



EUDAMED user guide

Notified Bodies & Certificates

Production v 2.15.1
2025



Table of Contents

1. Introduction	1
2. Basic Concepts – certificates types	2
3. Getting started	3
4. Register an issued certificate	4
4.1. Quality-type certificate	4
4.1.1. Provide core data	4
4.1.2. Provide certificate language	5
4.1.3. Provide device group data	6
4.1.4. Provide device data	6
4.1.5. Provide SPP details	8
4.1.6. Provide certificate details	9
4.1.7. Provide SS(C)P documents	10
4.1.8. Create new version of a registered SS(C)P	13
4.2. Register an issued certificate: Product-type	18
4.2.1. Provide core data	18
4.2.2. Provide certificate language	19
4.2.3. Provide device data	20
4.2.4. Provide certificate details	20
4.2.5. Provide SS(C)P documents	21
5. Register a refused certificate	29
5.1. Product-type certificate	29
5.1.1. Provide core data	29
5.1.2. Decision languages	30
5.1.3. Add a device	30
5.1.4. Reasons for decision	35
5.2. Quality-type certificate	36
5.2.1. Provision of core data	36
5.2.2. Decision languages	37
5.2.3. Device group and device	38
5.2.4. Reasons for the decision	41
6. Update an issued certificate	43
6.1. Amend	44
6.2. Supplement	47

6.3. Restrict certificate	55
6.4. Re-issue a Quality/Product certificate	60
6.4.1. Merge certificates when re-issuing a Quality certificate	74
7. Decisions over an issued certificate	78
7.1. Suspend	78
7.2. Withdraw	80
7.3. Cancel (by MF)	81
7.4. Re-instate certificate	83
8. Certificate management	85
8.1. Issued certificates	85
8.1.1. View certificate	85
8.1.2. Delete a draft certificate	86
8.1.3. Discard a certificate version	87
8.2. Refused certificates	93
8.2.1. View certificate	93
8.2.2. Delete a draft certificate	93
8.2.3. Discard a refused certificate	94
9. SS(C)P Management	98
9.1. Register a new SS(C)P	99
9.2. Create new SS(C)P version	103
9.3. Add translations	106
9.4. Inactivate an SS(C)P	109
9.5. View SS(C)P version history	111
10. Register an application	112
10.1. Register a withdrawn application	112
10.2. Register a refused application	119
11. Manage applications	121
11.1. Discard a refused/withdrawn application	121
12. Search and view	124
12.1. Search and view certificates	124
12.1.1. Download certificates and refused certificates in a structured format	126
12.2. Search and view refused/withdrawn applications	128

1 Introduction

The purpose of this user guide is to help you navigate through the Notified Bodies and Certificates process of registering certificates in EUDAMED.¹

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.



WARNING

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

¹For a wider understanding on how to use the platform, visit the [EUDAMED Information Centre](#).

2 Basic Concepts – certificates types

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 types: **Product** and **Quality**, with each having its own types of certificate.

Product certificates:

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

Quality certificates:

- 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](#)

For information on how to gain access to EUDAMED, please consult the Notified Bodies Access user guide in the [User guides](#) Section.

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 *LAA/LUA* user cannot approve their own profile change requests, these requests must be approved by a **different** user with *LAA/LUA* profile.

4 Register an issued certificate

Click on the following link to arrive to EUDAMED page:

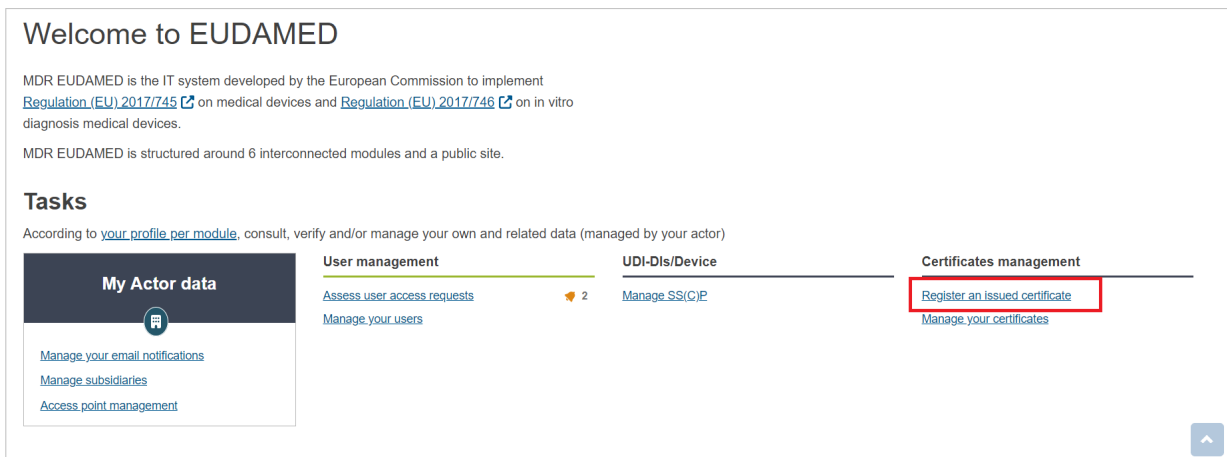
<https://webgate.ec.europa.eu/eudamed/landing-page#/>

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

The EUDAMED homepage opens on your personal dashboard.

4.1 Quality-type certificate

Click *Register an issued certificate* in the *Certificates management* section:



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.

Tasks

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data	User management	UDI-DIs/Device	Certificates management
Manage your email notifications Manage subsidiaries Access point management	Assess user access requests ★ 2 Manage your users	Manage SS(C)P	Register an issued certificate (highlighted in red) Manage your certificates

4.1.1 Provide core data

1. Select the applicable regulation, and the certificate type. The type of the certificate will change depending on the regulation, MDR or IVDR.



NOTE

In this scenario we will choose a *Quality* certificate type.

2. Select **Yes** or **No** whether the certificate is for a system or procedure pack.
3. Enter the *Certificate Number* and a *Revision number* if applicable.
4. Enter the *Date of issue*, the *Starting certificate validity date* and the *date of expiry*:

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**
Manufacturer information

Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, click **Find** and select from the list displayed.

5. Click **Save & Next**.

4.1.2 Provide certificate language

1. Click **Add languages** and select the certificate language(s) from the list of 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\(s\)](#) >

2. Click **Save** to save as a draft or click **Save & Next** to continue to the next step.

4.1.3 Provide device group data

1. Click **Add device group** 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 can select more than one risk class for a device group.

2. If you choose *Class I*, 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 Provide device data

If the certificate also includes devices, indicate whether the certificate is for a Custom made class III implantable, if yes provide a description, if no provide:

The name and the risk class, the reference/catalogue number and the risk class or the Basic UDI-DI (Basic UDI-DIs must be already submitted by the manufacturer in EUDAMED).

1. 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 Provide SPP details

1. If you have chosen a system or procedure pack (SPP), you must answer questions on sterilisation:

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

* Is SPP Producer a steriliser? Yes No

Steriliser(s)

[+ Add a steriliser](#)

* Are SPP Group/s applicable? Yes No

* Sterilisation method(s)

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

2. If the steriliser is not the SPP producer identified in the initial step of the certificate registration, answer *No* to *Is the SPP Producer the steriliser?* and provide the information requested about the sterilising organisation.

* Is SPP Producer the steriliser? Yes No

Steriliser

* Organisation name:

Street information, if applicable

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

* Street: Street number:

Address line 2:

PO box:

* City name: * Postal code:

* Country:

* 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 **Save** or **Save & Next**.

4.1.6 Provide certificate details

- Select the correct options:

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*.

2. Enter the conditions and limitations if there are any. If none, 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

3. 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.
4. Click on either **Save** or **Save & Next**.

4.1.7 Provide SS(C)P documents

For implantable devices of class IIa, some implantable devices of class IIb, and devices of class C that are not companion diagnostic and not self/near-patient testing, the provision of a Summary of Safety and Clinical Performance SS(C)P is required.²

INFOGRAPHIC: SS(C)P steps and principles

SS(C)P IDENTIFICATION

How is a Summary of Safety and (Clinical) Performance identified and linked?

The validated (or to be validated) SS(C)Ps are registered in EUDAMED **by the Notified Body**, in general **during the issued certificate registration**, and always linked to at least one Basic UDI-DI.

Language of the master document

Notified Body must **specify the language of the SS(C)P master document** (validated or to be validated) that is uploaded into EUDAMED.

SS(C)P reference number

An **SS(C)P reference number** (+ revision number) is assigned by the Manufacturer **and must remain the same** during its lifecycle (the revision number must change each time a new version of the SS(C)P is uploaded).

1. An SS(C)P can be attached to certificates, so 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 SS(C)P exists already in EUDAMED it will be selected and

²For background information, see the MDCG guidance: [Summary of safety and clinical performance - A guide for manufacturers and notified bodies](#).

displayed. Otherwise, you may enter a new SS(C)P. You may also create a new SS(C)P version of an already registered SS(C)P (see [Create a new SS\(C\)P version of a registered SS\(C\)P \[13\]](#)).

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



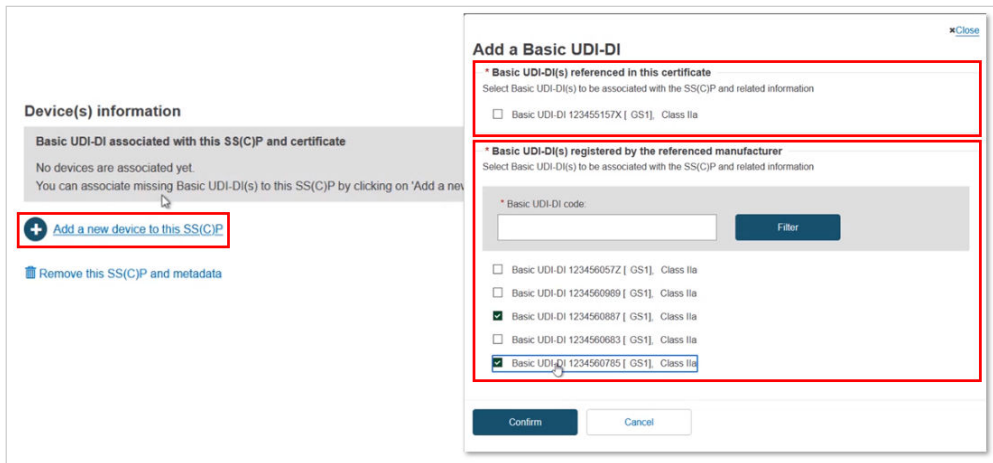
NOTE

The SS(C)P master document should contain information for both lay persons and healthcare professionals. Please read the [Summary of safety and clinical performance - A guide for manufacturers and notified bodies](#) document for more information.

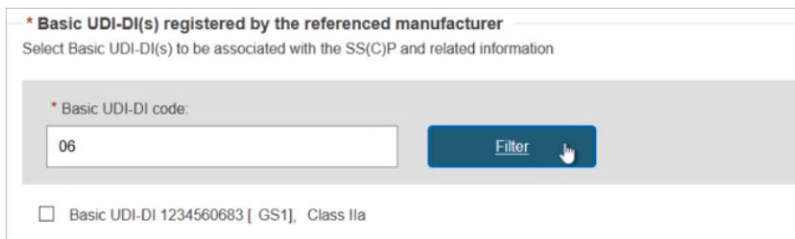
2. Click **Yes** to the question *Is this SS(C)P validated* to indicate that the uploaded master document is validated, otherwise click **No**:

3. In order to register an SS(C)P, the reference of the related Basic UDI-DIs within the scope of the certificate is required. Within the *Device(s) information* box, a respective Basic UDI-DI can be added:

4. The *Device(s) 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-DIs referenced in this certificate of class IIa implantable and relevant class IIb implantable or relevant class C, and (for Quality certificates only) a list of all Basic UDI-DIs of class IIa implantable and relevant class IIb implantable or relevant class C registered by the referenced manufacturer. You can select multiple devices:

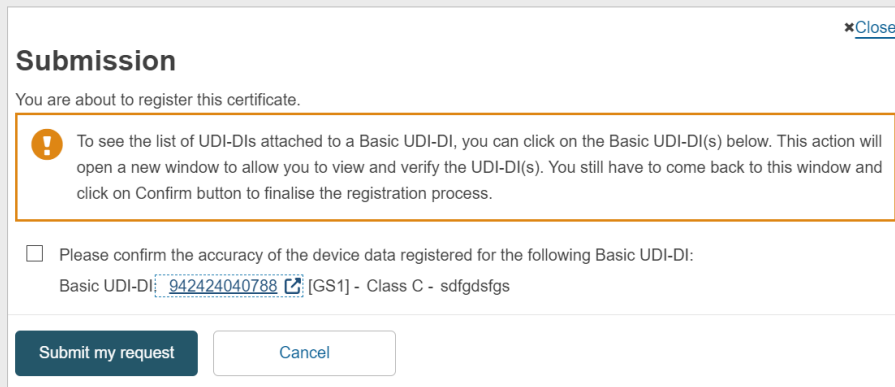


5. You can input a partial Basic UDI-DI number and click **Filter** to narrow down the search results:



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:



After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DIs and their related UDI-DIs will then become visible on the EUDAMED public site.

6. 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 **Preview** 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 other steps 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 *Confirmation* page:

Submission [Close](#)

Are you sure you want to register the issued certificate?

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 confirmation 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 new version of a registered SS(C)P

You can reference an existing SS(C)P that is already registered, and link other devices to it. However, you can also create a new SS(C)P version, while referencing an existing SS(C)P.

1. Click **Create new version**:

2. 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:

3. Click **Browse** to upload the new master document in the pre-selected language, and confirm that it has been validated where applicable (SS(C)P on devices that only need a quality certificate may not necessarily be validated already):

! 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 *Device(s) 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 of class IIa implantable and relevant class IIb implantable or relevant class C, and (for Quality certificates only) a list of all Basic UDI-DIs of class IIa implantable and relevant class IIb implantable or relevant class C 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 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:

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 IIb

- 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 IIa



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

[✖Close](#)

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:

Basic UDI-DI: 942424040788 [GS1] - Class C - sdfgdsfgs

Submit my request
Cancel

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

- Once selected, click **Confirm** to link the devices to the SC(C)P new version. 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:

* SS(C)P revision number:

* Date issued:

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), 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: * 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 [Edit](#)

- Basic UDI-DI 123455157X [Class IIa - Implantable]
- Basic UDI-DI 123456057Z [Class IIa - Implantable]
- Basic UDI-DI 1234560989 [Class IIa - Implantable]

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

Submission [Close](#)

Are you sure you want to register this certificate?

Submit my request

Remove this SS(C)P and metadata

[+ Add SSCP](#)

Submit >

9. From the confirmation page, click *View the certificate you just created*:

European Commission > EUDAMED

Home Tasks Search & view Transmission News Help NB (CONFIRMER)

CURRENT ACTOR: Notified Body, NB-1030, SGS Belgium NV [Belgium]

Certificate registration

Congratulations. You have successfully registered your Issued certificate

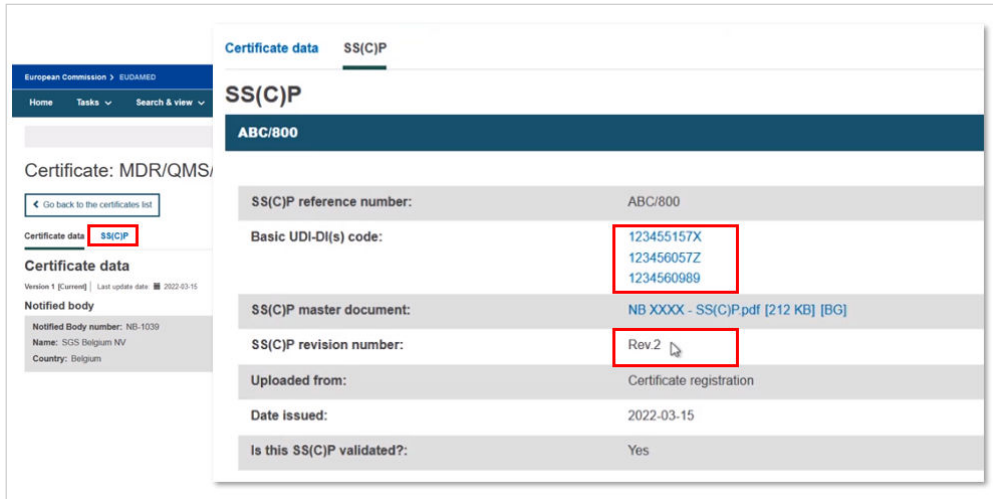
Your certificate number is MDR/QMS/Demo/22.Q1.2

What do you want to do now?

[View the certificate you just created - Certificate number MDR/QMS/Demo/22.Q1.2](#)

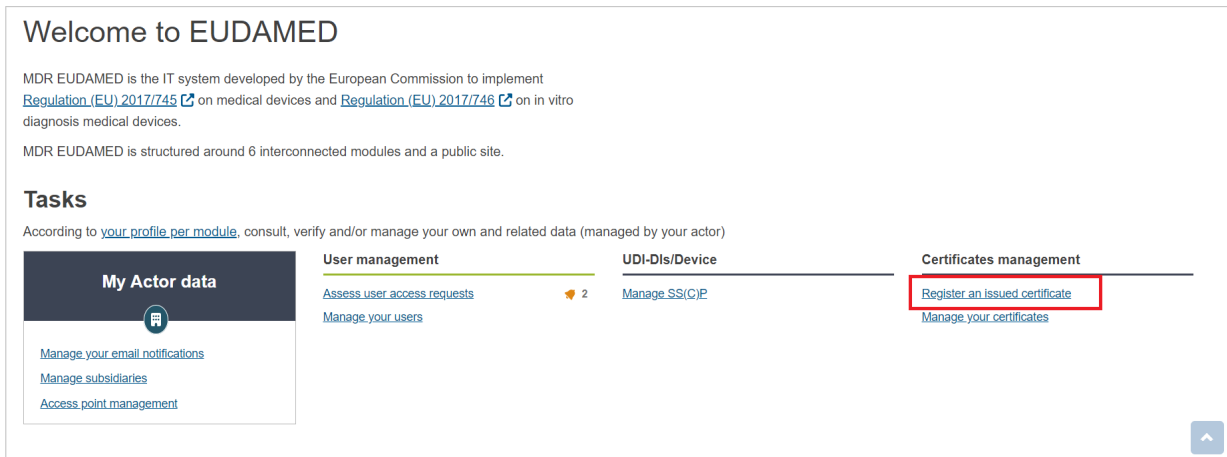
[Go to the homepage](#)

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



4.2 Register an issued certificate: Product-type

Click on *Register an issued certificate* in the *Certificates management* section:



4.2.1 Provide core data

1. Select the applicable regulation, and the certificate type.



NOTE

In this scenario we will choose a *Product* certificate type.

2. Enter the certificate number and a revision number if applicable:

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

3. Enter the *Date of issue*, the *Starting certificate validity date* and the *Date of expiry*.

4. **Manufacturer identification**

Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer. Click **Find** and select from the list displayed.

5. Click **Save & Next**.

4.2.2 Provide certificate language

1. Click *Add languages* and select the certificate language(s) from the list of EU languages:

1 Decision languages 2 Device(s) 3 Reasons for decision

Decision languages

Please provide decision language(s):

No selection

*** Add language(s) >**

Save Save & Next > Cancel

2. **Save** your draft or click **Save & Next** to continue to the next step.

4.2.3 Provide device data

1. Enter the Basic UDI-DI code and choose the codes for the device type from the drop-down list:

The screenshot shows a multi-step form titled 'Device(s)'. At the top, there are three steps: 'Certificate languages' (completed), 'Device(s)' (current step), and 'Certificate details'. The 'Basic UDI-DI' section contains a text input field for the code and a 'Search' button. Below this is the 'Device type' section, which includes a dropdown menu for codes, an 'Add' button, and an information icon with a link to a document. The 'Horizontal codes' section is similar, with a dropdown menu, an 'Add' button, and an information icon with a link.

2. Enter the Intended purpose of the device in each language you selected in the prior steps:

The screenshot shows the 'Intended purpose' section of the form. It includes a note: '* Intended purpose is required to be provided in at least one language:'. Below this, there is a dropdown menu for the language, currently set to 'Croatian (HR)'. Underneath, there is a text input field with the label 'Add the intended purpose (HR):' and a cursor inside the field.

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

4.2.4 Provide certificate details

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

Conditions and limitations

Yes No i 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):

2. Select the languages in which the electronic version of the certificate has been issued. Click **Browse** to upload the files. You may upload more than one file if it covers the chosen languages:

* Select the language of the certificate:

HR NL LV

Browse

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

4.2.5 Provide SS(C)P documents

For certain high-risk devices that are implantable, the provision of an SS(C)P applies.

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

2. If the record exists in EUDAMED, it will be displayed. Otherwise, you may enter a new SS(C)P registration. Enter the issued date and select the language of the document. Click **Browse** to upload the SS(C)P master document:

3. The *Device(s) 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:



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your request, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

[*Close](#)

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:

Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

Submit my request
Cancel

After the request is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

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 **Confirm**.

- To register additional SS(C)Ps, click on **Add SS(C)P**. You will be provided with a new SS(C)P search dialogue:

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: ABC/11
 SS(C)P rev: Rev.1

* Date issued: 2022-03-24
YYYY-MM-DD

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](#)

Add a Basic UDI-DI ✖Close

* 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



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

✖Close

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:
 Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

6. When finished, click **Save** or **Save & Next**.
7. 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 [Provision of SS\(C\)P documents \[10\]](#) for Quality certificates). Click *Add a new device to this SS(C)P* to add new devices to this new SS(C)P version:

8. 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**:

[✕Close](#)

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

The selected devices are listed:

ABC/800
▼

SS(C)P reference number

SS(C)P revision number

*** Date issued:**

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]

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

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

9. 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: * SS(C)P revision number:

* Date issued:
YYYY-MM-DD

Language of the master document:

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 ✎ Edit

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](#)

10. Click **Save** or **Save & Next**.


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

Submission ✕Close

Are you sure you want to register the issued certificate?

You will be shown a page confirming your registration:

Certificate registration

 Congratulations. You have successfully registered your Issued certificate

Your certificate number is

What do you want to do now?

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

[Go to the homepage](#)

From here you can click *View the certificate you just created* to view the certificate, or you can click the *Go to homepage*.

5 Register a refused certificate

Click *Register a refused certificate* in the *Application/Refused Certificates* section.

5.1 Product-type certificate

5.1.1 Provide core data

1. Enter the core information for the refused certificate:

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

Notified Body number: 2797
Name: BSI Group The Netherlands B.V.
Country: Netherlands

* **Applicable regulation**

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

* Conformity assessment procedure:
 (MDR) EU technical documentation assessment certificate (... ▼)

* Application reference number:
 * Application submission date:
 YYYY-MM-DD

Refusal reference number:
 * Date of issue of the refusal:
 YYYY-MM-DD

2. Select the applicable Regulation and the conformity assessment procedure. Then enter the application reference.



NOTE

In this scenario we will choose a Product certificate type.

3. Provide the dates for both the application submission and the date of issue of the refusal.
4. **Manufacturer identification**
Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, then select the appropriate one from the displayed list:

Manufacturer identification

[Change Manufacturer](#)

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

[Save & Next](#)

5. Click **Save & Next**.

5.1.2 Decision languages

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

1
Decision languages

2
Device(s)

3
Reasons for decision

Decision languages

Please provide decision language(s):

No selection

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

Save

Save & Next >

Cancel

You can remove languages using the x symbol, or add more if you wish to:

[Remove all](#)

Spanish (ES) ✕

Swedish (SV) ✕

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

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

5.1.3 Add a device

Is the **Basic UDI-DI** known?:

Refused certificate registration

Manufacturer identification
[NL-MF-000000041, Johnson & Johnson Medical](#)

Refused Certificate Identification
 Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands
 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
 Certificate type: (MDR) EU technical documentation assessment certificate (Annex IX Chapter II)

Application reference number: TDA/Ref Cert
 Application submission Date: 2022-11-23
 Refusal reference number: -
 Date of issue of refusal: 2022-11-23

Decision languages (1) → Device(s) (2) → Reasons for decision (3)

Device(s)

Item #1

* Is the Basic UDI-DI known?
 Yes No

Remove this device

Add a device

Save Save & Next > Cancel

CASE A: The Basic UDI-DI is known

1. Select Yes in the field *Is the Basic UDI-DI known?*:

Refused certificate registration

Manufacturer identification
[NL-MF-000000041, Johnson & Johnson Medical](#)

Refused Certificate Identification
 Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands
 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
 Certificate type: (MDR) EU technical documentation assessment certificate (Annex IX Chapter II)

Application reference number: TDA/Ref Cert
 Application submission Date: 2022-11-23
 Refusal reference number: -
 Date of issue of refusal: 2022-11-23

Decision languages (1) → Device(s) (2) → Reasons for decision (3)

Device(s)

Item #1

* Is the Basic UDI-DI known?
 Yes No

Remove this device

Add a device

Save Save & Next > Cancel

2. Enter part/all of the Basic UDI-DI code and click on **Check registry**. Only devices that are eligible for this type of procedure or certificate, and only those related to the manufacturer, will appear.

Device(s)

Item #1
▼

*** Is the Basic UDI-DI known?**

Yes No

*** Enter Basic UDI-DI code:**

Check registry

* Required

Device type

Codes according to the device type

*** Codes:**

▼

Add

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

MDA 0000

Horizontal codes

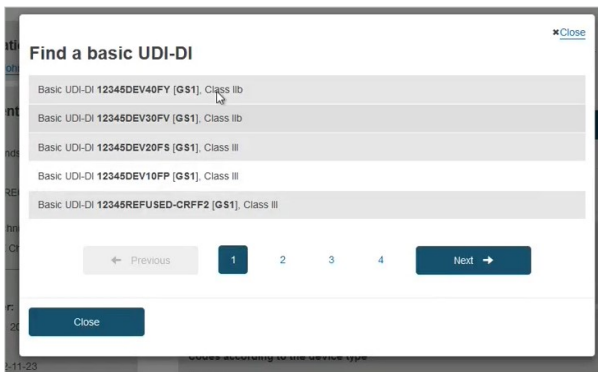
Codes:

▼

Add

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

- If the device is already registered in EUDAMED, then select the device from the list:



- Otherwise, if the device is not yet registered in EUDAMED, click on the **Enter data manually** button:

[*Close](#)

Find a basic UDI-DI

No data available

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

Enter data manually

Cancel

Select the Issuing Agency and the risk class of the device and specify if the device is implantable or not (property applicable only for MDR):

Device(s)

Item #1 ▼

* Basic UDI-DI:

* Issuing Agency:

--
▼

* Risk class

The device is of:

Class IIb

Class III

* Implantable

Yes No

Specify if the device model is applicable or not:

Device model applicable

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

* Device Model:

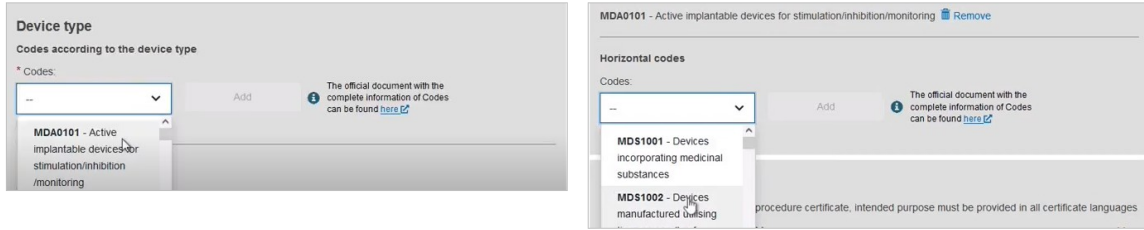
Name:

Device model applicable

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

* Name:

3. Add some characteristics of the device:



4. Add a description of the purpose:

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

Intended purpose - Greek (EL)

* Add the intended purpose (EL):

Some purpose

5. Click **Save** or **Save & Next**.

6. For additional devices, click + *Add a device*.

CASE B: The Basic UDI-DI is not known

1. Select *No* in the field *Is the Basic UDI-DI known?*:

Refused certificate registration

1 Decision languages 2 Device(s) 3 Reasons for decision

Manufacturer identification
NL-MF-00000041: Johnson & Johnson Medical

Refused Certificate Identification
Notified Body number: 2797
Name: BSI Group The Netherlands B.V.
Country: Netherlands
Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type: (MDR) EU technical documentation assessment certificate (Annex IX Chapter II)

Application reference number: TDA/Ref.Cert
Application submission Date: 2022-11-23
Refusal reference number: -
Date of issue of refusal: 2022-11-23

Device(s)

Item #1

* Is the Basic UDI-DI known?
 Yes No

[Remove this device](#)

[+ Add a device](#)

Save Save & Next > Cancel

2. Identify the device by *Name* or alternatively, provide the *Reference/Catalogue number* in free-text and select the *Risk Class*. Note the *Name* or *Reference/Catalogue number* options also apply when registering Refused/withdrawn applications:

3. Provide the device type and the intended purpose:

4. Click **Save** or **Save & Next**.

5. For additional devices, click + *Add a device*.

5.1.4 Reasons for decision

1. Select one or more reasons from the list below, and enter the *Reason for refusal* comment in the languages you chose in the *Decision languages* step:



NOTE


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

- The refusal document is optional:

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.

- You can **Preview** your choices, or click **Submit** to complete the registration:

Save


Preview

Submit >

Cancel

- A confirmation message displays:

Refused certificate registration



Congratulations. You have successfully registered your refused certificate

Your refused certificate application reference number is Demo.TW

What do you want to do now?

[View the refused certificate you just created - application reference number Demo.TW](#)

[Go to the homepage](#)

5.2 Quality-type certificate

5.2.1 Provision of core data


- Enter the core information for the refused certificate.
- Select the applicable Regulation and the conformity assessment procedure.



NOTE

In this scenario we will choose a *Quality* certificate type.

- Indicated **Yes** or **No** for a System Procedure Pack, then, enter the application reference number.
- Provide the dates for both the application submission and the date of issue of the refusal:


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

Notified Body number: 2797
Name: BSI Group The Netherlands B.V.
Country: Netherlands


*** Applicable regulation**

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


*** Conformity assessment procedure:**

(MDR) EU quality management system certificate (Annex IX ... 


System or Procedure pack applicable



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

*** Application reference number:**

*** Application submission date:** 
YYYY-MM-DD

Refusal reference number:

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


Nov 2022  Today 

Mo	Tu	We	Th	Fr	Sa	Su
31	01	02	03	04	05	06
07	08	09	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	01	02	03	04

5. Manufacturer information

Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, then select the appropriate one from the displayed list:

Manufacturer identification

 [Change Manufacturer](#)

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

6. Click **Save & next**.

5.2.2 Decision languages

Select one, or multiple, languages in which the certificate was issued:

The screenshot shows a progress bar 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):'. There is a 'Remove all' link and a button labeled 'Portuguese (PT)' with an 'X' icon. Below that is a link '*Add more language(s) >'. At the bottom, there are three buttons: 'Save', 'Save & Next >', and 'Cancel'.

5.2.3 Device group and device

A device group or a device is mandatory to provide for Quality-type certificates.

1. Click + *Add a device group*:

The screenshot shows a progress bar with four steps: 1. Decision languages (completed with a green checkmark), 2. Device group(s) (active), 3. Device(s), and 4. Reasons for decision. The title 'Device group(s)' is followed by a dropdown menu labeled 'A group of devices'. Below this is a text input field with the placeholder text 'A group of devices'. Underneath is a section titled '* Risk class' with the instruction 'The device group contains device(s) of:'. There are four radio button options: 'Class I', 'Class IIa', 'Class IIb' (which is selected), and 'Class III'. At the bottom left, there is a trash icon and the text 'Remove this device group'. At the bottom right, there is a plus icon and the text 'Add a device group'.

2. Provide either a *Name*, *Reference/Catalogue number* or *Basic UDI-DI*. Note that these options also apply when registering a **Refused/withdrawn application** for a Quality-type certificate:

The screenshot shows a section titled '* Provide one of the below' with three radio button options: 'Name', 'Reference/Catalogue number', and 'Basic UDI-DI'.

3. Choose the *Risk class*:

4. Depending on the risk class, choose *Yes* or *No* whether the device is custom-made or not:

5. Click **Save & Next**.

6. Add a device and its Basic UDI-DI by clicking + *Add a device*:

7. Provide either a *Name*, *Reference/Catalogue number* or *Basic UDI-DI*:

If you select the *Basic UDI-DI*, the *Enter Basic UDI-DI code* field is displayed. Enter the Basic UDI-DI code and click **Check registry**:

Device(s)

Basic UDI-DI -
▼

*** Provide one of the below**

Name

Reference/Catalogue number

Basic UDI-DI

*** Enter Basic UDI-DI code:**

Check registry

[Remove this device](#)

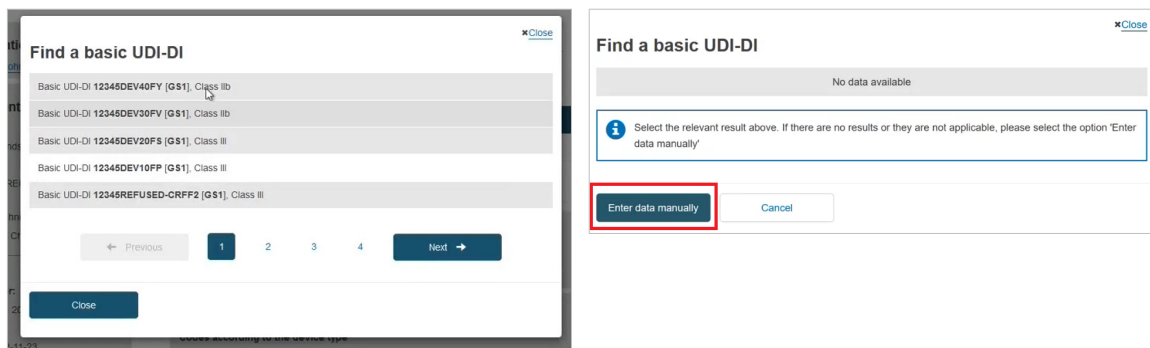
+ [Add a device](#)

Save

Save & Next >

Cancel

In the pop-up window either select the device from the list (if the device is already registered in EUDAMED) or click the **Enter data manually** button (if the device is not yet registered in EUDAMED) to add the Basic UDI-DI manually:



After clicking **Enter data manually**, a new screen appears. Provide the Issuing Agency and the risk class of the device:

Basic UDI-DI - 12345-not-in-UDI-2X5
▼

*** Basic UDI-DI:**

*** Issuing Agency:**

*** Risk class**

The device is of:

Class A (Sterile)

Class B

Class C

Class D

Specify if the device model is applicable or not:

Device model applicable

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

*** Device Model:**

Name:

Device model applicable

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

*** Name:**

8. Click **Save & Next**.

5.2.4 Reasons for the decision

Select one, or multiple, reason(s) for the refusal/withdrawal decision and provide a comment. The **Decision on refusal document** is optional:

Decision languages ✓ Device group(s) ✓ Device(s) ✓ 4 Reasons for decision

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

* Reason for refusal/withdrawal comment (PT):


Some reason

Decision on refusal document

Upload refusal document

You may preview your choice, or click **Submit**:

Refused certificate registration

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

Your refused certificate application reference number is Demo.TW2

What do you want to do now?

[View the refused certificate you just created - application reference number Demo.TW2](#)

[Go to the homepage](#)

6 Update an issued certificate

1. On the EUDAMED Dashboard, click on *Manage your certificates*:

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.

Tasks

According to your profile per module, consult, verify and/or manage your own and related data (managed by your actor)

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

CECP

[Register a Clinical Evaluation Consultation Procedure \(CECP\)](#)
[Manage your CECPs](#)

2. Filter the certificates to state *Registered*, by default, the state filter is on *draft*:

Filter

Certificate Type: --

Certificate number: [input field]

Role: --

Actor ID/SRN: [input field]

Name: [input field]

Status: --

* State: Draft (selected)

Registered

Discarded

Active filters: State: Draft Clear search

3. Click on the three dots under *Action* for the certificate you want to update, a contextual menu will display the possible operations over the selected certificate:

Active filters: State: Registered Clear search

Showing 1 to 20 of 32 entries

Show 20 entries per page

MF/IPR Actor ID/SRN	MF/IPR Name	Certificate number II	Certificate type	Date of issue II	Date of expiry II	Status	State	Actions
BE-MF-00000662	Alfa Industries [All languages]	my - number %*#%*&#HKJHK 128 characters	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2022-03-30	2027-06-30	Issued	Registered	⋮
BE-MF-00000662	Alfa Industries [All languages]	MDR/QMS/Demo/22 Q1 2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2022-03-11	2027-03-11	Issued		View Certificate Amend Certificate Restrict Certificate Supplement Certificate Suspend Certificate Withdraw Certificate Cancel (by MF) Certificate Re-issue Certificate
BE-MF-00000662	Alfa Industries [All languages]	Test005	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2022-03-10	2023-03-10	Supple		
BE-MF-00000662	Alfa Industries [All languages]	Test006	(MDR) EU quality management system certificate (Annex IX Chapter I)	2022-03-10	2027-03-10	Issued		
BE-MF-00000381	New Release Test and Playground Org [All languages], New Release Test and Playground Org [FR]	test-13458	(MDR) EU type-examination certificate (Annex X)	2022-03-10	2023-03-10	Issued		



TIP

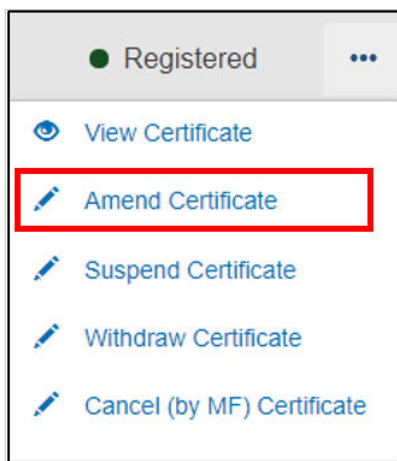
The certificate you want to update is missing?

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

If a draft version exists, it must be registered or deleted; only certificates in *registered* state can be updated.

6.1 Amend

- To amend a certificate, repeat steps from [Update a certificate \[43\]](#), click the three dots under *Actions* and click *Amend Certificate*:



- 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: 2021-04-10

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 one 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 the 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: 

Status: Amended * Starting validity date: 

6. The certificate number might change, if it is the case, enter the new *Certificate Number* and add a revision number. 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 language in which 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):

7. In the next steps, you will have to enter the information as if you were creating a new certificate:

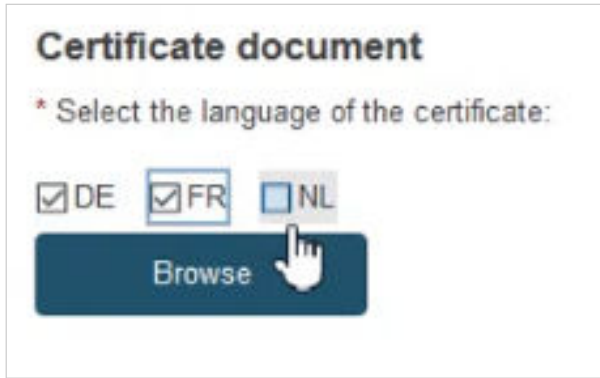
* Certificate identification

(*) Certificate language(s)

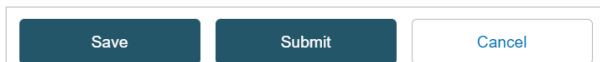
Device(s)

* Certificate details

8. 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:



- Once complete, click either **Save** to save your work without submitting, or **Submit**:



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 ID	Certificate type	Date of issue ID	Date of expiry ID	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		

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 in the *Certificate identification* section:

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 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:	Rev.2
Date of issue:	2021-09-15
Starting certificate validity date:	2021-09-15
Date of expiry:	2026-09-15
Status:	Reinstated

2. Scroll down and fill in the *New Certificate Information*:

New Certificate Information

* Certificate Number: Revision number:

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

Status: * Starting validity date:  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):

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

* Comment (FR):
new device

* Comment (DE):
new device

Save Submit Cancel

4. Click on the **Devices** tab on the menu on the left, then 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



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

✕Close

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:
Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

Submit my request Cancel

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

5. 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

6. 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:
 -- Add The official document with the complete information of Codes can be found [here](#)

MDA 0000

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

Supplemented Certificate registration

* 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 code: 123455007J
 Issuing Entity: GS1
 Risk class: Class IIb

Device type
 Codes according to the device type

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

MDA0101 - Active implantable devices for stimulation/inhibition /monitoring
 MDA0102 - Active implantable devices delivering drugs or other substances [Remove](#)

MDA 0000

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

Intended purpose - German (DE)

* Add the intended purpose (DE):

intended purpose|

[Remove this device](#)

[+ Add a device](#)

Save **Submit** **Cancel**

- 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 **Save**.

Certificate document

* Select the language of the certificate:

DE FR NL

1 file uploaded successfully

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

- 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

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] | | 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

i Be aware that if there are devices within the scope of the certificate that are:
> IIA implantable that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
> IIA 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:

Language of the master document: Dutch

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

- 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

i 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 SSCP](#)

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

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: N/A

SS(C)P revision number: Rev.

Uploaded from: Cert

Date issued: 2022

+ Be aware that if there are devices within the scope of the certificate that are sutures, staples, dental fillings, connectors, Ila implantable, 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.

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:

- Basic UDI-DI 123456057Z [GS1] Class Ila
- Basic UDI-DI 1234560989 [GS1] Class Ila
- Basic UDI-DI 1234560887 [GS1] Class Ila
- Basic UDI-DI 1234560883 [GS1] Class Ila
- Basic UDI-DI 1234560785 [GS1] Class Ila



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

[Close](#)

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:

Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

- 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:

SS(C)Ps

ABC/100

Create new version

SS(C)P reference number: ABC/100

Basic UDI-DI(s) code: 123456167Z, 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)P.pdf [212 KB] [BG]

SS(C)P revision number: Rev 1

Uploaded from: Certificate registration

Date issued: 2022-03-10

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

Save Submit Cancel

19. 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 certificate

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 ¹	Date of expiry ¹	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	Registered	<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	...

On the next screen, you will find all information relevant to the specific certificate and a menu with different sections on the left.

1. 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

<div style="background-color: #2c5e8c; color: white; padding: 5px; text-align: center; margin-bottom: 5px;">Certificate identification</div> <div style="background-color: #f0f0f0; padding: 5px; margin-bottom: 5px;">(*) Certificate language(s)</div> <div style="background-color: #f0f0f0; padding: 5px; margin-bottom: 5px;">* Device(s)</div> <div style="background-color: #f0f0f0; padding: 5px; margin-bottom: 5px;">* Certificate details</div> <div style="background-color: #f0f0f0; padding: 5px;">(*) SS(C)Ps</div>	<h3>Certificate identification</h3> <p>Notified body information</p> <p>Notified Body number: Name: Country: Germany</p> <p>Manufacturer identification</p> <p>Actor ID/SRN: Organisation name: Address:</p> <p>Preceding certificate information</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Applicable legislation:</td> <td>MDR (REGULATION (EU) 2017/745 on medical devices)</td> </tr> <tr> <td>Certificate type:</td> <td>(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)</td> </tr> <tr> <td>Certificate identifier:</td> <td>MDR/TDA/BUDI/SS(C)P</td> </tr> <tr> <td>Revision number:</td> <td>Rev.1</td> </tr> <tr> <td>Date of issue:</td> <td>2021-09-23</td> </tr> <tr> <td>Starting certificate validity date:</td> <td>2021-09-23</td> </tr> <tr> <td>Date of expiry:</td> <td>2022-09-23</td> </tr> <tr> <td>Status:</td> <td>Supplemented</td> </tr> </table>	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
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																

2. Scroll down and fill in the *New Certificate Information*:
 - The certificate number might change, if it is the case, enter the new *Certificate number* and a revision number. 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: <input style="width: 90%;" type="text" value="test2-III"/>	Revision number: <input style="width: 90%;" type="text"/>
<div style="display: flex; align-items: center;"> ⊗ Duplicate preceding certificate information found </div>	
* Date of issue: <input style="width: 90%;" type="text" value=""/> <small>YYYY-MM-DD</small>	* Date of expiry: <input style="width: 90%;" type="text" value="2026-08-31"/> <small>YYYY-MM-DD</small>
Status: Restricted	* Starting validity date: <input style="width: 90%;" type="text"/> <small>YYYY-MM-DD</small>

3. 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):

4. Provide comments in all the languages of the certificate and click **Save**:

* Comment (NL):

* Comment (FR):

5. 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:

...

▼

Add

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

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

Codes:

...

▼

Add

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

MDA 0000

MDS1005 - Devices in sterile condition [Remove](#)

MDT2001 - Devices manufactured using metal processing [Remove](#)

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

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

- 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:

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

Certificate document

* Select the language of the certificate:

FR NL

1 file uploaded successfully

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

- 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

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

- 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:

YYYY-MM-DD

Language of the master document: French

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

- 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

Discard

SS(C)P reference number: Test2 III

Basic UDI-DI(s) code: 1234567894C

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

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

SS(C)P 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

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

SS(C)P revision number: Rev.3

Uploaded from: Certificate registration

Date issued: 2021-08-24

Save Submit Cancel

6.4 Re-issue a Quality/Product certificate

- To re-issue a certificate, for example due to its imminent expiry, click on 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 Show 20 entries per page

MPPR Actor ID/URN	MPPR Name	Certificate number ID	Certificate type	Date of issue	Date of expiry	Status	State	Actions
BE-MF-00000662	Allis Industries [All languages]	MDR/GMS/Demo22-Q1.2	(MDR) EU quality management system certificates (Annex IX Chapter I)	2022-03-16	2027-03-16	Renowned	Draft	...
BE-MF-00000662	Allis Industries [All languages]	MDR/TDA/Demo22-Q1.2	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2022-03-11	2027-03-11	Issued	Draft	...

Manage your certificates

- 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

Showing 1 to 20 of 31 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
BE-MF-000000662	Alfa Industries [All languages]	MDR/QMS/Demo/22 Q1 2	(MDR) EU quality management system certificate (Annex IX Chapter I)	2022-03-11	2027-03-11	Issued	Registered	View Certificate Amend Certificate Restrict Certificate Supplement Certificate Suspend Certificate Withdraw Certificate Cancel (Draft) 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	Supple		
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 Oig [All languages]	test-13458	(MDR) EU type-examination certificate (Annex X)	2022-03-10	2023-03-10	Issued		

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

- 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 [Update with new actor version](#)

Actor ID/SRN:
 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](#)

- 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:
Role: Manufacturer
Country: Belgium
Actor / Organisation name:
Address:
Email:
Telephone number:

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 **Save & Next** to proceed:

Applicable legislation: MDR (REGULATION (EU) 2017/745 ON MEDICAL DEVICES)
(MDR) EU quality management system certificate (Annex IX Chapter I)

Certificate type: MDR/QMS/Demo22 Q1.2
Certificate identifier: MDR/QMS/Demo22 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/Demo22 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:

Re-issued certificate registration

1 Certificate languages 2 Device group(s) 3 Device(s) 4 Certificate details 5 SS(C)Ps

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 languages
 Please provide certificate language(s):
 Polish (PL) Slovak (SK) Slovenian (SL)
 Add more language(s) >

Save Save & Next Cancel

Certificate Number: new-cert-number
 Revision number: -
 Status: Reissued
 Starting certificate validity date: 2021-08-24
 Date of issue: 2021-08-24
 Date of expiry: 2026-08-24

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

Greek	Hungarian ✓
Irish	Italian
Latvian	Lithuanian
Maltese	Polish ✓
Portuguese	Romanian
Slovak ✓	Slovenian ✓
Spanish	Swedish

Select Cancel

8. Click **Save & Next** to proceed to the next section:

Re-issued certificate registration

1 Certificate languages 2 Device group(s) 3 Device(s) 4 Certificate details 5 SS(C)Ps

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 languages
 Please provide certificate language(s):
 Hungarian (HU) ✕ Polish (PL) Slovak (SK) Slovenian (SL)
 Add more language(s) >

Save Save & Next Cancel

Certificate Number: new-cert-number
 Revision number: -
 Status: Reissued
 Starting certificate validity date: 2021-08-24
 Date of issue: 2021-08-24
 Date of expiry: 2026-08-24

- Fill in the information required to complete the *Device group(s)* step, when a certificate is re-issued, no change can be made.

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

- 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 *Device(s)* 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

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

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* and then click on the *Item* that displays under *Device(s)*:

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

Device(s)

- Device - QMS1
- Item #2

[+ Add a device](#)

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

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

Device(s)

- Device - QMS1
- Item #2

* Custom made class III implantable Yes No

* Description:

Remove this device

[+ Add a device](#)

15. 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

[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

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

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

Conditions and limitations

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

Conditions and limitations - Italian (IT) ▼

16. 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**:

At this point, depending on the specifics of the certificate, the system may take you to the next step called *SS(C)Ps*. 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**:



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

[✖Close](#)

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:

Basic UDI-DI: 942424040788 [🔗](#) [GS1] - Class C - sdfgdsfgs

Submit my request
Cancel

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

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:

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 [Edit](#)

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](#)

✔
Certificate languages

✔
Device group(s)

✔
Device(s)

✔
Certificate details

5
SS(C)Ps

SS(C)Ps

ABC/800
▼

[Create new version](#)

SS(C)P reference number:	ABC/800
Basic UDI-DI(s) code:	123456057Z 1234560989 1234560683 🗑️ 123455157X

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

Master document version 1 [Current] | ✔ Validated | Upload date 2022-03-15

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

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

Update an issued certificate

69

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

SS(C)Ps
ABC/800

Create new version

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

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

Master document version 1 [Current] | Validated | Upload date 2022-03-15

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

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](#)

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

SS(C)Ps
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|

* Date issued:

Language of: Bulgarian

Browse

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

Browse

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 123456057Z [Class Ila - Implantable]

Basic UDI-DI 1234560989 [Class Ila - Implantable]

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

+ Add a new device to this 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 Close

*** 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:**

- 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



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your certificate, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

Submission Close

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:
Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

After the certificate is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

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

SS(C)Ps
 ABC/800
 Delete this draft

SS(C)P reference number: ABC/800
 Basic UDI-D(s) code: 123455157X, 123456057Z, 1234560989, 1234560887

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 SS(C)P**, 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

+ Add SSCP

SS(C)P reference number

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

Save **Preview** **Submit >** **Cancel**

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

i 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

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**, then select the device(s). Click **Confirm** and **Save**:

Close

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

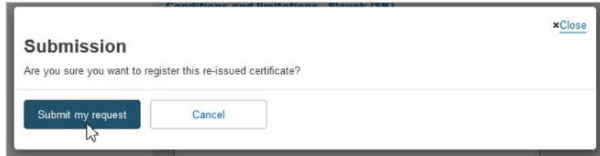
Remove this SS(C)P and metadata

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

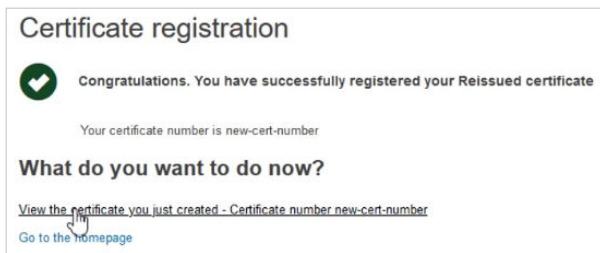


The system will prompt you to confirm your submission of a re-issued certificate.

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



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



6.4.1 Merge 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		<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	Supplement		

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:

* Date of issue:  * Date of expiry: 

YYYY-MM-DD YYYY-MM-DD

Status: Reissued

* Starting validity date: 

YYYY-MM-DD

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

Preceding certificate information

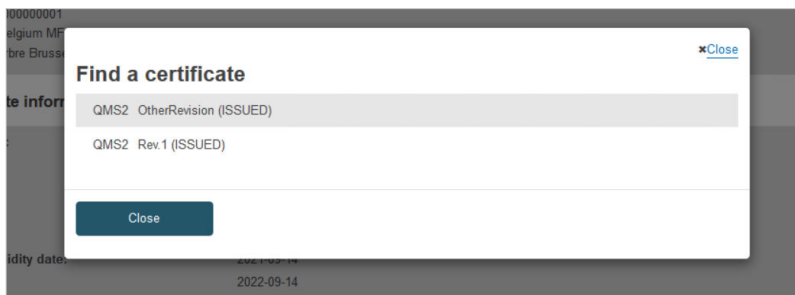
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality management system certificate (Annex IX Chapter I)
Certificate identifier:	QMS1
Revision number:	Rev.1
Date of issue:	2021-09-14
Starting certificate validity date:	2021-09-14
Date of expiry: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

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

* Preceding certificate number: Preceding certificate revision number:

[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:



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:
<input type="text" value="cert-merge-2"/>	<input type="text"/>
* Date of issue:	* Date of expiry:
<input type="text" value="2021-08-24"/>	<input <img="" alt="calendar icon" type="text" value="2026-" }=""/>
YYYY-MM-DD	YYYY-MM-DD
Status:	* Starting validity date:
Reissued	<input type="text" value="2021-08-24"/>
	YYYY-MM-DD
<input type="button" value="Save & Next"/> <input type="button" value="Cancel"/>	

7. The next screen will display a timeline of steps. 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: [input]
 Name: [input]
 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

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: [input]
 Name: [input]
 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**:

Re-issued certificate registration

Manufacturer identification

Certificate identification

Notified Body number: [input]
 Name: [input]
 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: 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](#)

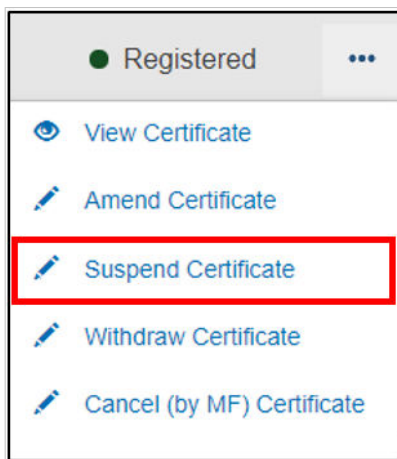
Save Save & Next Cancel

As the remaining actions to complete the process are identical to re-issuing a Quality certificate, please consult steps 11-20 of [Re-issuing a Quality/Product certificate \[60\]](#).

7 Decisions over an issued certificate

7.1 Suspend

1. Click on the *Certificates management* page and then filter to identify the certificate you want to suspend.
2. Click on the three dots under *Actions* 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 registered or deleted. The *Suspend Certificate* operation will now be available.

3. 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

4. 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**.

Decision

* Decision date:  YYYY-MM-DD

* Starting decision applicability date:  YYYY-MM-DD

* **Status change reason**

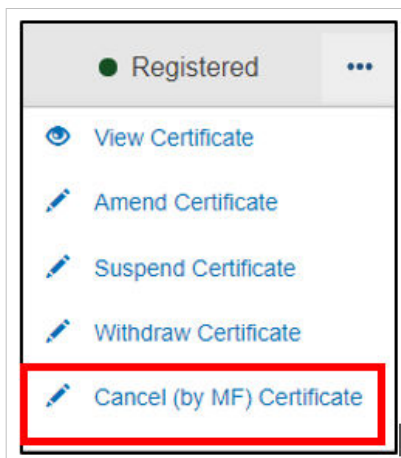
- Compliance: substantial changes implemented before approval
- Compliance: failure to close non-conformities
- Compliance: Quality Management System failure
- Compliance: product quality issues
- Compliance: Requirements of the MDR/IVDR Regulations not met
- Product: obsolete – no longer placed on the 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):

5. 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.
6. Upload the decision document in the correct language. Once you are done, click **Submit**:

7.3 Cancel (by MF)

1. To cancel a certificate (by the manufacturer), click on the three dots under *Actions* to cancel and then click **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 registered or deleted. The *Cancel (by MF) Certificate* operation will now be available.

2. You will arrive to the following page:

Certificate cancellation

Notified Body number: [redacted]
 Name: [redacted]
 Country: Germany

Manufacturer identification

Organisation name: [redacted]
 Actor ID/SRN: [redacted]
 Address: [redacted]
 Telephone number: [redacted]
 Email: [redacted]

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

3. 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

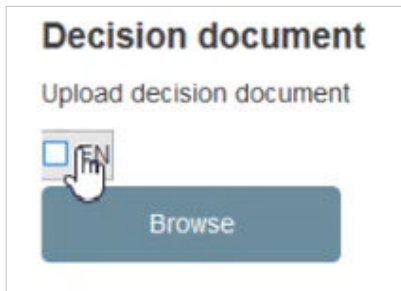
* **Status change reason**

Other

* Other reason (EN):

* Comment (EN):

4. Upload the decision document in the correct language:

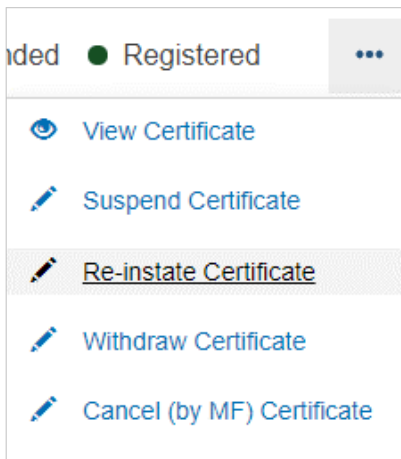


5. Once you are done, click **Submit**.



7.4 Re-instate certificate

1. To re-instate a certificate, click on the three dots under *Actions* to reinstate and click *Re-instate Certificate*:



TIP

Re-instate Certificate is missing?

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

2. 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

3. 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):

4. 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.

5. Upload the decision document in the correct language:

Decision document

Upload decision document

FI

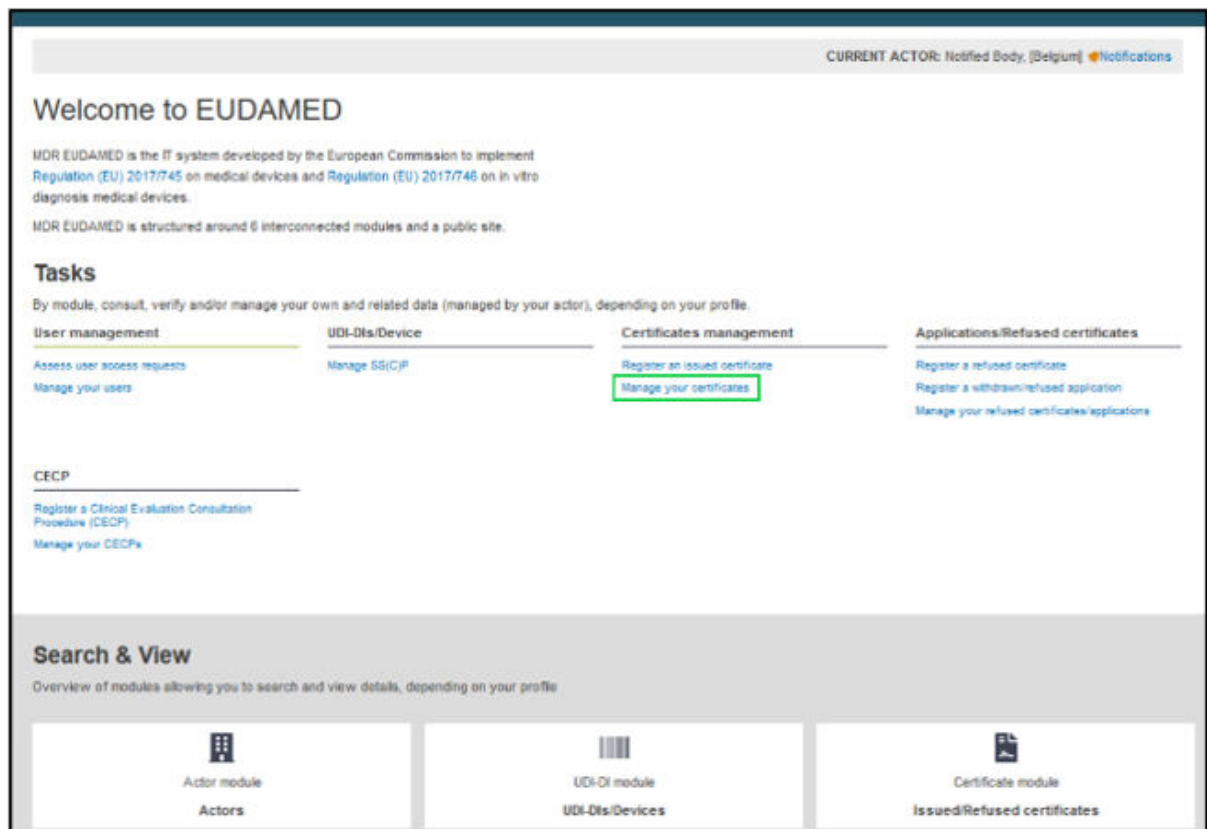
6. Once you are done, click **Submit**.

8 Certificate management

8.1 Issued certificates

8.1.1 View certificate

1. Click **Manage your certificates** on your dashboard:



2. By default the system will display your certificates in Draft state. Use the **Filter** button to help find the required certificate, enter your search criteria (at least one). Then click **Apply filters**:

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


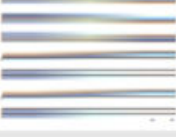

Certificates management

[Register an issued certificate](#)

Filter ▼

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

Showing 1 to 20 of 24 entries Show entries per page

MF/PR Actor ID/SRN	MF/PR Name	Certificate number ID	Certificate type	Date of issue ID	Date of expiry ID	Status	State	Actions
CR-PR-00000383		mdr/gms/app-only	(MDR) EU quality management system certificate (Annex IX Chapter I)	-	2026-08-03	Supplemented	● Draft	⋮
CJ-MF-00000402, AL-PR-00000219		mdr-ga-both	(MDR) EU quality assurance certificate (Annex X Part A)	-	2026-08-03	Restricted	● Draft	⋮
BE-MF-00000662		IVDR/TDA/MIS	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	-	2022-11-17	Supplemented	● Draft	⋮

8.1.2 Delete a draft certificate

1. Within the result list, click on the three dots under the *Actions* column for a specific entry. A drop-down menu displays:

Showing 1 to 20 of 24 entries Show entries per page

Date of expiry ID	Status	State	Actions
2026-08-03	Supplemented	● Draft	⋮

- [View Certificate](#)
- [Edit Certificate](#)

2. Click on **View Certificate** to see its details. Within the view page, click **Delete** at the top right:

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: [redacted]
 Name: [redacted]
 Country: [redacted]

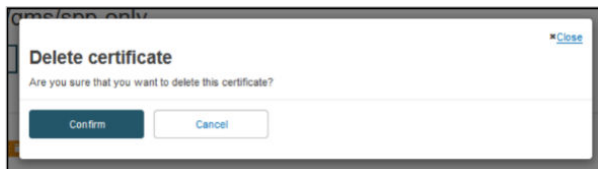
Certificate details

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: [redacted]
 Actor ID/SRI: [redacted]
 Address: 1 [redacted]
 Telephone number: [redacted]

3. A confirmation dialog displays. Click **Confirm**, and the certificate will be deleted:



8.1.3 Discard a certificate version



IMPORTANT

When discarding a certificate version two cases apply:

1. **If there is only one certificate version:** The entire certificate along with its single version will be discarded.
2. **If there are multiple certificate versions:** The certificate version will be discarded and the preceding certificate version will become the latest registered version.

To discard a certificate version follow the steps listed below.

1. Click the *Manage your certificates* link on the dashboard:

Tasks

According to [your profile, per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data

- [Manage your email notifications](#)
- [Manage subsidiaries](#)
- [Access point management](#)

User management

- [Assess user access requests](#)
- [Manage your users](#)

UDI-DIs/Device

- [Manage SS\(C\)P](#)

Certificates management

- [Register an issued certificate](#)
- [Manage your certificates](#)

- By default the system will display your certificates in *Draft* state. Use the **Filter** button to search for registered certificates. Then click **Apply filters**:

Filter ▼

Certificate Type

Certificate number

Role

Actor ID/SRN

Name

Date of issue

Between and

YYYY-MM-DD YYYY-MM-DD

Status

* State

Apply filters

Clear all filters

- Select the desired certificate from the list and click the *View* link under the three dots:

MF/PR Actor ID/SRN	MF/PR Name	Certificate number	Certificate type	Date of issue	Date of expiry	Status	State	Actions
FR-MF-000004867	Martin-Moreau & Fils.	crf-reissue-0023	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-09-02	2025-09-02	Reissued	Registered	⋮
FR-MF-000004867	Martin-Moreau & Fils.	BRB-CRF-0023	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-09-02	2025-09-02	Sus	Registered	View Certificate
CL-MF-000003268	McCullough, Dietrich y Cremin	cc2024-09-02-102	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-09-02	2028-09-02	Issu	Registered	Amend Certificate
FR-MF-000004867	Martin-Moreau & Fils.	brb-amd-1_2	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	2024-08-20	2025-08-20	Res	Registered	Restrict Certificate
NL-MF-000000041	Medical Device Manufacturer [All languages]	brb-1-reopened	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-08-05	2025-08-05	Issu	Registered	Supplement Certificate
NL-MF-000000041	Medical Device Manufacturer [All languages]	BRB-TEST-1	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-06-04	2025-06-04	Issu	Registered	Suspend Certificate
NL-MF-000000041	Medical Device Manufacturer [All languages]	BRB-NEW-EXPIRED	(MDR) EU quality management system certificate (Annex IX Chapter I)	2024-01-01	2024-08-06	Issu	Registered	Withdraw Certificate
								Cancel (by MF) Certificate
								Re-issue Certificate

- Click **Discard**:

Certificate data

Certificate data

Version 1 [Current] | Last update date: 2024-05-24

Discard

Notified Body

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands

Certificate details

Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Certificate type:	(MDR) EU quality assurance certificate (Annex XI Part A)
Certificate identifier: ⓘ	MDR/PQA/IIa/1
Date of issue:	2024-05-24



NOTE

The **Discard** button is visible only when the following conditions are met:

1. You have a Confirmer profile for the Certificates module
2. You must be the owner of the registered certificate (MDR/IVDR)
3. The certificate version is the latest version and is in *Registered* state
4. The certificate version does not have another version in *Draft* state
5. The certificate version is not linked to a re-issued certificate version in either the *Draft* or *Registered* state.

5. A confirmation window will pop-up. Click **Confirm** to discard the certificate. The message displayed in the confirmation window depends on the cases listed below:
 - The certificate version is associated with a device that did not require NB's confirmation during registration. Therefore, no reversal of their state will be performed:

[✕Close](#)

Discard certificate version

You are about to discard this certificate version. The operation cannot be reverted.
Do you want to confirm the operation?


Confirm
Cancel


After clicking **Confirm**, the certificate version will be discarded.

- The certificate version is associated with a high-risk device (MDR: Class III / Class IIb and IVDR: Class D / Class C) in *Registered* state and no other certificate is associated with that device:

[✕Close](#)

Discard certificate version

 You are about to discard this certificate version. The operation cannot be reverted.
After discarding this certificate version the following Basic UDI-DI(s) will be changed to Submitted state and it/they will not be visible in the EUDAMED public website.

- [12345-stem-B-5X](#) 

Do you want to confirm the operation?

Confirm


Cancel


After clicking **Confirm**, the certificate version will be discarded and the device will revert to the *Submitted* state and will no longer be visible on the public website.

- There is an SS(C)P associated with the certificate version that was registered during the certificate registration process:


[✕Close](#)

Discard certificate version

 You are about to discard this certificate version. The operation cannot be reverted.
After discarding this certificate version the following Basic UDI-DI(s) will be changed to Submitted state and it/they will not be visible in the EUDAMED public website.

- [12345-Q3.1-ClassC-4-W9](#) 

The following linked SS(C)P will be deleted

- SS(C)P 1: [ABC/052](#) [Rev.1](#) 

Do you want to confirm the operation?

Confirm


Cancel

After clicking **Confirm**, the certificate version will be discarded and the SS(C)P will be deleted.



- There are SS(C)Ps that were registered before they were associated with the certificate version and existing SS(C)Ps that were referenced during certificate version registration:

[✕Close](#)



Discard certificate version

 You are about to discard this certificate version. The operation cannot be reverted.

The following linked SS(C)P will be deleted

- SS(C)P 1: [ABC/950 Rev.1](#) 
- SS(C)P 2: [ABC/852 Rev.1](#) 

The following linked SS(C)P version will be deleted

- SS(C)P 1: [ABC/852 Rev.2](#) 
- SS(C)P 2: [ABC/852 Rev.3](#) 

Do you want to confirm the operation?

Confirm


Cancel


After clicking **Confirm**, the certificate version will be discarded, and both the SS(C)P versions referenced in this certificate version, as well as SS(C)P records registered during the registration of this certificate version, will be deleted.

- There is a CECP linked to the certificate version:

[✕Close](#)

Discard certificate version

 You are about to discard this certificate version. The operation cannot be reverted.

The CECP: [2797-2024-1084](#)  will be changed to its preceding status: Opinion

Do you want to confirm the operation?

Confirm


Cancel



After clicking **Confirm**, the certificate version will be discarded and the CECP will revert to its preceding status.


- There is a CECP linked to the certificate version and the certificate version is associated with a high-risk device (MDR: Class III / Class IIb) in *Registered* state:

[✕Close](#)

Discard certificate version

 You are about to discard this certificate version. The operation cannot be reverted. After discarding this certificate version the following Basic UDI-DI(s) will be changed to Submitted state and it/they will not be visible in the EUDAMED public website.

- [12345-24.Q1-III-mfs-3-L3](#) 
- [12345-24.Q1-III-mfs-6-LC](#) 

The CECP: [2797-2024-1061](#)  will be changed to its preceding status: Opinion


Do you want to confirm the operation?

Confirm

Cancel

After clicking **Confirm**, the certificate version will be discarded, the CECP will revert to its preceding status and the device will return to the *Submitted* state and will no longer be visible on the public website.

When the certificate version is discarded, a red banner will appear at the top of the *Certificate data* page:

 Certificate successfully discarded

Certificate: MDR/PQA/IIa/1

[← Go back to the list](#)

Certificate data

This certificate version has been discarded | Last update: 2024-09-04

Certificate data

Version 1 [Discarded] | Last update date: 📅 2024-05-24

Notified Body

Notified Body number: 2797

Name: BSI Group The Netherlands B.V.



NOTE

The NB owner of the certificate, as well as all CAs and DAs, can view certificates in *Discarded* state.

8.2 Refused certificates

8.2.1 View certificate

1. Click the *Manage your refused certificates/applications* link on the dashboard:

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.

Tasks

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data

- [Manage your email notifications](#)
- [Manage subsidiaries](#)
- [Access point management](#)

User management

- [Assess user access requests](#) 🔥 2
- [Manage your users](#)

UDI-DIs/Device

- [Manage SS\(C\)P](#)

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](#)

CECP

- [Register a Clinical Evaluation Consultation Procedure \(CECP\)](#)
- [Manage your CECPs](#)

Vigilance

- [Manage Vigilance reports](#)

2. By default the system will display your certificates in Draft state. Use the **Filter** button to help find the required certificate, enter your search criteria (at least one). Then click **Apply filters**:

Showing 1 to 20 of 56 entries Show entries per page

MF/PR Actor ID/SRN	MF/PR Name	Application reference number	Conformity assessment procedure	Decision	State	Actions
BE-MF-000001281			(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮
BE-MF-000001281			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮
BE-MF-000001281			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮

3. Click the *View* link under the three dots to view details on the selected certificate:

Showing 1 to 20 of 56 entries Show entries per page

MF/PR Actor ID/SRN	MF/PR Name	Application reference number	Conformity assessment procedure	Decision	State	Actions
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	Test12java.util.Random@76219fe	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	Test12java.util.Random@4a0c3aa8	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	👁 View
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	Test12java.util.Random@49cd946c	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮

8.2.2 Delete a draft certificate

1. Within the result list, click *View* under the three dots for a specific entry:

Showing 1 to 20 of 48 entries Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Application reference number	Conformity assessment procedure ID	Decision ID	State	Actions
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	TA24040812173522	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Draft	View
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	TA240408121625318	(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)		Edit
BE-MF-000001281	ARMEN EU MF Q2.6tgm [All languages]	TA240408120742222	(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)		

2. Within the view page, click **Delete** at the top right:

Refused certificate: TA24040812173522

[Go back to the applications list](#)

Refused certificate data

Refused certificate data Edit Delete

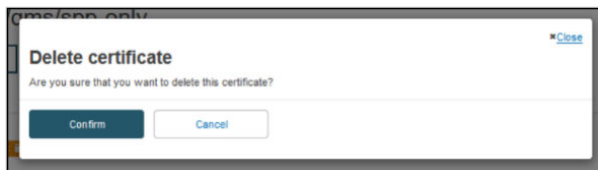
Notified Body

Notified Body number: 1912
 Name: Kiwa Dare B.V.
 Country: Netherlands

Refused certificate details

Decision Type: Refused certificate (by NB)
 Applicable legislation: IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)
 Conformity assessment procedure: (IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)
 Application reference number: TA24040812173522
 Application submission date: 2024-04-08
 Certificate refusal date: 2024-04-08

3. A confirmation dialog displays. Click **Confirm** to delete the draft certificate:



8.2.3 Discard a refused certificate

To discard a refused certificate follow the steps listed below.

1. Click the *Manage your refused certificates/applications* link on the dashboard:

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.

Tasks

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data

- Manage your email notifications
- Manage subsidiaries
- Access point management

User management

- Assess user access requests 🔥 2
- Manage your users

UDI-DIs/Device

- Manage SS(C)P

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

CECP

- Register a Clinical Evaluation Consultation Procedure (CECP)
- Manage your CECPs

Vigilance

- Manage Vigilance reports

- By default the system will display your certificates in *Draft* state. Use the **Filter** button to search for registered certificates. Then click **Apply filters**:

Refused certificates/applications management

Filter ▼

Conformity assessment procedure: -- x v Application reference number:

Role: -- x v Actor ID/SRN: Name:

Application Decision: -- x v

* State: Registered v

Apply filters Clear all filters

- Select the refused certificate from the list and click the *View* link under the three dots:

Showing 1 to 20 of 56 entries Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Application reference number IT	Conformity assessment procedure IT	Decision IT	State	Actions
BE-MF-000001281			(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮
BE-MF-000001281			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮
BE-MF-000001281			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	⋮

- Click the **Discard** button:

Refused certificate: Demo.24.Q1.3

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

Refused certificate data

Refused certificate data Discard

Notified Body

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands

Refused certificate details

Decision Type:	Refused certificate (by NB)
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:	Demo.24.Q1.3
Application submission date:	2024-03-21

5. A confirmation window will pop-up. Click **Confirm** to discard the refused certificate.

When the refused certificate is discarded, a red banner will appear at the top of the *Refused certificate data* page:

Refused certificate data

This refused certificate has been discarded | Last update: 2024-03-22

Refused certificate data

Notified Body

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands

Refused certificate details

Decision Type:	Refused certificate (by NB)
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:	Demo.24.Q1.3
Application submission date:	2024-03-21
Certificate refusal date:	2024-03-21
Refusal reference number:	-

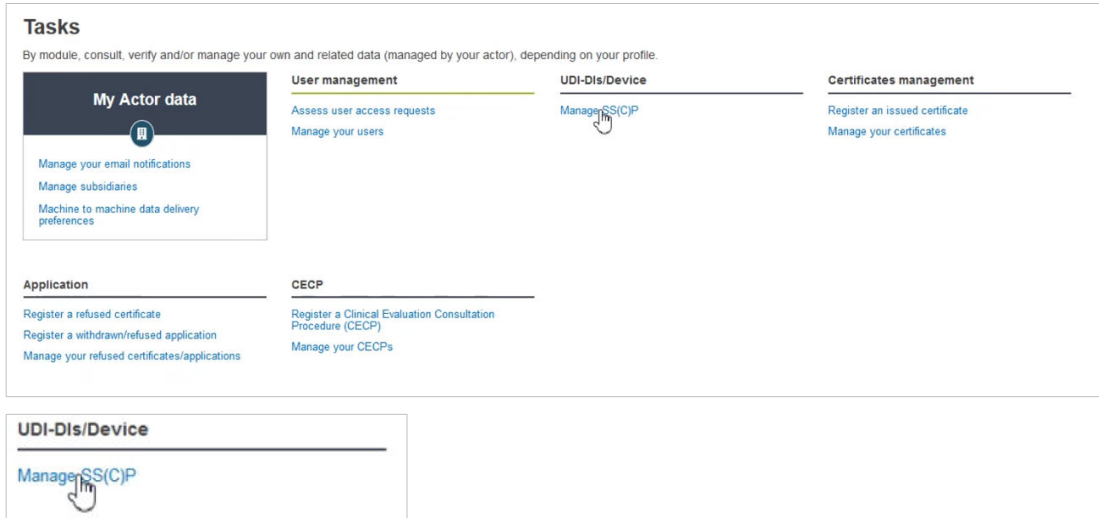


NOTE

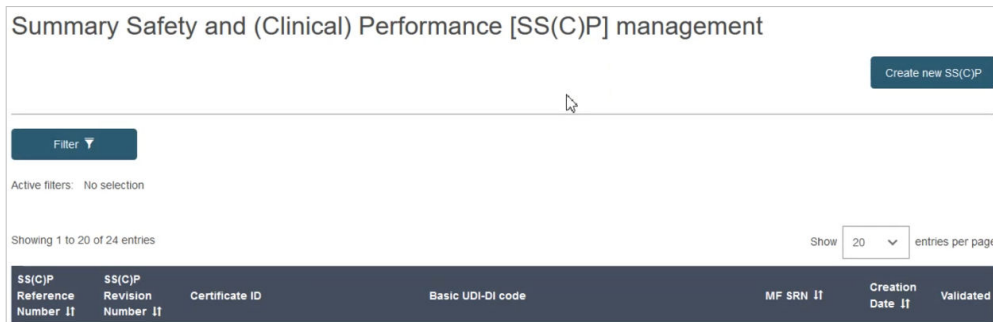
The owner NB of the discarded certificates as well as all CAs and DAs can view refused certificates in *Discarded* state.

9 SS(C)P Management

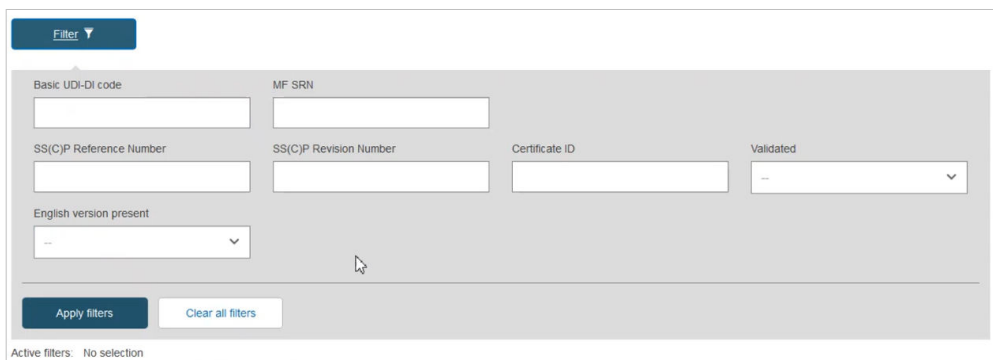
1. Click **Manage SS(C)P** under *UDI-DIs/Device*:



The following page will display:



2. You are 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:



3. 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.

Click on the SS(C)P in the list you would like to manage:

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
30345	123	NB-1039324	12345Test1PDSK/12345Test1PDSK	BE-MF-000000001	2021-06-15	Yes

4. A summary of SCCP-related information displays:

Manufacturer identification

Actor ID/SRN: BE-MF-000000662
Organisation name: Medical Device Manufacturer
Address: Antwerpen

SS(C)P details

[Actions -](#)

Notified Body identification

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

SS(C)P Reference Number: ABC/885

Basic UDI-DI(s) code: [12345-23.Q4.1-Ila-8-VU](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))
[12345-23.Q4.1-Ila-7-VR](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))

Master document version 1 [Current] | ⚠ Not validated | Upload date 2023-12-13

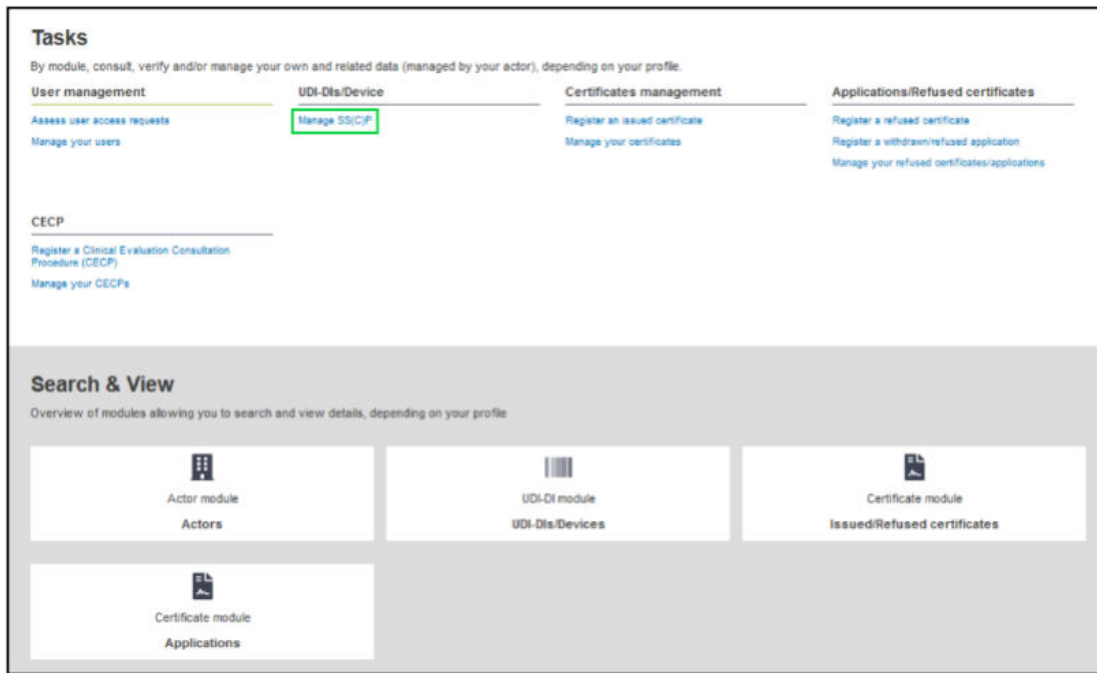
SS(C)P master document: [zeventien-bytes](#) [PDF 17 Bytes] [NL]

SS(C)P revision number: Rev.1

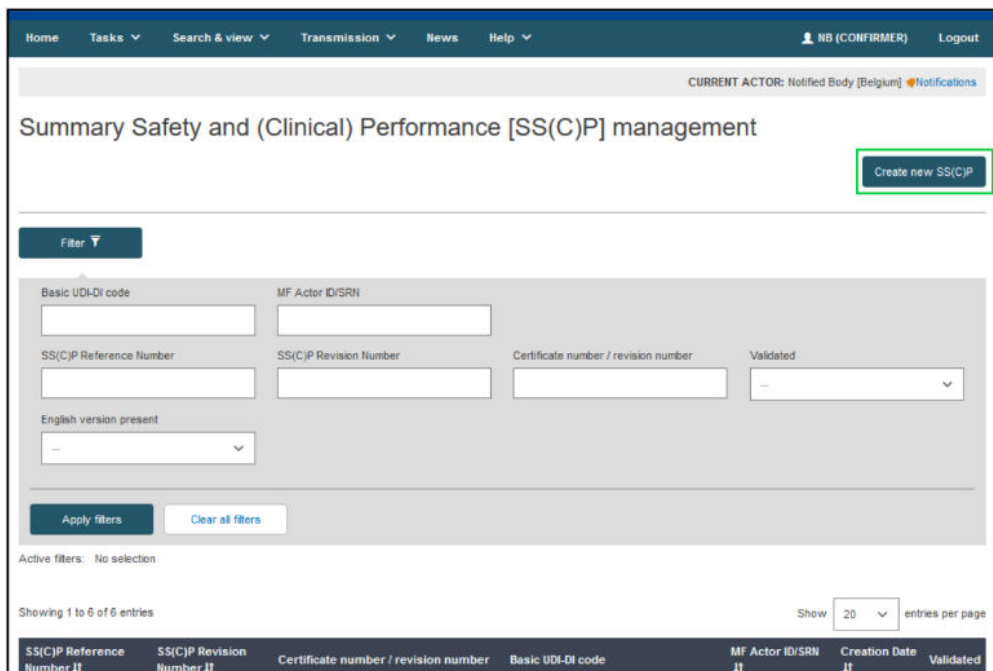
5. Clicking on the Basic UDI-DI codes will open the Basic UDI-DI in a new tab. Next to this code is the certificate data that is linked to the Basic UDI-DI.

9.1 Register a 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 the certificate's number, and its revision number if applicable, to identify the certificate registered before. 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, if applicable, the Authorised Representative:

Create new SS(C)P

Notified Body identification

Notified Body number:

Name:

Country:

Certificate identification

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*, enter the Basic UDI-DI to be linked to this SS(C)P:

[Remove Certificate information](#)

Device(s) information

* Enter Basic UDI-DI code:

SS(C)P information

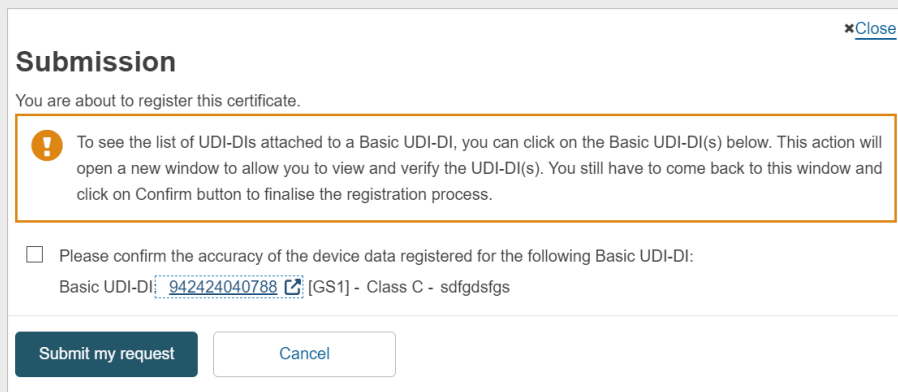
* SS(C)P reference number: * SS(C)P revision number:

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



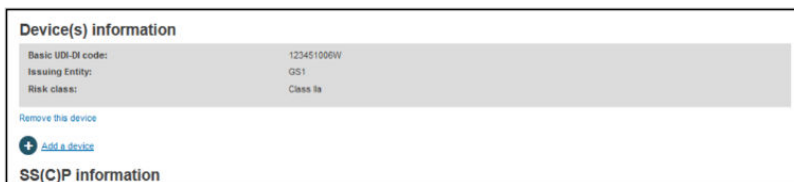
NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your SS(C)P, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:



After the SS(C)P is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

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

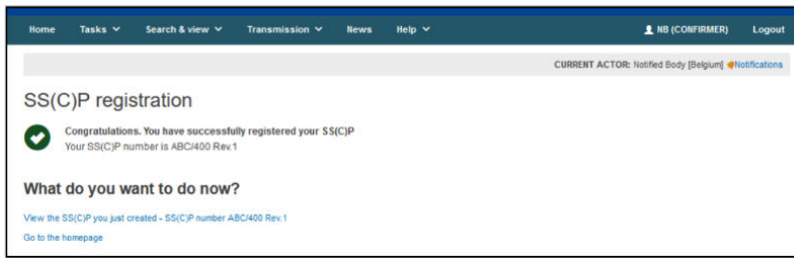


You may add another Basic UDI-DI by clicking on the *Add a device* link, or remove this Basic UDI-DI by clicking on the *Remove this device* link.

- 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 confirmation page will appear:

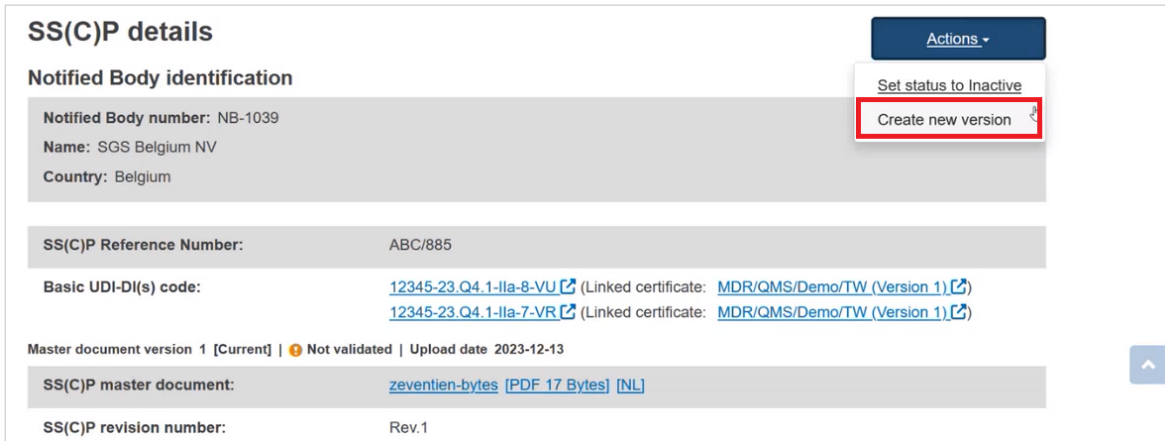


Your new SS(C)P record will appear under the list of SS(C)Ps within the SS(C)P management page.

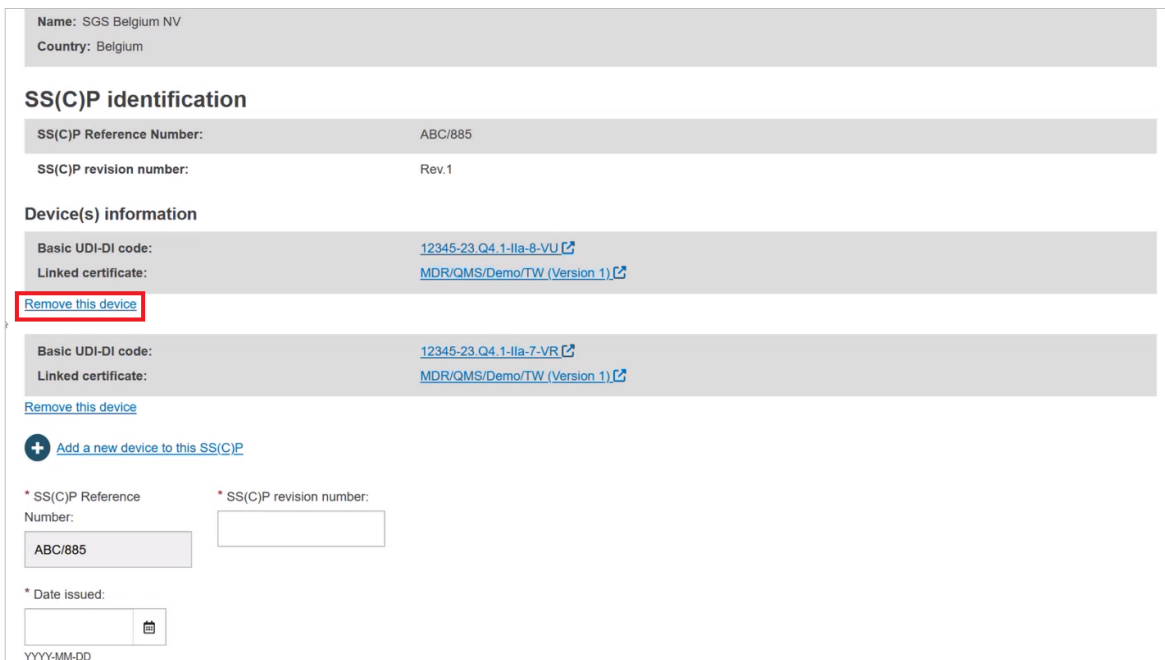
9.2 Create new SS(C)P version

To create a new SS(C)P version, please follow the steps in [SS\(C\)P Management \[98\]](#) (steps 1-4) and then continue with the steps below:

- Click *Create new version* under the **Actions** button:



Click on the *Remove this device* link to remove a device:





NOTE

If there is only one device linked to the selected SS(C)P, you will not be able to remove that device:

Device(s) information

Basic UDI-DI code: [12345-23-Q4-1-lla-7-VR](#)

Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#)

ⓘ This Basic UDI-DI cannot be removed from the SS(C)P as it is in the scope of the linked certificate or it is the last Basic UDI-DI associated to this SS(C)P.

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

A pop-up window displays; click **Confirm** to remove the device:

[✕Close](#)

Remove Basic UDI-DI

You are about to remove this Basic UDI-DI from the associated SS(C)P.

Confirm
Cancel

Click on the *Add a new device to this SS(C)P* link to associate a new device to the selected SS(C)P:

SS(C)P identification

SS(C)P Reference Number: ABC/885

SS(C)P revision number: Rev.1

Device(s) information

Basic UDI-DI code: [12345-23-Q4-1-lla-7-VR](#)

Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#)

ⓘ This Basic UDI-DI cannot be removed from the SS(C)P as it is in the scope of the linked certificate or it is the last Basic UDI-DI associated to this SS(C)P.

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

A new field is displayed. Enter the Basic UDI-DI code and click **Check registry**:

*** Enter Basic UDI-DI code:**

I
Check registry

[Remove this device](#)

In the pop-up window, select the Basic UDI-DI from the list:

[✖Close](#)

Find a basic UDI-DI

- Basic UDI-DI 12345-23.Q4.1-Ila-10-CA [GS1], Class IIa
- Basic UDI-DI 12345-23.Q4.1-Ila-12-CG [GS1], Class IIa
- Basic UDI-DI 12345-23.Q4.1-Ila-9-VX [GS1], Class IIa
- Basic UDI-DI 12345-23.Q4.1-Ila-11-CD [GS1], Class IIa
- Basic UDI-DI 12345-subst-23.Q4.3-1-45 [GS1], Class IIa

← Previous

1

2

3

Next →

Cancel



NOTE

If you have referenced a Basic UDI-DI in *Submitted* state, then upon submitting your SS(C)P, you will be asked to confirm the accuracy of the device data registered for the referenced Basic UDI-DI:

[✖Close](#)

Submission

You are about to register this certificate.

! To see the list of UDI-DIs attached to a Basic UDI-DI, you can click on the Basic UDI-DI(s) below. This action will open a new window to allow you to view and verify the UDI-DI(s). You still have to come back to this window and click on Confirm button to finalise the registration process.

Please confirm the accuracy of the device data registered for the following Basic UDI-DI:
 Basic UDI-DI: [942424040788](#) [GS1] - Class C - sdfgdsfgs

Submit my request
Cancel

After the SS(C)P is submitted, the state of the Basic UDI-DI will be updated to *Registered*. The Basic UDI-DI(s) and their related UDI-DI(s) will then become visible on the EUDAMED public site.

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

* SS(C)P Reference Number:

* SS(C)P revision number:

* Date issued:

Language of the master document:

- After the document is uploaded, the *Is this SS(C)P validated?* field appears. Select **Yes** or **No** and click **Submit**:

Language of the master document:

1 file uploaded successfully

zeventien-bytes [NL] [PDF 17 Bytes]

* Is this SS(C)P validated?

Yes No

- In the pop-up window, click **Confirm** to submit your registration:

[Close](#)

Register a new SS(C)P version

You are about to register a new version of this SS(C)P



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 Add translations

To add a translation to an SS(C)P, please follow the steps in [SS\(C\)P Management \[98\]](#) (steps 1-3) and then continue with the steps below:

- Scroll to the bottom of the page and click on **Add Translation**:

Manufacturer identification

Actor ID/SRN: NL-MF-000000041
 Organisation name: Johnson & Johnson Medical
 Address: NL-8000 Amersfoort

SSCP details Create new version

Notified Body identification

Notified Body number: [REDACTED]
 Name: [REDACTED]
 Country: [REDACTED]

SS(C)P identification

SS(C)P reference number: [REDACTED]
 Basic UDI-DI(s) code: [REDACTED]

Master document version 1 [Current] | ! Not validated | Upload date 2022-12-07

SS(C)P master document: [NB XXXX - SS\(C\)P.pdf \[212.48 KB\] \[HR\]](#)

SS(C)P revision number: Rev.1

Uploaded from: SS(C)P management

Date issued: 2022-12-07

Translation(s) Add Translation

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

- In the new window, select the date by clicking on the calendar icon and select the document language from the drop-down list.

Add translations to SS(C)P - [REDACTED]

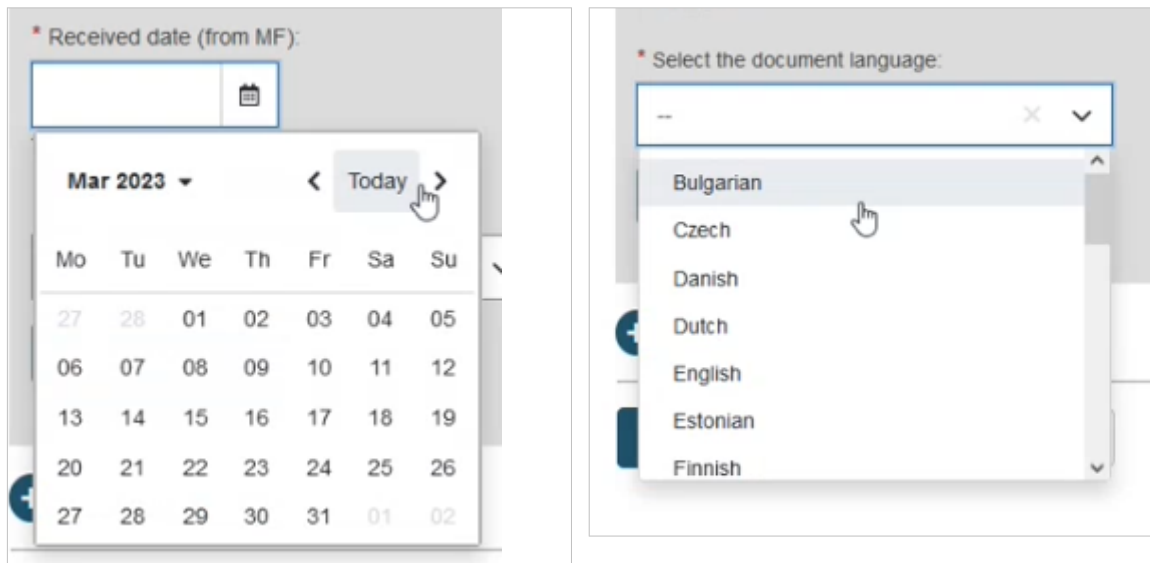
Upload translation with their metadata

* SS(C)P reference number: [REDACTED] * SS(C)P revision number: Rev.1

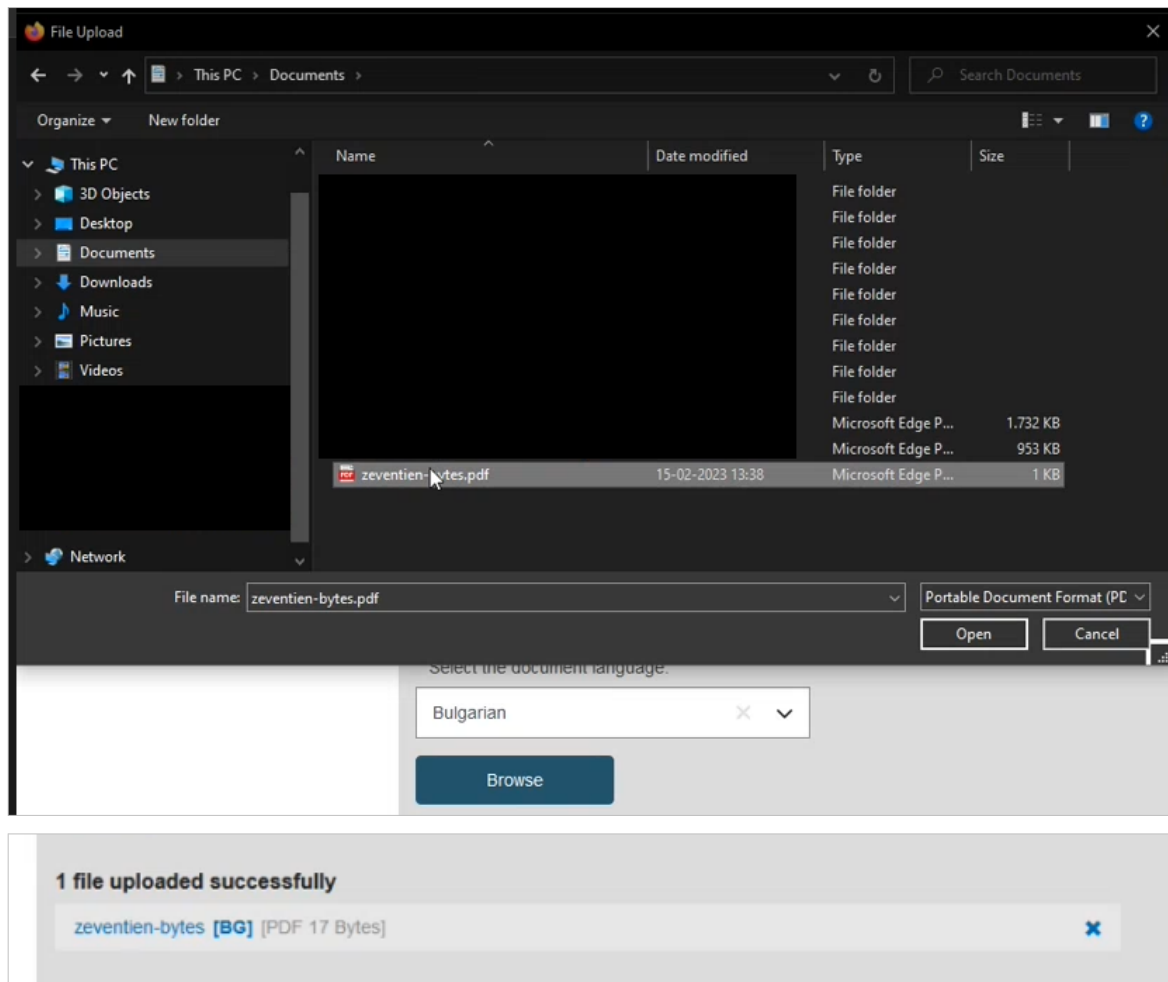
* Received date (from MF):
YYYY-MM-DD

* Select the document language: x v

+ [Add Translation](#)



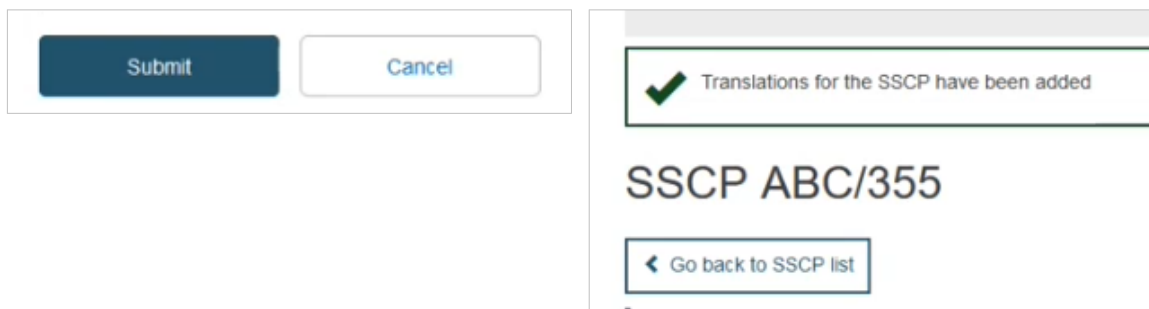
3. Click on **Browse** and select the document from your computer, click **Open**, you will receive a message that the file was successfully uploaded:



NOTE

You can also add multiple translations at once by clicking + *Add translation*.

4. When you are done, click **Submit**; a success message will appear:



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 - Bulgarian ▼

SS(C)P translation document (Document and Language):	zeventien-bytes.pdf [17 Bytes] [BG]
Upload date:	2023-03-17
Received date (from MF):	2023-03-17

[Discard this document](#)



NOTE

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

9.4 Inactivate an SS(C)P

To inactivate an SS(C)P, please follow the steps in [SS\(C\)P Management \[98\]](#) (steps 1-4) and then continue with the steps below:

1. Click *Set status to inactivate* under the **Actions** button:

SS(C)P details

Actions ▾

Set status to *Inactive*
Create new version

Notified Body identification

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

SS(C)P Reference Number: ABC/885

Basic UDI-DI(s) code: [12345-23.Q4.1-Ila-7-VR](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))
[12345-23.Q4.1-Ila-9-VX](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))

Master document version 2 [Current] | ! Not validated | Upload date 2023-12-13 | [See version history](#)

SS(C)P master document: [zeventien-bytes](#) [PDF 17 Bytes] [NL]

SS(C)P revision number: Rev.2

Uploaded from: SS(C)P management

2. A pop-up window displays. Click **Confirm** to inactivate the selected SS(C)P:

✕ [Close](#)

Inactivating SS(C)P

! You are about to inactivate this SS(C)P. Once inactivated you will not be able to reference it in any other certificate registrations and the following Basic UDI-DI(s):

- 12345-23.Q4.1-Ila-8-VU
- 12345-23.Q4.1-Ila-7-VR
- 12345-23.Q4.1-Ila-7-VR
- 12345-23.Q4.1-Ila-9-VX

can be associated to any other SS(C)Ps.

Confirm

Cancel

!

IMPORTANT

Keep in mind that a Basic UDI-DI can be associated to one SS(C)P only.

The SS(C)P is now marked as *Inactive*:

SS(C)P ABC/885 (Inactive)

[Go back to SS\(C\)P list](#)

Manufacturer identification
[SS\(C\)P details](#)

Manufacturer identification

Actor ID/SRN: BE-MF-00000662
 Organisation name: Medical Device Manufacturer
 Address: Antwerpen

SS(C)P details Inactive (From: 2023-12-13)

Notified Body identification

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

SS(C)P Reference Number: ABC/885 Inactive (From: 2023-12-13)

Basic UDI-DI(s) code: [12345-23.Q4.1-lla-7-VR](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))
[12345-23.Q4.1-lla-9-VX](#) (Linked certificate: [MDR/QMS/Demo/TW \(Version 1\)](#))

Master document version 2 [Current] | Not validated | Upload date 2023-12-13 | [See version history](#)

SS(C)P master document: [zeventien-bytes](#) (PDF 17 Bytes) [NL]

SS(C)P revision number: Rev.2

Uploaded from: SS(C)P management

9.5 View SS(C)P version history

If you want to check the SS(C)P version history, click 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](#)

A list with the different versions for the SS(C)P displays:

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 Register an application

10.1 Register a withdrawn application

VIDEO: Register a withdrawn application



Click *Register a withdrawn/refused application* in the *Applications/refused certificates* section:

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

My Actor data	User management	UDI-DIs/Device	Certificates management
<ul style="list-style-type: none"> Manage your email notifications Manage subsidiaries Machine to machine preferences 	<ul style="list-style-type: none"> Assess user access requests Manage your users 	<ul style="list-style-type: none"> Manage SS(C)P 	<ul style="list-style-type: none"> Register an issued certificate Manage your certificates
<ul style="list-style-type: none"> Register a refused certificate Register a withdrawn/refused application Manage your refused certificates/applications 	<ul style="list-style-type: none"> CECP Register a Clinical Evaluation Consultation Procedure (CECP) Manage your CECPs 		

1. Select what you want to register:

Home Tasks Search & view Transmission News Help NB (CONFIRMER) Logout

CURRENT ACTOR: Notified Body, 2797, BSI Group The Netherlands B.V. [Netherlands] Notifications

Registration of a withdrawn/refused application for conformity assessment

Application core information

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands

* What do you want to register?

Withdrawn application (by MF)

Application refusal (by NB)

* Applicable regulation

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

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

2. Select the applicable regulation, in this case IVDR, and then select the conformity procedure:

The screenshot shows a form with two sections. The first section, titled '* Applicable regulation', contains two radio button options: 'MDR (REGULATION (EU) 2017/745 on medical devices)' and 'IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)'. The second option is selected. The second section, titled '* Conformity assessment procedure:', contains a dropdown menu currently showing '--'. A list of options is visible below the dropdown: '(IVDR) EU quality management system certificate (Annex IX Chapter I)', '(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)', '(IVDR) EU type-examination certificate (Annex X)', and '(IVDR) EU production quality assurance certificate (Annex XI)'. A mouse cursor is pointing at the first option in the list.

3. Provide the *Application reference number*, the *Decision date* and the *Date of submission by MF/Producer*:

The screenshot shows a form with three input fields. The first field is a dropdown menu for '* Conformity assessment procedure:' with the selected option '(IVDR) EU quality management system certificate (Annex I...'. The second field is '* Application reference number:' with the text 'applica-01'. The third field is '* Decision date:' with a date picker showing '2022-09-12' and the format 'YYYY-MM-DD'. Below these is '* Date of submission (by MF/Producer):' with a date picker showing '2022-08-01' and the format 'YYYY-MM-DD'.

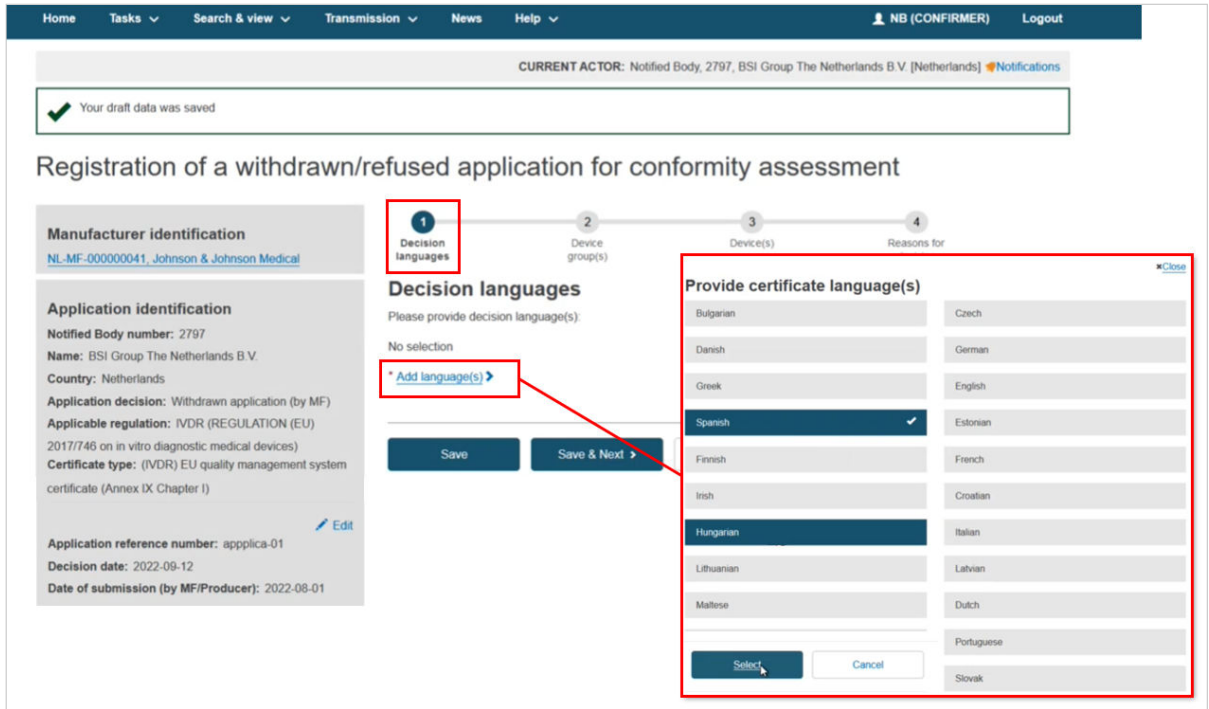
4. Enter the Actor ID/SRN or name of the manufacturer or the system/procedure pack producer, click **Find** and select from the list displayed:

The screenshot shows a 'Manufacturer identification' form. At the top, there is a 'Find manufacturer' modal window with a search input containing 'john' and a 'Find' button. Below the modal, the main form has a search input also containing 'john' and a 'Find' button highlighted with a red box. A list of search results is displayed in the modal: 'Manufacturer, AF-MF-00000122, John's NonEU MF [Afghanistan]', 'Manufacturer, BE-MF-00000123, John's EU MF [Belgium]', and 'Manufacturer, NL-MF-00000041, Johnson & Johnson Medical [Netherlands]'. A 'Close' button is at the bottom of the modal.

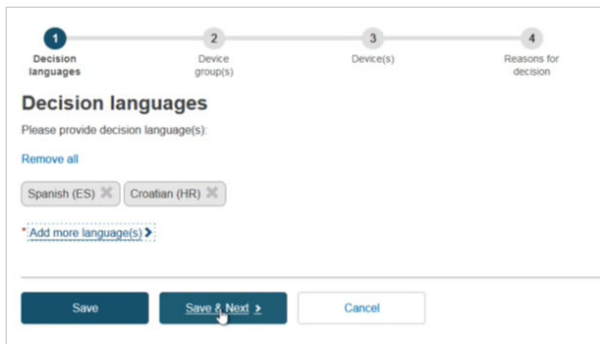
5. Click **Save & Next**:

The screenshot shows the 'Manufacturer identification' form with the following details: 'Organisation name: Johnson & Johnson Medical', 'Actor ID/SRN: NL-MF-00000041', 'Address: Amersfoort, Netherlands', 'Telephone number: -', and 'Email: tst@tst.nl'. A 'Change Manufacturer' link is visible. At the bottom, there is a 'Save & Next' button with a right-pointing arrow.

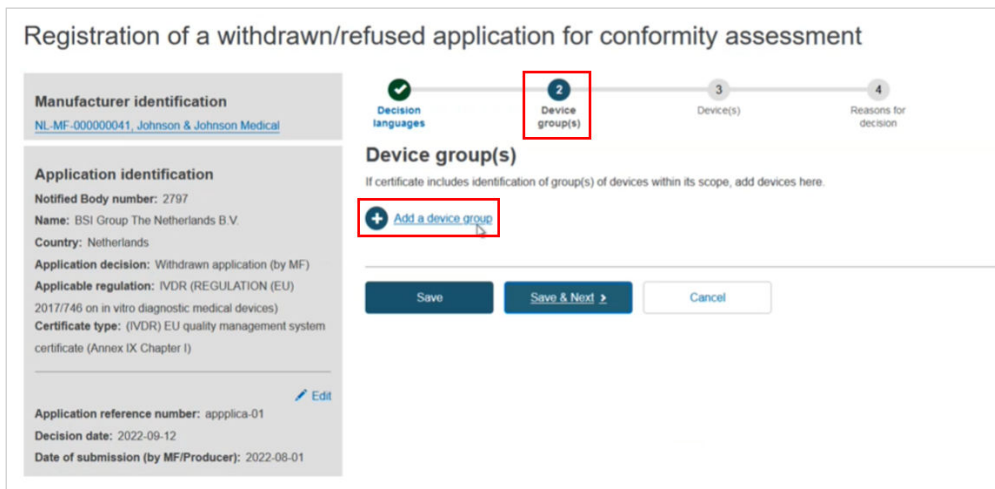
6. The process flow displays. First add the *Decision language(s)*. You can select multiple languages, then click **Select**:



7. The language tabs display, which can be removed using the x. Click **Save & Next**:



8. The next step in the flow is **Add a device group**:



9. Enter the device group identification and select the risk class. Click **Save & Next**:

Device group(s)

My device group

* Identification of the device group:

My device group

* Risk class

The device group contains device(s) of:

Class A (Sterile)

Class B

Class C

Class D

[Remove this device group](#)

[+ Add a device group](#)

Save Save & Next > Cancel

10. Add a device. Click + *Add a device*:

Decision languages ✓ Device group(s) ✓ 3 Device(s) 4 Reasons for decision

Device(s)

If the certificate includes identification of device(s) within its scope, add devices here.

[+ Add a device](#)

Save Save & Next > Cancel

11. Select *Yes* or *No* in the field *Custom made class III implantable* and specify if you will provide the *Name*, the *Reference/Catalogue number* or the *Basic UDI-DI* of the device:
- If you select the *Name*, then you must provide the *Name* and the *Risk class* of the device:

- If you select the *Basic UDI-DI*, then you must fill in the field *Enter the Basic UDI-DI code* and click **Check registry**:

In the pop-up window either select the device from the list (if the device is already registered in EUDAMED) or click **Enter data manually** (if the device is not yet registered in EUDAMED) to add the Basic UDI-DI manually:

Select the Issuing Agency and the risk class of the device and specify if the device is implantable or not (applicable for MDR):

* Basic UDI-DI:

* Issuing Agency:

* Risk class
 The device is of:
 Class IIb
 Class III

* Implantable
 Yes No

Specify if the device model is applicable or not:

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

* Device Model:

Name:

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

* Name:

12. Click **Save & Next**.

13. The reasons for the withdrawal/refusal in the language indicated above the text box. You can click **Preview** to double-check the content in each step:

Manufacturer identification
 NL-MF-000000041, Johnson & Johnson Medical

Application identification
 Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands
 Application decision: **Withdrawn application (by MF)**
 Applicable regulation: IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)
 Certificate type: (IVDR) EU quality management system certificate (Annex IX Chapter I)

Application reference number: applica-01 [Edit](#)
 Decision date: 2022-09-12
 Date of submission (by MF/Producer): 2022-08-01

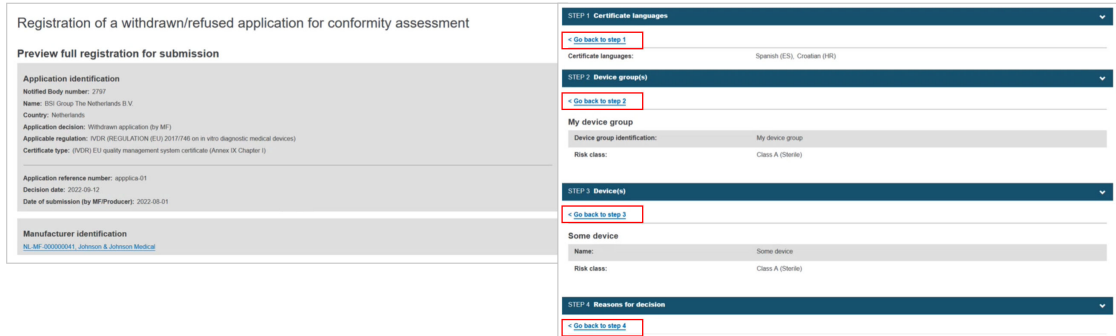
Decision languages Device group(s) Device(s) **Reasons for decision**

Reasons for decision
 Reason for refusal/withdrawal comment (ES):

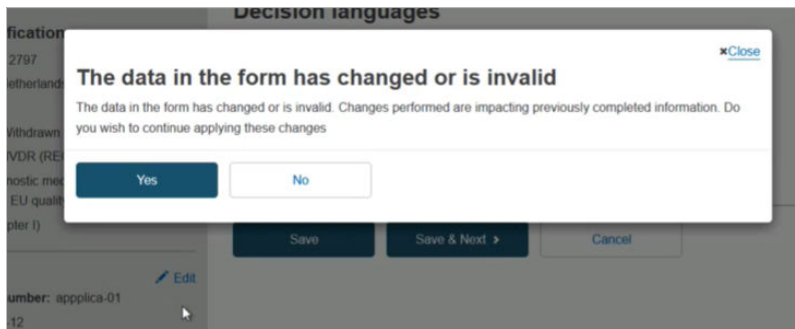
 Reason for refusal/withdrawal comment (HR):

Save **Preview** Submit > Cancel

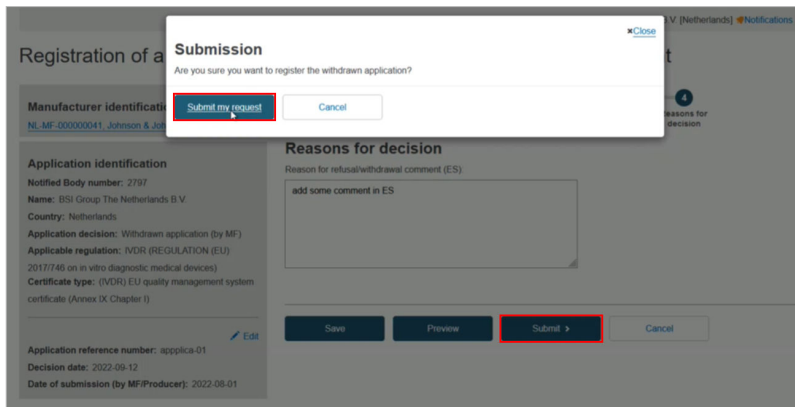
- a. Scroll through the preview. You can return to a specific step by clicking **Go back to step x** to make edits:



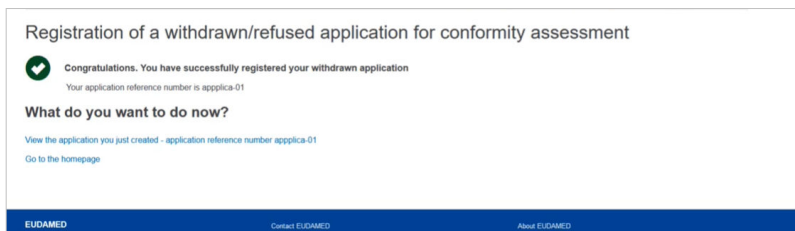
- b. If you make edits, click **Save & Next**, then you will see this confirmation message. Click **Yes**, and proceed out of any further steps until you reach the last one:



14. Click **Submit my request**:



15. The *Confirmation* message displays:



10.2 Register a refused application

Select **Application refusal (by NB)**, then the steps are the same as when [registering a withdrawn application \[112\]](#), until you are asked to provide the reason:

1. From the list provided, select the reason for refusal. If you choose *Other*, provide the explanation in the *Other reason* text box:

2. Provide the reason for the refusal in the language(s) previously selected and upload the refusal document if applicable.

Click **Preview** to see and/or edit your entries, or click **Submit**:

* Reason for refusal/withdrawal comment (FI):

Mandatory to be provided

Decision on refusal document

Upload refusal document

1 file uploaded successfully

NB XXXX - Refusal document [PDF 212.48 KB] ✕

Save
Preview
Submit >
Cancel

3. Scroll through the preview screen. Click the step 'x' link to return to that section:

Preview full registration for submission

Application identification

Notified Body number: 2797
 Name: BSI Group The Netherlands B.V.
 Country: Netherlands
 Application decision: Application refused (by NB)
 Applicable regulation: MDR (REGULATION (EU) 2017/745 on medical devices)
 Certificate type: MDR EU quality assurance certificate (Annex XI Part A)
 System or Procedure pack applicable: Yes

Application reference number: application-02
 Decision date: 2022-08-12
 Date of submission (by MFP/Producer): 2022-08-04

Manufacturer identification

NL_MF-000000651_Sobson & Sobson Medical
 System and/or Procedure Pack Producer Identification
 BE_FR-000000651_ARMEN_Q3.1 EU SYS PACK PROD

Open all | Close all

STEP 1: Certificate languages

< Go back to step 1

Certificate languages: Finnish (FI)

STEP 2: Device group(s)

< Go back to step 2

STEP 3: Device(s)

< Go back to step 3

Some custom made device

Custom made class III implantable: Yes
 Description: Some custom made device

4. Click **Submit my request**:

Submission ✕Close

Are you sure you want to register the refused application?

Submit my request
Cancel

5. The request is submitted, and the *Confirmation* message displays:

Home Tasks Search & view Transmission News Help NB (CONFIRMER) Logout

CURRENT ACTOR: Notified Body, 2797, BSI Group The Netherlands B.V. [Netherlands] Notifications

Registration of a withdrawn/refused application for conformity assessment

✔
Congratulations. You have successfully registered your refused application
 Your application reference number is application-02

What do you want to do now?

[View the application you just created - application reference number application-02](#)
[Go to the homepage](#)

11 Manage applications

11.1 Discard a refused/withdrawn application

To discard a refused/withdrawn application follow the steps listed below.

1. Click the *Manage your refused certificates/applications* link on the dashboard:

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.

Tasks

According to [your profile per module](#), consult, verify and/or manage your own and related data (managed by your actor)

My Actor data	User management	UDI-DIs/Device	Certificates management
Manage your email notifications Manage subsidiaries Access point management	Assess user access requests 🔥 2 Manage your users	Manage SS(G)P	Register an issued certificate Manage your certificates
Applications/Refused certificates	CECP	Vigilance	
Register a refused certificate Register a withdrawn/refused application Manage your refused certificates/applications	Register a Clinical Evaluation Consultation Procedure (CECP) Manage your CECPs	Manage Vigilance reports	

2. By default the system will display your certificates in *Draft* state. Use the **Filter** button to search for registered certificates. Then click **Apply filters**:

Refused certificates/applications management

Filter ▼

Conformity assessment procedure: -- x v Application reference number:

Role: -- x v Actor ID/SRN: Name:

Application Decision: -- x v

* State: **Registered** v

Apply filters Clear all filters

3. Select the refused/withdrawn application from the list and click the *View* link under the three dots:

Showing 1 to 20 of 137 entries Show 20 entries per page

MF/PR Actor ID/SRN	MF/PR Name	Application reference number	Conformity assessment procedure	Decision	State	Actions
EL-MF-000005607			(IVDR) EU quality management system certificate (Annex IX Chapter I)	Withdrawn application (by MF)	Registered	...
BE-MF-000001281			(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	...
BE-MF-000001281			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Refused certificate (by NB)	Registered	...
BE-MF-000001281			(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Withdrawn application (by MF)	Registered	...
IN-MF-000005648			(IVDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Withdrawn application (by MF)	Registered	...
BD-MF-000002487			(MDR) EU technical documentation assessment certificate (Annex IX Chapter II)	Application refusal (by NB)	Registered	...

4. Click the **Discard** button:

Withdrawn application: app141

[Go back to the applications list](#)

Withdrawn application data

Withdrawn application data [Discard](#)

Notified Body

Notified Body number: 1912
 Name: Kiwa Dare B.V.
 Country: Netherlands

Withdrawn application details

Decision Type:	Withdrawn application (by MF)
Applicable legislation:	MDR (REGULATION (EU) 2017/745 on medical devices)
Conformity assessment procedure:	(MDR) EU quality assurance certificate (Annex XI Part A)
Application reference number:	app141
Decision date:	2023-08-17
Date of submission (by MF/Producer):	2023-08-17

5. A confirmation window will pop-up. Click **Confirm** to discard the refused/withdrawn application.

When the refused/withdrawn application is discarded, a red banner will appear at the top of the *Withdrawn application data/Refused application data* page:

Withdrawn application: app141

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

Withdrawn application data

This application has been discarded | Last update: 2024-04-05

Withdrawn application data

Notified Body

Notified Body number: 1912

Name: Kiwa Dare B.V.

Country: Netherlands

Withdrawn application details

Decision Type: Withdrawn application (by MF)

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

Conformity assessment procedure: (MDR) EU quality assurance certificate (Annex XI Part A)

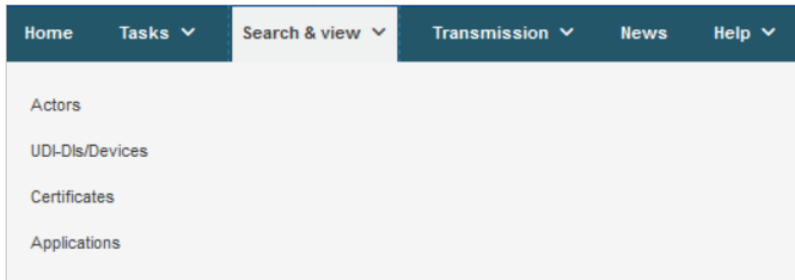
Application reference number: app141

Decision date: 2023-08-17

12 Search and view

12.1 Search and view certificates

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



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

Welcome to EUDAMED

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

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

[See all the news](#)

Tasks

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

My Actor data

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

User management

- Assess user access requests
- Manage your users

UDI-DIs/Device

- Manage SS(C)P

Certificates management

- Register an issued certificate
- Manage your certificates

Application

- Register a refused certificate
- Register a withdrawn/refused application
- Manage your refused certificates/applications

CECP

- Register a Clinical Evaluation Consultation Procedure (CECP)
- Manage your CECPs

Search & View

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

- Actor module
Actors
- UDI-DI module
UDI-DIs/Devices
- Certificate module
Certificates
- Certificate module
Applications

3. EUDAMED will display the filters available for searching:

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:

Device data

Device identification:

Enter the device identification value/text:

Risk class:

4. Click **Search**. A list of matching records will be displayed:

Showing 1 to 6 of 6 entries Show entries per page

NB number II	MF/PR SRN II	SRN AR II	Certificate number II	Certificate type II	Date of issue II	Date of expiry II	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

5. 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: [Lang.Certificate.pdf \[174 KB\] IPTJ](#)

12.1.1 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 [Search and view certificates \[124\]](#) to search and view certificates.

1. 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 * and

YYYYMM-DD YYYYMM-DD

Date of submission

Between and

YYYYMM-DD YYYYMM-DD

Date of expiry

Between and

YYYYMM-DD YYYYMM-DD

2. Complete the search criteria, and click **Search** to generate the result:

Search results for certificates

Active search fields:

Searching for: Certificates Enable filters for certificates bulk download: Certificate Type: (MDR) EU quality assurance certificate (Annex XI Part A) Between: 2021-01-01

and: 2022-01-01

Showing 1 to 20 of 23 entries Show entries per page

NEB number <input type="button" value="X"/>	MF/PR SRN <input type="button" value="X"/>	SRN AR <input type="button" value="X"/>	Certificate number <input type="button" value="X"/>	Certificate type <input type="button" value="X"/>	Date of issue <input type="button" value="X"/>	Date of expiry <input type="button" value="X"/>	Status
NE-1039	BE-PR-000000022		MDR/quality/ia	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-21	2024-07-06	Amended
NE-1039	BE-MF-000000121		5321_13	(MDR) EU quality assurance certificate (Annex XI Part A)	2021-07-20	2022-07-31	Issued
NE-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
NE-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

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



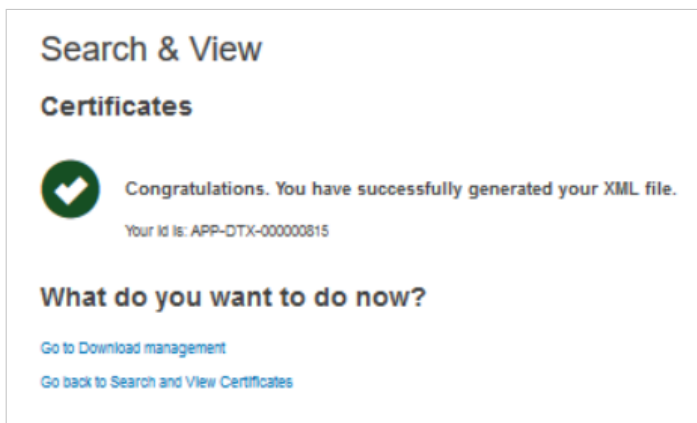
NOTE

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

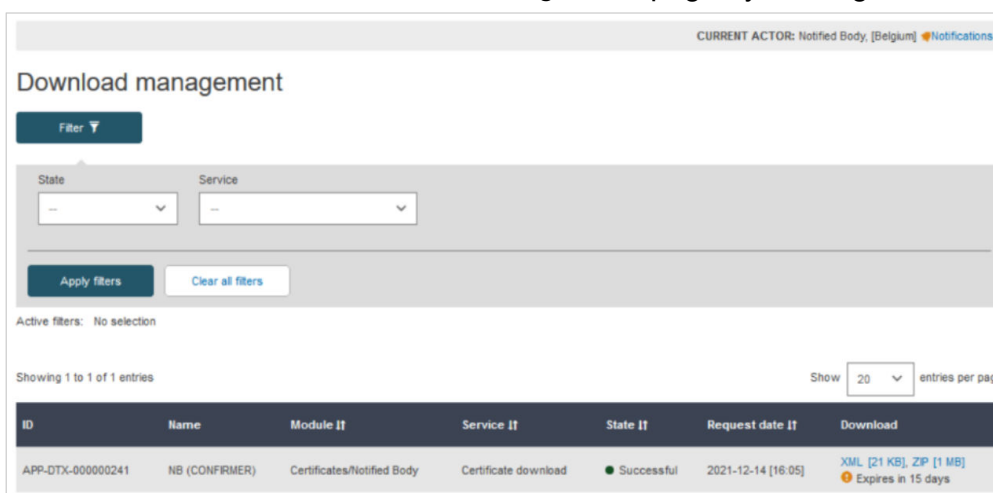
- A pop-up window prompts you to confirm your action:



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

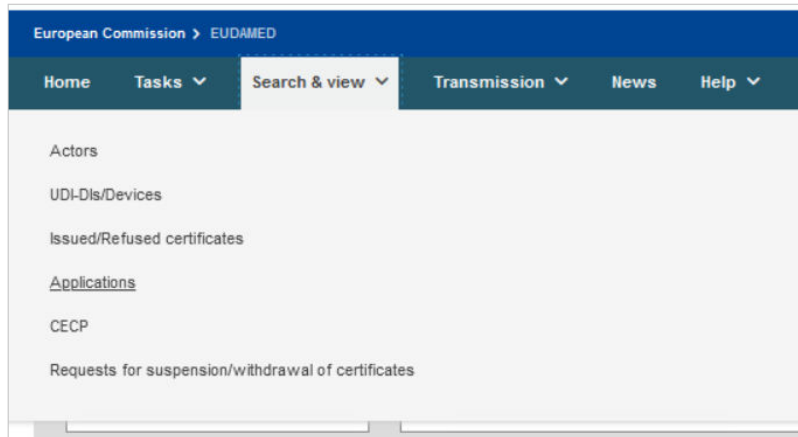


- The generated XML response file, along with related zipped documents, can be downloaded within the *Download management* page by clicking on it:

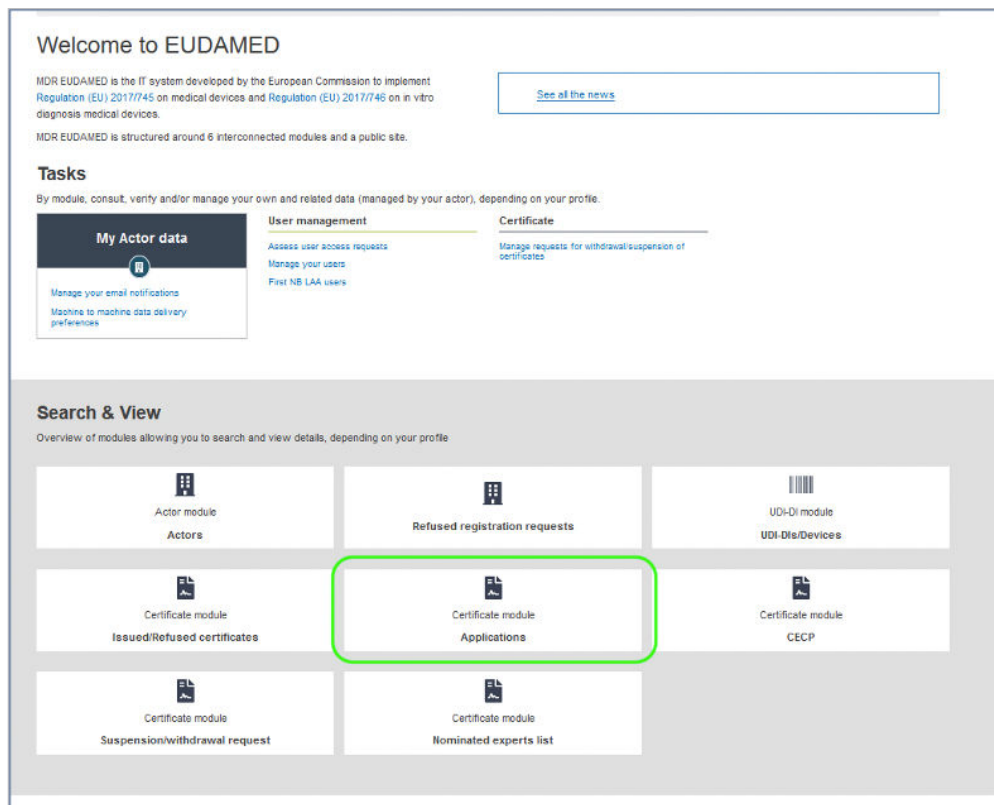


12.2 Search and view refused/withdrawn applications

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



Alternatively, use the *Search & View* section in the dashboard:



2. Next, the refused/withdrawn applications search page will be displayed:

Applications

Application data

Searching for: NB identification: Conformity assessment procedure:

Application reference number: Economic operator Actor ID/SRN: Economic operator name:

Decision date: Between and

Device data

Device identification: Enter the device identification value/text:

Risk class:

- Enter the search criteria and click on **Search**. A list of refused/withdrawn applications will be displayed:

Search results for refused/withdrawn applications

Active search fields: Searching for:

Showing 1 to 13 of 13 entries Show entries per page

NB number	MF/PR Actor ID/SRN	Actor ID/SRN AR	Application reference number	Conformity assessment procedure	Decision date	Decision
	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)

- Click on the desired result record to see its details:

