Are you importing devices from outside the European Union onto the European market?

Then the new MDR regulations also apply to you as manufacturer!

At first glance, you might be wondering why you need an MDR or IVDR importer for Europe. The reason is that article 13 of the EU MDR and IVDR requires that all device manufacturers selling in Europe have an importer, a distributor and an authorized representative.

The importing EU is the one who makes the final decision to allow its products to enter the EU or reject them, following the MDR or IVDR regulations, as appropriate. The importer is the one who must double-check that all required compliance steps have been taken, including UDI, EUDAMED device registration, and more.

By working with RQMIS you will be able to centrally have the three requirements that are requested for the entry of a medical product to the EU, UK and US: official importer, distributor and authorized representative, all services in the EU, US and UK. These economic operators are mandatory and having them centralized in the same company is of great advantage to achieve greater marketing and time efficiency.

RQMIS serves in the EU, US and, UK as your:

Official Importer

Official Distributor

Authorized Representative

Tasks RQMIS performs as your official European Importer:

- **Verify** that the devices sold in EU carry the CE Mark
- **Verify** that EU declaration of conformity and technical documentation exist
- **Verify** that correct conformity assessment procedure has been performed
- **Verify** Labelling and accompanying information (IFU)
- **Verify** that Manufacturer has assigned UDI
- **Verify** that EU Importer is identifiable with name and contact details
- **Verify** that Manufacturer is identified/ authorized rep has been assigned
- **Verify** that storage and transportation requirements are fulfilled
- **Check** EUDAMED registration of all Economic Operators
- **Report** to competent authority regarding Serious Incidents/Serious Risks
- **Cooperate** with competent authorities regarding CAPA
- **Store** UDI for Class III implantable devices
- **Check** identification of devices within the supply chain

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