

Notified Bodies user guide

– for the Production environment

EUDAMED v2.7
April 2022

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1. Introduction

The purpose of this user guide is to help you navigate through the process of registering certificates into EUDAMED.

In order to successfully register a certificate in EUDAMED, this guide illustrates two scenarios including additional pre-requisite steps when registering a certificate issued for a high risk class device.

This guide assumes the reader is acquainted with the [Regulation \(EU\) 2017/745](#) on medical devices and [Regulation \(EU\) 2017/746](#) on in vitro diagnostic medical devices, hence no rules or any other guidance will be provided in relation to certain registration steps.

2. Basic Concepts – types and classes of certificates

In EUDAMED and in line with the [Regulation \(EU\) 2017/745](#) on medical devices and [Regulation \(EU\) 2017/746](#) on *in vitro* diagnostic medical devices, certificates are classified into two main classes: Product class and Quality class, with each class having its own types of certificates.

Certificate types of product class:

- EU Type Examination certificate (Annex X);
- EU Technical Documentation certificate (Annex IX Chapter II);
- EU Product Verification certificate (Annex XI Part B).

Certificate types of quality class:

- EU Quality Management System certificate (Annex IX chapter I);
- EU Quality Assurance certificate (Annex XI part A);
- EU Production Quality Assurance certificate (Annex XI).

3. Getting started

Prerequisites to access EUDAMED: [EU Login \(ECAS\) account](#)

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

For information on how to gain access to EUDAMED, please consult the the *User Access Guide for Notified Bodies*.

Once the first Local Actor Administrator (LAA) is approved by your designating authority, subsequent user access or profile change requests for the Notified Body will be approved by this user (not the designating authority). This responsibility can then be delegated to other LAA/LUAs in the Notified Body. It is good practice for each actor to have **at least two LAAs**.

Every user in EUDAMED is granted the profile *Viewer* . They can search and view registered certificates. In order to register a certificate in EUDAMED, you must request access to the Notified Bodies & Certificates module as:

- **Proposer**: this profile may create and delete draft records in the Certificates module
- **Confirmer**: this profile may also submit and discard records in the Certificates module



IMPORTANT

As a user cannot approve their own profile change requests, these requests must be approved by a **different** LAA/LUA from the Notified Body.

Before you start entering details of a certificate in EUDAMED, please make sure that you have all required information at hand.

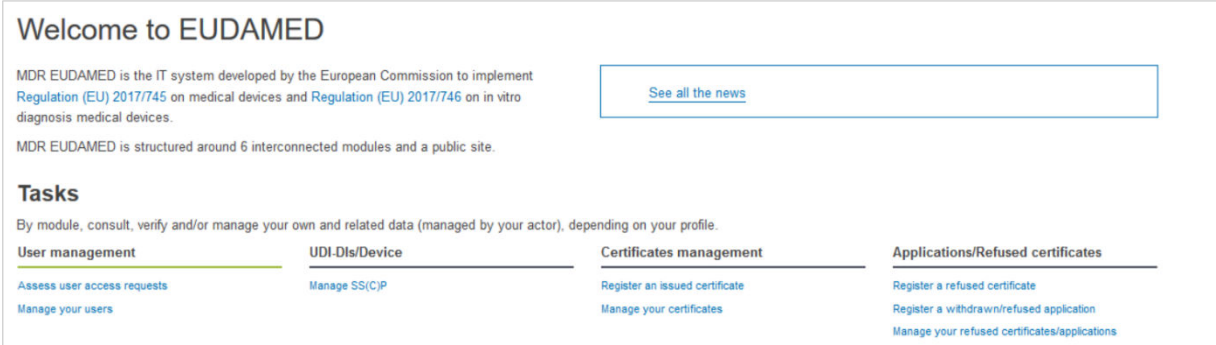
4. Registering an issued certificate

Click on the following link to arrive to EUDAMED Production page: <https://webgate.ec.europa.eu/eudamed>.

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

4.1. Quality class certificate registration

On the dashboard of EUDAMED, click **Register an issued certificate** on the Notified Bodies homepage:



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.

User management	UDI-DIs/Device	Certificates management	Applications/Refused certificates
Assess user access requests Manage your users	Manage SS(C)P	Register an issued certificate Manage your certificates	Register a refused certificate Register a withdrawn/refused application Manage your refused certificates/applications

4.1.1. Provision of core data

In the first step, you must choose between one of two applicable regulation types, then a certificate type. The type of the certificate will change depending on which option you choose, MDR or IVDR.



NOTE

In this scenario we will choose a quality class certificate type

You must also enter a certificate number and an optional revision number.

Enter the correct dates concerning the certificate, and enter the Actor ID/SRN or name of the manufacturer or the system or procedure pack producer:

Certificate core information

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

*** Applicable regulation**

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

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

*** Certificate type:**

(MDR) EU quality assurance certificate (Annex XI Part A) ▼

System or Procedure pack applicable

Yes ☒ No ☐ System or Procedure pack required unless you select the option - No

☐ Includes both devices and System and/or Procedure Packs

☐ Includes only System and/or Procedure Packs

*** Certificate Number:**

Revision number:

*** Date of issue:** YYYY-MM-DD

*** Starting certificate validity date:** YYYY-MM-DD

*** Date of expiry:** YYYY-MM-DD



NOTE

You may specify whether your certificate contains System or Procedure Pack(s) sterilisation by choosing MDR (Regulation (EU) 2017/745 and selecting any quality certificate type.

Click **Save & Next**.

4.1.2. Provision of certificate language

Click 'Add languages' and the system will display a dialog from where you can multi-select from a list of official EU languages:

1

Certificate languages

2

Device group(s)

3

Device(s)

4

System or Procedure Pack(s)

5

Certificate details

Certificate languages

Please provide certificate language(s):

No selection

*** Add language(s)** >

Save

Save & Next

Cancel

Once you are done you can **Save** your draft or click **Save & Next** to continue to the next step.

4.1.3. Provision of device group data

Click 'Add device group data' and complete the required information:

Device group(s)

Device Group #1

* Identification of the device group:

* Risk class

The device group contains device(s) of:

☐ Class I

☐ Class IIa

☐ Class IIb

☐ Class III

Remove this device group

You may provide more than one risk class for a device group by selecting the corresponding checkboxes.

If you choose class I, you will have to provide the characteristics of class I devices in the device group:

* Characteristic(s) of class I devices in the device group

☐ Re-usable surgical instrument

☐ With a measuring function

☐ Placed on the market in sterile condition

4.1.4. Provision of device data

The device registered can be a:

- Custom made device
- Device referenced by name
- Device referenced by a reference/catalogue number
- Basic UDI-DI

In this step you may choose to provide a custom-made device by selecting 'Yes' within *Custom made class III implantable* box:

Device(s)

Item #1

* Custom made class III implantable

☐ Yes ☒ No

[Remove this device](#)

[+ Add a device](#)

By doing so, EUDAMED will allow you to provide a description for the custom-made device:

Device(s)

Item #1

* Custom made class III implantable

☒ Yes ☐ No

* Description:

[Remove this device](#)

[+ Add a device](#)

When you select 'No', then the system will provide a dialog to select 'Name' or 'Reference/ Catalogue number' options in order to register a device by its name, its reference/ catalogue number or its basic UDI-DI:

Device(s)

Item #1

* Custom made class III implantable

☐ Yes ☒ No

* Provide one of the below

☒ Name
☐ Reference/Catalogue number
☐ Basic UDI-DI

[Remove this device](#)

[+ Add a device](#)

When either 'Name' or 'Reference/catalogue number' is selected, you must provide the risk class of the device.

Device(s)

Item #1

* Custom made class III implantable

☐ Yes
☒ No

* Provide one of the below

☐ Name
☒ Reference/Catalogue number
☐ Basic UDI-DI

* Enter Reference/Catalogue number:

* Risk class

The device is of:

☐ Class I
☐ Class IIa
☐ Class IIb
☐ Class III

Remove this device

+ Add a device

Click **Save** to save your draft or **Save & Next** to continue to the next step.

4.1.5. Provision of SPP details

If you have chosen a system or procedure pack, you must answer questions on sterilisation:

System(s) and/or Procedure pack(s) sterilisation

* Is SPP Producer the steriliser?

☒ Yes
☐ No

* Are SPP Group/s applicable?

☐ Yes
☒ No

* Sterilise method

☐ Aseptic processing
☐ Ethylene oxide gas sterilisation
☐ Low temperature steam and formaldehyde sterilisation
☐ Moist heat sterilisation
☐ Radiation sterilisation (gamma,x-ray,electron beam)
☐ Others

If the steriliser is not the SPP producer identified in the initial step of the registration wizard, answer 'No' to 'Is the SPP Producer the steriliser?' and provide the information requested to identify the sterilising organisation.

*** Is SPP Producer the steriliser?**


☐ Yes
 ☒ No

Steriliser

*** Organisation name:**

Street information, if applicable

Yes ☒ No ☐

 Street information is required unless you select the option - No

*** Street:****Street number:**

Address line 2:

PO box:

*** City name:***** Postal code:**

*** Country:**

--

▼

*** Are SPP Group/s applicable?**

☐ Yes
 ☒ No



NOTE

You may now add sterilisers in addition to the SPP Producer being a steriliser. More than one steriliser can be referenced in System and/or Procedure pack(s) sterilisation step.

By default, the system assumes there are no SPP Group(s) within this sterilised SPP. If you click 'Yes' to 'Are SPP Group/s applicable?', you will be asked to enter information about the SPP group:

System and/or Procedure pack group(s)


[Add SPP group](#)

Add at least one SPP group:

SPP Group #1
▼

* Identification of the SPP group:

🗑️
Remove SPP Group

Once complete, click on **Save** or **Save & Next**.

4.1.6. Provision of certificate details

Select the correct options in the following list:

Certificate details

*** Special Device Type within the scope**

Devices manufactured utilising tissues or cells of animal origin or their derivatives:

☐ Yes ☐ No

Devices manufactured utilising tissues or cells of human origin or their derivatives:

☐ Yes ☐ No

Devices in sterile condition:

☐ Yes ☐ No

Devices incorporating as an integral part an in vitro diagnostic device:

☐ Yes ☐ No

Devices without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745:

☐ Yes ☐ No



NOTE

When you have defined the scope of the certificate with a device group and/or device having risk class I that has the property 'Placed on the market in sterile condition', then the system will set 'Yes' for the 'Devices in sterile condition' question within the 'Special Device Type within the scope'.

Enter the conditions and limitations if there are any, if none you can toggle to 'No':

Conditions and limitations

Yes ☒ No ☐

Conditions or limitations are required unless you select the option - No

Conditions and limitations - English (EN)

* Conditions and limitations (EN):

Certificate document

* Select the language of the certificate:

☐ EN

Browse

Select the languages in which the electronic version of the certificate is issued. You may upload more than one electronic document if it covers different languages, and you may upload several documents at once.

Click on either **Save** or **Save & Next**.

4.1.7. Provision of SS(C)P documents

For certain high-risk devices that are implantable as required by the Regulation, the provision of an SS(C)P is required. An SS(C)P record within EUDAMED can be attached to many certificates. Hence, the initial dialog requires the provision of 'SS(C)P reference number' and 'SS(C)P revision number'.

Once provided, click **Check registry**. If the record exists in EUDAMED that record will be displayed. Otherwise, you may enter a new SS(C)P registration. You may also create a new SS(C)P version of a reused SS(C)P (see [Step 4.1.8 \[14\]](#)):

SS(C)Ps

Be aware that if there are devices within the scope of the certificate that are:

- implantable that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
- implantable a sscp with related information such as the Basic UDI-DI (if not already provided) will be required to provide in the SSCP step.

SS(C)P reference number

SS(C)P reference number

SS(C)P revision number

Check registry

Remove this SSCP and metadata

SS(C)P ABC/10 Rev 1 is not registered in EUDAMED. Please provide the information below.

SS(C)P reference number

SS(C)P revision number

Date issued:

YYYY-MM-DD

* Select the document language:

Browse

Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document.

Click 'Yes' to the question 'Is this SS(C)P validated' to indicate that the uploaded master document is validated, otherwise click on 'No':

* Is this SS(C)P validated?

☐ Yes ☐ No

In order to register an SS(C)P, a Basic UDI-DI is required. Within the 'Device(s) information' box a respective Basic UDI-DI can be added.

The *Devices information* box confirms no associated devices. Click 'Add a new device to this SC(C)P'. The pop-up shows two sections: the Basic UDI-DI(s) referenced in this certificate, and (for quality certificates only) a list of all devices registered by the referenced manufacturer. You can select multiple devices.:

You can input a partial Basic UDI-DI number and click **Filter** to narrow down the search results.

Once selected, click **Confirm** to link the devices to this new SC(C)P. Nothing is yet submitted, and you can delete this SS(C)P by clicking 'Remove this SS(C)P and metadata' to return to the previous screen.

When finished click on the **Preview** button to review the provided information:

Preview full registration for submission

Certificate identification

Notified Body number: 2409

Name: CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.

Country: Hungary

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: Yes

Certificate Number: MDR/QMS/Alles/089-654 [Edit](#)

Revision number: Rev.1

Status: Issued

Starting certificate validity date: 2021-04-01

Date of issue: 2021-04-01

Date of expiry: 2026-04-01

Manufacturer identification

[BE-MF-000000004_Alexandru Release Manufacturer](#)

System and/or Procedure Pack Producer Identification

[BE-PR-000000217_B6-Belgium-System/Procedure Pack Producer56659](#)

[Open all](#) | [Close all](#)

STEP 1 **Certificate languages** [^](#)

STEP 2 **Device group(s)** [^](#)

STEP 3 **Device(s)** [^](#)

STEP 4 **System or Procedure Pack(s)** [^](#)

STEP 5 **Certificate details** [^](#)

STEP 6 **SS(C)Ps** [^](#)

From this page you can easily access desired step of the wizard by clicking the respective link:

[Open all](#) | [Close all](#)

STEP 1 **Certificate languages** [v](#)

[Go back to step 1](#)

Certificate languages: Estonian (ET)

When you click **Submit** and confirm your submission, the certificate will be registered in EUDAMED and you will see a *Congratulation* page.


Submission

Are you sure you want to register the issued certificate?

Submit my request

Cancel

Certificate registration

 **Congratulations. You have successfully registered your Reissued certificate**

Your certificate number is new-cert-number

What do you want to do now?

[View the certificate you just created - Certificate number new-cert-number](#)

[Go to the homepage](#)

From the congratulation page you can click on *View the certificate you just created* to open the registered certificate view page or you can click on *Go to homepage* to return to your homepage.

4.1.8. Create a new SS(C)P version of a reused SS(C)P

You can reuse an existing SS(C)P if one is already registered, and link your devices to it. However, you can also create a new SS(C)P version, while referencing an existing SS(C)P. Click **Create new version**.

The screenshot shows a form titled 'ABC/800' with a dropdown arrow. A red box highlights the 'Create new version' button. Below it, there are two input fields: 'SS(C)P reference number' with the value 'ABC/800' and 'SS(C)P revision number' with the value 'Rev.1'. A 'Date issued' field shows '2022-01-12' with a calendar icon. Below the date field is a text input field containing 'NB XXXX - SS(C)P [BG] [PDF 212 KB]'.

The warning message requests a revision number that must be different from the previous version, a manufacturer-provided issue date and a new master document. Click 'Date issued' and input the date.

The screenshot shows the 'SS(C)P information' form. At the top right is a 'Delete this draft' button. A warning message box states: 'You are registering a new version of this SS(C)P. You will be asked to change the revision number, provide the date issued by the manufacturer and upload a new master document. You may optionally link new Basic UDI-DI(s) to this SS(C)P version.' Below this, the 'SS(C)P information' section has two input fields: 'SS(C)P reference number' with 'ABC/800' and 'SS(C)P revision number' with 'Rev.2'. A red box highlights the 'Rev.2' field. The 'Date issued' field is open, showing a calendar for March 2022. The calendar has a red border and shows dates from 27 to 02. Below the calendar is a text input field with the placeholder 'P and certificate'. At the bottom, there is a button with a plus icon and the text 'Add a new device to this SS(C)P'.

Click **Browse** to upload the new master document in the pre-selected language, and confirm that it has been validated.

! You are registering a new version of this SS(C)P. You will be asked to change the revision number, provide the date issued by the manufacturer and upload a new master document. You may optionally link new Basic UDI-DI(s) to this SS(C)P version.

SS(C)P information

* SS(C)P reference number:

* SS(C)P revision number:

* Date issued:

YYYY-MM-DD

Language of the master document: Bulgarian

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

☒ I confirm that this version is the validated Master Document of the SS(C)P

The *Devices information* box confirms no associated devices. Click 'Add a new device to this SC(C)P'. The pop-up shows two sections: the Basic UDI-DI(s) referenced in this certificate, and (for quality certificates only) a list of all devices registered by the referenced manufacturer. You can select multiple devices.

Device(s) information

Basic UDI-DI associated with this SS(C)P and certificate

No devices are associated yet.

You can associate missing Basic UDI-DI(s) to this SS(C)P by clicking on 'Add a new device to this SS(C)P'.

Add a new device to this SS(C)P

Remove this SS(C)P and metadata

Add a Basic UDI-DI

* Basic UDI-DI(s) referenced in this certificate

Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☐ Basic UDI-DI 123456157X [GS1], Class Ila

* Basic UDI-DI(s) registered by the referenced manufacturer

Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

* Basic UDI-DI code:

☐ Basic UDI-DI 123456057Z [GS1], Class Ila

☐ Basic UDI-DI 1234560989 [GS1], Class Ila

☒ Basic UDI-DI 1234560887 [GS1], Class Ila

☐ Basic UDI-DI 1234560683 [GS1], Class Ila

☒ Basic UDI-DI 1234560785 [GS1], Class Ila

You can input a partial Basic UDI-DI number and click Filter to narrow down the search results.

* Basic UDI-DI(s) registered by the referenced manufacturer

Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

* Basic UDI-DI code:

☐ Basic UDI-DI 1234560683 [GS1], Class Ila

Once selected, click **Confirm** to link the devices to the revised SC(C)P. Nothing is yet submitted, and you can delete the inputs/links by clicking **Delete this draft** to return to the previous screen.

ABC/800

Delete this draft

! You are registering a new version of this SS(C)P. You will be asked to change the revision number, provide the date issued by the manufacturer and upload a new master document. You may optionally link new Basic UDI-DI(s) to this SS(C)P version.

SS(C)P information

* SS(C)P reference number:

ABC/800

* SS(C)P revision number:

Rev 2

* Date issued:

2022-03-15

YYYY-MM-DD

Language of the master document:

Bulgarian

You may also perform the tasks in reverse order. First select the Basic UDI-DI(s) so they display, then click Create new version and input the revision number, date and master document etc.

Create new version

! You are registering a new version of this SS(C)P. You will be asked to change the revision number, provide the date issued by the manufacturer and upload a new master document. You may optionally link new Basic UDI-DI(s) to this SS(C)P version.

SS(C)P information

* SS(C)P reference number:

ABC/800

* SS(C)P revision number:

* Date issued:

YYYY-MM-DD

Language of the master document:

Bulgarian

Browse

Device(s) information

Basic UDI-DI associated with this SS(C)P

Basic UDI-DI 123455157X [Class IIa - Implantable]

Basic UDI-DI 123456057Z [Class IIa - Implantable]

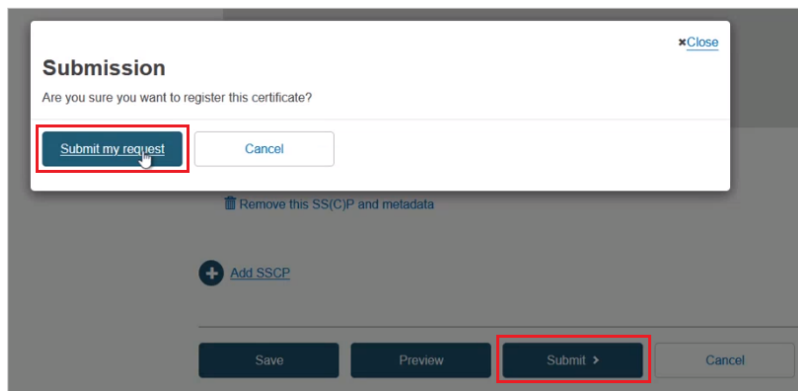
Basic UDI-DI 1234560989 [Class IIa - Implantable]

Edit

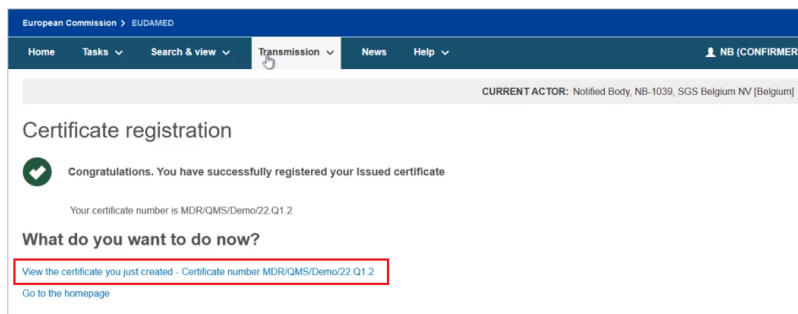
Click **Save** to continue, or **Submit**. In the confirmation click **Submit my request**.

Quality class certificate registration

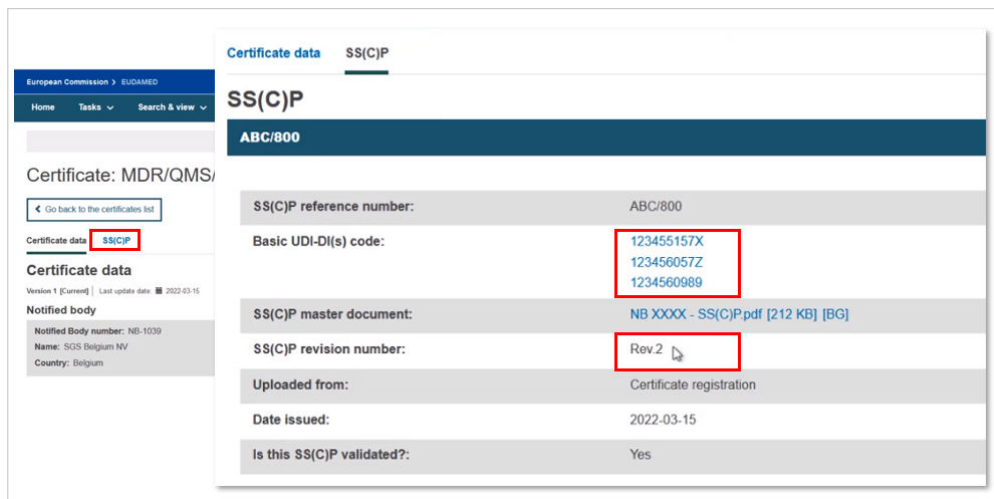
16



From the congratulation page, click 'View the certificate you just created'.



You can view the newly created certificate version, and all the devices linked to the new registered SS(C)P version.



4.2. Product class certificate registration

On the homepage of EUDAMED, click on 'Register an issued certificate'. In this scenario we will choose a product type certificate:

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.

User management	UDI-DIs/Device	Certificates management	Applications/Refused certificates
Assess user access requests Manage your users	Manage SS(C)P	Register an issued certificate Manage your certificates	Register a refused certificate Register a withdrawn/refused application Manage your refused certificates/applications

4.2.1. Provision of core certificate data

In the first step you must choose between one of two applicable regulation types, then a certificate type.

You must also enter a certificate number and an optional revision number.

Enter the correct dates concerning the certificate, and enter the Actor ID/SRN or name of the manufacturer:

Certificate core information

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

*** Applicable regulation**

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

*** Certificate type:**

*** Certificate Number:**

Revision number:

*** Date of issue:**

YYYY-MM-DD

*** Starting certificate validity date:**

YYYY-MM-DD

*** Date of expiry:**

YYYY-MM-DD

Click on **Save & Next**.

4.2.2. Provision of certificate language

Click 'Add languages' and the system will display a dialog from where you can multi-select from a list of official EU languages:

The screenshot shows a progress bar at the top with five steps: 1. Certificate languages (active), 2. Device group(s), 3. Device(s), 4. System or Procedure Pack(s), and 5. Certificate details. Below the progress bar, the title 'Certificate languages' is displayed. The text 'Please provide certificate language(s):' is followed by 'No selection'. A link '* Add language(s) >' is provided. At the bottom, there are three buttons: 'Save', 'Save & Next', and 'Cancel'.

Once you are done you can either **Save** your draft or click **Save & Next** to continue to the next step.

4.2.3. Provision of device data

In this step, you must enter a Basic UDI-DI code and choose the codes for the device type from the dropdown list:

The screenshot shows a progress bar at the top with three steps: 1. Certificate languages (completed), 2. Device(s) (active), and 3. Certificate details. Below the progress bar, the title 'Device(s)' is displayed. A section titled 'Basic UDI-DI -' contains a text input field for 'Enter Basic UDI-DI code:' and a 'Search' button. Below this, a section titled 'Device type' contains a dropdown menu for 'Codes according to the device type'. The dropdown is currently showing 'MDA 0000'. There is an 'Add' button with a red prohibition sign. A link with an information icon states 'The official document with the complete information of Codes can be found [here](#)'. Below this, a section titled 'Horizontal codes' contains another dropdown menu for 'Codes:' and an 'Add' button. A link with an information icon states 'The official document with the complete information of Codes can be found [here](#)'.

Enter the Intended purpose of the device in each language you have chosen in the prior steps:

Intended purpose

* Intended purpose is required to be provided in at least one language:

Intended purpose - Croatian (HR)

Add the intended purpose (HR):

Click either **Save** or **Save & Next**.

4.2.4. Provision of certificate details

Enter the conditions and limitations, if any, in each language:

Conditions and limitations

Yes ☒ No ☐ Conditions or limitations are required unless you select the option - No

Conditions and limitations - Croatian (HR)

* Conditions and limitations (HR):

Conditions and limitations - Latvian (LV)

* Conditions and limitations (LV):

Select the languages in which the electronic version of the certificate is issued. You may upload more than one electronic document if it covers different languages:

* Select the language of the certificate:

☒ HR ☒ NL ☒ LV

Browse

Click either **Save** or **Save & Next**.

4.2.5. Provision of SS(C)P documents

For certain high risk devices that are implantable as required by the Regulation, the provision of an SS(C)P is required.

An SS(C)P record within EUDAMED can be attached to many certificates. Hence, the initial dialog requires the provision of 'SS(C)P reference number' and 'SS(C)P revision number'. Once provided, click **Check registry**.

If the record exists in EUDAMED that record will be displayed. Otherwise, you may enter a new SS(C)P registration:

SS(C)Ps

Only the 'validated' SSCP in the main language must be provided.

SS(C)P reference number

SS(C)P reference number: SS(C)P revision number: **Check registry**

[Remove this SSCP and metadata](#)

[+ Add SSCP](#)

SS(C)P ABC10 Rev 1 is not registered in EUDAMED. Please provide the information below.

SS(C)P reference number: SS(C)P revision number:

* Date issued:

YYYY-MM-DD

* Select the document language:

Browse

Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document.

The *Devices information* box confirms no associated devices. Click 'Add a new device to this SC(C)P'. The pop-up shows the Basic UDI-DI(s) referenced in this certificate. You can select multiple devices to associate to this SS(C)P.

Device(s) information

Basic UDI-DI associated with this SS(C)P and certificate

No devices are associated yet.

You can associate missing Basic UDI-DI(s) to this SS(C)P by clicking on the **+ Add a new device to this SS(C)P** button.

+ Add a new device to this SS(C)P

[Remove this SS\(C\)P and metadata](#)

Add a Basic UDI-DI

* Basic UDI-DI(s) referenced in this certificate

Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☐ Basic UDI-DI 123451013J4 [GS1], Class III

☐ Basic UDI-DI 123451012J2 [GS1], Class III

Confirm **Cancel**

Once selected, click **Confirm** to link the devices to the SC(C)P. Nothing is yet submitted, and you can remove this SS(C)P by clicking on 'Remove this SS(C)P and metadata' and return to the previous screen.

You may register more than one SS(C)P. Select the device that is described by the SS(C)P being registered and click the **Confirm** button.

SS(C)P reference number

SS(C)P revision number

* Date issued:

YYYY-MM-DD

1 file uploaded successfully

NB XXXX - SS(C)P [CS] [PDF 212 KB]

Basic UDI-DI associated with this SS(C)P

Edit

Basic UDI-DI 123455017L [Class IIb - Implantable - Non suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector]

Remove this SSCP and metadata

Add SSCP

To register additional SS(C)Ps, click on 'Add SSCP'. You will be provided with a new search dialog for an SS(C)P.

SS(C)P reference number

SS(C)P revision number

* Date issued:

YYYY-MM-DD

1 file uploaded successfully

NB XXXX - SS(C)P [CS] [PDF 212 KB]

Basic UDI-DI associated with this SS(C)P

Edit

Basic UDI-DI 123455017L [Class IIb - Implantable - Non suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector]

Remove this SSCP and metadata

SS(C)P reference number

SS(C)P reference number

SS(C)P revision number

Check registry

Remove this SSCP and metadata

When registering additional SS(C)Ps, by clicking on 'Add a new device to this SS(C)P', the system will display the remaining devices in the scope of the certificate to be linked to the additional SS(C)P.

ABC/11

i SS(C)P ABC/11 Rev.1 is not registered in EUDAMED for the selected manufacturer. Please provide the information below.

SS(C)P reference number	SS(C)P revision
ABC/11	Rev.1

* Date issued:

2022-03-24	
------------	--

YYYY-MM-DD

Add a Basic UDI-DI

- Basic UDI-DI(s) referenced in this certificate
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☐ Basic UDI-DI 123451013J4 [GS1], Class III

Confirm Cancel

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

Device(s) information

Basic UDI-DI associated with this SS(C)P and certificate

No devices are associated yet.
You can associate missing Basic UDI-DI(s) to this SS(C)P by clicking on 'Add a new device to this SS(C)P'

[Add a new device to this SS\(C\)P](#)

[Remove this SS\(C\)P and metadata](#)

ABC/11

SS(C)P ABC/11 Rev.1 is not registered in EUDAMED for the selected manufacturer. Please provide the information below.

SS(C)P reference number

ABC/11

SS(C)P revision number

Rev.1

* Date issued:

YYYY-MM-DD

* Select the document language:

--

Browse

* Select Basic UDI-DI(s)

Select Basic UDI-DI(s) associated with this SS(C)P
You can select more than one Basic UDI in order to attach them to the same SS(C)P

☐ Basic UDI-DI 123455027N

☐ Basic UDI-DI 123455057U

Confirm

Cancel

When finished click **Save** or **Save & Next**.

Alternatively, you can create a new version of an existing SS(C)P. Click 'Create new version' and provide a version number, issue date and master document (see [Step 4.1.7 \[11\]](#) for Quality certificates). Click 'Add a new device to this SS(C)P' to add new devices to this new SS(C)P version:

ABC/800

Create new version

SS(C)P reference number

ABC/800

SS(C)P revision number

Rev.2

* Date issued:

2022-03-15

YYYY-MM-DD

NB XXXX - SS(C)P [BG] [PDF 212 KB]

Device(s) information

Basic UDI-DI associated with this SS(C)P and certificate

No devices are associated yet.

You can associate missing Basic UDI-DI(s) to this SS(C)P by clicking on "Add a new device to this SS(C)P"

+ Add a new device to this SS(C)P

The pop-up lists Basic UDI-DI(s) which are referenced in the certificate. No others can be added. Select one or multiple from the display, and click Confirm:

Add a Basic UDI-DI

* Basic UDI-DI(s) referenced in this certificate

Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☒ Basic UDI-DI 123451013J4 [GS1], Class III
 ☐ Basic UDI-DI 123451012J2 [GS1], Class III

Confirm

Cancel

The selected devices are listed:

ABC/800

Create new version

SS(C)P reference number

ABC/800

SS(C)P revision number

Rev.2

* Date issued:

2022-03-15

YYYY-MM-DD

NB XXXX - SS(C)P [BG] [PDF 212 KB]

Device(s) information

Basic UDI-DI associated with this SS(C)P

Basic UDI-DI 123451013J4 [Class III - Implantable]

Basic UDI-DI 123451012J2 [Class III - Implantable]

Edit

+ Add a new device to this SS(C)P

Remove this SS(C)P and metadata

You can still create a new version using the Create new version button as shown previously, and the selected devices will link to it. Click **Save & Next** to proceed:

ABC/800

Delete this draft

You are registering a new version of this SS(C)P. You will be asked to change the revision number, provide the date issued by the manufacturer and upload a new master document. You may optionally link new Basic UDI-DI(s) to this SS(C)P version.

SS(C)P information

* SS(C)P reference number:

ABC/800

* SS(C)P revision number:

Rev.3

* Date issued:

2022-03-15

YYYY-MM-DD

Language of the master document:

Bulgarian

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

☒ I confirm that this version is the validated Master Document of the SS(C)P

Device(s) information

Basic UDI-DI associated with this SS(C)P

Basic UDI-DI 123451013J4 [Class III - Implantable]

Basic UDI-DI 123451012J2 [Class III - Implantable]

+ Add a new device to this SS(C)P

Remove this SS(C)P and metadata

Save

Save & Next >

Cancel

Click **Save** to save as a draft, **Preview** to verify the information provided, or **Submit** to submit your registration.

Confirm your submission by clicking on **Submit my request** in the pop-up window:

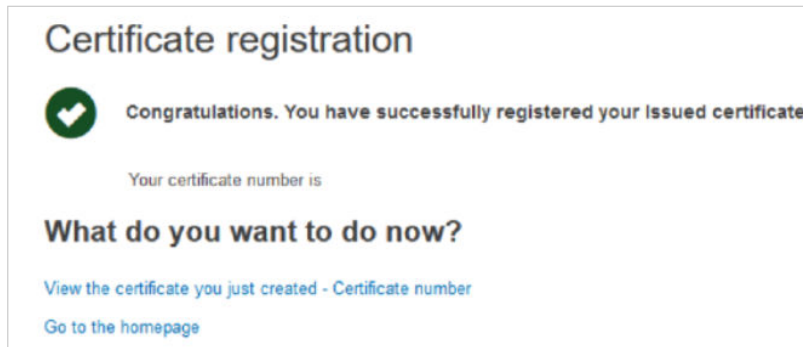
Submission

Are you sure you want to register the issued certificate?

Submit my request

Cancel

You will be shown a page confirming your registration.



From here you can click 'View the certificate you just created' to view the certificate, or you can click the 'Go to homepage' link in order to return to your homepage.

5. Register a refused certificate

To register a refused certificate, go to the homepage of EUDAMED as a Notified Body, look for the *Application/Refused* section and there click 'Register a refused certificate'.

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.

User management	UDI-DIs/Device	Certificates management	Applications/Refused certificates
Assess user access requests Manage your users	Manage SS(C)P	Register an issued certificate Manage your certificates	Register a refused certificate Register a withdrawn/refused application Manage your refused certificates/applications

Applications/Refused certificates


[Register a refused certificate](#)

[Register a withdrawn/refused application](#)

[Manage your refused certificates/applications](#)

5.1. Provision of core data


You are now brought to the core information page for the refused certificate, this step resembles the process for registering a normal certificate.


(*)required field
 Fields next to this symbol will not be publicly available

Notified Body number: NB-1039
Name: SGS Belgium NV
Country: Belgium

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

*** Conformity assessment procedure:**

*** Application reference number:**
*** Application submission date:** 

Refusal reference number:
*** Date of issue of the refusal:** 

Save & next

Select the applicable Regulation and the conformity assessment procedure from the list. Then, enter the application reference number.



NOTE

The system will warn you when the application reference number is not unique.

Provide the correct dates for both the application submission and the date of issue of the refusal.

Enter the Manufacturer information (after entering the Actor ID/SRN or Name).

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

[Change Manufacturer](#)

Save & Next

Click **Save & next**.

5.2. Decision languages

In this step, click 'Add language(s)' and select the languages from pop-up.

The screenshot shows a progress bar at the top with four steps: 1. Decision languages (active), 2. Device group(s), 3. Device(s), and 4. Reasons for decision. Below the progress bar, the title 'Decision languages' is followed by the instruction 'Please provide decision language(s):'. Below this, it says 'No selection' and provides a link '* Add language(s) >'. At the bottom, there are three buttons: 'Save', 'Save & Next' (which is highlighted with a mouse cursor), and 'Cancel'.

You can remove all the languages or add more if you wish to.

This screenshot shows a 'Remove all' link at the top. Below it are two buttons: 'Spanish (ES) X' and 'Swedish (SV) X'. At the bottom, there is a link '*Add more language(s) >'.

When you are done click **Save & Next**.

5.3. Device group(s)

Next, you will need to add a device group.

Click **+ Add a device group**.

The screenshot shows a progress bar at the top with four steps: 1. Decision languages (completed with a green checkmark), 2. Device group(s) (active), 3. Device(s), and 4. Reasons for decision. Below the progress bar, the title 'Device group(s)' is followed by the instruction 'If certificate includes identification of group(s) of devices within its scope, add devices here.'. Below this, there is a link '+ Add a device group' with a mouse cursor hovering over it. At the bottom, there are three buttons: 'Save', 'Save & Next' (which is highlighted with a mouse cursor), and 'Cancel'.

Enter the identification of the device group and the risk class.

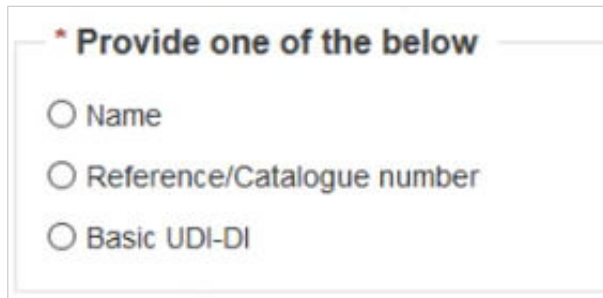
Click **Save & Next**.

5.4. Devices

Click **+ Add a device**.

Choose 'Yes' or 'No' whether the device is custom made or not.

Provide either a Name/Reference/Basic UDI-DI.



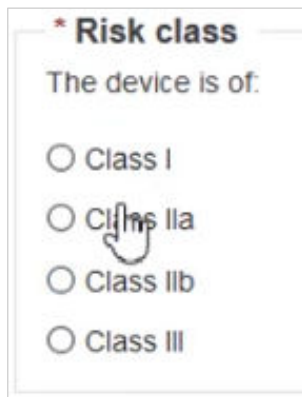
*** Provide one of the below**

☐ Name

☐ Reference/Catalogue number

☐ Basic UDI-DI

Choose the 'Risk class'.



*** Risk class**

The device is of:

☐ Class I

☐ Class IIa

☐ Class IIb

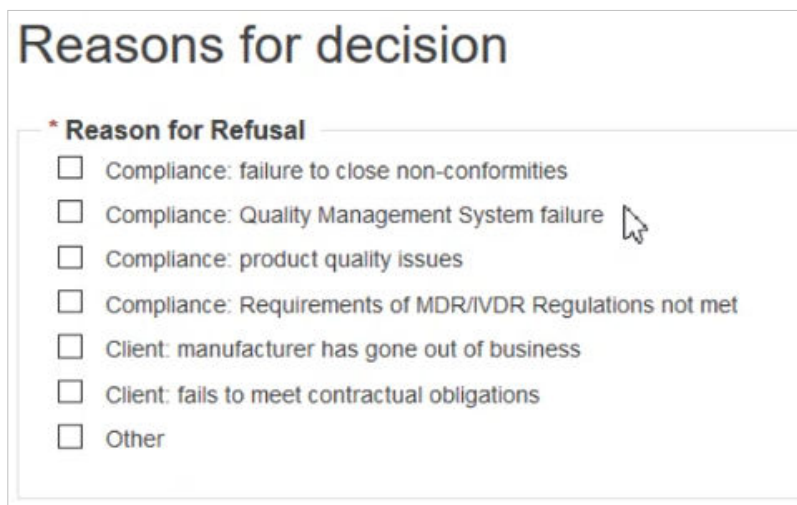
☐ Class III

Click **Save & Next**.

5.5. Reasons for decision

In this step you need to provide the information to why you have refused this certificate.

Select one or more reasons from the list below, and enter the reason for the refusal comment in the languages you have chosen in the *Decision languages* step (in this case, Spanish and Slovak).



Reasons for decision

*** Reason for Refusal**

☐ Compliance: failure to close non-conformities

☐ Compliance: Quality Management System failure

☐ Compliance: product quality issues

☐ Compliance: Requirements of MDR/IVDR Regulations not met

☐ Client: manufacturer has gone out of business

☐ Client: fails to meet contractual obligations

☐ Other



NOTE

If you select 'Other', you will have to provide the reason in the languages you have chosen in the *Decision languages* step.

* Reason for refusal comment (ES):

* Reason for refusal comment (SV):

Decision on refusal document

Upload refusal document

Browse



IMPORTANT

Decision on refusal document will be accessible only by competent authorities, the European Commission, and the Notified Body that registered it.

Click **Submit** to finish the registration:

Refused Certificate Registration



Congratulations. You have successfully registered your refused certificate

Your refused certificate application reference number is My-appl-1

What do you want to do now?

[Go to the homepage](#)

6. Update a certificate

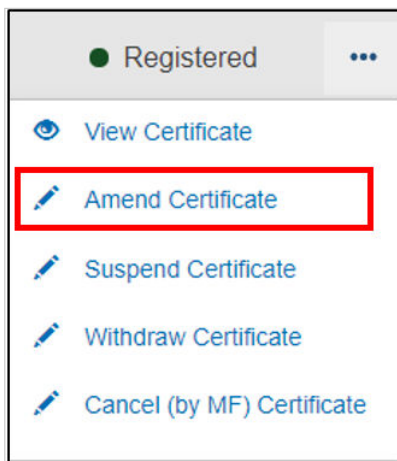


NOTE

In order to update a certificate, be sure to change the status in the search filters on the *Manage your certificates* page to 'Registered'.

6.1. Amend

To amend a certificate, you will have to click the three dots next to the certificate you wish to amend and click 'Amend Certificate'.



TIP

'Amend Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Amend Certificate' operation will now be available.

You will arrive to the following page.

Amended Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

- * Certificate identification
- (*) Certificate language(s)
- Device group(s)
- Device(s)
- * Certificate details

Certificate identification

Notified body information

Notified Body number:
Name:
Country:

Manufacturer identification

Version 2 [Current] | Last update date: 2021-04-19

Actor ID/SRN:
Organisation name:
Address:

[Update with new actor version](#)

Authorised representative identification

Version 1 [Current] | Last update date: 2021-04-16

Actor ID/SRN:
Organisation name:
Address:

[Update with new actor version](#)

[Remove this authorised representative](#)

To select another version of the Manufacturer, Producer or Authorised representative, click on 'Update with new actor version' link.

You will see a dialog to select another version of this actor (if it exists):

Manufacturer identification

Version 2 [Current] | Last update date: 2021-04-19

Select the new actor version in the list

[Version 2]

Actor ID/SRN:
Role: Manufacturer
Country: United Kingdom (excl. Northern Ireland)
Actor / Organisation name:
Address: London
Email:
Telephone number: -

Select this version

[Version 1]

[Cancel](#)

Click the **Select this version** button to select actor version and close this dialog.

The preceding certificate information box displays core information about the preceding certificate.

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU type-examination certificate (Annex X)
Certificate identifier:	MDR/TE/SS(C)/P/089-654
Revision number:	Rev.1
Date of issue:	2021-06-29
Starting certificate validity date:	2021-06-29
Date of expiry:	2022-06-29
Status:	Issued

Below that, you will see the following.

New Certificate Information

* Certificate Number:

Revision number:

* Date of issue:

YYYY-MM-DD

Status:

Amended

* Starting validity date:

YYYY-MM-DD

Enter the new 'Certificate Number' and add a revision number if you want to. Enter the date of issue and the starting validity date.

Select one of the reasons for the change to the certificate and add a comment in the comment box in the language the certificate was registered.

* Status change reason

- ☐ Editorial change of manufacturer/authorized representative
- ☐ Change of manufacturer's data
- ☐ Change of Authorised representative's data
- ☐ Change of Authorised representative (SRN)
- ☐ Other

* Comment (DE):

In the next steps, you will have to enter the information as if you are creating a new certificate. When you are done, click *Submit*.

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

Once you are done, click either **Save** to save your work without submitting or **Submit** to submit it straight away.

Save

Submit

Cancel

6.2. Supplement

To supplement a certificate, click the three dots next to the desired certificate and then click 'Supplement Certificate' from the dropdown menu:

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

Showing 1 to 20 of 34 entries Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Certificate number ¹	Certificate type	Date of issue ¹	Date of expiry ¹	Status	State	Actions
BE-MF-000000065	Business B6 Unit Manufacturer [All languages]	Test3-D-01	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-08-20	2026-08-20	Issued	Registered	...
BE-MF-000000065	Business B6 Unit Manufacturer [All languages]	test2-III	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-08-20	2026-08-31	Issued		<ul style="list-style-type: none"> View Certificate Amend Certificate Restrict Certificate Supplement Certificate Suspend Certificate Withdraw Certificate Cancel (by MF) Certificate Re-issue Certificate
IE-MF-000000221	QUASAR [All languages]	MDR/QA/DeviceGroup/72	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-08-18	2021-08-19	Reinstated		



TIP

'Supplement Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Supplement Certificate' operation will now be available.

On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left. Complete the information on the *Certificate identification* tab:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

Certificate identification

(*) Certificate language(s)

* Device(s)

* Certificate details

(*) SSC(C)Ps

Certificate identification

Notified body information

Notified Body number:

Name:

Country: Germany

Manufacturer identification

Actor ID/SRN:

Organisation name:

Address:

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)
Certificate identifier:	MDR/TDA/SS(C)P
Revision number:	Rev2
Date of issue:	2021-09-15
Starting certificate validity date:	2021-09-15
Date of expiry:	2026-09-15
Status:	Reinstated

Scroll down and fill in the 'New Certificate Information':

New Certificate Information

* Certificate Number:

Test3-D-01

Revision number:

Rev.1

* Date of issue:

2021-08-24

YYYY-MM-DD

* Date of expiry:

2026-08-20

YYYY-MM-DD

Status:

Supplemented

* Starting validity date:

2021-08-24

YYYY-MM-DD

* Status change reason

☒ Product: add a device(s)/group of device(s)
☐ Product: change to the approved type/device
☐ Other

* Comment (NL):

new device

Provide comments in each certificate language and click **Save** to proceed:

* Comment (FR):

new device

* Comment (DE):

new device

Save Submit Cancel

Click on the section *Devices* from the menu on the left and click 'Add a device':

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SS(C)Ps

Device(s)

Basic UDI-DI - 123455017L

Basic UDI-DI - 123455007J

Basic UDI-DI - 123455027N

+ Add a device

Save Submit Cancel

Click on the banner marked *Item* to expand the information for this device:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SS(C)Ps

Device(s)

Basic UDI-DI - 123455017L

Basic UDI-DI - 123455007J

Basic UDI-DI - 123455027N

Item #4

+ Add a device

Save Submit Cancel

Type the desired Basic UDI-DI code and click **Search**:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SS(C)Ps

Device(s)

Basic UDI-DI - 123455017L

Basic UDI-DI - 123455007J

Basic UDI-DI - 123455027N

Item #4

* Enter Basic UDI-DI code:

12345 Search

Device type

Codes according to the device type

* Codes:

MDA 0000 Add

The official document with the complete information of Codes can be found [here](#)

Fill in all the new details for the supplement, i.e. choose 'Device type' and provide the intended purpose:

Device(s)

Basic UDI-DI - 123455017L

Basic UDI-DI - 123455007J

Basic UDI-DI code: 123455007J
Issuing Entity: GS1
Risk class: Class IIb

Device type
Codes according to the device type

* Codes:

MDA0101 - Active implantable devices for stimulation/inhibition /monitoring

MDA0102 - Active implantable devices delivering drugs or other substances

MDA 0000

Figure 97: Provision of details to a Basic UDI-DI

Once you have provided the necessary information, click on **Save**:

Intended purpose - German (DE)

* Add the intended purpose (DE):

intended purpose

Remove this device

+ Add a device

Save Submit Cancel

Figure 98: Intended purpose of a Basic UDI-DI

Click on the *Certificate details* section from the menu on the left and complete all the steps:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
 (*) Section in which it is optional to enter/modify data

* Certificate identification
 (*) Certificate language(s)
 * Device(s)
Certificate details
 (*) SS(C)Ps

Certificate details

Conditions and limitations
 Yes ☒ No ☐ Conditions or limitations are required unless you select the option - No

Conditions and limitations - German (DE)

* Conditions and limitations (DE):
 Some conditions

Conditions and limitations - French (FR)

* Conditions and limitations (FR):
 Some limitations

To provide the new 'Certificate document', tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document containing one/some language(s) or one document covering all languages:

Certificate document

* Select the language of the certificate:

☒ DE ☒ FR ☐ NL

Browse

Once you have successfully uploaded the new certificate document(s), click on **Save**.

Certificate document

* Select the language of the certificate:

☐ DE ☐ FR ☐ NL

Browse

1 file uploaded successfully

NB XXXX - Certificate [DE, FR, NL] [PDF 212 KB]

Save **Submit** **Cancel**

Next, decide either to create a new version of the SS(C)Ps, or link new devices to the existing one. Click on the next menu section, i.e. *SS(C)Ps*, then click 'Create new version':

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

Certificate language(s)

(*) Device group(s)

(*) Device(s)

* Certificate details

(*) SS(C)Ps

SS(C)Ps

ABC/100

Create new version

SS(C)P reference number: ABC/100

Basic UDI-DI(s) code: 123455167Z

+ Add a new device to this SS(C)P

Master document version 1 [Current] | Not validated | Upload date 2022-03-10

SS(C)P master document: NB XXXX - SS(C)P.pdf [212 KB] [BG]

SS(C)P revision number: Rev.1

Uploaded from: Certificate registration

Date issued: 2022-03-10

Be aware that if there are devices within the scope of the certificate that are:

- > lib implantable that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
- > Ila implantable

a sscp with related information such as the Basic UDI-DI(if not already provided) will be required to provide in the SSCP step.

Fill in the information for the new SS(C)P document version and upload the new master document in the pre-selected language.

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

(*) Certificate language(s)

* Device(s)

* Certificate details

(*) SS(C)Ps

SS(C)Ps

ABC/500

Create a new version of this SS(C)P master document

Upload a new version of the master document

* SS(C)P reference number: ABC/500

* SS(C)P revision number: new revision number

* Date issued:

YYYY-MM-DD

Language of the master document: Dutch

Browse

☐ I confirm that this version is the validated Master Document of the SS(C)P

Confirm

Cancel

Once you have uploaded the new SS(C)P master document, tick the confirmation box and click **Confirm**.

Language of the master document: Dutch

1 file uploaded successfully

NB XXXX - SS(C)P [NL] [PDF 212 KB] ✕

☒ I confirm that this version is the validated Master Document of the SS(C)P

Confirm Cancel

The system will display your newly created SS(C)P version for you to review. If you discover a mistake, you can click **Discard** and re-do the process, alternatively click **Save**:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification
(*) Certificate language(s)
* Device(s)
* Certificate details
(*) **SS(C)Ps**

SS(C)Ps

ABC/500 ▼ Discard

SS(C)P reference number: ABC/500

Basic UDI-DI(s) code: 123455017L

Master document version 2 [Current] | ☒ Validated | Upload date 2021-08-11 | [See version history](#)

SS(C)P master document: NB XXXX - SS(C)P.pdf [212 KB] [NL]

SS(C)P revision number: Rev.5

Uploaded from: Certificate registration

Date issued: 2021-08-11

ⓘ Only the 'validated' SS(C)P in the main language is mandatory. Please ensure that all Basic UDI-DIs have been entered before entering SS(C)P details. If Basic UDI-DIs are changed afterwards, SS(C)P information must be re-entered.

+ [Add SS\(C\)P](#)

Save Submit Cancel

Rather than create a new SS(C)P version, the Notified Body may instead link new devices to the original SS(C)P (version) by clicking 'Add a new device to this SS(C)P'. Select the device(s) from the pop-up display, then click **Confirm**:

Supplemented Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

*** Certificate identification**

Certificate language(s)

(*) Device group(s)

(*) Device(s)

*** Certificate details**

(*) SS(C)Ps

SS(C)Ps

ABC/100

SS(C)P reference number: ABC/100

Basic UDI-DI(s) code: 1234

[+ Add a new device to this SS\(C\)P](#)

Master document version 1 [Current] | Not validated

SS(C)P master document: NB XXXX

SS(C)P revision number: Rev. 1

Uploaded from: Certificate registration

Date issued: 2022-03-10

Add a Basic UDI-DI

* Basic UDI-DI(s) referenced in this certificate
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☒ Basic UDI-DI 123455167Z [GS1], Class Ila
☐ Basic UDI-DI 1234530078 [GS1], Class Ila

* Basic UDI-DI(s) registered by the referenced manufacturer
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

* Basic UDI-DI code:
 [Filter](#)

☐ Basic UDI-DI 123456057Z [GS1], Class Ila
☒ Basic UDI-DI 1234560989 [GS1], Class Ila
☐ Basic UDI-DI 1234560887 [GS1], Class Ila
☐ Basic UDI-DI 1234560683 [GS1], Class Ila
☐ Basic UDI-DI 1234560785 [GS1], Class Ila

[Confirm](#) [Cancel](#)

Be aware that if there are devices within the scope of the certificate that are sutures, staples, dental fillings, connectors, or Ila implantable, a sscp with related information such as the Basic UDI-DI (if not already provided) will be required to provide in the SSCP step.

The selected device(s) will appear on the SS(C)P window, removable by clicking the dustbin icon. You will notice the 'Create new version' button is now inactive, only reactivated if all newly linked devices are removed:

*** Certificate identification**

Certificate language(s)

(*) Device group(s)

(*) Device(s)



*** Certificate details**

(*) SS(C)Ps

SS(C)Ps

ABC/100

SS(C)P reference number: ABC/100

Basic UDI-DI(s) code: 123455167Z
1234560887 
1234560683 

[+ Add a new device to this SS\(C\)P](#)

Master document version 1 [Current] | Not validated | Upload date 2022-03-10

SS(C)P master document: NB XXXX - SS(C)Ppdf [212 KB] [BG]

SS(C)P revision number: Rev. 1

Uploaded from: Certificate registration

Date issued: 2022-03-10


[Create new version](#)

When you have fully reviewed all the information provided, click **Submit**:

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

The system will confirm the successful registration of the Supplemented certificate.

Certificate registration



Congratulations. You have successfully registered your Supplemented certificate

Your certificate number is Test3-D-01

What do you want to do now?

[View the certificate you just created - Certificate number Test3-D-01](#)

[Go to the homepage](#)

6.3. Restrict

To restrict a certificate, click on the three dots next to the desired certificate and then from the dropdown menu, click 'Restrict Certificate':

Showing 1 to 20 of 34 entries

Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Certificate number ¹	Certificate type	Date of issue ²	Date of expiry ³	Status	State	Actions
BE-MF-000000065	Business B6 Unit Manufacturer [All languages]	test2-III	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-08-20	2026-08-31	Issued	Registered	...
BE-MF-000000065	Business B6 Unit Manufacturer [All languages]	Test3-D-01	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-08-20	2026-08-20	Issued		<ul style="list-style-type: none"> View Certificate Amend Certificate Restrict Certificate Supplement Certificate Suspend Certificate Withdraw Certificate Cancel (by MF) Certificate Re-issue Certificate
IE-MF-000000221, BE-PR-000000324	QUASAR [All languages], SPPP_Release71 [All languages]	MDR/QMS/Other/Comments	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-08-18	2026-08-11	Supplemented	Registered	...



TIP

'Restrict Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Restrict Certificate' operation will now be available.

On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left. Complete the details for the default *Certificate identification* tab:

Restricted Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

- Certificate identification
- (*) Certificate language(s)
- * Device(s)
- * Certificate details
- (*) SS(C)Ps

Certificate identification

Notified body information

Notified Body number:
Name:
Country: Germany

Manufacturer identification

Actor ID/SRN:
Organisation name:
Address:

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)
Certificate identifier:	MDR/TDA/BUDI/SS(C)P
Revision number:	Rev 1
Date of issue:	2021-09-23
Starting certificate validity date:	2021-09-23
Date of expiry:	2022-09-23
Status:	Supplemented

Scroll down and fill in the 'New Certificate Information':

- Make sure to change the Certificate Number, otherwise the system will recognise the restricted certificate as a duplicate of the registered certificate (see below). Alternatively, provide a Revision Number while keeping the same Certificate Number.
- Select the date of expiry for this certificate and the starting date of validity of the restriction.

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)
Certificate identifier:	test2-III
Revision number:	-
Date of issue:	2021-08-20
Starting certificate validity date:	2021-09-01
Date of expiry:	2026-08-31
Status:	Issued

New Certificate Information

* Certificate Number: Revision number:

Duplicate preceding certificate information found

* Date of issue:

* Date of expiry:

YYYY-MM-DD

Status:

* Starting validity date:

YYYY-MM-DD

Scroll further down to the section *Status change reason* and select the reasons for the certificate's restriction (you can select more than one). In case you select *Other*, you **must** provide comments in all relevant languages of the specific certificate.

*** Status change reason**

- ☐ Compliance: substantial changes implemented before approval
- ☐ Compliance: failure to close non-conformities
- ☒ Compliance: Quality Management System failure
- ☐ Compliance: product quality issues
- ☒ Compliance: Requirements of the MDR/IVDR Regulations not met
- ☐ Product: obsolete – no longer placed on the market
- ☐ Product: has been reclassified
- ☐ NB reduces certificate scope
- ☒ Other

* Other reason (NL):

* Other reason (FR):

Provide comments in the Comment box in all the languages of the certificate and click **Save**.

* Comment (NL):

* Comment (FR):

Save
Submit
Cancel

Review all information under the *Device(s)* section, e.g. intended purpose, and where needed/possible, update or remove information accordingly.

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SSCP(s)

Device(s)

Basic UDI-DI - 12345567894C
▼

Basic UDI-DI code: 12345567894C

Issuing Entity: GS1

Risk class: Class III

Device type

Codes according to the device type

* Codes:

stimulation/inhibition /monitoring
MDA0102 - Active implantable devices delivering drugs or other

▼
Add

The official document with the complete information of Codes can be found [here](#)

table devices for administration, channelling and removal of substances, including devices for

Codes:

MDA 0000

▼
Add

The official document with the complete information of Codes can be found [here](#)

MDS1005 - Devices in sterile condition Remove

MDT2001 - Devices manufactured using metal processing Remove

Fill in the intended purpose of the device in all the certificate's languages and click **Save**:

Intended purpose
For devices in scope of a product procedure certificate, intended purpose must be provided in all certificate languages

Intended purpose - Dutch (NL)

* Add the intended purpose (NL):

new intended purpose of this device

Intended purpose - French (FR)

[Remove this device](#)

Save **Submit** **Cancel**

Review and update information under the *Certificate details* section in all relevant languages:

Certificate details

* Certificate identification
(* Certificate language(s)
Device(s)
Certificate details
(* SSCP(s)

Conditions and limitations

Yes ☒ No ☐ [Conditions or limitations are required unless you select the option - No](#)

Conditions and limitations - Dutch (NL)

* Conditions and limitations (NL):

Conditions test2

Conditions and limitations - French (FR)

Certificate document

* Select the language of the certificate:

☒ FR ☒ NL

Browse

To provide the new Certificate document, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document per language or one document covering all languages:

Certificate document

* Select the language of the certificate:

☒ FR ☒ NL

Browse

Once you have successfully uploaded the new certificate document(s), click **Save**:

Certificate document

* Select the language of the certificate:

☐ FR
 ☐ NL

Browse

1 file uploaded successfully

NB XXXX - Certificate [FR, NL] [PDF 212 KB]
 ✕

Save

Submit

Cancel

Click on the **SS(C)Ps** section from the menu on the left and click **Create new version**:

Restricted Certificate registration

* Section in which it is mandatory to provide new data or modify existing data
(*) Section in which it is optional to enter/modify data

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SSCP(s)

SSCP(s)

Test2 III

Create new version

SS(C)P reference number:

Test2 III

Basic UDI-DI(s) code:

1234567894C

Master document version 1 [Current] | Validated | Upload date 2021-08-20

SS(C)P master document:

mdcg_2019_9_sscp_en.pdf [128 KB] [FR]

SS(C)P revision number:

-

Uploaded from:

Certificate registration

Date issued:

2021-08-20

Save

Submit

Cancel

On the next screen, complete all the steps to create a new version, i.e. provide SS(C)P revision number, issue date, upload SS(C)P document and click **Confirm**:

* Certificate identification

(*) Certificate language(s)

Device(s)

* Certificate details

(*) SSCP(s)

SSCP(s)

Test2 III

Create a new version of this SS(C)P master document

Upload a new version of the master document

* SS(C)P reference number:

Test2 III

* SS(C)P revision number:

* Date issued:

Language of the master document:

French

Browse

☐ I confirm that this version is the validated Master Document of the SS(C)P

Confirm

Cancel

Save

Submit

Cancel

Next, the system will display your newly created SS(C)P version for you to review. If you discover a mistake, you can click **Discard** and re-do the process, alternatively click **Save**:

SSCP(s)

Test2 III

SSCP reference number: Test2 III

Basic UDI-DI code: 1234567894C

Master document version 1 [Current] | Validated | Upload date: 2021-08-23

SSCP master document: NB XXXX - SSCP.pdf [212 KB] [FR]

SSCP revision number: Rev.2

Uploaded from: Certificate registration

Date issued: 2021-08-23

Save Submit Cancel

When you have fully reviewed all the information provided, click **Submit**. The system will prompt you to confirm your submission. Click **Yes** to complete the process.

Submission

Are you sure you want to register this certificate?

Yes No

SSCP master document: NB XXXX - SSCP.pdf [212 KB] [FR]

SSCP revision number: Rev.3

Uploaded from: Certificate registration

Date issued: 2021-08-24

Save Submit Cancel

6.4. Re-issuing a quality/product certificate

- To re-issue a certificate, for example due to its imminent expiry, click to the *Certificates management* page then filter to identify the certificate you want to re-issue:

Certificates management

Register an issued certificate

Filter

Active filters: State: Draft Clear search

Showing 1 to 13 of 13 entries

MPR Actor (IDSN)	MPR Name	Certificate number ID	Certificate type	Date of issue ID	Date of expiry ID	Status	State	Actions
RE-MF-000000062	Alla Industries [All languages]	MDR/QMS/Demo/22 Q1 2	(MDR) EU quality management system certificate (Annex IX, Chapter II)	2022-03-16	2027-03-16	Reissued	Draft	
RE-MF-000000062	Alla Industries [All languages]	MDR/QMS/Demo/22 Q1 2	(MDR) EU technical documentation assessment certificate (Annex IX, Chapter II)	2022-03-11	2027-03-11	Issued	Draft	

Tasks

User management: Assess user access requests, Manage your users

UDI-DI/Device: Manage SSCP

Certificates management: Register an issued certificate, **Manage your certificates**

Applications/Refused certificates: Register a refused certificate, Register a withdrawn/refused application, Manage your refused certificates/applications



TIP 'Re-issue Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The *Re-issue Certificate* operation will now be available.

2. Select *Registered* as the state. From the list generated, in the 'Actions' menu click the three dots next to the intended issued certificate and select 'Re-issue Certificate':

Certificates management Register an issued certificate

Filter Show 20 entries per page

Certificate Type:

Role: Actor ID/SRN:

Status:

* State: Registered Discarded Draft Registered Clear all filters

Active filters: State: Registered Clear search

MF/PR Actor ID/SRN	MF/PR Name	Certificate number II	Certificate type	Date of issue II	Date of expiry II	Status	State	Actions
BE-MF-000000662	Alfa Industries [All languages]	MDR/QMS/Demo22 Q1.2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2022-03-11	2027-03-11	Issued	Registered	View Certificate Amend Certificate Rescind Certificate Supplement Certificate Suspend Certificate Withdraw Certificate Cancel (Re-FF) Certificate Re-issue Certificate
BE-MF-000000662	Alfa Industries [All languages]	Test005	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2022-03-10	2023-03-10	Suppl		
BE-MF-000000662	Alfa Industries [All languages]	Test006	(MDR) EU quality management system certificate (Annex IX Chapter I)	2022-03-10	2027-03-10	Issued		
BE-MF-000000381	New Release Test and Playground Org [All languages]	test-13458	(MDR) EU type-examination certificate (Annex X)	2022-03-10	2023-03-10	Issued		

3. The next screen will display all relevant information of the certificate. If necessary, click 'Update with new actor version'.

Re-issued Certificate registration

Notified body information

Notified Body number:

Name:

Country: Germany

Manufacturer identification

Version 6 [History] | Last update date: 2021-06-14

Actor ID/SRN: Update with new actor version

Organisation name:

Address:

Preceding certificate information

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

Certificate identifier: QMS1+QMS2

Revision number: Rev 1

Date of issue: 2021-09-15

Starting certificate validity date: 2021-09-15

Date of expiry: 2026-09-15

Status: Reissued

+ Add another preceding certificate

4. Select the right actor version from the list:

Manufacturer identification
Version 6 [History] | Last update date: 2021-06-14

Select the new actor version in the list

BE-MF- [Version 7]

Actor ID/SRN: [text]
Role: Manufacturer
Country: Belgium
Actor / Organisation name: [text]
Address: [text]
Email: [text]
Telephone number: [text]

Select this version

BE-MF- [Version 6]
BE-MF- [Version 5]
BE-MF- [Version 4]
BE-MF- [Version 3]
BE-MF- [Version 2]
BE-MF- [Version 1]

Cancel

5. Scroll down to the *New Certificate Information* section. Duplicate the certificate identifier, and note the duplication warning message. Add a 'Revision number' so it differs from the preceding certificate – the warning disappears. Select the new issue date, validity date and expiry date (noting the maximum period is five years). Now click on **Save & Next** to proceed:

Re-issued Certificate registration

Notified body information
Notified body number: NB.1039
Name: SGS Belgium NV
Country: Belgium

Manufacturer identification
Version 1 [Cancel] | Last update date: 2021-11-09
Actor ID/SRN: BE-MF-000000602
Organisation name: Alfa Industries
Address: Antwerpen

Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier: MDR/QMS/Demo/22.Q1.2
Revision number: -
Date of issue: 2022-03-11
Starting certificate validity date: 2022-03-11
Date of expiry: 2027-03-11
Status: Issued

+ Add another preceding certificate

New Certificate Information

* Certificate Number: MDR/QMS/Demo/22.Q1.2
Revision number: Rev 1

* Date of issue: 2022-03-17
* Date of expiry: 2027-03-17
* Starting validity date: 2022-03-17

Status: Reissued

Duplicate preceding certificate information found

Save & Next > Cancel

The next screen will display a timeline of steps to follow. Follow the order starting from the first section 'Certificate languages'.

6. Click on 'Add more languages' if necessary: Click 'Add more languages' if necessary:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: new-cert-number [Edit](#)

Revision number: -

Status: Reissued

Starting certificate validity date: 2021-08-24

Date of issue: 2021-08-24

Date of expiry: 2026-08-24

Certificate languages

Please provide certificate language(s):

Polish (PL) Slovak (SK) Slovenian (SL)

[Add more language\(s\) >](#)

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

- On the pop-up window, click on the desired languages and press **Select**:

Greek	Hungarian <input checked="" type="checkbox"/>
Irish	Italian
Latvian	Lithuanian
Maltese	Polish <input checked="" type="checkbox"/>
Portuguese	Romanian
Slovak <input checked="" type="checkbox"/>	Slovenian <input checked="" type="checkbox"/>
Spanish	Swedish

[Select](#) [Cancel](#)

- Click **Save & Next** to proceed to the next section:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: new-cert-number [Edit](#)

Revision number: -

Status: Reissued

Starting certificate validity date: 2021-08-24

Date of issue: 2021-08-24

Date of expiry: 2026-08-24

Certificate languages

Please provide certificate language(s):

Hungarian (HU) Polish (PL) Slovak (SK) Slovenian (SL)

[Add more language\(s\) >](#)

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

9. Fill in the information required to complete the *Device group(s)* step:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: QMS1+QMS2

Revision number: Rev.2

Status: Reissued

Starting certificate validity date: 2021-09-23

Date of issue: 2021-09-23

Date of expiry: 2026-09-23

Device group(s)

A device group - QMS1

* Identification of the device group:

A device group - QMS1

* Risk class

The device group contains device(s) of:

☒ Class I

☐ Class IIa

☐ Class IIb

☐ Class III

* Characteristic(s) of class I devices in the device group

10. Click **+ Add a device group** and then again on the appearing 'Device group' item:

* Characteristic(s) of class I devices in the device group

☒ Re-usable surgical instrument

☐ With a measuring function

☐ Placed on the market in sterile condition

Remove this device group

+ Add a device group

Save Save & Next Cancel

* Characteristic(s) of class I devices in the device group

☒ Re-usable surgical instrument

☐ With a measuring function

☐ Placed on the market in sterile condition

Remove this device group

Device Group #3

+ Add a device group

Save Save & Next Cancel

11. Fill in the required information and click **Save & Next**:

Third device group

* Identification of the device group:

Third device group

* Risk class

The device group contains device(s) of:

☐ Class I

☐ Class IIa

☒ Class IIb

☐ Class III

Remove this device group

+ Add a device group

Save Save & Next Cancel

12. Fill in the information for the *Devices*: step:

Re-issued certificate registration

✓ Certificate languages
✓ Device group(s)
3 Device(s)
4 Certificate details

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

[Edit](#)

Certificate Number: QMS1+QMS2

Revision number: Rev.2

Status: Reissued

Starting certificate validity date: 2021-09-23

Date of issue: 2021-09-23

Date of expiry: 2026-09-23

Preceding certificate information

[QMS1+QMS2Rev.1](#)

Device(s)

Device - QMS1

* Custom made class III implantable

☐ Yes ☒ No

* Provide one of the below

☒ Name

☐ Reference/Catalogue number

☐ Basic UDI-DI

* Name:

Device - QMS1

* Risk class

The device is of:

☒ Class I

☐ Class IIa

☐ Class IIb

☐ Class III

13. Click **+ Add a device group** and then click on the appearing 'Item' under 'Devices':

✓ Certificate languages
✓ Device group(s)
3 Device(s)
4 Certificate details
5 SS(C)Ps

Device(s)

Device - QMS1

Item #2

+ Add a device

Save Save & Next Cancel

14. Add the required information to complete this step and then click **Save & Next**:

Device(s)

Device - QMS1

Item #2

* Custom made class III implantable

☒ Yes ☐ No

* Description:

Remove this device

+ Add a device

Save Save & Next Cancel

- Fill in the information required to complete the *Certificate details* step:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: QMS1+QMS2

Revision number: Rev.2

Status: Reissued

Starting certificate validity date: 2021-09-23

Date of issue: 2021-09-23

Date of expiry: 2026-09-23

Conditions and limitations

Yes No

Conditions or limitations are required unless you select the option - No

Conditions and limitations - Italian (IT)

- Provide comments regarding Conditions and Limitations in each language you selected:

Conditions and limitations - Slovenian (SL)

* Conditions and limitations (SL):

Comments - QMS2

Conditions and limitations - Slovak (SK)

* Conditions and limitations (SK):

Limitations QMS1

17. To provide the new re-issued certificate document, tick the relevant languages and click **Browse** to upload the document(s) from your computer. You can upload either one document per language or one document covering all languages:

Certificate document

* Select the language of the certificate:

☒ HU ☒ PL ☒ SK ☒ SL

Browse

18. Once you have successfully uploaded the new certificate document(s), click **Save & Next**:

Certificate document

* Select the language of the certificate:

☐ HU ☐ PL ☐ SK ☐ SL

Browse

1 file uploaded successfully

NB XXXX - Certificate [HU, PL, SK, SL] [PDF 212 KB] ✕

Save Save & Next Cancel

At this point, depending on the specifics of the certificate, the system may take you to the next step called *SS(C)Ps* step; if not relevant for the specific certificate, this step will be omitted. You have three possibilities when adding new devices:

- **Add device(s) to an existing *SS(C)P* from the preceding certificate** (see *Step 19*).

■ **Add device(s) to a new version of the SS(C)P from the preceding certificate** (see *Step 20*).

■ **Add device(s) to a newly registered SS(C)P** (see *Step 21*).

19. Add device(s) to an existing SS(C)P from the preceding certificate
Click on 'Add SS(C)P'. The existing devices show, but are inactive. Select any new device(s) and click **Confirm**.

The screenshot shows the 'Add a Basic UDI-DI' modal. It contains two sections: 'Basic UDI-DI(s) referenced in this certificate' and 'Basic UDI-DI(s) registered by the referenced manufacturer'. The second section has a search bar and a list of UDI-DI codes. The code '1234560683' is selected and highlighted with a red box. A red arrow points from the 'Add a new device to this SS(C)P' button in the main interface to this modal.

The new device appears next to the dustbin icon. If you save now, the new device will be linked to this version of the SS(C)P:

The screenshot shows the 'SS(C)Ps' section of the interface. The 'ABC/800' SS(C)P is selected. Below it, the 'Basic UDI-DI(s) code:' field shows a list of codes: '123456057Z', '1234560989', '1234560683', and '123455157X'. The code '1234560683' is highlighted with a red box, and a dustbin icon is next to it, indicating it has been added. The 'Add a new device to this SS(C)P' button is also visible.

20. Add devices to a new version of the SS(C)P from the preceding certificate. With this approach, click **Create new version**:

Notified Bodies user guide

Manufacturer identification
BE-MF-00000662, Alfa Industries

Certificate identification
Notified Body number: NB-1039
Name: SGS Belgium NV
Country: Belgium
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)
System or Procedure pack applicable: No

Certificate Number: MDR/QMS/Demo/22.Q1.2
Revision number: Rev.1
Status: Reissued
Starting certificate validity date: 2022-03-17
Date of issue: 2022-03-17
Date of expiry: 2027-03-17

Preceding certificate information
NB-1039MDR/QMS/Demo/22.Q1.2

SS(C)Ps
ABC/800

SS(C)P reference number: ABC/800
Basic UDI-DI(s) code: 123456057Z
1234560989
123455157X

SS(C)P master document: NB XXXX - SS(C)P.pdf [212 KB] [BG]

SS(C)P revision number: Rev.2

Uploaded from: Certificate registration

Date issued: 2022-03-15

Create new version

Input the SS(C)P reference number, and create a revision number, then specify the issue date:

Manufacturer identification
BE-MF-00000662, Alfa Industries

Certificate identification
Notified Body number: NB-1039
Name: SGS Belgium NV
Country: Belgium
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)
System or Procedure pack applicable: No

Certificate Number: MDR/QMS/Demo/22.Q1.2
Revision number: Rev.1
Status: Reissued
Starting certificate validity date: 2022-03-17
Date of issue: 2022-03-17
Date of expiry: 2027-03-17

Preceding certificate information
NB-1039MDR/QMS/Demo/22.Q1.2

SS(C)Ps
ABC/800

SS(C)P information

* SS(C)P reference number: ABC/800

* SS(C)P revision number: Rev|

* Date issued: Mar 2022

Language of Bulgarian

Browse

Click Browse to locate and upload the master document, and click to confirm it is validated:

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

☒ I confirm that this version is the validated Master Document of the SS(C)P

Click **+ Add a new device** to this SS(C)P, locate and select the new device, and click **Confirm** to link it to this new SS(C)P version:

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

☒ I confirm that this version is the validated Master Document

Device(s) information

Basic UDI-DI associated with this SS(C)P

Basic UDI-DI 123456057Z [Class IIa - Implantable]

Basic UDI-DI 1234560989 [Class IIa - Implantable]

Basic UDI-DI 123455157X [Class IIa - Implantable]

+ Add a new device to this SS(C)P

Add a Basic UDI-DI

*** Basic UDI-DI(s) referenced in this certificate**
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

☒ Basic UDI-DI 123455157X [GS1], Class IIa

*** Basic UDI-DI(s) registered by the referenced manufacturer**
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

*** Basic UDI-DI code:**

Filter

☒ Basic UDI-DI 123456057Z [GS1], Class IIa

☒ Basic UDI-DI 1234560989 [GS1], Class IIa

☒ Basic UDI-DI 1234560887 [GS1], Class IIa

☐ Basic UDI-DI 1234560683 [GS1], Class IIa

☐ Basic UDI-DI 1234560785 [GS1], Class IIa

Confirm **Cancel**

Click **Save**, and when you register the certificate, this SS(C)P will be saved:

Certificate identification

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: MDR/QMS/Demo/22 Q1.2

Revision number: Rev 1

Status: Reissued

Starting certificate validity date: 2022-03-17

Date of issue: 2022-03-17

Date of expiry: 2027-03-17

Preceding certificate information

NB-1039/MDR/QMS/Demo/22 Q1.2

SS(C)Ps

ABC/800

SS(C)P reference number: ABC/800

Basic UDI-DI(s) code:

123455157X

123456057Z

1234560989

1234560887

+ Add a new device to this SS(C)P

Master document version 1 [Current] | Validated | Upload date 2022-03-17

SS(C)P master document: NB XXXX - SS(C)P.pdf [212 KB] [BG]

SS(C)P revision number: Rev 2

Uploaded from: Certificate registration

Date issued: 2022-03-17

Save **Preview**

21. Registering a new SS(C)P, then adding device(s) to it. Click **+ Add SSCP**, then provide the reference and revision number:

Master document version 1 [Current] | Validated | Upload date 2022-03-17

SS(C)P master document: NB XXXX - SS(C)P.pdf [212 KB] [BG]

SS(C)P revision number: Rev.2 SS(C)Ps

Uploaded from: Certificate registration

Date issued: 2022-03-17

Be aware that if the
 > lib implantable th
 pins, clips or conn
 > lib implantable
 a sscp with related
 step.

SS(C)P reference number

SS(C)P reference number: ABC/805 SS(C)P revision number: Rev.1

[Check registry](#)

[Remove this SS\(C\)P and metadata](#)

[+ Add SSCP](#)

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

Click **Check registry**. The system will confirm this is a new SS(C)P:

SS(C)P ABC/805 Rev.1 is not registered in EUDAMED for the selected manufacturer. Please provide the information below.

Complete the fields for the new SS(C)P, including the master document language. Click **Browse** to locate and upload the master document, confirming it is validated (for quality-type certificates):

ABC/805

SS(C)P ABC/805 Rev.1 is not registered in EUDAMED for the selected manufacturer. Please provide the information below.

SS(C)P reference number: ABC/805 SS(C)P revision number: Rev.1

* Date issued: 2022-03-17

YYYY-MM-DD

* Select the document language: Bulgarian

* Provide SS(C)P document: [Browse](#)

1 file uploaded successfully

NB XXXX - SS(C)P [BG] [PDF 212 KB]

* Is this SS(C)P validated?

☒ Yes ☐ No

* Is this SS(C)P validated?

☐ Yes ☐ No

Device(s) information

Basic UDI-DI associated with this SS(C)P and certificate

No devices are associated yet.

Scroll to the bottom, and click **+ Add a new device to this SS(C)P**, and select the device(s). Click **Confirm**, then **Save**:

Add a Basic UDI-DI

* Basic UDI-DI(s) registered by the referenced manufacturer
Select Basic UDI-DI(s) to be associated with the SS(C)P and related information

* Basic UDI-DI code:

[Filter](#)

- ☒ Basic UDI-DI 123456057Z [GS1], Class IIa
- ☐ Basic UDI-DI 1234560989 [GS1], Class IIa
- ☐ Basic UDI-DI 1234560887 [GS1], Class IIa
- ☐ Basic UDI-DI 1234560683 [GS1], Class IIa
- ☐ Basic UDI-DI 1234560785 [GS1], Class IIa

[Confirm](#) [Cancel](#)

[+ Add a new device to this SS\(C\)P](#)

[Remove this SS\(C\)P and metadata](#)

22. After having reviewed all information, click **Submit**:

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

The system will prompt you to confirm your submission of a re-issued certificate.

23. Click **Submit my request** to finalise the process:

Submission

Are you sure you want to register this re-issued certificate?

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

24. The system will confirm your submission has been successful. You can also view the newly created certificate by clicking on the link provided:

Certificate registration

Congratulations. You have successfully registered your Reissued certificate

Your certificate number is new-cert-number

What do you want to do now?

[View the certificate you just created - Certificate number new-cert-number](#)

[Go to the homepage](#)

6.4.1. Merging two or more certificates when re-issuing a quality certificate

1. Click on the three dots next to the desired certificate, then click 'Re-issue Certificate':

IE-MF-000000221	QUASAR [All languages]	QMS1+QMS2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-08-18	2026-08-18	Reissued	Registered	...
IE-MF-000000221	QUASAR [All languages]	MDR/QA/Group+Devices	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-08-18	2026-06-07	Restricted		
IE-MF-000000221,BE-PR-000000324	QUASAR [All languages], SPPP_Release71 [All languages]	MDR/QMS/Other/Comments	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-08-18	2026-08-11	Supplement		



TIP

'Re-issue Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Re-issue Certificate' operation will now be available.

2. On the next screen, click **+ Add another preceding certificate:**

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS1+QMS2
Revision number:	Rev.2
Date of issue:	2021-08-18
Starting certificate validity date:	2021-08-18
Date of expiry:	2026-08-18
Status:	Reinstated

+ Add another preceding certificate

New Certificate Information

* Certificate Number:	Revision number:
<input type="text"/>	<input type="text"/>
* Date of issue:	* Date of expiry:
<input type="text"/>	<input type="text"/>
YYYY-MM-DD	YYYY-MM-DD
Status:	* Starting validity date:
Reissued	<input type="text"/>
	YYYY-MM-DD

3. Type the new preceding certificate number and optional revision number and click **Find:**

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS1
Revision number:	Rev.1
Date of issue:	2021-09-14
Starting certificate validity date:	2021-09-14
Date of expiry:	2022-09-14
Status:	Issued

Provide the Certificate number of the Certificate(s) you want to merge

* Preceding certificate number: Preceding certificate revision number:

[Find](#)

[Remove this preceding certificate](#)

4. When there is more than one certificate with the same reference number and no revision number is provided, the system will display a selection dialog:

Find a certificate [Close](#)

QMS2 OtherRevision (ISSUED)

QMS2 Rev.1 (ISSUED)

[Close](#)

5. The new preceding certificate information will appear on the list. You have the option of removing it:

Preceding certificate information

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS1+QMS2
Revision number:	Rev.2
Date of issue:	2021-08-18
Starting certificate validity date:	2021-08-18
Date of expiry:	2026-08-18
Status:	Reinstated

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS2
Revision number:	Rev.1
Date of issue:	2021-06-16
Starting certificate validity date:	2021-06-16
Date of expiry:	2026-06-16
Status:	Issued

[Remove this preceding certificate](#)

6. Next, fill in the 'New Certificate Information' and click **Save & Next**:

New Certificate Information

* Certificate Number:

Revision number:

* Date of issue:

YYYY-MM-DD

* Date of expiry:

YYYY-MM-DD

Status: Reissued

* Starting validity date:

YYYY-MM-DD

Save & Next **Cancel**

7. The next screen will display a timeline of steps to follow. Follow the order starting from the first section *Certificate languages*. Click Add more languages if necessary and click **Save & Next** to complete this step:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: new-cert-number [Edit](#)

Revision number: -

Status: Reissued

Starting certificate validity date: 2021-08-24

Date of issue: 2021-08-24

Date of expiry: 2026-08-24

Certificate languages

Please provide certificate language(s):

[*Add more language\(s\) >](#)

Save **Save & Next** **Cancel**

8. In the next step – *Device group(s)* – EUDAMED will populate the device groups from the preceding certificate(s), if any. Verify the merged certificate and fill in any required information:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex IX Chapter I)

System or Procedure pack applicable: No

Certificate Number: QMS1+QMS2 [Edit](#)

Revision number: Rev 2

Status: Reissued

Starting certificate validity date: 2021-09-23

Date of issue: 2021-09-23

Date of expiry: 2026-09-23

Device group(s)

A device group - QMS1

* Identification of the device group:

A device group - QMS1

* Risk class

The device group contains device(s) of:

☒ Class I

☐ Class IIa

☐ Class IIb

☐ Class III

* Characteristic(s) of class I devices in the device group

9. To proceed to the next step, click **Save & Next**:

Manufacturer identification

Certificate identification

Notified Body number:

Name:

Country: Germany

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

Certificate type: (MDR) EU quality management system certificate (Annex D Chapter I)

System or Procedure pack applicable: No

Certificate Number: cert-merge-2 [Edit](#)

Revision number: -

Status: Reissued

Starting certificate validity date: 2021-08-24

Date of issue: 2021-08-24

Date of expiry: 2026-08-24

Device group(s)

Device group - QMS1

Device group - QMS2

Device group - QMS2

+ Add a device group

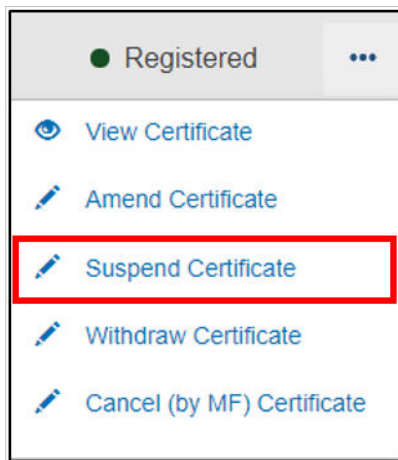
Save Save & Next Cancel

As the remaining actions to complete the process are identical to re-issuing a quality certificate, please consult steps 11-20 of [section 6.4 \[50\]](#).

7. Decisions over a certificate

7.1. Suspend

To suspend a certificate, click on the three dots next to the certificate you wish to suspend and click 'Suspend Certificate':



TIP

'Suspend Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Suspend Certificate' operation will now be available.

You will arrive to the following page:

Certificate suspension

Notified Body number:

Name:

Country: Germany

System and/or Procedure Pack Producer Identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number: -

Email:

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	MDR/QMS/SPP-only -
Date of issue:	2021-09-21
Starting certificate validity date:	2021-09-21
Date of expiry:	2022-09-21
Status:	Issued

Below you will find the *Decision* section:

Decision

* Decision date:

YYYY-MM-DD

* Starting decision applicability date:

YYYY-MM-DD

*** Status change reason**

- ☐ Compliance: substantial changes implemented before approval
- ☐ Compliance: failure to close non-conformities
- ☒ Compliance: Quality Management System failure
- ☐ Compliance: product quality issues
- ☐ Compliance: Requirements of the MDR/IVDR Regulations not met
- ☐ Client: fails to meet contractual obligations
- ☐ Other

* Comment (FR):

* Comment (EL):

Enter the date when the decision to suspend the certificate was taken, the date it will apply from, and the reason for the suspension.

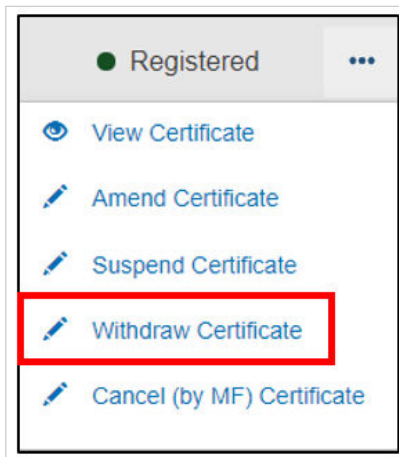
Upload the decision document in the correct language, once you are done, click **Submit**.

Submit

Cancel

7.2. Withdraw

To withdraw a certificate, click on the three dots next to the certificate you wish to withdraw and click 'Withdraw Certificate'.



TIP

'Withdraw Certificate' is missing?

Verify that your certificate is not in draft state within the certificate management page.

If a draft version exists, it must be finalised or deleted. The 'Withdraw Certificate' operation will now be available.

You will arrive to the following page:

Certificate withdrawal

Notified Body number:

Name:

Country: Germany

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

Certificate details

Applicable legislation:	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)
Certificate type:	(IVDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier: ⓘ	IVDR/QMS/Supplemented Rev.2
Preceding certificate identifier:	IVDR/QMS/Supplemented
Date of issue:	2021-09-15
Starting certificate validity date:	2021-09-15
Date of expiry:	2022-09-14
Status:	Supplemented
Status reason:	Product: add a device(s)/group of device(s)
Decision comments:	Added a device [ET]

Below you will find the *Decision* section:

Decision

* Decision date:

YYYY-MM-DD

* Starting decision applicability date:

YYYY-MM-DD

* Status change reason

- ☐ Compliance: substantial changes implemented before approval
- ☐ Compliance: failure to close non-conformities
- ☒ Compliance: Quality Management System failure
- ☐ Compliance: product quality issues
- ☐ Compliance: Requirements of the MDR/IVDR Regulations not met
- ☐ Product: obsolete – no longer placed on the market
- ☐ Product: has been reclassified
- ☐ Client: is no longer the legal manufacturer
- ☐ Client: has transferred to another NB
- ☐ Client: fails to meet contractual obligations
- ☐ Other

* Comment (IT):

Enter the date when the decision to withdraw the certificate was taken, the date it will apply from, and the reason it is being withdrawn.

Upload the decision document in the correct language, once you are done, click **Submit**.

Submit

Cancel

7.3. Cancel by MF Certificate

To cancel a certificate (by the manufacturer), click on the three dots next to the certificate you wish to cancel and then click 'Cancel (by MF) Certificate'.

Registered

...

View Certificate

Amend Certificate

Suspend Certificate

Withdraw Certificate

Cancel (by MF) Certificate



TIP

'Cancel (by MF) Certificate' is missing?

- Verify that your certificate is not in draft state within the certificate management page.
- If a draft version exists, it must be finalised or deleted. The 'Cancel (by MF) Certificate' operation will now be available.

You will arrive to the following page:

Certificate cancellation

Notified Body number:

Name:

Country: Germany

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier: ⓘ	QMS1 Rev.1
Date of issue:	2021-09-14
Starting certificate validity date:	2021-09-14
Date of expiry:	2022-09-14
Status:	Issued

Below you will find the *Decision* section. Enter the date when the decision to cancel the certificate was taken, the date the cancellation applies from, and the reason for the cancellation:

Decision

* Decision date:

YYYY-MM-DD

Starting decision applicability date:

YYYY-MM-DD

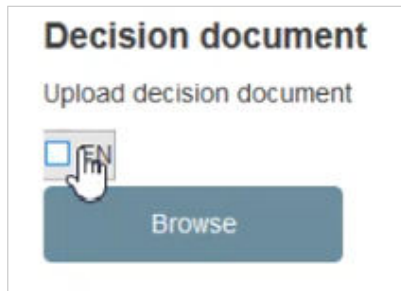
* Status change reason

☒ Other

* Other reason (EN):

* Comment (EN):

Upload the decision document in the correct language:

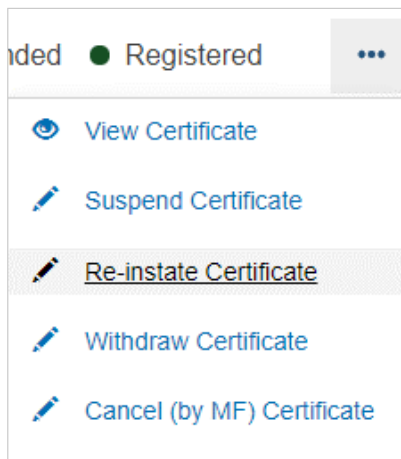


Once you are done, click **Submit**.



7.4. Reinstate

To re-instate a certificate, click on the three dots next to the certificate you wish to reinstate and click 'Reinstate Certificate'.



TIP

'Reinstate Certificate' is missing?

- Verify that the status of the certificate is 'Suspended'.
- Only suspended certificates can be reinstated.

You will arrive to the following page:

Certificate reinstatement

Notified Body number:

Name:

Country: Germany

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS2 OtherRevision
Date of issue:	2021-09-20
Starting certificate validity date:	2021-09-20
Date of expiry:	2026-09-20
Status:	Suspended
Status reason:	Compliance: Requirements of the MDR/IVDR Regulations not met

Below you will find the *Decision* section:

Decision

* Decision date:

YYYY-MM-DD

* Starting decision applicability date:

YYYY-MM-DD

* Status change reason

☐ Certificate reinstated as issue now resolved

☐ Other

* Comment (FI):

Enter the date when the decision to reinstate the certificate was taken, the date from which the reinstatement applies, and the reason for the reinstatement.

Upload the decision document in the correct language.

Decision document

Upload decision document

☐ FI

Browse

Once you are done, click **Submit**.

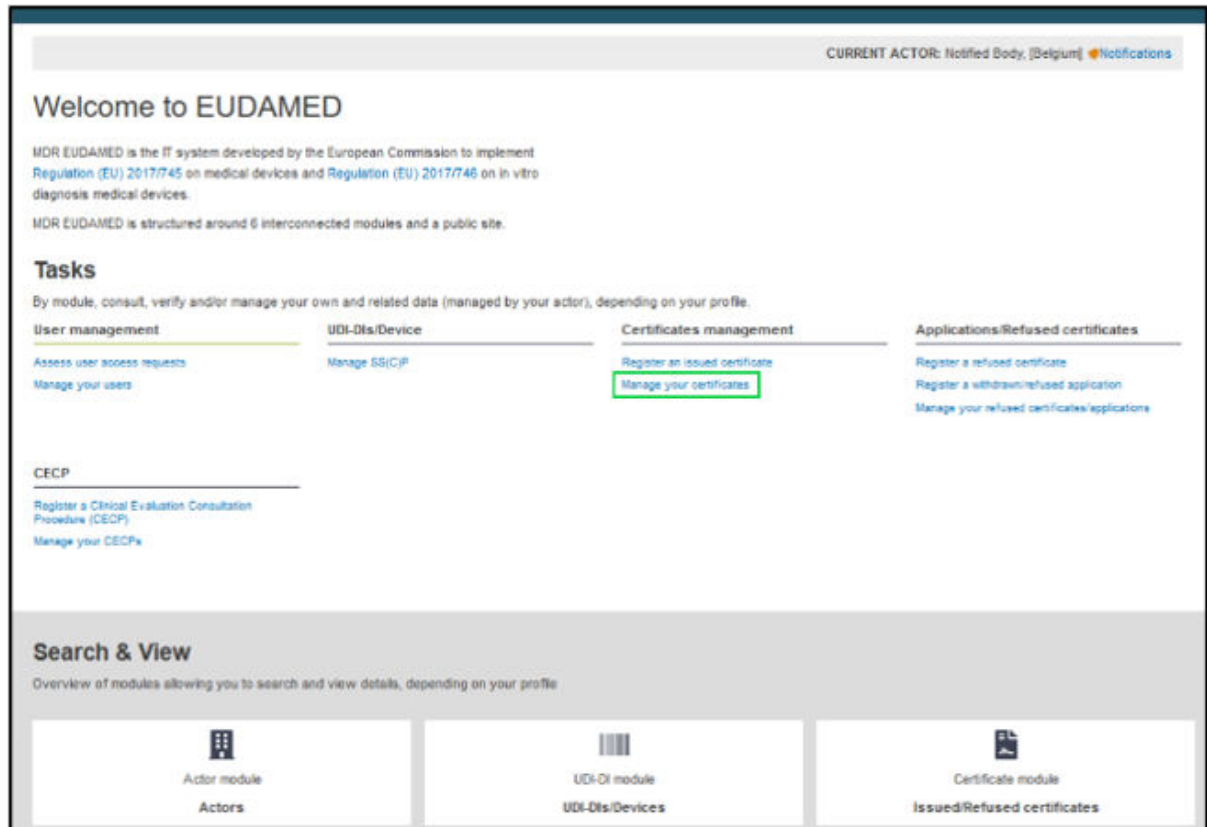
Submit

Cancel

8. Certificate management

8.1. View certificate

1. Click on 'Manage your certificates' link within your dashboard



2. On the following certificate management page, by default, the system will display your certificates in draft state. Click the **Filter** button and select a certificate type from the dropdown list, select the role of an economic operator and fill in any other criteria, such as SRN etc. and click on 'Apply filters':

CERTIFICATES MANAGEMENT

CURRENT ACTOR: Notified Body, [Belgium] [Notifications](#)

[Register an issued certificate](#)

Filter ▼

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

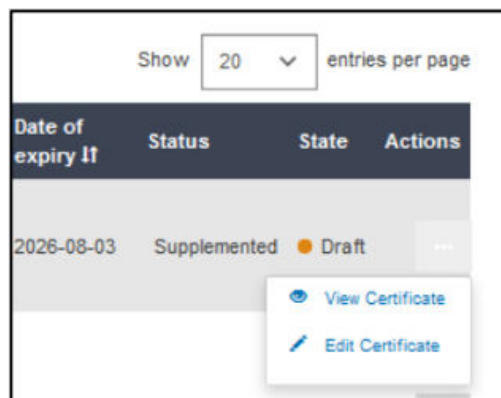
Showing 1 to 20 of 24 entries

Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Certificate number II	Certificate type	Date of issue II	Date of expiry II	Status	State	Actions
CR-PR-00000383		mdr/qms/app-only	(MDR) EU quality management system certificate (Annex IX Chapter I)	-	2026-08-03	Supplemented	● Draft	...
CU-MF-000000402, AL-PR-000000219		mdr-qa-both	(MDR) EU quality assurance certificate (Annex X Part A)	-	2026-08-03	Restricted	● Draft	...
BE-MF-000000662		IVDR/TDA/MIS	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	-	2022-11-17	Supplemented	● Draft	...

8.2. Delete a draft certificate

1. Within the result list, click on the three dots under the Actions column for a specific entry. A contextual menu will show:



2. Then click on 'View Certificate' to see its details. Within the view page, click the **Delete** button:

Certificate: mdr/qms/spp-only

[← Go back to the certificates list](#)

Certificate data

Certificate data [Delete](#)

Version 2 [Draft] | Last update date: 2021-10-07

Notified body

Notified Body number:

Name:

Country:

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier: ⓘ	mdr/qms/spp-only -
Preceding certificate identifier(s):	mdr/qms/spp-only
Date of issue:	-
Starting certificate validity date:	-
Date of expiry:	2026-08-03
Status:	Supplemented

System and/or Procedure Pack Producer Identification

Organisation name:

Actor ID/SRN:

Address: 1

Telephone number:

- A confirmation dialog will display. Click **Confirm**, and the certificate will be purged from EUDAMED:

Delete certificate [Close](#)

Are you sure that you want to delete this certificate?

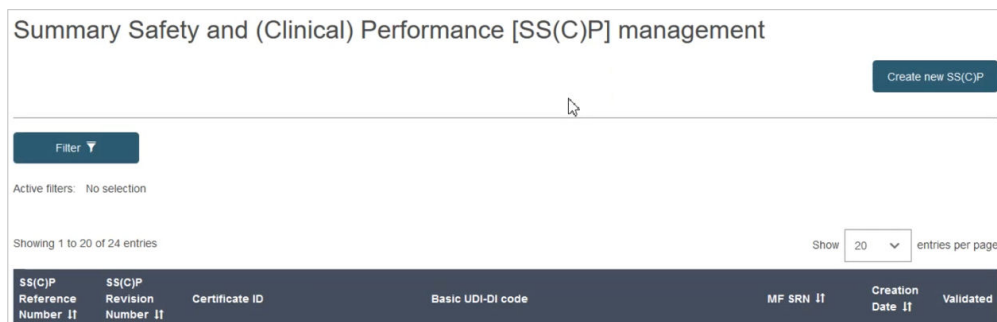
[Confirm](#) [Cancel](#)

9. SS(C)P management

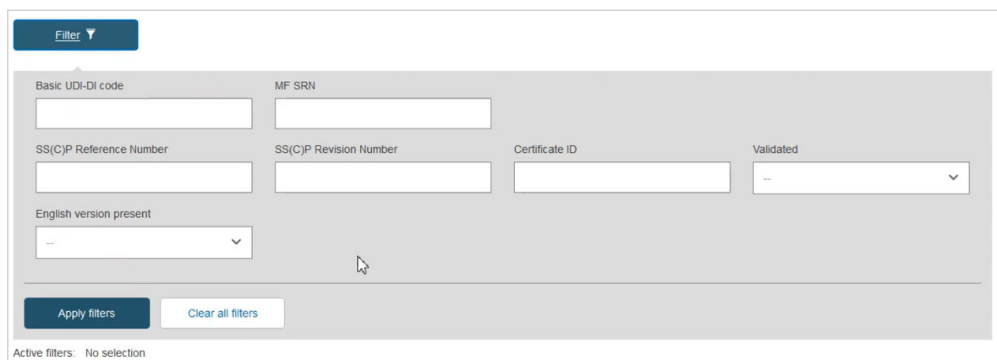
To manage your SS(C)Ps, under 'UDI-Dis/Device' on the Notified Body dashboard click 'Manage SS(C)P':



Once you have clicked 'Manage SS(C)P', you will be brought to the following page:



You will be presented with a list of all the SS(C)Ps to which you have access. Use the **Filter** button to find the required SS(C)P:



You can search by different values.

You can enter a Basic UDI-DI code, the Manufacturer's Actor ID/SRN, SS(C)P Reference/Revision number, Certificate ID (whether it was validated or not, and whether an English translation version exists or not).

When you are done, click 'Apply filters' to refresh your list.

When you find the SS(C)P you want to manage in the list, simply click on it:

SS(C)P Reference Number II	SS(C)P Revision Number II	Certificate ID	Basic UDI-DI code	MF SRN II	Creation Date II	Validated
35345	123	NB-1039324	12345Test1PD3KV.12345Test1PD3K	BE-MF-000000001	2021-06-15	Yes

You will see a summary of the information related to the SSCP:

Manufacturer identification

SRN: BE-MF-000000001
 Organisation name: Belgium MF A V4_test
 Address: Avenue des arbre Brussels

SSCP details

Create new version

Notified Body identification

Notified Body number: NB-1039
 Name: SGS Belgium NV
 Country: Belgium

SS(C)P identification

SS(C)P reference number: 35345
 Basic UDI-DI(s) code: [12345Test1PD3KV - NB-10393243](#)
[12345Test1PD3KV - NB-10393243](#)

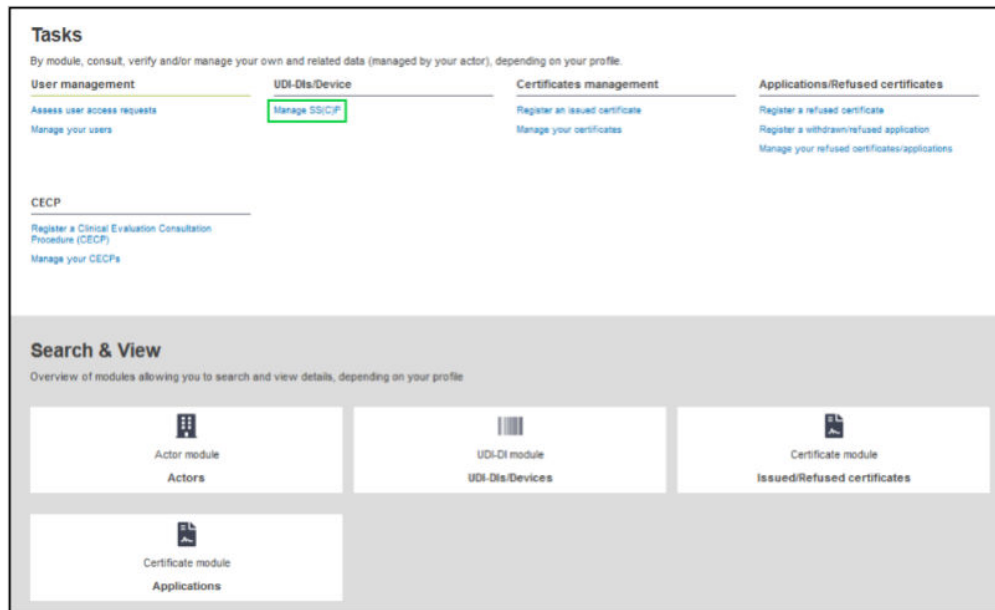
Master document version 3 [Current] | Validated | Upload date 2021-06-15 | [See version history](#)

SS(C)P master document: [NB XXXX - SS\(C\)P.pdf \[212 KB\] \[HR\]](#)
 SS(C)P revision number: 123
 Uploaded from: SS(C)P management
 Date issued: 2021-06-15

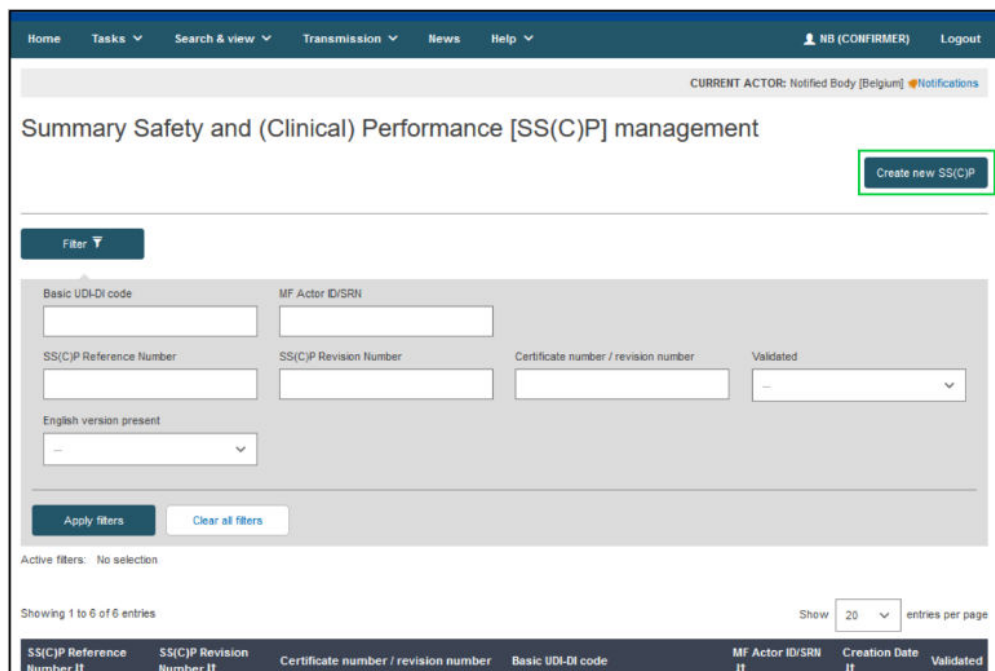
Clicking on the Basic UDI-DI codes will open the Basic UDI-DI in a new tab. Next to this code is the certificate data that is linked to the Basic UDI-DI.

9.1. Register new SS(C)P

1. Click on 'Manage SS(C)P' to navigate to SS(C)P Management page from your dashboard:



2. On the next page, click on **Create new SS(C)P**:



3. Provide certificate's number and optionally revision number to identify the certificate registered before and click **Find**:



NOTE

Only the following certificate types can be linked to new SS(C)P created within the SS(C)P management page:

- (MDR/IVDR) EU Quality Management System certificate (Annex IX Chapter I)
- (MDR) EU Quality Assurance certificate (Annex XI Part A)

Create new SS(C)P

Notified Body identification

Notified Body number:

Name:

Country:

Certificate identification

* Certificate number: Revision number:

SS(C)P information

* SS(C)P reference number: * SS(C)P revision number:

* Date issued:

YYYY-MM-DD

* Select the document language:

- Once the certificate has been identified, its link will be populated in the box along with information about the manufacturer, and the applicable authorised representative(s):

Create new SS(C)P

Notified Body identification

Notified Body number:

Name:

Country:

Certificate identification

MDR/QMS/MS

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

Authorised representative identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

[Remove Certificate information](#)

Device(s) information

- Click the 'Remove Certificate information' link if the certificate displayed is not the intended one. The process to identify the certificate will restart.
- Within 'Device(s) information' you need to identify the Basic UDI-DI to be linked to this SS(C)P:

Create new SS(C)P

[Remove Certificate information](#)

Device(s) information

* Enter Basic UDI-DI code:

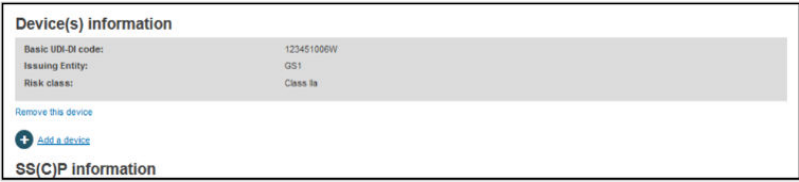
SS(C)P information

* SS(C)P reference number: * SS(C)P revision number:

- You may provide at least five first characters of a Basic UDI-DI and click **Search**. The system will provide Basic UDI-DI(s) according to quality certificate types, risk class and their specific characteristics.



- Once a Basic UDI-DI is selected, the system will populate its details:

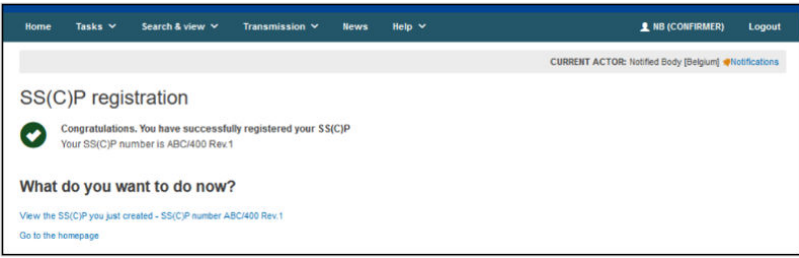


You may add another Basic UDI-DI by clicking on the 'Add a device' link, or remove this Basic UDI-DI by clicking on 'Remove this device' link.

- You need to specify SS(C)P reference and revision numbers, date issued and the language in which the SS(C)P master document is provided. Click **Browse** to upload the SS(C)P master document. Select 'Yes' if this SS(C)P master document is validated, otherwise select 'No':



- Click **Submit** and confirm when asked. A congratulations page will appear:



Your new SS(C)P record will appear under the list of SS(C)Ps within the SS(C)P management page.

9.2. Create new SS(C)P version

- When viewing an SS(C)P record, click on **Create new version**:

CURRENT ACTOR: Notified Body, [Belgium] [Notifications](#)

SSCP ABC/200

[Go back to SSCP list](#)

Manufacturer identification

[SSCP details](#)

Manufacturer identification

Actor ID/SRN:
 Organisation name:
 Address:

SSCP details

[Create new version](#)

Notified Body identification

Notified Body number:
 Name:
 Country:

SS(C)P identification

SS(C)P reference number: ABC/200
 Basic UDI-DI(s) code: 92841111021N7 (Linked certificate: QA2)
 Master document version: 1 [Current] | [Not validated](#) | Upload date: 2021-11-08
 SS(C)P master document: NB XXXX - SS(C)P.pdf (212 KB) [IT]
 SS(C)P revision number: Rev.1
 Uploaded from: Certificate registration
 Date issued: 2021-11-08

Translation(s)

[Add Translation](#)

2. Provide the 'SS(C)P revision number', 'Date issued', and then upload the SS(C)P master document for the new version:

CURRENT ACTOR: Notified Body, [Belgium] [Notifications](#)

Create new version for the SS(C)P Master document ABC/200

Notified Body identification

Notified Body number:
 Name:
 Country:

SS(C)P identification

SS(C)P reference number: ABC/200
 SS(C)P revision number: Rev.1
 Basic UDI-DI(s) code: 92841111021N7 (Linked certificate: QA2)

* SS(C)P reference number: * SS(C)P revision number:

* Date issued:

Language of the master document: Italian

[Browse](#)

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

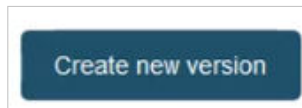


NOTE

The new SS(C)P version will be automatically linked to the last active version of the certificates it is linked to.

9.3. Adding translations

If you want to add a translation to a SS(C)P that is not validated you must create a new version.



When you click on it, a new window will open:

Notified Body identification

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

SS(C)P identification

SS(C)P reference number: ABC090

SS(C)P revision number: Rev.1

Basic UDI-DI(s) code: 12345Test1PD5KZ - NB-1039MDR/QMS/Re-use/SS(C)P/Not-ValidatedRev.1
12345Test1PD3KV - NB-1039MDR/QMS/Re-use/SS(C)PRev.2

* SS(C)P reference number: ABC090

* SS(C)P revision number:

* Date issued:

YYYY-MM-DD

* Select the document language:

Browse

You **must** enter a new SS(C)P revision number.

Choose the date and upload the master document.

Check the *I confirm* box and click *Submit*.

To add translations to a SS(C)P, click *Add Translation* on the right side of the screen:

Translation(s)

Add Translation

The uploaded Master Document is not in English language. Please provide an English translation

There is no translation available for this SSCP

In the new window, select the date by clicking on the calendar icon and select the document language from the dropdown list. You can add multiple translations at once by clicking on + *Add translation*.


Add translations to SS(C)P - 35345 123

Upload translation with their metadata

* SS(C)P reference number:
35345

* SS(C)P revision number:
123

* Received date (from MF):


YYYY-MM-DD

* Select the document language:

[Browse](#)

[+ Add Translation](#)


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

Click *Submit*.

Translation documents are displayed within the Translation(s) section.

Translation(s)

[Add Translation](#)

 The uploaded Master Document is not in English language. Please provide an English translation

[Open all](#) | [Close all](#)

SSCP document - Danish

SS(C)P translation document (Document and Language):	SS(C)P - Translation.pdf [212 KB] [DA]
Upload date:	2021-07-23
Received date (from MF):	2021-07-06

[Discard this document](#)



NOTE


If a translation in English is not provided, the system will display a warning message that an English translation must be provided.

9.4. View version history

If you want to check the SS(C)P version history, you can do so by clicking on 'See version history' under the Basic UDI-DI codes.

SS(C)P identification

SS(C)P reference number:	35345
Basic UDI-DI(s) code:	12345Test1PD3KV - NB-10393243 12345Test1PD3KV - NB-10393243

Master document version 3 [Current] |  Validated | Upload date 2021-06-15 | [See version history](#)

After clicking on it, you will see a list with the different versions for the SS(C)P:

Version history SS(C)P master document - 35345

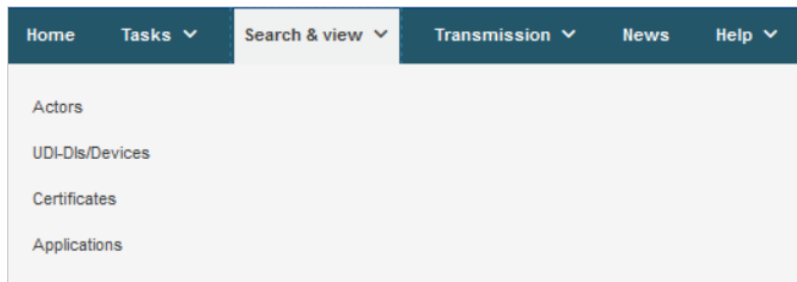
[← Go back to the current version](#)

Version 2 - Last update date: 2021-05-20	>
Version 1 - Last update date: 2021-05-20	>

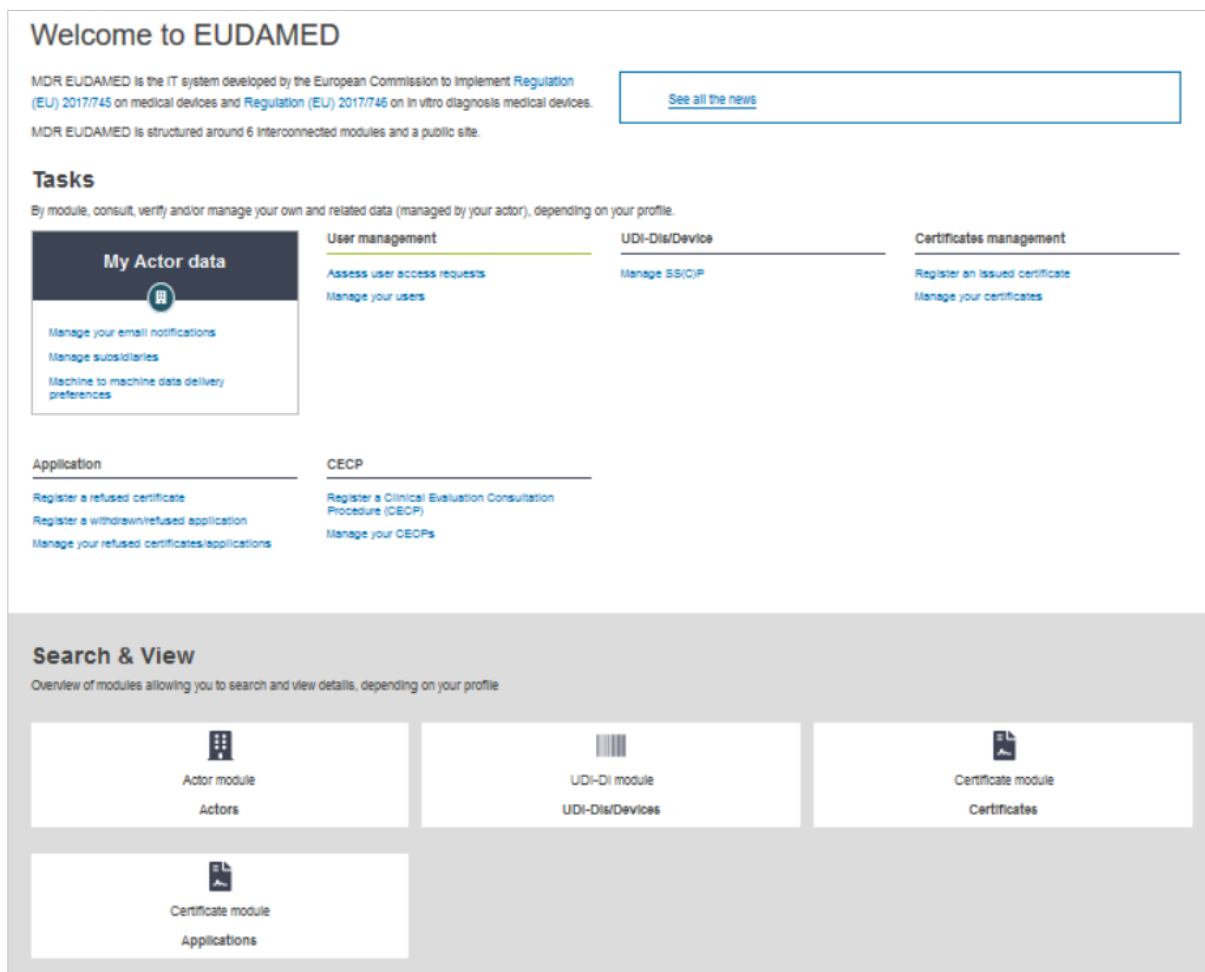
Click on the version you wish to review, opening a summary of it.

10. Search and view certificates

On the header menu, click **Search & View** and then 'Certificates':



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



EUDAMED will display the filters available for searching through the list of certificates registered in EUDAMED:

Notified Bodies user guide

☒ Enable filters for certificates bulk download

Searching for
☒ Certificates ☐ Refused certificates

Certificate data

NB identification

Certificate Type

Certificate number

Status

Economic operator SRN

Economic operator name

Date of issue

Between

and

Special device properties

YYYY-MM-DD

YYYY-MM-DD

You can select more than one value

Device data

Device identification

Enter the device identification value/text

Risk class

Search

Generate XML file

Clear search

Once you have entered the desired search filters, click **Search**. A list of certificates will be displayed:

Showing 1 to 6 of 6 entries

Show 20 entries per page

NB number IT	MF/PR SRN IT	SRN AR IT	Certificate number IT	Certificate type IT	Date of issue IT	Date of expiry IT	Status
NB-1039	BE-MF-000000121		3317_44	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-22	2021-07-31	Issued
NB-1039	BE-MF-000000001		mdr-tech-doc-B	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-08	2024-07-29	Issued
NB-1039	BE-MF-000000001		mdr-tech-doc-C	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-07-01	2021-07-31	Issued
NB-1039	JP-MF-000000061	BE-AR-000000021	suspended-suspend-product-A	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-06-01	2021-10-01	Suspended
NB-1039	JP-MF-000000061	BE-AR-000000021	suspended-suspend-product-B	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-06-01	2021-10-01	Suspended
NB-1039	BE-MF-000000001		123	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2021-04-01	2021-04-30	Reinstated

Click on the desired result record to see the details of that record:

Version 1 - Date: 2021-07-22

Certificate data

Notified body

Notified Body number: NB-1039

Name: SGS Belgium NV

Country: Belgium

Certificate details

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

Certificate type: (MDR) EU technical documentation assessment certificate (Annex IX Chapter II)

Certificate identifier:  3317_44 -

Date of issue: 2021-07-22

Starting certificate validity date: 2021-07-22

Date of expiry: 2021-07-31

Status: Issued

Manufacturer identification

Organisation name: Dev Env - Manufacturer_Shriya

SRN: BE-MF-000000121

Address: 23 Rue willems 9089 Brussels

Telephone number: +32567654545

Email: manu_dev@eudamed.com

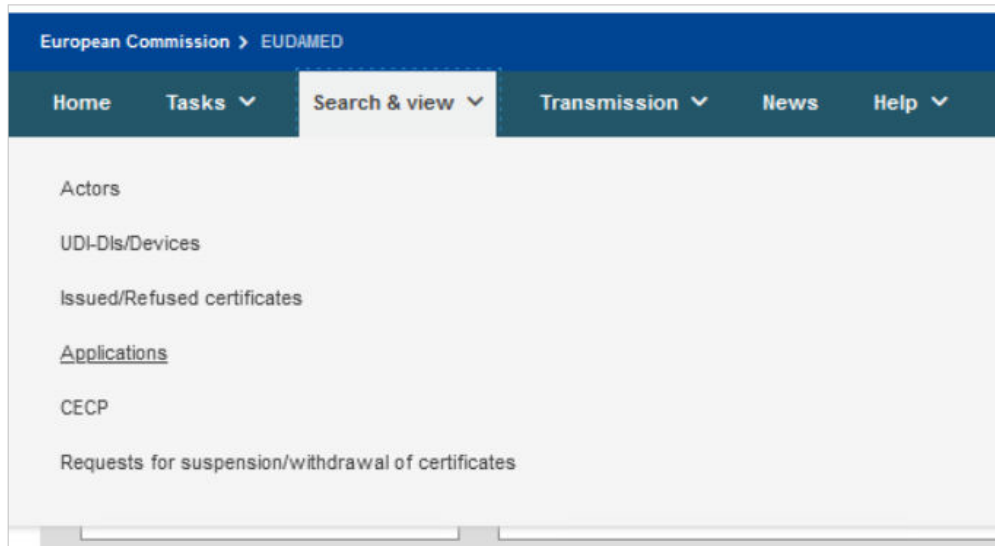
Certificate details

Certificate languages: Portuguese (PT)

Certificate document: [Lano Certificate.pdf \[174 KB\] \[PT\]](#)

11. Search and view refused/withdrawn applications for conformity assessment

1. On the header menu, click on **Search & View**, then click on *Applications*:



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

Notified Bodies user guide

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 email notifications

Machine to machine data delivery preferences

User management

Assess user access requests

Manage your users

First NB LAA users

Certificate

Manage requests for withdrawal/suspension of certificates

Certificate

Nominated experts list

Search & View

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

Actor module

Actors

Refused registration requests

UDI-DI module

UDI-DIs/Devices

Certificate module

Issued/Refused certificates

Certificate module

Applications

Certificate module

CECP

Certificate module

Suspension/withdrawal request

- When clicked, the search for applications page will be displayed:

Applications

Application data

Searching for: All

NB identification: --

Conformity assessment procedure: --

Application reference number:

Economic operator Actor ID/SRN:

Economic operator name:

Decision date: Between and

YYYY-MM-DD YYYY-MM-DD

Device data

Device identification: --

Enter the device identification value/text:

Risk class: --

Search Clear search

- Once you have entered the desired search filters, click **Search**. A list of applications will be displayed:

Notified Bodies user guide

Search results for refused/withdrawn applications

Active search fields:
Searching for: All [Clear search](#)

Showing 1 to 13 of 13 entries Show 20 entries per page

NB number IT	MF/PR Actor ID/SRN IT	Actor ID/SRN AR IT	Application reference number IT	Conformity assessment procedure IT	Decision date IT	Decision IT
=====	BE-MF-000000803, BE-PR-000000804		STERI-WITH-1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-14	Withdrawn application (by MF)
=====	BE-MF-000000803, BE-PR-000000804		STERI-REFU-1	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-12-14	Application refusal (by NB)
=====	BE-MF-000000803, BE-PR-000000804		REF-APP-3426236	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Application refusal (by NB)
=====	BE-MF-000000803, BE-PR-000000804		WITHD-234467	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-12-02	Withdrawn application (by MF)
=====	IN-MF-000000451	BE-AR-000000447	11398_1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Withdrawn application (by MF)
=====	IN-MF-000000451	BE-AR-000000447	11398_2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-11	Application refusal (by NB)
=====	BR-MF-000000585, BE-PR-000000584	BE-AR-000000582	WITH-NOT-1314	(MDR) EU quality management system certificate (Annex IX Chapter I)	2021-11-08	Withdrawn application (by MF)

4. Click on the desired result record to see the details of that record:

Withdrawn application: STERI-WITH-1

[Go back to the applications list](#)

Withdrawn application data

- [Application data](#)
- [Application details](#)
- [Device\(s\)](#)
- [System Procedure Pack\(s\)](#)

Application data

Notified body

Notified Body number: =====
Name: =====
Country: =====

Application details

Decision Type: Withdrawn application (by MF)
Applicable legislation: MDR (REGULATION (EU) 2017/745 on medical devices)
Conformity assessment procedure: (MDR) EU quality management system certificate (Annex IX Chapter I)
Application reference number: STERI-WITH-1
Decision date: 2021-12-14
Date of submission (by MF/Producer): 2021-12-14

Manufacturer identification

Organisation name: =====
Actor ID/SRN: =====
Address: =====
Telephone number: -
Email: =====

System and/or Procedure Pack Producer Identification

12. Download certificates and refused certificates in a structured format



NOTE

Notified Bodies can only download **their own** registered certificates or refused certificates.

Follow the steps in [chapter 11 \[87\]](#) to search and view certificates.

On the search parameters screen, slide the toggle to enable only the search criteria that can be downloaded in an XML format, and enter your search criteria:

Search & View

Certificates

☒ Enable filters for certificates bulk download

Searching for
☒ Certificates ☐ Refused certificates

Certificate data

* Certificate Type

Certificate number

Status

Economic operator SRN

* Date of issue

* Between

YYYYMMDD

* and

YYYYMMDD

Date of submission

Between

YYYYMMDD

and

YYYYMMDD

Date of expiry

Between

YYYYMMDD

and

YYYYMMDD

Search

Generate XML file

Clear search

Complete the search criteria you wish to enter, and click **Search**, to generate the result:

Search

Generate XML file

Clear search

Search results for certificates

Active search fields:

Searching for: Certificates

Enable filters for certificates bulk download: X

Certificate Type: (MDR) EU quality assurance certificate (Annex XI Part A) X

Between: 2021-01-01 X

and: 2022-01-01 X

Clear search

Showing 1 to 20 of 23 entries

Show 20 entries per page

NB number IT	MF/PR SRN IT	SRN AR IT	Certificate number IT	Certificate type IT	Date of issue IT	Date of expiry IT	Status
NB-1039	BE-PR-000000022		MDR/quality/11a	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-21	2024-07-06	Amended
NB-1039	BE-MF-000000121		5321_13	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-20	2022-07-31	Issued
NB-1039	AQ-MF-000000127	BE-AR-000000126	ARMEN_CERT-1112	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-19	2023-07-12	Issued
NB-1039	AQ-MF-000000127	BE-AR-000000126, BE-AR-000000126	ARMEN-00330033	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-19	2024-07-12	Issued

Once there is at least one result click **Generate XML file**:

Search

Generate XML file

Clear search



NOTE

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

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

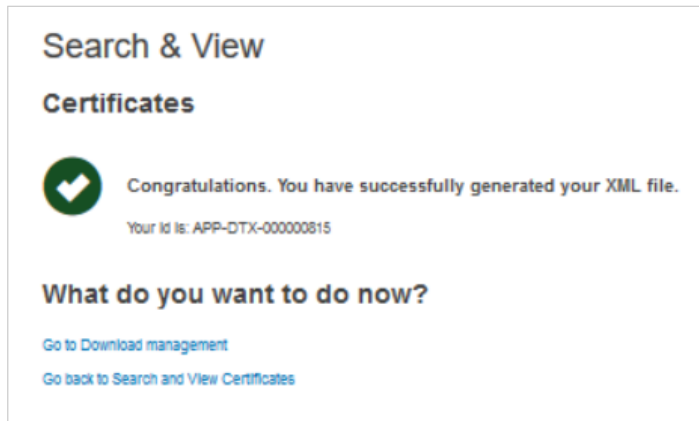
Download

Are you sure you want to generate XML file...?

Confirm

Cancel

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



The generated XML response file along with related zipped documents can be downloaded within the 'Download management' page by clicking on it.

