Whitepaper:

Is your European medical device importer MDR Compliant?

EU-MDR Compliant Importing Services

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If you are a non-EU manufacturer of medical devices you need to comply with the Medical Device Regulation (MDR). The Regulation states manufacturers must select an importer that will have to meet the requirements and will be liable and responsible for placing products on the EU market.

At the end of the day the manufacturer remains responsible and liable for the supply chain stated in the MDR/IDR, 2017/745. It is therefore a necessity manufacturers evaluate their economic operating partners such as the importer to guarantee compliance.

This article will provide more information on who you can designate and qualify as your MDR importer in the EU.

Whitepaper read tip:
(Multiple) distributor as importer compliance risk and market complications

GrowthImports is an independent European wide MDR compliant importer that provides hassle-free, cost-effective importing services while allowing our clients to maintain full control and flexibility.

What is the definition of an MDR importer?

According to the Blue Guide / MDR the definition of the Importer is "Any natural or legal person established within the Union that places a device from a third country on the Union market". A product is placed on the market when it is made available for the first time on the Union market.

A product is made available on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. Such supply includes any offer for distribution, consumption or use on the Union market which could result in actual supply (e.g. an invitation to purchase, advertising campaigns). Supplying a product is only considered as making available on the Union market, when the product is intended for end use on the Union market. The supply of products whether for further distribution, for incorporation into a final product, or for further processing or refinement with the aim to export the final product outside the Union market is not considered as making available. Commercial activity is understood as providing goods in a business related context.

As for ‘making available’, the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series. Consequently, even though a product model or type has been supplied before new Union harmonisation legislation laying down new mandatory requirements entered into force, individual units of the same model or type, which are placed on the market after the new requirements have become applicable, must comply with these new requirements.

Who can be the MDR importer?

The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, the operation is always labelled in legal terms as ‘placing on the market’. Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.

You as the manufacturer can also be the importer if you have an entity within the European Union and supply in the market.
If you are selling goods through online resellers such as Amazon or other e-commerce sites and if they are stocking and purchasing from the manufacturer they can be labelled as importer of they are relabelling and reselling they can be defined as the importer. A manufacturer can also designate multiple distributors.

The risks and complications involved in designating (multiple) distributors are explained in this whitepaper.

How to verify compliance of your MDR importer?

Now it is clear who can be the MDR importer it is important to understand the risks and benefits of choosing your importer as the manufacturer will in any case be liable for incompliance in the supply chain.

The first thing to do would be to map your supply chain and determine each role of the economic operators. There is a clear overlap between some of the obligations of the importer and distributor. The main fundamental difference is that the importer will jointly be liable for all products placed in the Union. Once you have selected your importer it is necessary to check whether your importer has the capabilities, processes and willingness to comply with the MDR obligations.

Therefore a manufacturer must understand the level of knowledge and expertise, determine how audits will take place with your importer, do they have an internal PRRC or similar associate, how will they assure compliance, what is their auditing-, inspection- aswell as their traceability procedure, are they registered in EUDAMED and do they have the appropriate labels and symbols. Is there a QMS available that specifically defines the role of the distributor (art. 14) as well as the importer (art. 13) and is there a legal contract with joint liability clearly defined? These are some of the key questions that should be answered and periodically evaluated in a quality agreement.

If your distributor is not specialized, does not have the man power nor the MDR experience, it will raise more risks and concerns for the manufacturer. The manufacturer will be at all times end responsible and so if the distributor or importer fail to comply. This will result into additional efforts, costs and audits to support and verify the compliance of the distributor / importer.

<u>The importer needs to fulfill the following obligations:</u>

√ A natural or legal person established in the European Union

√ Registered and verified by the local authorities

√ Ensure the appropriate conformity assessment procedure has been carried out by the manufacturer

√ If the importer has reasons to believe about the conformity of the product the importer must refrain from placing in the market and shall immediately take the corrective measures necessary to bring that product into conformity and with risks involved inform the CA

√ When placed on the market taking corrective actions

√ The manufacturer has drawn up the technical documentation and affixed the relevant conformity marking (CE)

√ Fulfill its traceability obligations and accompanied, where relevant, the product by the instructions and safety information in a language easily understood by consumers and other end-users as determined in the IFU and labelling procedure in the MDR

√ Indicate the necessary elements on the label and its visibility of safety information printed on the product or the accompanying documents

√ Ensure while a product is under his responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in the applicable legislation

√ Keep a copy of the EU DoC for 10 years or for the period specified in the relevant Union harmonisation act

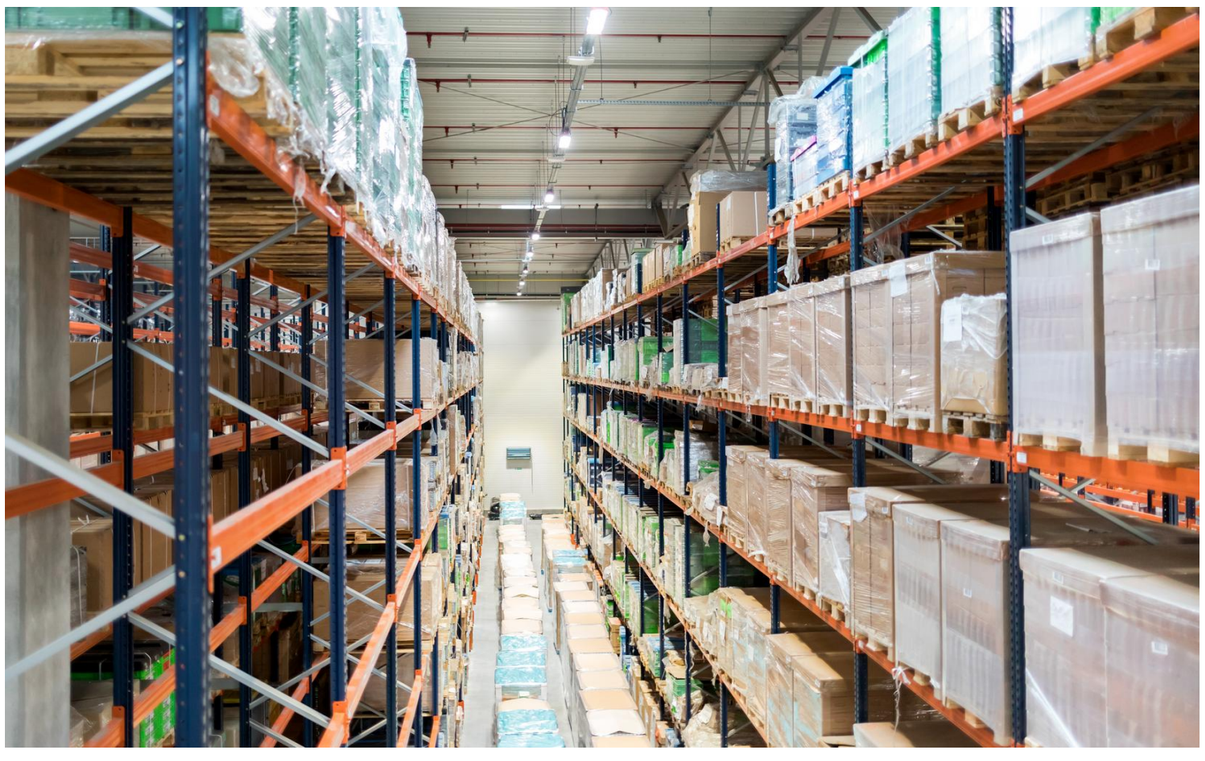
√ Ensure the technical documentation can be made available to the competent authority upon request

√ Cooperate with the CA and upon request provide the necessary information and documentation

√ The Importer must identify any economic operator who has supplied him and to whom he has supplied the product for a period of 10 years after the products has been supplied

√ Inspections of products placed in the market

If you need help in this qualification process and with contracting your importer, please feel free to reach out to us, we would be glad to assist.



Your distributor as your MDR importer?

If your distributor imports your goods directly from the manufacturer and supplies the end-user, it would make your distributor your importer as defined in the MDR. You can also choose to have multiple distributors as your importer. Be aware that distributors have different obligations than importers. That would mean your distributor needs to comply with additional importer obligations.

It can bring substantial risks of incompliance as well as market complications when you designate your distributor as both your importer. You can read **this article** to learn about the compliance risks and complications and why it may be more beneficial to designate 1 independent EU-wide specialized importer.

The importing value of GrowthImports

GrowthImports is an independent MDR compliant importer providing **hassle-free market access while maintaining flexibility, compliance and Increased quality standards.** With over 30 years of combined experience, GrowthImports is dedicated to ensure the facilitation of a compliant and smooth international MDR/IVDR compliant importing process in the European market.

The independence provides flexibility in service, maintained control of the supply chain for manufacturers, reduced incompliance risks and cost effective importing. Channel conflicts can be avoided and distributors who have a wide range of products can focus on their sales and marketing efforts.

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Article:

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Your dedicated EU-MDR compliant import partner

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