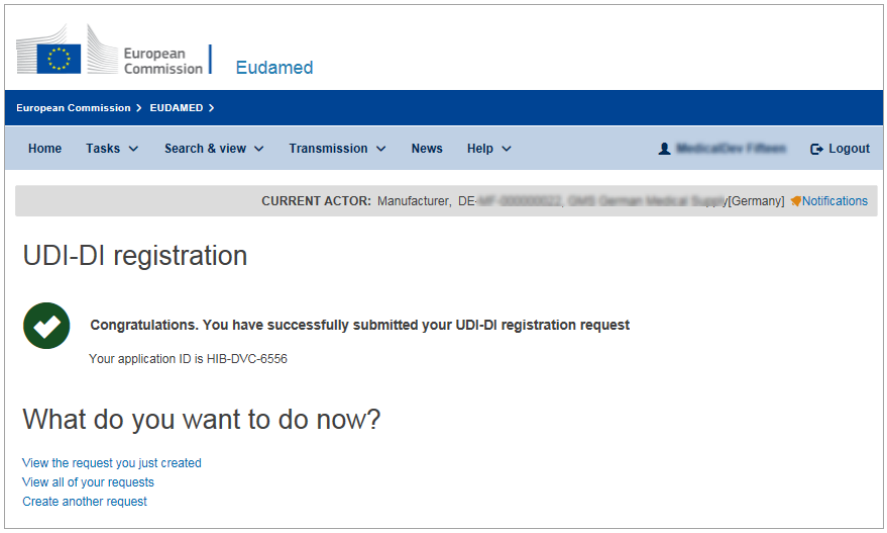
2. Before submitting the UDI device registration form, first click **Preview** at the bottom of the page and check every information that you have completed. If necessary, you can still click the **Back to form** button to make changes to the form before submitting it for goo.
3. When you have check the information and you are ready, click **Submit** .

Result: EUDAMED prompts you to confirm you submission:

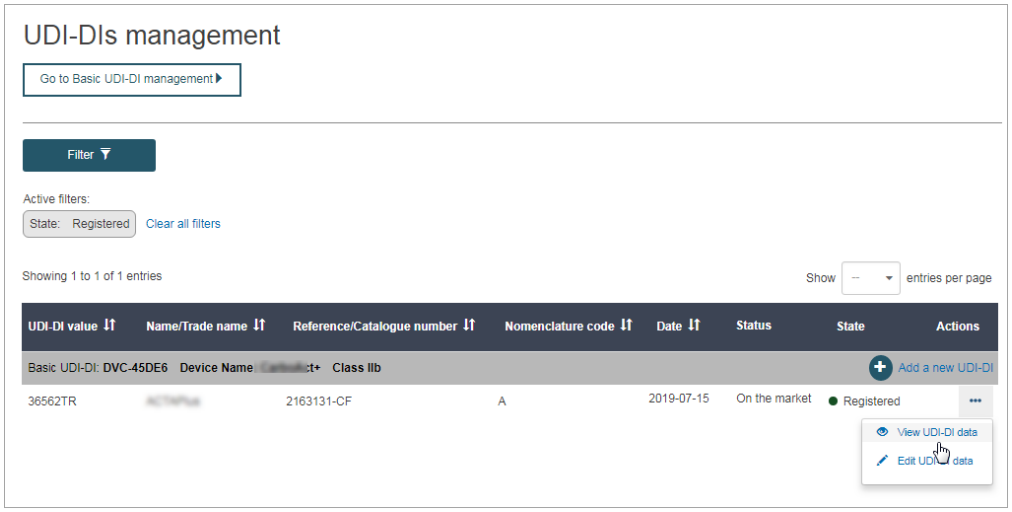


4. Read the message and then click **Submit my request**.

Result: You are informed that the device has been successfully submitted and that a unique application ID has been assigned to it. We suggest that you write down this ID for future reference purposes:



The newly submitted device simultaneously appears on the *UDI-DI Management* page (homepage > **UDI-DIs/Device > Manage your UDI-DIs**) with a state of 'Registered'. You can view (and edit) the submitted information from there if necessary:



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