

EUDAMED

European Database
on Medical Devices

Market surveillance module

Stuttgart Workshop – 21 May 2025

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Competent authorities

This module is dedicated to Competent authorities since about market surveillance, most of the functionalities and obligation are for them

EC

May view all and add objections for measures taken by CAs due to device presenting an unacceptable risk

Notified bodies

Only rights to view some information to which they are related/referenced

Market surveillance has links with all modules of EUDAMED but not necessarily dependencies since it can provide reference to for example organisations and devices not registered in EUDAMED.

Annual summary reports

- Annual summary reports of the results of the surveillance activities made and provided by the national Competent authority responsible for market surveillance
- As a PDF document with few meta-data (including year)
- Only for CAs/DAs and EC

4 years reports and their summary

- 4 years reports and their summary of the results of the reviews and assessments of the market surveillance activities of the Member States
- To be provided by the national Competent authorities responsible for market surveillance
- As a PDF document with few meta-data (including period year-month)
- Only for CAs/DAs and EC except for the summaries that are publicly available

Final Inspection reports

- Final inspection reports made and provided by national Competent authorities responsible for market surveillance
- As a PDF document with few meta-data (including economic operator concerned)
- Only for CAs/DAs, EC and referenced NB(s)

Devices presenting an unacceptable risk

- Information from national Competent authorities in relation to devices presenting an unacceptable risk to health and safety (Procedures, Corrective actions and if applicable Measures, Additional information and Objections)
- To be provided by the national Competent authorities responsible for market surveillance (initiating CAs and other CAs)
- Only for CAs/DAs, EC and partially to referenced NB(s)

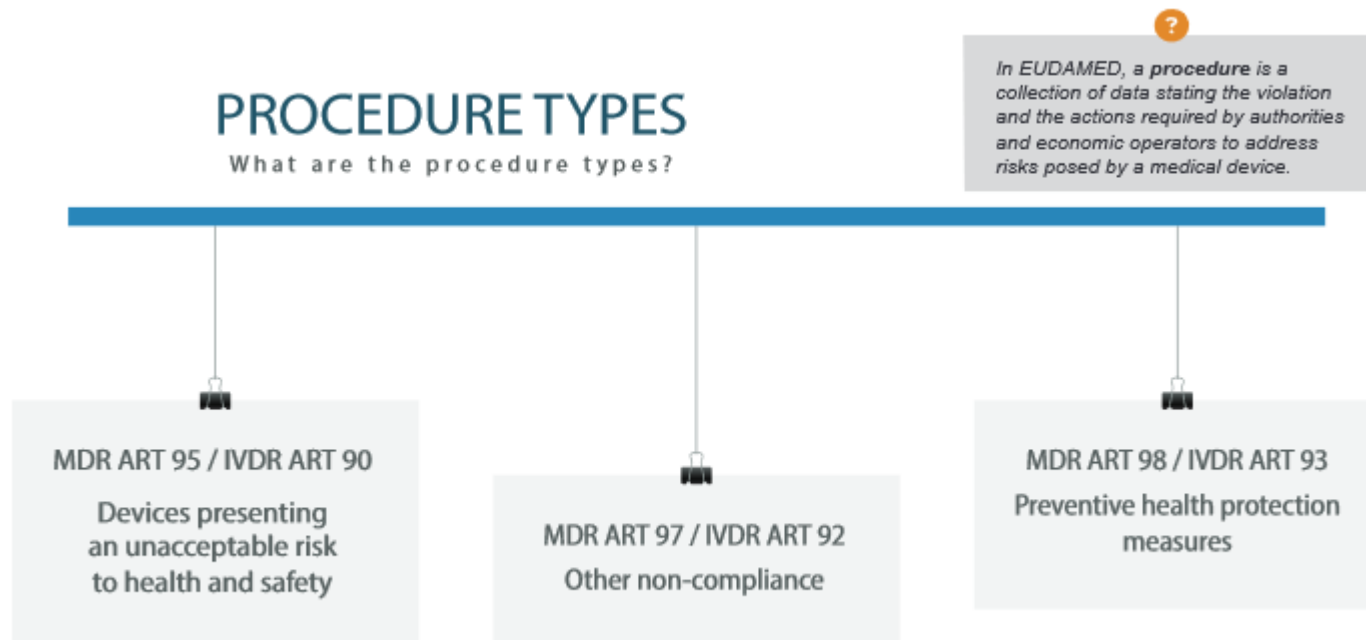
Other non-compliance measures

- Information from national Competent authorities on measures they have taken due to non-compliance of products not presenting an unacceptable risk to health and safety or to other aspects of the protection of public health
- To be provided by the national Competent authorities responsible for market surveillance
- Only for CAs/DAs, EC and partially to referenced NB(s)

Preventive health protection measures

- Information from national Competent authorities on the preventive health protection measures they have taken
- To be provided by the national Competent authorities responsible for market surveillance
- Only for CAs/DAs, EC and partially to referenced NB(s)

Infographic on market surveillance procedures



Market surveillance procedures

Procedures for devices presenting an unacceptable risk, other non-compliance measures and preventive health protection measures

User profile for CAs/DAs/EC and NBs

- **Slim viewer for NBs:** May view some market surveillance registered data in which they are referenced
- **Slim viewer for CAs/DAs and EC:** May view all market surveillance registered data

Note: Users accessing on behalf of a Notified body may only have the Slim viewer profile

User profiles for CAs and EC

- **Confirmer:** May submit market surveillance data on behalf of their authority for having them registered and has the rights of a Proposer
- **Proposer:** May create market surveillance draft item versions and delete them and has the rights of a Fat viewer
- **Fat Viewer:** May view draft market surveillance data owned by his/her authority and has the rights of a Slim viewer

Bulk and M2M download

Only for Final
inspection reports and
procedures/measures

No bulk or M2M upload
(First priority after
MVP: Final inspection
report upload)



Thank you!



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