# Document from Commission services

**DG Health and Food Safety - Unit B6**
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## Fact sheet on MDR requirements for Transparency and Public Information

The purpose of this fact sheet is to list information which will be available to the public in accordance with transparency obligations in MDR considering that some requirements will be applicable only once the European database on medical devices (Eudamed) is fully functional.

Transparency is a key objective of the Medical Devices Regulation (MDR) aiming at providing a large access to relevant information to the public and strengthening public and patient confidence in the safety of medical devices placed on the EU market.

The transparency requirements under the MDR can be divided in different categories:

- information on medical devices made accessible to the public in Eudamed.
- Information which is pro-actively made publicly available outside Eudamed by the Commission, the national competent authorities, the industry or the notified bodies.

Most of the requirements on Transparency and public access to information are linked to the Eudamed, which is planned to become fully functional by May 2022.

The public access to the information registered in the different modules of Eudamed is extensive. It will provide citizens with the possibility to search for information related to devices, their manufacturers and certificates of conformity, the notify bodies which have delivered them and some information related to the clinical investigations and the incident reports associated with the devices.

For each module of Eudamed, two interfaces are being developed: one accessible only by the actors (Member States, operators and notified bodies) and one for the public. It means that each time a new module is released (e.g. actors, devices or certificates), the two interfaces are simultaneously made available.

The MDR transparency requirements listed below are presented separately depending whether they will be available in or outside the Eudamed database. The list below focusses on key information to be made available and is not exhaustive:

### 1. List of key information which will be accessible to the public in Eudamed

The information accessible to the public in Eudamed relates to the:

- **Registration of all manufacturers**, their **authorised representatives** and **importers** which are placing medical devices on the EU market,

- **Registration of devices,** the **core elements of the UDI database** of part B of Annex VI, including the basic UDI and UDI-DI of devices,

- **Registration of certificates of conformity**, their scope and validity period,

- **List of notified bodies designated under the MDR**, their identification numbers and their conformity assessment activities through a link to NANDO database and the **list of their subsidiaries**,

- **Scientific opinions of the expert panels** and the written justification of the notified body where it has not followed the scientific opinion of the expert panel**,**

- **Clinical investigation reports and their summary**,

- The **summary of safety and clinical performance** reports for implantable devices and class III devices,

- **Manufacturer incident reports** (partial access) and the **field safety notices** for Vigilance activities,

- **Summary of the results of market surveillance activities** on their national territory by each EU Member State.

**2. List of key information which shall be publicly available outside Eudamed**

This information is related to the general transparency requirement in the MDR and will be made publicly available outside Eudamed:

- **National measures** taken by competent authorities for the placing on the market of **single use devices which are reprocessed,**

- **Types and levels of fees** levied by Member States for funding activities carried out by the competent authorities**,**

- **National measures** governing the assessment, designation and notification of notified bodies**,**

- **List of standard fees** from notified bodies**,**

- **Summary of each Member State report** on its monitoring and on-site assessment activities regarding notified bodies,

- **Commission annual summary report of the peer review activitie**s of authorities responsible for notified bodies,

- **Declaration of interests** of top-level management of notified bodies,

- **Declaration of interests** of each member of the MDCG, of its sub-groups except for stakeholder organisations, and of the advisors within the expert panels and expert laboratories,

- **Advice** provided by the expert panels,

- **Names and affiliation** of the members of the MDCG.

The above lists indicates the information which will be made available to the public respectively in Eudamed and outside Eudamed, respectively from the entry into application of the MDR (May 2021) and the release of Eudamed (planned for May 2022).

However, it does not necessarily mean that the information made available in the future will be strictly limited to the one listed. Transparency in the context of the MDR can be considered as a step by step process that may include other areas in the future.

More information, could progressively be made available in Eudamed based on experience gained on the impact of transparency in particular on the various reporting activities and the way this information is beneficial to the public.