



EUDAMED user guide

Legacy Devices

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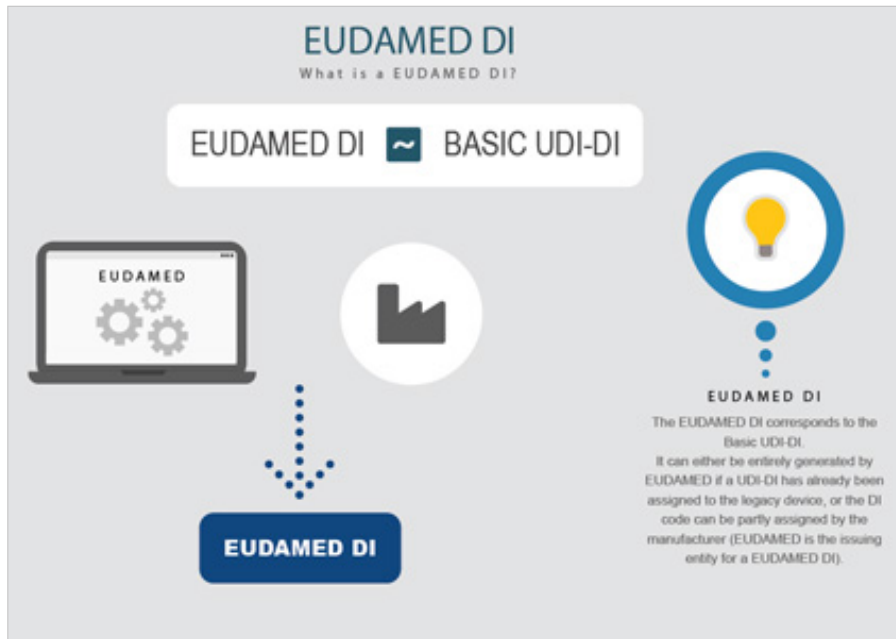
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1 Introduction

This document contains the details of how Legacy Devices are identified in EUDAMED and how you can register a Legacy Device in EUDAMED.¹

INFOGRAPHIC: Identifiers of a legacy device



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](#).

2 Identification details

To keep the same standard structure and identification elements for all Devices registered in EUDAMED, an identification element EUDAMED DI (the equivalent of the Basic UDI-DI) will be required, and a EUDAMED ID (in case no UDI-DI has been assigned) will be generated from the EUDAMED DI.

2.1 Generation of identification details for a Legacy Device when a UDI-DI already exists

In case the manufacturer has already a UDI-DI assigned to a Legacy Device, they will be able to use it as a device identifier for the Legacy Device. In this case, the EUDAMED DI is automatically generated from the UDI-DI value.

The Legacy Device will therefore have the following identification elements: a EUDAMED DI (equivalent of the Basic UDI-DI and generated based on the UDI-DI) and a UDI-DI (provided by the manufacturer).

In order to generate the EUDAMED DI identification element from the UDI-DI provided, EUDAMED will use a standard format, placing the characters "**B-**" in front of the UDI-DI.

UDI-DI: **M991CVS12130NES2**

Generated EUDAMED DI: **B-M991CVS12130NES2**

2.2 Generation of identification details for a Legacy Device when a UDI-DI does not exist

In case the manufacturer does not have a UDI-DI assigned for a Legacy Device, the manufacturer will have to assign a EUDAMED DI and EUDAMED ID.

The EUDAMED DI will have a strict format, starting with 'B-' as a prefix and continuing with a set of characters. For further information on the EUDAMED DI format please consult the [Format of the EUDAMED DI identification number](#) document.

The EUDAMED ID will have the same format and value as EUDAMED DI except the first prefix character. It will start with 'D' instead of 'B'.

EUDAMED DI: **B-BEMF000000106CR023335WE**

EUDAMED ID: **D-BEMF000000106CR023335WE**

3 Registering Legacy Devices

On the dashboard, click on *Register a Legacy device*:

The screenshot shows the EUDAMED dashboard. At the top, it says 'Welcome to EUDAMED' and provides information about MDR EUDAMED. Below this, there is a 'Tasks' section. The 'Tasks' section is divided into three columns: 'My Actor data', 'UDI-DIs/Device', and 'User management'. In the 'UDI-DIs/Device' column, the option 'Register a legacy device' is highlighted with a red rectangular box. Other options in this column include 'Register a new Basic UDI-DI', 'Manage your Basic UDI-DIs / EUDAMED Dis', and 'Manage your Devices details'. The 'My Actor data' column has options for 'Manage your actor data' and 'Manage your email notifications'. The 'User management' column has options for 'Assess user access requests' and 'Manage your users'. There is also a 'See all the news' button in the top right corner.

3.1 Step 1: EUDAMED DI identification information

1. Select the applicable legislation:

Legacy Device registration

Manufacturer identification

Organisation name:	Belgian MF A
SRN:	BE-MF-00000041
Address:	Rue A, 1 1060 Brussels
Telephone number:	-
Email:	public-contact@belgian-mf-a.be

*** Applicable Legislation**

IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)

MDD (Directive 93/42/EEC on Medical Devices)

AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

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

Basic UDI-DI main information

* Is it a kit?
 Yes No

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

* Special device type:
 Software

3. Non-EU manufacturers have to select the authorised representative (AR) for the current device from the options available. If there is only one AR with an active Mandate with the 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

4. Click on **Save & Next** to save it as a draft and continue with the following steps:

Save & Next >

5. On the left you will see a summary of the device characteristics. Choose a *Risk class* from the list and select **Yes** or **No** for each of the options.

Legacy device registration

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

Manufacturer identification
 BE-MF-000000041, Belgian MFA

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

EUDAMED DI code: B-56909
 Issuing Entity: EUDAMED

Kit: No
 Special device type: Software

EUDAMED DI information

* Risk class:

* Near-patient testing
 Yes No

* Self-patient testing
 Yes No

* Companion diagnostic
 Yes No

* Reagent
 Yes No

* Instrument
 Yes No

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

Device model applicable

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

* Device model:

Device Name:

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

Save

Save & Next >

3.2 Step 2: Certificate information

Select a certificate type, enter the NB number or name and click **Find**. Enter the *Certificate number* and *Expiry date*. If applicable, enter a *Revision number*.



NOTE

[Annex - Legacy Device Certificate Types \[17\]](#) lists the certificate types for Legacy Devices.

Certificate information

Item #1
▼

* Certificate Type:

EC Certificate Full Quality Assurance System
▼

[Change Notified Body](#)

Organisation name: EVPU a.s.

NB number: 1293

Address:

Telephone number: 421 42 44 03 600

Email: hudak@evpu.sk

* Certificate number: Revision number:

* Expiry date:

YYYY-MM-DD

3.3 Step 3: Device identification information

EUDAMED will display the identifier of the Device (the previously provided UDI-DI or the EUDAMED **ID** generated based on the provided/generated EUDAMED **DI**. EUDAMED ID has the same code as the EUDAMED DI, except that it is with a “**D-**” prefix instead of the “**B-**” prefix):

Device identification

* Issuing Entity: EUDAMED ▼

* EUDAMED ID code: D-LM100X3PL

1. Enter the EMDN code. Click on **Find** and select the correct one:

* Enter the nomenclature code (EMDN code):

[Advanced search of device nomenclature](#)

2. If applicable, enter the trade name and select the language, otherwise select **No**:

Trade name applicable

Yes No

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

* Trade name:

* Select the language: — I ▼

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

3. Enter a reference/catalogue number and any additional information you might have:

* Reference/Catalogue number:

Additional product description:

Select the language:

-- ✕ ▼

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

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

* Device status:

On the EU market ▼

4. You can choose the market status of the Device:

* Device status:

On the EU market ▼

On the EU market

No longer placed on the EU market

3.4 Step 4: Device characteristics

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

* **Labelled as single use**

Yes No

* **Need for sterilisation before use**

Yes No

* **Device labelled as sterile**

Yes No

Storage/handling conditions, if applicable

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

* Storage/handling conditions type: Description:

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

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

Storage/handling conditions, if applicable

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

* Storage/handling conditions type: Description:

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

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

Critical warnings or contra-indications, if applicable

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

* Critical warning type: Description:

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

3.5 Step 5: Device information

1. 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

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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:

🔍 Check registry

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'

Enter data manually
Cancel

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: I * Postal code:

* Country: x v

Telephone:

Telephone format example: +32 x xxx xx xx

* Email:

2. Select **Yes** or **No** to provide the Clinical Investigation reference(s):

Clinical Investigation

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

Clinical investigation conducted inside EU?:

Yes No

[+ Add new Clinical Investigation](#)

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

*** Tissues and cells**

Presence of human tissues or cells, or their derivatives:

Yes No

Presence of animal tissues or cells, or their derivatives:

Yes No

Presence of cells or substances of microbial origin:

Yes No

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

Belgium ▼

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

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

France ▼

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

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

[Select one or more countries >](#)

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

Legacy Device registration



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

What do you want to do now?

[Register a legacy device](#)

[Go to the dashboard](#)

4 Management of Regulation Devices and Legacy Devices

For further information on how to manage Regulation and Legacy Devices please consult the following chapters of the dedicated [UDI Devices user guide](#):

- Manage your device Basic UDI-DI/EUDAMED DI details
- Manage your device UDI-DI/EUDAMED ID details
- Search & View Devices, Systems and/or Procedure Packs

5 Linking the Regulation Devices to Legacy Devices

EUDAMED will allow linking a Regulation Device with the correspondent Legacy Device and it will perform this linking automatically when both have the same UDI-DI. The link will be made at the level of the UDI-DI.



NOTE

See Sections *Link a registered Regulation Device to a registered Legacy Device* and *Delete the link between a Regulation Device and a Legacy Device* of the [UDI Devices user guide](#).

6 Annex – Legacy Device certificate types

The Annex presents the certificate types that can be used when registering a Legacy Device.

Certificate types depend on the applicable legislation of the Device.

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

