



# EUDAMED

Asphalion provides dedicated services for all EUDAMED related activities with an impact on manufacturers of medical devices, whether you only need initial assistance for the registration of your company or you would like full support for uploading all the data related with the module of UDI/Device of EUDAMED

## Actor registration module

The first module of EUDAMED, actor registration, was opened in December 2020.

This module allows to identify the economic operators (manufacturers, authorised representatives, system and procedure pack producer and importers) related to the medical devices on the European market.

This registration process will include obtaining the Single Registration Number (SRN), a code specific for each role of an entity: for example, would your company act as a manufacturer and as an importer, two codes would be necessary.

These codes will be granted once the economic operator has introduced all the necessary information to EUDAMED and provided the requested documentation.

**Asphalion can assist you with the registration in the actor's module, ensuring a smooth process.**

## UDI/Device module

EUDAMED's second module is planned to become available by September 2021 (if there are no delays).

This module will be critical, as it will gather all the information related to the medical devices marketed in Europe.

The upload of the information to EUDAMED can be performed in three different ways: through the user interface, through XML upload or through machine-to-machine data exchange.

The final approach will mostly depend on the size of your portfolio, along with the available IT resources.

Asphalion can help you identify the best approach, **designing a tailored solution and taking care of all the process** accordingly, so that you do not have to worry about the upload of the data nor of its future maintenance.

## What can Asphalion help you with?

- Assistance on the **obtention of your UDI codes.**
- Assistance on the **registration on the Actors** module of EUDAMED.
- **Full upload of device data** to UDI/Device upload.



If you are interested and want to learn more about the latest EUDAMED developments our about our services, please contact us at: [info@asphalion.com](mailto:info@asphalion.com)