European Commission

EUDAMED

European Database on Medical Devices

Where **the Competent Authority (CA) of a Member State**, based on data obtained by Vigilance or Market Surveillance activities or on other information, has reason to believe that a device may present an unacceptable risk or does not comply with the requirements laid down in the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), it shall carry out **an evaluation of the device concerned** covering all requirements laid down in the Regulation relating to the risk presented by the device, or to any other non-compliance of the device.

In case the evaluation finds that **corrective actions are required and/or measures have to be taken** because a device presents an unacceptable risk, other non-compliance or the preventive health protection, **it must be reported to EUDAMED by the Competent Authority**.

PROCEDURE TYPES

What are the procedure types?

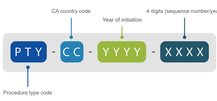
In EUDAMED, a **procedure** *is a collection of data stating the violation and the actions required by authorities and economic operators to address risks posed by a medical device.*

MDR ART 95 / IVDR ART 90
Devices presenting an unacceptable risk to health and safety

MDR ART 97 / IVDR ART 92
Other non-compliance

MDR ART 98 / IVDR ART 93
Preventive health protection measures

The Procedure ID is generated by the system when the Competent Authority initiates the creation of a new procedure.



'UNR' for procedure type 'Devices presenting an unacceptable risk to health and safety'
'ONC' for procedure type "Other non-compliance"
'PHP' for procedure type "Preventive health protection measures"

PROCEDURE REGISTRATION

How to register a procedure and any additional information?

The **Competent Authority shall notify** the Commission, the other Member States and the Notified Body (that issued the certificate), **via EUDAMED, of the corrective actions** it required the Economic Operator to take in the case of devices presenting an unacceptable risk to health and safety, **and of the measures** taken because the Economic Operator did not perform the corrective actions in due time for devices presenting an unacceptable risk to health and safety, or for other non-compliance, or because of preventive health protection.

DEVICES PRESENTING AN UNACCEPTABLE RISK TO HEALTH AND SAFETY

Initiating Competent Authority

Other competent authorities

MEASURE & ADDITIONAL INFORMATION BY OTHER CA
Any Member State CA, other than that which initiated the procedure, shall inform the Commission and the other Member States of **any additional relevant information at their disposal** relating to the non-compliance of the device concerned, and of any measures adopted by them in relation to the device concerned.

OBJECTION BY OTHER CA
In the event of **disagreement** with the notified national measure from the initiating CA, the **other CAs shall inform** the Commission and the other Member States of their objections **without delay and within two months of receipt of the notification**.
Commission may also enter objections

OTHER NON-COMPLIANCE / PREVENTIVE HEALTH PROTECTION MEASURES

For the creation of a procedure and all related actions, the system sends a notification to the relevant actors:
- Notified Body (as referred to in the MSU Procedure)
- CA (owner and other CAs responsible for market surveillance)
- EC (Confirmer profile for MSU module)

PROCEDURE INFORMATION

PROCEDURE TRIGGER(S) IDENTIFICATION

What information to provide for a trigger?

For the following trigger type(s)
Final Inspection Report (MSU)
Incident (Vigilance)
FSCA (Vigilance)
Serious Adverse Event (CIPS-Incident)

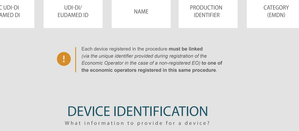
The CA may provide **the trigger link** in EUDAMED by entering an identifier corresponding to a report/incident registered in EUDAMED and selecting the record from the registry.

In all other cases
The user may provide an identifier corresponding to an existing report/incident.

In all cases, a **procedure trigger file** *can be provided.*

ECONOMIC OPERATOR(S) IDENTIFICATION

What information to provide for an economic operator?



Economic Operator is registered in EUDAMED
The system automatically populates the information of this Economic Operator.

Economic Operator is not registered in EUDAMED
General information for this Economic Operator must be entered manually.

For non-registered economic operators, **a unique identifier** for this procedure must be given, in order **to link the EO to its device identified in this same procedure.**

DEVICE SCOPE TYPES

What are the different device scope types?

The user must provide device information based on **following device scope types**

- BASIC UDI-DI /EUDAMED DI
- UDI-DI/ EUDAMED ID
- NAME
- PRODUCTION IDENTIFIER
- CATEGORY (EMDN)

Each device registered in the procedure **must be linked** *via the unique identifier provided during registration of the Economic Operator in the case of a non-registered EO* to **one of the economic operators registered in this same procedure**.

DEVICE IDENTIFICATION

What information to provide for a device?

NOTIFIED BODY IDENTIFICATION

Which Notified Body has access to the procedure?

The Competent Authority can select one or more notified bodies from predefined list.

Notified Body

Notified Body referenced in this procedure will have access to this procedure and related items.

DG Health and Food Safety