EUDAMED

European Database on Medical Devices

The Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) require that **the manufacturer draws up an SS(C)P** – Summary of Safety and (Clinical) Performance – for devices of high-risk classes (III, D and C) and implantable devices.

The **SS(C)P must be validated by the Notified Body (NB) involved in the conformity assessment** and made available to the public via EUDAMED.

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.

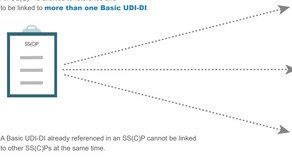
Language of the master document

SS(C)P reference number

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

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).

An SS(C)P is allowed to reference and to be linked to **more than one Basic UDI-DI**.



A Basic UDI-DI already referenced in an SS(C)P cannot be linked to other SS(C)Ps at the same time.

CERTIFICATE REGISTRATION

When can an SS(C)P be uploaded during certificate registration?

For the following combinations of certificate type, device risk class, and type of devices, an **SS(C)P is required** for new issued certificate registration:

QUALITY TYPE CERTIFICATE

EU Quality Assurance certificate (Annex XI Part A)
MDR Class IIa (implantable)

EU Quality Management System certificate (Annex IX Chapter I)
MDR Class IIb (implantable that are sutures/staples/dental fillings/…)
MDR Class IIa (implantable)
IVDR Class C (not for self-testing, near-patient testing nor *in vitro* diagnostic)

PRODUCT TYPE CERTIFICATE

EU Technical Documentation certificate (Annex IX Chapter II)
MDR Class III
MDR Class IIb (implantable)
IVDR Class D
IVDR Class C

EU Type Examination certificate (Annex X)
MDR Class III
MDR Class IIb (implantable)
IVDR Class D
IVDR Class C

EU Product Verification certificate (Annex XI Part B)
Class IIa (implantable)

A new version of SS(C)P can be created when amending, supplementing, restricting, re-instating and re-issuing a certificate.

SS(C)P INFORMATION

What information should be provided when registering a certificate?

Notified Body must provide the following information in order to register an SS(C)P during the certificate registration process:

- SS(C)P reference number + SS(C)P revision number
- Date issued
- SS(C)P PDF master document with its language
- The related (at least one) Basic UDI-DI(s)

Only during the **Quality type certificate registration** must the Notified Body specify if **the SS(C)P master document is validated or not**. It must be already validated for Product type certificates.

SS(C)P MANAGEMENT

How to manage and upload translations

Several translations can be added to a version of the master document by the Notified Body via the SS(C)P management page (a current feature that will change in the future).

Notified Body must provide the following information in order to upload new translation(s) to the master document:

- Received date (from MF)
- SS(C)P translation document + translation language

NEW SS(C)P REGISTRATION

How to register a new SS(C)P outside certificate registration

Notified Body can add **a new SS(C)P** from the SS(C)P Management screen **for already registered Basic UDI-DI(s)** and **an already registered Quality type certificate**.

Notified Body must select the following information:

- **Certificate ID** (existing certificate)
- **Manufacturer** (automatically populated from the selected certificate)
- **Basic UDI-DI(s)** (one or many)

Notified Body must provide the following information:

- SS(C)P reference number
- SS(C)P revision number for the first version of the SSCP
- Issued date
- Master document
- Language of the master document
- Specify if master document is validated