European Commission

EUDAMED

European Database on Medical Devices

The **Notified Body** must follow the clinical evaluation consultation procedure (CECP), where applicable, when performing a conformity assessment of class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product (Article 54 of Regulation (EU) 2017/745 on medical devices (MDR)).

CECP

REGISTRATION CONDITIONS

Conditions for being able to register a Clinical Evaluation Consultation Procedure

Only Notified Bodies designated under the MDR can register a CECP in EUDAMED.

The Notified Body must assign an **Application ID** to the application requests for conformity assessment it receives. When registering a CECP in EUDAMED, the Application ID is required.

A CECP must be associated to **a single Notified Body**, and to **a single manufacturer**.

REQUIREMENTS

For which procedure and risk class is a CECP relevant?

A CECP can be registered for the following combinations of procedure (certificate) type under MDR and device risk class:

FOR PRODUCT CERTIFICATE

TD

Certificate type

EU Technical Documentation certificate (Annex IX Chapter II)

Device risk class

- ✔ Class III (implantable)

TE

Certificate type

EU Type Examination certificate (Annex X)

Device risk class

- ✔ Class III (implantable)
- ✔ Class IIb active devices intended to administer and/or remove a medicinal product

FOR QUALITY CERTIFICATE

QMS

Certificate type

EU Quality Management System certificate (Annex IX Chapter I)

Device risk class

- ✔ Class IIb active devices intended to administer and/or remove a medicinal product

REQUIRED INFORMATION

What kind of information is required for the registration?

When **following** a CECP

The **Basic UDI-DI(s) must always be known** and **provided**

When **not following** a CECP

The Basic UDI-DI can be already registered in the **EUDAMED UDI-DI/Device module** or not

Class IIb active intended to administer and/or remove a medicinal product

The device can be provided by Name or Model (when Basic UDI-DI is not known)

Notified Body must provide the following document:
Clinical Evaluation Assessment Report (CEAR)

Additionally, Notified Body must provide a reason for not following the CECP with complementary information explaining the reason

CECP

CECP is only applicable for **MDR** in EUDAMED

MECHANISM FOR SCRUTINY

Mechanism for scrutiny is relevant for both **MDR** and **IVDR** in EUDAMED

MECHANISM FOR SCRUTINY

REQUIREMENTS

When can a link to a CECP be required for MDR certificate registration in EUDAMED?

FOR PRODUCT CERTIFICATE

TD / TE

FOR QUALITY CERTIFICATE

QMS

(Class IIb non-implantable active devices intended to administer and/or remove a medicinal product)

Basic UDI-DI is known and the CECP references the same Basic UDI-DI

Link to CECP for the concerned Basic UDI-DI(s) is automatically made

Basic UDI-DI is not provided in certificate

If the certificate covers class IIb device(s), the system warns the user of the possible necessity to link a CECP (mechanism for scrutiny) and provides a list of possible CECPs (if any) for the Notified Bodyto select from, together with the related Basic UDI-DI(s)

Mechanism for scrutiny could be done outside EUDAMED in the absence of the features in EUDAMED, in this case, the system will allow the registration of certificates without mechanism for scrutiny

FOR REFUSED CERTIFICATE

OR

FOR WITHDRAWN APPLICATION

CECP

Same Application ID

Link between the refused certificate or withdrawn application and the CECP is automatically created

REQUIRED INFORMATION

What information to provide when registering a certificate

Within the mechanism for scrutiny step, Notified Body must select (where applicable) from a pre-defined list, the **Basic UDI-DI(s)** related to the mechanism for scrutiny that is/are within the scope of the Certificate.

For **MDR**, the **registered CECP(s)** are automatically linked for the related Basic UDI-DI(s). Except for QMS, where the CECP and related Basic UDI-DI(s) must be selected manually.

Notified Body must provide the following documents besides the SSCP(s):

- Experts panel scientific opinion document (if applicable)
- Instructions for use document(s) per Basic UDI-DI
- Justification document (in case of divergent views with the expert panel)

For MDR, mechanism of scrutiny only applies when CECP was followed.

For **IVDR**, Notified Body must provide the **following documents besides the SSP(s)**:

- Laboratory tests and the scientific opinion by the EU reference laboratory (EURL), if applicable
- Expert panel views, if applicable
- Instruction for use document per Basic UDI-DI
- Justification document (if not following the scientific opinion)

For IVDR, mechanism of scrutiny applies for class D devices.

DG Health and Food Safety