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MDR / IVDR
EU Importer Services

What Is An EU Importer?
Entity that checks your compliance with the EU MDR and IVDR.

Why Do We Need One?
Article 13 of MDR and IVDR mandates it.

When Do We Need One?
Starting May 26, 2021 for all devices exported to EU under MDD *or* MDR.

Background on the need for the Importer

With the introduction of the European Union's (EU) new Medical Device Regulation (MDR) and the In-vitro Diagnostic Regulation (IVDR), the requirements and responsibilities of four "economic operators" have been defined more prominently:

1) Legal Manufacturer
2) **Importer**
3) Authorized Representative
4) Distributor.

Many of these responsibilities are overlapping and duplicate the activities of these respective economic operators.

As a result, the MDR/IVDR requirements have put more burden and costs on the industry to ensure compliance with the new regulations. MedEnvoy offers an independent Importer service designed to meet your MDR/IVDR obligations while minimizing disruption of your product release and shipping processes.

Benefits of selecting a single independent importer

Why selecting an independent Importer such as MedEnvoy over a distributor or multiple distributors?

- The Importer must be identified on the labeling and distributors would not want to see another distributor as the Importer listed
- The Importer must have access to the Technical File and sharing technical information is better done with a professional independent
- More centralized control over the total European supply chain when a legal manufacturer selects one independent Importer
- Selecting multiple distributors as an Importer will increase the administration and management of contracts, labeling, shipping and overall MDR/IVDR compliance
- Our independent importer services offers the client more control and more efficient and cost-effective management of the

Article 13 Requirements

These are the general obligations as mentioned in Article 13 of the MDR and IVDR. The Importer must:

- Verify that device is CE marked and a Declaration of Conformity has been drawn up
- Manufacturer is identified and Authorized Representative designated
- Device is labelled according to requirements and accompanied by the required Instructions For Use (IFU)
- Unique Device Identification (UDI) has been assigned
- Device is registered in EUDAMED
- Device labeling identifies the importer's name, place of business and address
- Non-compliant products are not placed on the market
- Storage and transportation conditions are suitable
- Register complaints, non-conforming devices, recalls and withdrawals (and keep manufacturer, distributors and EAR informed)
- Inform Competent Authority, the manufacturer and EAR if the importer believes the device is not in conformity with MDR
- Maintain on record a copy of Declaration of Conformity and relevant certificates
- Cooperate with Competent Authorities.

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Service and Fee Structure

MedEnvoy has developed a process that prevents duplication of efforts among your other economic operators.

We have structured our process by utilizing technology to streamline the review and approval of your documentation and other obligations. As a result, there is minimal disruption to your product release, ordering and shipping processes.

The process

For maximum efficiency we will work with you to develop contractual arrangements and QMS procedures which will prevent that redundant activities are being performed by any of your economic operators, while ensuring your compliance with the MDR or IVDR.

Responsibilities that are solely specific to the Importer will be put in place and supported by procedures and work instructions that MedEnvoy will co-develop with you during the service implementation (onboarding), outlining an efficient mode of operandi in the product release, ordering and shipment processes.

The service onboarding includes a QMS procedures review, amendments, and development; CE technical file review where needed; verification of contractual arrangements between manufacturer and relevant economic operators so that applicable MDR / IVDR obligations are addressed.

Notes

- *Non-EU based Legal Manufacturers that have established a subsidiary in the EU can designate that entity to operate as the Importer. MedEnvoy can provide back-office services to the EU entity to ensure all obligations in the role of Importer are being met*
- *MedEnvoy established offices in Great Britain (GB) and Northern Ireland (NI) to provide GB/NI Importer services similar to the MDR/IVDR service for the EU.*
- *MedEnvoy established offices in Switzerland to provide Swiss Importer and Swiss Authorised Representation (CH-REP) services.*

Flat Service Fees

- We charge a one-time flat fee for the onboarding (service implementation).
- Your annual importer service flat fee is based on the anticipated number of shipments and device families in each shipment, not the quantity or value of each shipment.

Request a Proposal

If you have more questions and/or would like to receive a formal proposal, please don't hesitate to contact us:

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