SOŁTYSIŃSKI KAWECKI SZLĘZAK

Legal Alert

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EUDAMED database launch time!

On 27 November 2025, the long-awaited decision regarding the functionality of electronic systems belonging to the European database on medical devices (***EUDAMED***) was published in the Official Journal of the European Union![1]

What does this mean for the medical device industry, and what is worth remembering??

1. Modules such as:
   a) the registration of actors – manufacturers, authorized representatives, and importers,
   b) the registration of UDI codes and medical devices,
   c) notified bodies and certificates, and
   d) market surveillance

- are **operational and meet the functional specifications** required by the MDR[2] regulation.

2. Obligations related to the above-mentioned modules will start to apply **from 28 May 2026**, i.e:
   a) registration of actors in EUDAMED will become an obligation, not just a possibility!
   b) medical devices placed on the market will be registered in the EUDAMED database, not notified to the supervisory authorities (in Poland, the *URPL*[3]).
3. Manufacturers of medical devices placed on the market before 27 May 2026, will be obliged to register them in EUDAMED **by 27 November 2026**.

Remember!

1. Distributors of medical devices based in Poland are not obliged to register in EUDAMED. According to the Medical Devices Act,[4] distributors:
   a) "*register*" in the register of distributors of medical devices, systems, and procedure packs maintained by *URPL*, and
   b) enter information about each medical device, system, and procedure pack, imported for the first time into the register
2. The EUDAMED database is still waiting for the development and confirmation of the functionality of the last two modules: (a) clinical investigations and performance studies, and (b) vigilance and post-market surveillance. The European Commission estimates that achieving the full functionality of these modules will be confirmed in Q4 2026.[5]

Are you placing medical devices on the market or distributing them? We will be happy to answer your questions and help you go through the EUDAMED registration process!

[1] Commission Decision (EU) 2025/2371 of 26 November 2025 on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices referred to in Article 34(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council.

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

[3] Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

[4] Act of 7 April 2022 on medical devices.

[5] Health.cc.eurpa.eu (accessed: 27 November 2025)

Contact us!

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