EU MEDICAL DEVICE REGULATION (MDR)

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FREQUENTLY ASKED QUESTIONS

What is MDR?

The European Union Medical Device Regulation, EU-MDR 2017/745, or MDR, is a new set of regulations that governs the production and distribution of medical devices in Europe, including medical gloves and masks. Compliance with the regulation is mandatory for companies that want to sell medical devices in the European marketplace. The MDR replaces the previous European Council Directive 93/42/EEC, or MDD.

Why is the MDR being introduced?

The European Council introduced the MDR for several reasons. One is a wish to restore confidence in the regulatory oversight system following several scandals involving companies that marketed unsafe medical devices under the MDD. The Council also wanted to create a single approach to medical device regulation that would be common across all EU member states, rather than continue to allow for differences in interpretation and application across Europe. Finally, the Council wanted to keep pace with scientific and technological developments such as modern software or devices that collect health data. The new MDR will ensure high standards of quality and safety for medical devices being produced in or supplied to Europe. It will do this by establishing a robust, transparent, predictable and sustainable regulatory framework that supports innovation while ensuring better protection of public health and patient safety.

How is the MDR different than the MDD?

While the old MDD was a “directive” that served as a manual for medical device manufacturers who wanted to get a CE marking, the MDR is a “regulation” that more broadly aims to enhance safety for people across Europe. It introduces new responsibilities for economic operators across the medical device supply chain and requires each to verify that a previous operator is compliant. The MDR also introduces new requirements in areas such as clinical evaluation, post-market surveillance, and labelling, as well as new systems that make tracing medical devices easier. **As a regulation, the MDR is legally binding and enforced across all member states with less room for differences in interpretation or enforcement.**

What devices are covered by the MDR?

The MDR defines "medical device" as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings. A full definition can be found in Article 2(1) of the MDR. It is worth noting that a product need not be designed for medical use to be considered a medical device. For example, non-corrective contact lenses, equipment for liposuction and equipment intended for brain stimulation are all considered medical devices according to the definition in the MDR.

Who are the economic operators in the medical device supply chain?

The economic operators in the medical device supply chain are defined in the MDR as follows:

Manufacturer

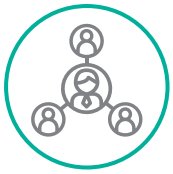
A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Importer

Any natural or legal person established within the Union that places a device from a third country on the EU market.

Authorised Representative

Any natural or legal person established within the EU 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 MDR obligation.



Distributor

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

What are the responsibilities under MDR for each operator in the supply chain?

The MDR elevates the responsibilities of each economic operator in the supply chain, and requires they verify that previous operators have properly complied with relevant MDR requirements. Some examples of important responsibilities for each economic operator are marked in teal in the below table. Those that are new responsibilities for an economic operator are noted by the word "NEW".

Responsibility	Manufacturer	Authorised Representative	Importer	Distributor
EUDAMED Registration	NEW	NEW	NEW	
Product Compliance			NEW	NEW
Conformity after Handling, Storage & Distribution			NEW	NEW
Management of Nonconformities			NEW	NEW
Vigilance Reporting, Including Recalls			NEW	NEW
Correct Labelling / Unique Device Identification	NEW		NEW	NEW
Complaint Management			NEW	NEW
Post Market Surveillance				NEW
Person Responsible for Regulatory Compliance	NEW	NEW		
Sufficient Financial Coverage in Case of Liability	NEW	NEW		

How will MDR ensure devices can be traced across their lifecycle, throughout the supply chain?

Under the MDR, all medical devices will be required to have a Unique Device Identification label (UDI). This information must be visible on either the product itself, or the product package or label. The UDI is intended to improve the traceability of medical devices throughout the supply chain by connecting all the information about each medical device through a digital information repository called EUDAMED. MDR requires that a UDI label be directly attached to a medical device or to its packaging.

When will the MDR go into effect?

The final MDR document was published in May 2017, and the regulations will come into force in May 2021. During the transition period, devices may be placed on the market under either AIMDD/MDD or EU MDR. Medical device companies can receive compliance certification from Notified Bodies up to the effective date of May 26, 2021, and these certificates will remain valid for five years from the date of issuance, allowing for a smooth transition period. Devices that are legally placed on the market before the effective date of May 26, 2021 can be sold until five years after the MDR takes effect – May 27, 2025.

How will the MDR impact medical glove and mask manufacturers like Ansell?

Once the new MDR goes into effect in May of 2021, all previous "directives" will no longer exist or be applicable. All medical glove and face mask manufacturers must be able to prove they have a quality management system and technical documentation to show the products meet the General Safety and Performance Requirements and therefore comply with MDR by May 2021 if they intend to sell gloves and face masks in the European Union. **Ansell already has a certified quality management system and all technical files have been updated, ensuring we are fully compliant with this requirement.** MDR also requires that glove and mask manufacturers follow certain new requirements with regards to document storage, post-market surveillance, and risk assessments of new and existing medical gloves, as well as a Person Responsible for Regulatory Compliance.

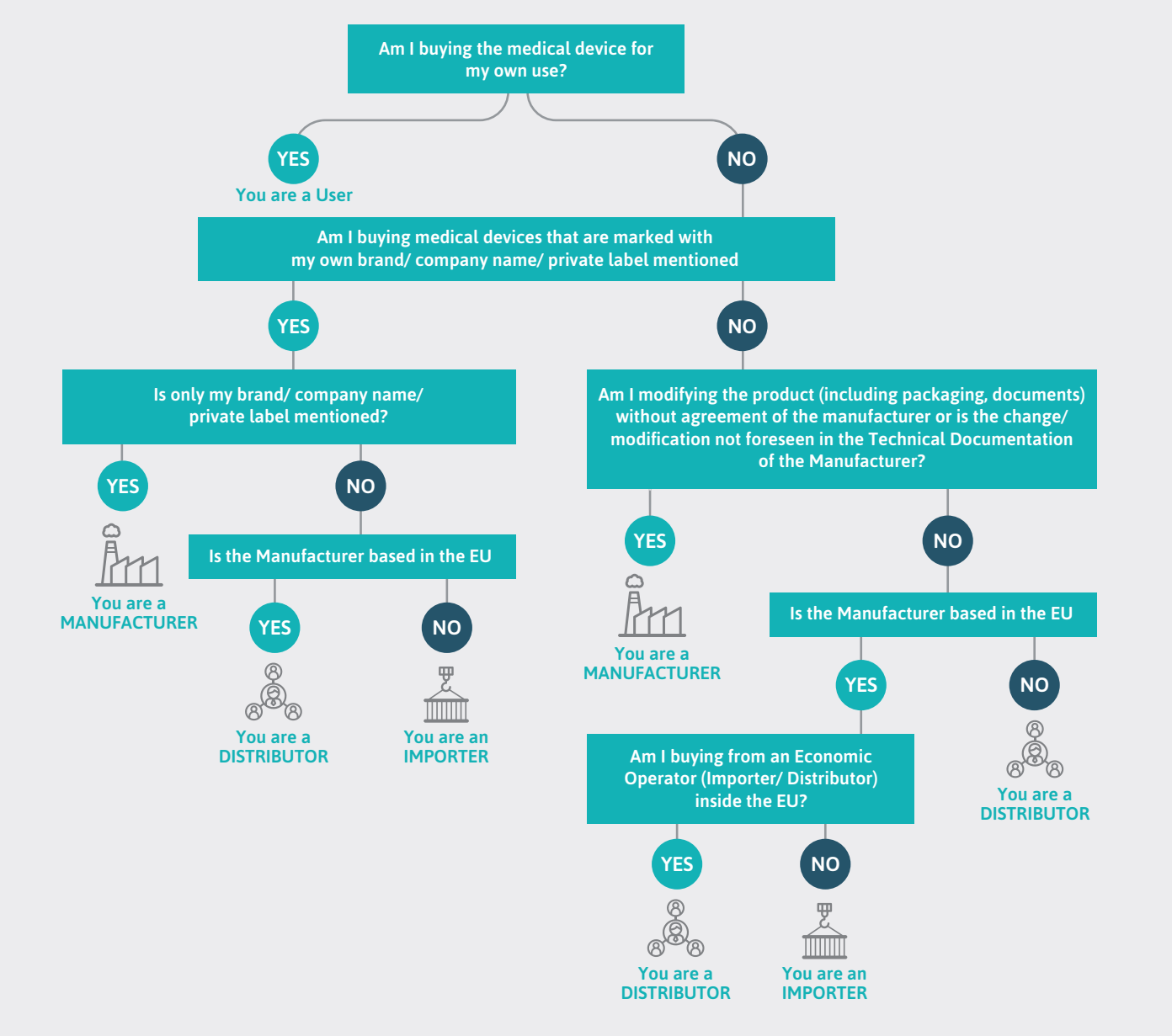
Have the language requirements for labels and instructions changed compared to the current MDD?

Yes. The MDD's passive Article 4 (4) which states that "Member States may require…" the information accompanying the device in national language(s), has been replaced by the EU MDR's active Article 10 (11) which states "Manufacturers shall ensure…" the information accompanying the device is in national language(s). Furthermore, the new EU MDR Annex I (23.1) also requires the information accompanying the device to be made available via the manufacturer's website.

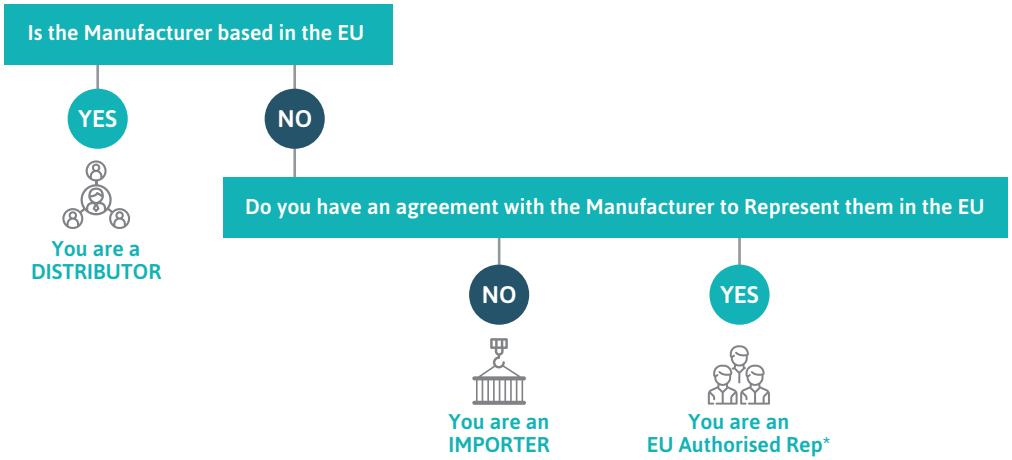
IMPORTANT MDR DATES

How do I know what Economic Operator I am considered to be under the new MDR?

Ansell can help you understand which Economic Operator you are. One tool we have developed to simplify this process is our decision tree below. Ask yourself each question and follow the flow chart to see which economic operator you are based on a few key questions.



Are you an Importer or an Authorised Representative?



*An EU Authorised Representative will have a separate agreement with the Manufacturer to represent them and deal with any enquires from any Competent Authorities. They still can be an Importer and Distributor and will also need to comply with the obligations set out for them.

How will the new MDR impact me as an importer or distributor of medical gloves and masks?

Under MDR, there are new requirements related to post-market importation and distribution activities of medical devices in the European market. MDR states that each economic operator in the medical supply chain must verify that a previous economic operator has complied with the MDR requirements. Thus, importers and distributors must ensure independently that, prior to placing a medical device on the market, the manufacturer, importer and the device itself meet the stipulated regulatory requirements. The device label must include the importer's name and address and must be registered in EUDAMED.
As a manufacturer, Ansell will be fully compliant with MDR requirements by May 2021.

I have my own private label gloves / masks. How will MDR impact me?

Under the previous MDD requirements, many small, private label manufacturers were not required to have technical documentation available in their facilities, so long as it was available at the OEM manufacturer. Under the new MDR, however, all private label manufacturers will be known as "Virtual Manufacturers" and therefore will have the same responsibilities as stipulated for actual device manufacturers. This means they must have a full quality management system, ensure devices are fully compliant with proper labels and UDI, handle complaints, conduct post market surveillance, and manage many other responsibilities previously required only of the actual product manufacturer. Under the MDR, virtual manufacturers risk being non-compliant if they do not have a Person Responsible for Regulatory Compliance and other required systems in place.

Is my fulfillment partner now considered to be a distributor?

Under the MDD, fulfillment partners had few regulatory responsibilities. Under MDR, these same fulfillment partners may now be considered distributors if they do anything beyond clearance, sorting and delivery of medical gloves, masks and other devices. This means that if they perform tasks such as storing gloves, packaging gloves, relabeling gloves packages, or handling customer returns, they will likely be considered a distributor and therefore must have a quality management system and meet the obligations of a distributor as stipulated by the MDR. They must be compliant with the MDR as of May 2021.

What happens if Companies are not Compliant to the MDR?

Competent Authorities will be conducting Marketing Surveillance activities where they will be looking at products to confirm that devices on the market are compliant to the MDR. If found not to be the possible penalties include market recalls, cancellation of CE certificates, bans of all goods in the EU supplied by the manufacturer, distributor or importer, or prosecution – which could carry unlimited fines and even imprisonment. Remember, under the new MDR, all Economic Operators have a legal responsibility to ensure the devices they manage are compliant with MDR and safe.

Will Ansell be compliant with MDR?

Ansell Healthcare Europe has been working to ensure compliance with the new MDR for several years and will be fully compliant with MDR as of May 2021 for all Class I Products. We are well prepared to supply our customers and distributor partners with any technical information or documentation they may need as they prepare to meet MDR transition deadlines.

For surgical gloves, our Notified Body, BSI Netherlands, has been designated as a MDR Notified Body. We will be working with them to transition our existing CE Certificates under the MDD over to the MDR. While the process is taking place, we will still be able to place product onto the Market under our existing MDD CE Certificate until it expires - as stated in the MDR. There will be no disruption in supplying our customers with surgical gloves.

Ansell customers are always guaranteed to receive gloves and masks that are fully compliant with all applicable EU laws and regulations – including MDR.

Can Ansell help me ensure my business in compliant with MDR?

Yes. Ansell is eager to help its customers ensure compliance with new MDR. If your company is unable to manage MDR requirements regarding quality management, complaint or financial coverage in the event of liability, let us help.

We have global regulatory expertise, an enhanced quality management system and product requirements in place, the ability to manage the complexities associated with MDR and a strong financial position as a global leader in healthy and safety solutions. Contact our Director of Regulatory Affairs, Samantha Marshall, at **Samantha.Marshall@ansell.com** to discuss how we can put our expertise to work for you.

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