

**EUDAMED** 

European Database on Medical Devices

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)).

The **Notified Body** must follow the clinical evaluation consultation procedure (CECP), where applicable,

**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.





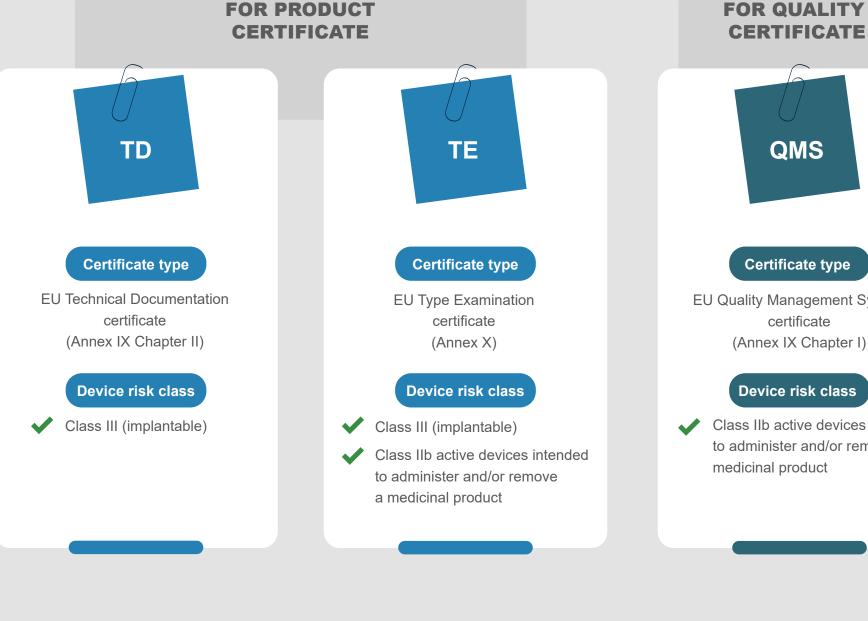
# A CECP can be registered for the following combinations of procedure (certificate) type under MDR and

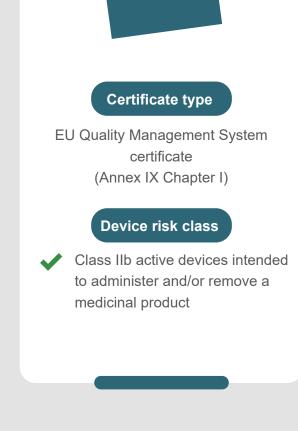
REQUIREMENTS

For which procedure and risk class is a CECP relevant?

device risk class:

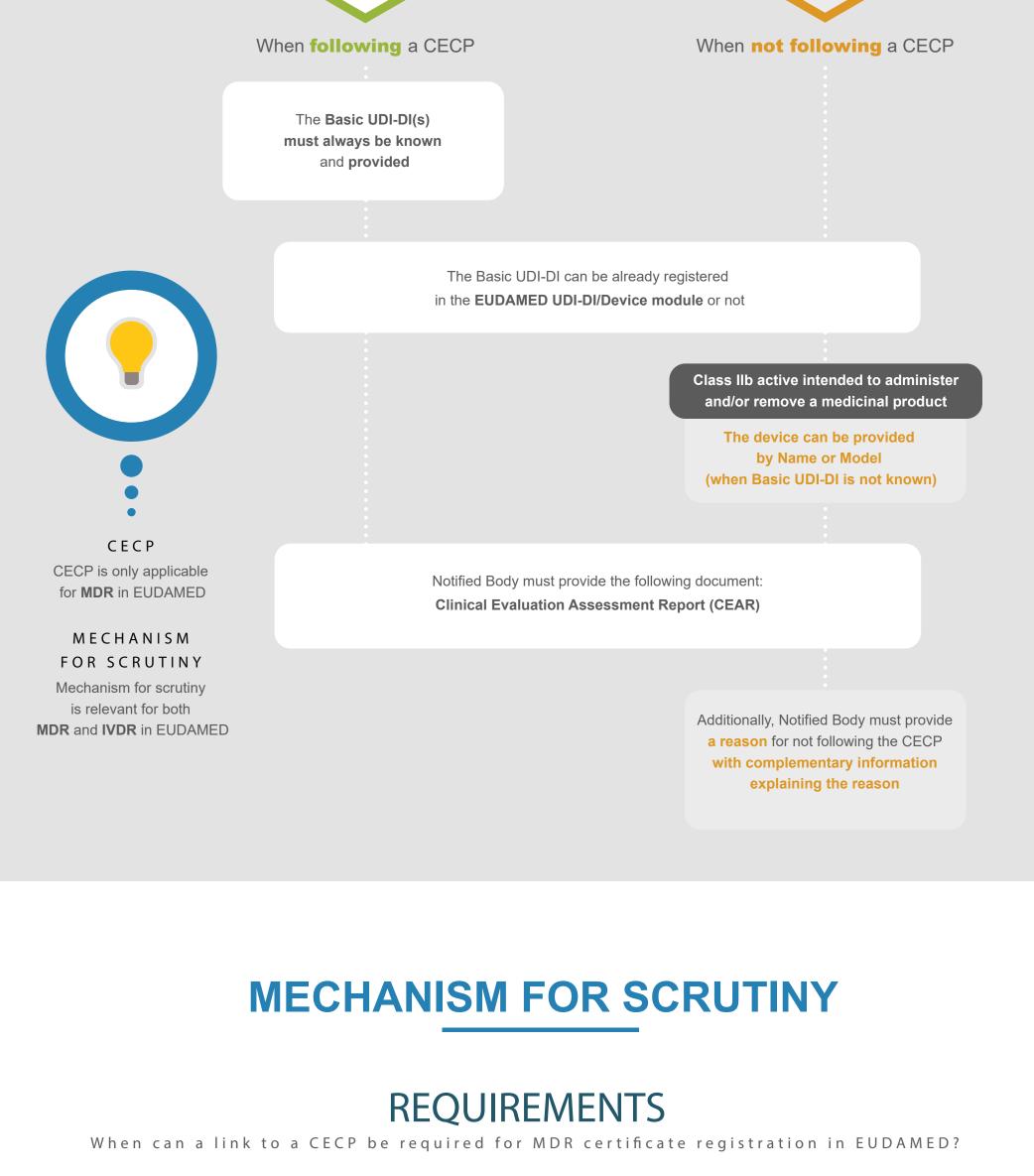
**FOR PRODUCT** 





REQUIRED INFORMATION

What kind of information is required for the registration?



## intended to administer and/or remove a medicinal product)

**FOR QUALITY** 

**CERTIFICATE** 

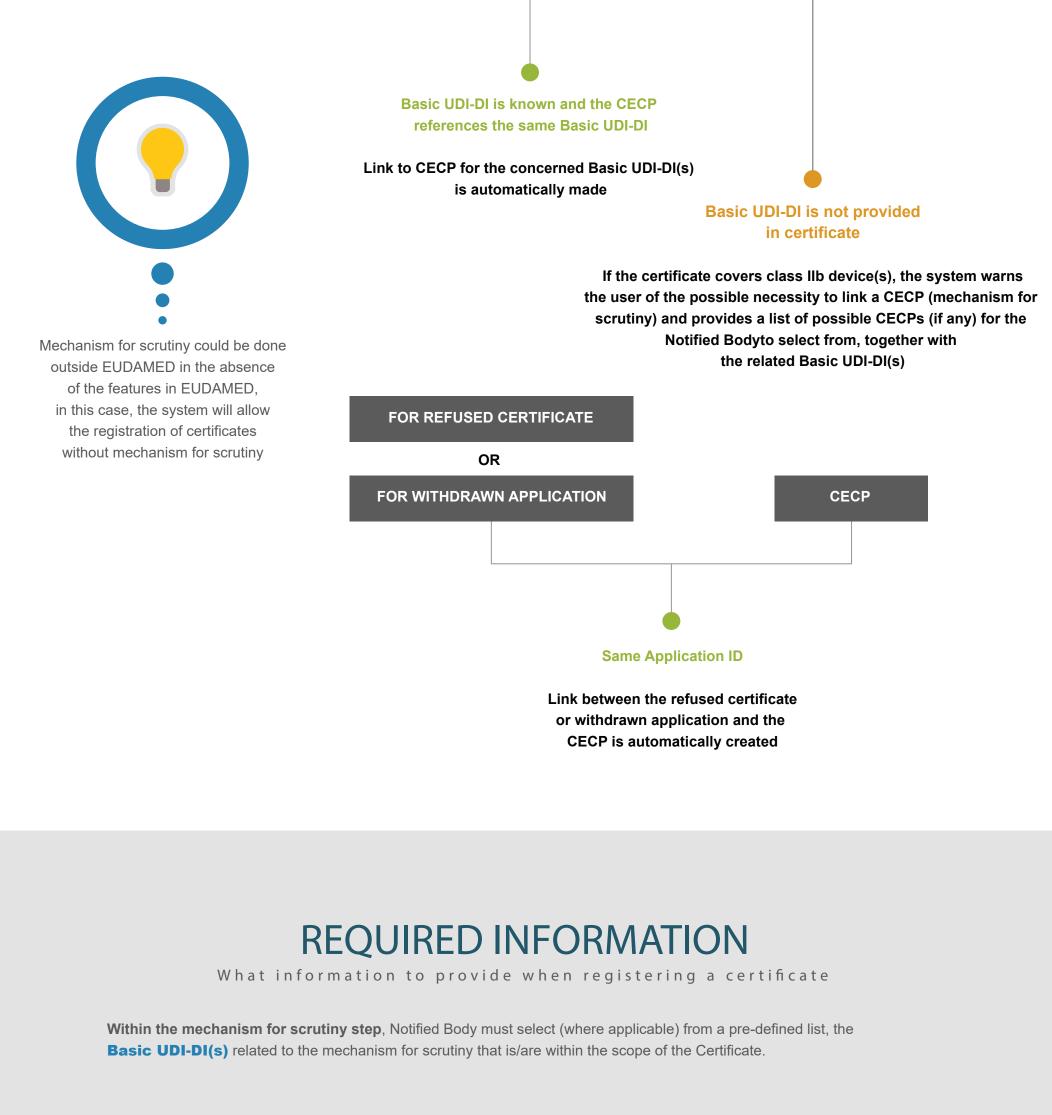
**QMS** 

(Class IIb non-implantable active devices

**FOR PRODUCT** 

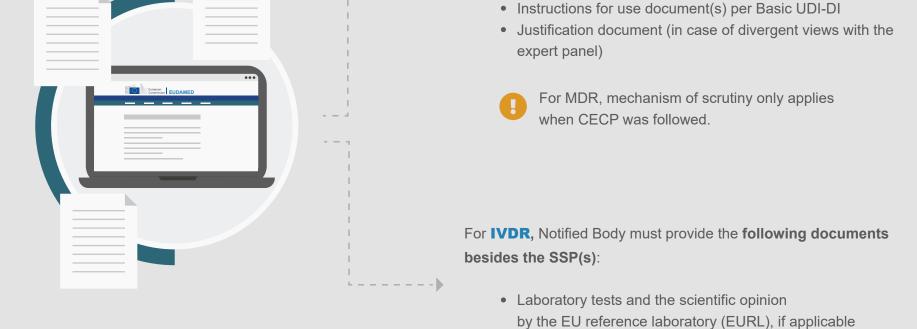
**CERTIFICATE** 

TD / TE



### 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):



Instruction for use document per Basic UDI-DI

• Justification document (if not following the scientific opinion)

Expert panel views, if applicable

• Experts panel scientific opinion document (if applicable)