NEW EU MDR FAST FACTS

On May 26th, 2021 the new European Union Medical Device Regulation or EU-MDR 2017/745 (MDR) comes into effect across member states. Ansell is proud to report that our quality management, market surveillance, and product registration systems will be up-to-date by the deadline. Contact info@ansell.eu or +32 2 528 74 00 to discuss how we can put our MDR expertise to work for you.

Overview of MDD & MDR Differences

MDD
MEDICAL DEVICE DIRECTIVE

20	60	12
articles	pages	annexes

Directives: Legislation that sets out general rules that are then transferred into national law by each member state.

MDR
MEDICAL DEVICE REGULATION

123	369	17
articles	pages	annexes

Regulations: Legislation that is directly applicable in all EU member states. No room for interpretation by individual member states.

Definitions of Economic Operators under MDR

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.

Note: Under the new MDR, many private label sellers will now be considered Manufacturers, and many fulfillment partners will be considered Distributors. They must therefore meet the related requirements associated with their new roles.

Examples of Economic Operator Responsibilities

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

○ = New Responsibility Under MDR
● = Previous Responsibility Under MDD That Continues

MDR Implementation Timeline

EU MEDICAL DEVICE REGULATION (MDR)

- **2017**
- **2018**
- **2019** — **March 2019** Transition to ISO 13485:2016 must be completed
- **2020**
- **2021** — **May 2021** MDR date of application
- **2022** — **March 2022** EC certificates of conformity issued before May 27, 2017 expire
- **2023**
- **2024**
- **2025** — **March 2025** Devices certified under the MDD can no longer be sold or distributed

Penalties for Non-Compliance

Under the new MDR, it is the responsibility of each economic operator in the supply chain to ensure the previous operator is compliant. This means that all economic operators are at risk and liable if Competent Authorities find that a product has been placed on the market improperly. **Possible penalties include:**

- Market recall of products and issuance of a Field Safety Notice
- Cancellation of CE Certificate – prohibiting future sales
- Ban of all goods in the EU supplied from the manufacturer
- Prosecution, unlimited fines and imprisonment

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