Exploring your opportunity in the European market?

Understanding the regulations and requirements for marketing medical devices in the European Union can be complex, especially for non-member countries looking to enter this market. These regulations are in place to guarantee that medical devices meet the EU standards, emphasizing safety and effectiveness, thus safeguarding the health of patients and users.

What is a Medical Device (MD)?

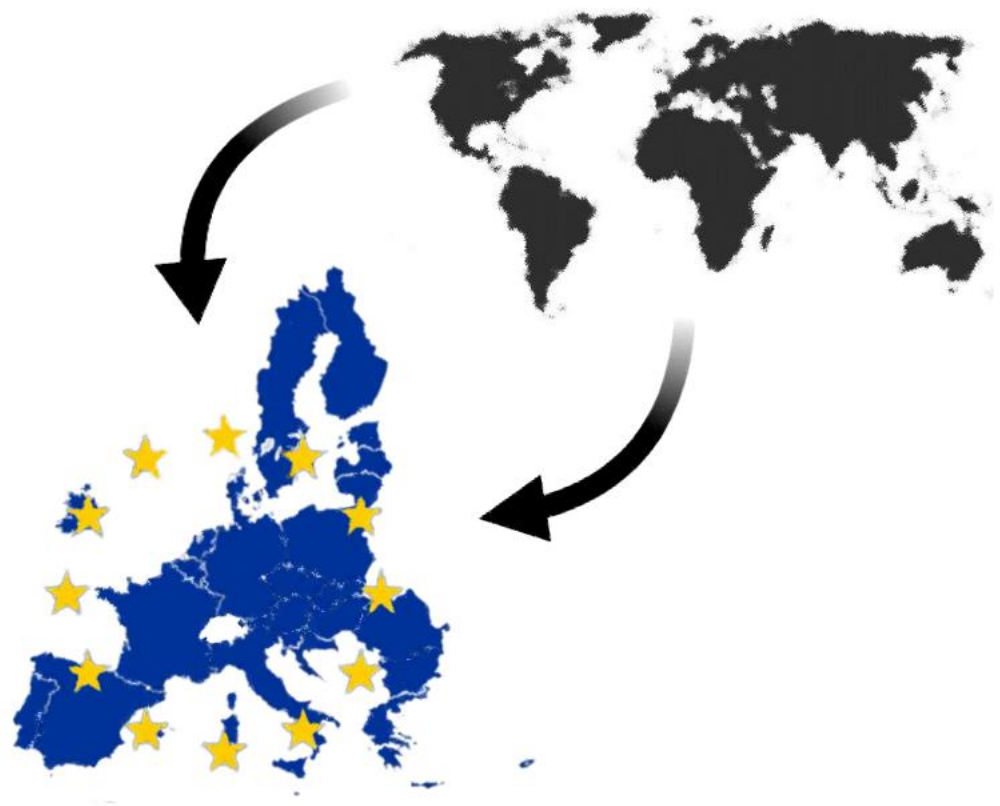
A Medical Device (MD) refers to any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used with the medical propose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, lesion, or disability as well as any modification or replacement of the anatomy or any physiological/pathological process. Products intended for cleaning and sterilization of the devices above fall as well under this definition. *(REGULATION (EU) 2017/745)*

And an *In Vitro* Diagnostic Medical Device (IVD-MD)?

An *In Vitro* Diagnostic (IVD) Medical Device means any medical device which is a reagent, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system intended by the manufacturer to be used in vitro for the examination of specimens (blood, tissue, cells, etc.) derived from the human body, for the purpose of providing information on physiological or pathological processes, predisposition of diseases, safety for recipients, predict treatment responses or monitoring therapeutic measures among others. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices. *(REGULATION (EU) 2017/746)*

How can I market a MD and an IVD-MD in the European Union if I'm not from a member country?

To market a product of this nature, you must ensure compliance with the certification, marking, registration, surveillance, and reporting obligations established by the current legislation (EU 2017/745 and EU 2017/746)



What obligations does current European legislation require?

- ✓ Ensure compliance with essential requirements.
- ✓ Establish risk management procedures.
- ✓ Conduct and maintain clinical evaluations.
- ✓ Manage technical documentation.
- ✓ Update conformity documentation for custom-made products.
- ✓ Apply the CE marking.
- ✓ Comply with identification and registration requirements.
- ✓ Retain accessible documentation for at least 10 years.
- ✓ Implement post-market surveillance.
- ✓ Ensure safe device usage.
- ✓ Remove non-compliant products when necessary.
- ✓ Record and report incidents.
- ✓ Provide conformity documentation upon authorities' request.

We can be your partner since we are accredited to be an Authorised Representative in the EU

By being your EU authorised representative, how can we assist you?

If your company is not part of the European Union, you must appoint an EU Authorised Representative who acts as a bridge between you and the competent health authorities.

Assist with Field Safety Corrective Actions and inform the manufacturer about suspected incidents related to the devices.

Assist with MD and IVD registration obligations.

Consulting on regulatory requirements for commercializing MD and IVD in the European Union.

Keep available a copy on the Technical Documentation and Declaration of Conformity or Certificate of Conformity.

Provide all the information and documentation required when requested by the Competent Authority.

There's more 300K Solutions can help you with:

	Spanish Companies	EU Companies	Non-EU Companies	Clinical Laboratories	Biobanks
Medical Devices Operating Licenses	✓				
Medical Devices Importing and Distribution			✓		
Regulation MD-IVD	✓	✓	✓	✓	
Implementation of Quality Management System	✓	✓	✓	✓	✓
Chemical Products	✓	✓	✓		

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