WHITE PAPER

EXPORTING MEDICAL DEVICES IN EUROPE? YOU NEED AN EUROPEAN AUTHORISED REPRESENTATIVE

This White Paper focuses on the figure of the European Authorised Representative (EU REP), who plays a fundamental role in the CE marking process of Medical Devices. In fact, if you are a Manufacturer based outside the EU, you must appoint an EU REP to export your Medical Devices to Europe. By reading this White Paper you will have useful information on the role of the European Authorised Representative, its responsibilities and how to select it.

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EUROPEAN AUTHORISED REPRESENTATIVE FOR NON-EUROPEAN MANUFACTURERS OF MEDICAL DEVICES

What you need to know!

OVERVIEW

This White Paper is addressed to **Manufacturers of Medical Devices (MD)** and **In Vitro Diagnostic Medical Devices (IVD)**, because with the MDR and IVDR Regulations - the regulatory scenario of the European Union is radically changing.
This implies that it is necessary to keep particular attention to the current **specific regulations in force** in order to market their Medical Devices in Europe.

In order **to market their own Medical Devices in the European Union, Manufacturers** who don't have a physical location in Europe, must necessarily appoint a **European Authorised Representative,** whose acronym could be AR, EU REP or EC REP.

According to **Medical Devices Regulation MDR (EU) 2017/745** and **In Vitro Diagnostic Medical Devices Regulation IVDR (EU) 2017/746**, a **very definitive role** is assigned to the European Authorised Representative.

WHO IS THE EUROPEAN AUTHORISED REPRESENTATIVE?

According to the **definition** in the MDR and IVDR Regulations *"authorised representative' means any natural or legal person established within the European Union who has received and accepted a written mandate from a Manufacturer, located outside the EU, to act on the Manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation"*.

Therefore, a European Authorised Representative must be a **physical or legal person** established in one of the **EU Countries**, that is expressly **designated by the Manufacturer** of Medical Devices and contact reference of the Competent national Authorities on behalf of the Manufacturer.

The EU Authorised Representative is legally liable for defective devices on the same basis as, and jointly and severally with, the Manufacturer in case the latter does not act in compliance with the obligations stated by the regulations (Art. 10). The EU REP contact details appear on the Medical Device label and in EUDAMED.

WHAT ARE THE RESPONSIBILITIES OF THE EUROPEAN AUTHORISED REPRESENTATIVE?

According to **Article 11** of **MDR** and **IVDR**, a European Authorised Representative must be in **full compliance** with the requirements written in this article and assure the compliance of Manufacturer's Medical Devices to the regulations.

In order to assure this the **European Authorised Representative** must designate at least one **Person Responsible for Regulatory Compliance (PRRC)** who is jointly and severally liable with the Manufacturer, in case the latter does not act in compliance with the obligations stated by the regulation.

The **European Authorised Representative EU REP** has the following **responsibilities**:

- Shall perform the tasks specified in the **mandate** agreed between it and the Manufacturer (MDR/IVDR Article 11(3)).
- Shall provide a **copy of the mandate** to the Competent Authority, upon request (MDR/IVDR Article 11(3)).
- Verify that the **EU declaration of conformity** and **Technical File** have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the Manufacturer (MDR/IVDR Article 11(3)(a)).
- **Keep a current copy of documentation**, together with the EU certificate when present, for the period of time set by the regulation (MDR/IVDR Article 11(3)(b)).
- Verify Manufacturer's registration details on **EUDAMED** (MDR/IVDR Article 11(3)(c)).
- Apply for the **CE marking**.

- In response to a request from a Competent Authority, provide all the **information and documentation necessary to demonstrate the conformity of a device**, in an official EU language determined by the Member State concerned.

- **Forward to the Manufacturer any request by a Competent Authority** of the Member State in which the Authorised Representative has its registered place of business for samples, or access to a device and verify that the Competent Authority receives the samples or is given access to the device.

- **Cooperate with the Competent Authorities** on any preventive or corrective action taken to eliminate or mitigate the risks posed by Medical Devices and comply with all post-market surveillance obligations.

- Immediately **inform the Manufacturer about complaints and reports** from healthcare professionals, patients and users about **suspected incidents** related to a device for which they have been designated.

- **Terminate the mandate** if the Manufacturer acts in contrast to its obligations under the regulations.

- In case of **termination of the agreement**, notify the designated entities and proceed to transfer the necessary information.

As an Economic Operator the European Authorised Representative can be subjected to inspections, announced or not, from the Notified Body designed by the Manufacturer, if necessary, and from the Competent Authorities in any case.

The Competent Authority, in fact, can inspect the European Authorised Representative at any time to determine if they understand their role, have direct access to Manufacturer's documents such as the Technical Documentation and have quality system processes in place.

The **Authorised Representative must be therefore very carefully selected**, as appointing for this role a European Importer or Distributor or an organization that do not have the minimum requirements needed to comply with the regulations is a high risk for the Manufacturer.

WHAT HAPPENS IF THE EUROPEAN AUTHORISED REPRESENTATIVE IS NOT APPOINTED?

Before issuing a CE certificate, the Notified Body requires the appointment of a European Authorised Representative.
In general, for any Medical Device placed on the European Union market, it is mandatory to comply with MDR (EU) 2017/745 and IVDR (EU) 2017/746 Regulation, even if the intervention of a Notified Body is not necessary; therefore, it is essential to identify and appoint a European Authorised Representative for Manufacturers located outside the European Union.
If the European Authorised Representative is not appointed, the Medical Devices may be stopped during customs controls.

HOW TO APPOINT A EUROPEAN AUTHORISED REPRESENTATIVE?

As already mentioned, for Manufacturers located outside EU it is necessary to **appoint an Authorised Representative** to represent their compliance and safety.

The European Authorised Representation must be appointed by a **written mandate**, which describe the obligations stated by the regulations and authorizes to act on behalf of the Manufacturer.

Importers and Distributors can represent the products they import or sell, but this could not be an adequate solution, as the Manufacturer, for reasons of confidentiality, may not want to share the technical documentation and product's know-how.

Appointing a third-party company with any interest to market the device could be the best solution in order to assure independence, compliance and liability of the European Authorised Representative.

➢ 7 GOOD REASONS NOT TO APPOINT THE IMPORTER OR DISTRIBUTOR AS EUROPEAN AUTHORISED REPRESENTATIVE

As anticipated, it may happen that Manufacturer of Medical Devices appoint an Importer or Distributor as their European Authorised Representative but this may cause problems.

Here are **7 important aspects** to consider when the Manufacturer has **to appoint the European Authorised Representative**:

1. **ROLE**
   Under MDR (EU) 2017/745 and IVDR (EU) 2017/746, European Authorised Representative is assigned a regulated role. Importer or distributor may have difficulties fulfilling the regulatory requirements as not adequately structured.

2. **REGULATORY COMPLIANCE**
   The European Authorised Representative has the task of verifying that the **Declaration of Conformity** and the **Technical Documentation** have been drawn up correctly and that the conformity assessment procedure has been carried out. Importer or Distributor is often not skilled enough to perform the regulatory controls and assessments.

3. **TECHNICAL FILE**
   The EU REP must keep a copy of the Manufacturer's Declaration of Conformity, the technical file and relevant certificates and must allow the Competent Authorities of the EU Member States access to this information. Sharing know-how and product information with Importer or Distributor could be dangerous!

4. **SURVEILLANCE AND INCIDENT REPORTING**
   It is the duty of the European Authorised Representative to manage product information and report any incidents. Therefore, the EU REP may have to take decisions that are contrary to the interests of the Importer or Distributor, such as the recall of products. For this reason, the European Authorised

Representative must be able to decide autonomously based on the best interests of the Manufacturer.

5. **ONE SINGLE EUROPEAN AUTHORISED REPRESENTATIVE**
   The Manufacturer must appoint a sole European Authorised Representative, which must appear on labels and on Eudamed. It could be undesirable for the other Importers or Distributors to see a competitor on the labelling of the product to which they must refer for post-market surveillance activities, for example.

6. **PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE**
   Importer or Distributor could not be able to appoint at least one Person Responsible for Regulatory Compliance (PRRC) with all minimum requirements and competencies.

7. **INDEPENDENCE**
   Choosing an independent European Authorised Representative, instead of your Importer or Distributor, represents a great advantage: in the event of termination of the relationship with Importer or Distributor, the devices can be put into the market without interruptions.

The Manufacturer, therefore, must be very careful in choosing the European Authorised Representative to be able to market its Medical Devices in the European Union market, to avoid increasing costs and stress.

CHANGE OF THE EUROPEAN AUTHORISED REPRESENTATIVE

Detailed arrangements for the change of the European Authorised Representative shall be clearly defined in an agreement between the Manufacturer, the outgoing Authorised Representative, and the incoming Authorised Representative. This agreement shall address at least the following aspects:

- The date of termination of the mandate of the outgoing Authorised Representative and date of beginning of the mandate of the incoming Authorised Representative.

- The date until which the outgoing Authorised Representative may be indicated in the information supplied by the manufacturer, including any promotional material.

- The transfer of documents, including confidentiality aspects and property rights.

- The obligation of the outgoing Authorised Representative after the end of the mandate to forward to the manufacturer or incoming Authorised Representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as Authorised Representative.

Furthermore, changing the EU REP involves the reprinting of labels and packaging in order to include the name and address of the European Authorised Representative.

WHY CHOOSE THEMA AS YOUR EUROPEAN AUTHORISED REPRESENTATIVE?

As your European Authorised Representative **Thema** can be in **full compliance with articles 11** and **12** of the **MDR/IVDR** and assure the compliance of your devices to the regulations as Thema:

- has an ISO 13485 certification including the EU Authorised Representative processes;
- executes an accurate pre-screening of the documentation in order to assess the conformity to EU regulations;
- has an adequate insurance policy in case of regulatory issues arising from the market;
- has appointed a Person Responsible for Regulatory Compliance (PRRC) – art. 15 – as requested by MDR/IVDR to the EU Authorised Representative;
- assures the availability to cooperate with Competent Authorities and Manufacturer in case of recalls and field safety corrective actions;
- can help the Manufacturer registering in EUDAMED and in the Member State national database.

THEMA'S EUROPEAN AUTHORISED REPRESENTATIVE SERVICE STEPS

Thema is able to carry out the **service of European Authorised Representative in full compliance with the local regulation**.
Thema ensures **compliance with the assigned obligations** through an **organization managed by processes according to the ISO 13485 standard**, adequate controls on the Manufacturer and the product as well as **adequate insurance coverage** to ensure device marketing compliant with mandatory regulatory requirements.

The European Authorised Representative (EU AR) service offered by Thema is divided in three steps:

- **STEP 1 - Documentation Screening**

In this first step, Thema's experts review all Technical Documentation (TD) and QS documentation.
This activity is important for Thema, because the European Authorised Representative has significant legal responsibilities and we need to make sure that the documentation is in order and correct.
The documentation will be reviewed in compliance with regulations.
This would be an una tantum activity but we would keep all your TD with us and each time you update it we would ask you to inform us and send the modifications. Also, if you add other devices, we would need to see their TD and start a new review.

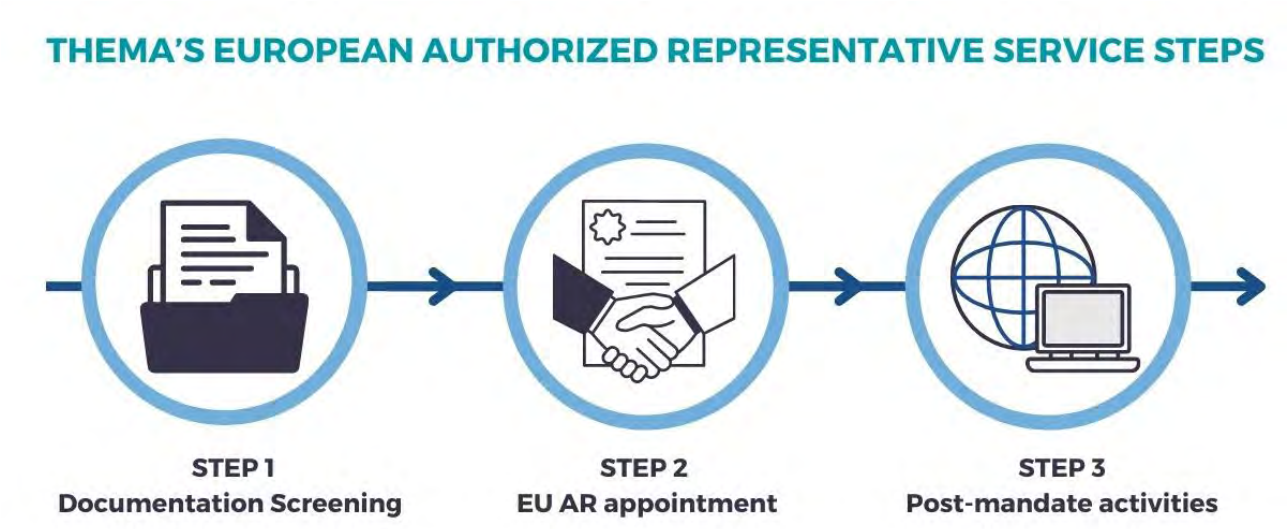
- **STEP 2 - EU AR appointment**

Once STEP 1 is over we can sign a mandate, the Quality Technical Agreement.
There's going to be an annual fee which depends on the highest risk class of your device.

Please keep in mind that **the European Authorised Representative is jointly and severally liable with the Manufacturer in case of non-fulfillment** by the latter of the requirements provided for by the regulations, therefore **EU AR** has a regulatory role with significant responsibilities.

- **STEP 3 - Post-mandate activities**

The **EU AR** should carry out other activities which are not included in the steps above such as: registration in the Italian database, registration in EUDAMED, manage the communications with the European authorities, check all your DHR and manage post-market activities.
These activities would also be carried out through our hourly packages called Hourly Rates for Professional Consultancy.



DO YOU NEED A EUROPEAN AUTHORISED REPRESENTATIVE?

Contact our Customer Service for further information and find out how we can help you!

SOURCES:

- *MDR (EU) 2017/745, Official Journal of the European Union*
- *IVDR (EU) 2017/746, Official Journal of the European Union*

For more information

Thema supports companies operating in the field of Medical Devices and in Vitro Diagnostic Medical Devices in the process of adapting to regulatory requirements, facilitating access to the global market.
For further information visit **www.thema-med.com**

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QUALITY&REGULATORY AFFAIRS

Thema offers **strategic - regulatory consultancy** services to companies producing and distributing **medical devices (MD)** and **in vitro diagnostic medical devices (IVD)**, on national and international markets.
We provide the customer with support in achieving its marketing goals, thanks to a reliable and highly specialized partnership.
Our branches and international partners collaborate with us to find out the solution that bests suits customer's specific needs, protecting even his interests.

CONTACT

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Our services

Strategic
and Regulatory Consulting

Supporting CE
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Italian and European
Ministerial Registrations

International Registrations
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Local Representative

Quality and International
GMPs

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