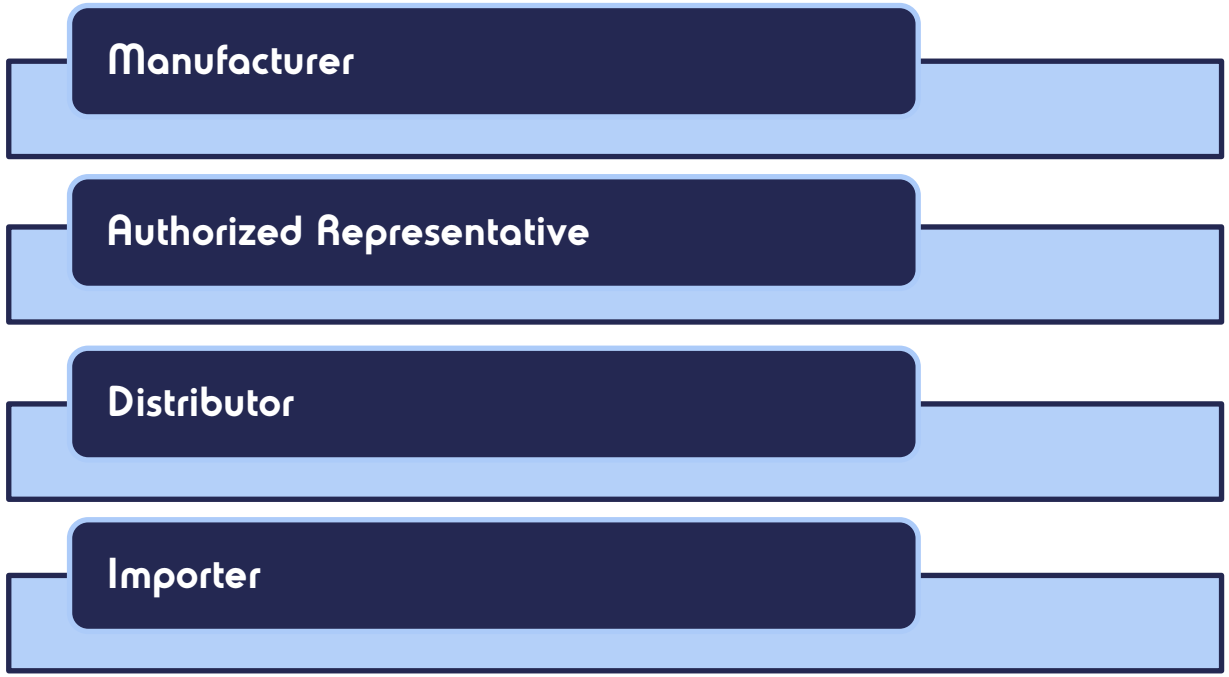
Economic Operators



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

Authorized representative means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the European Union, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation

Importer means any natural or legal person established within the Union who places a device from a third country on the Union market

Distributor means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service

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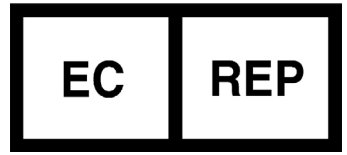
Economic Operators

- **Manufacturers:** responsible for Eudamed registration, technical documentation, design, development manufacture and assembly, handling, storage and distribution, corrective actions, UDI labeling, complaints, postmarket surveillance and the PRRC.

- **Authorized Representatives:** responsible for Eudamed registration, technical documentation, corrective actions, UDI labeling, postmarket surveillance and PRRC.



- **Importers:** responsible for Eudamed registration, handling, storage and distribution, corrective actions, UDI labeling, postmarket surveillance.

- **Distributors:** responsible for handling, storage and distribution, corrective actions, UDI labeling, complaints and postmarket surveillance.

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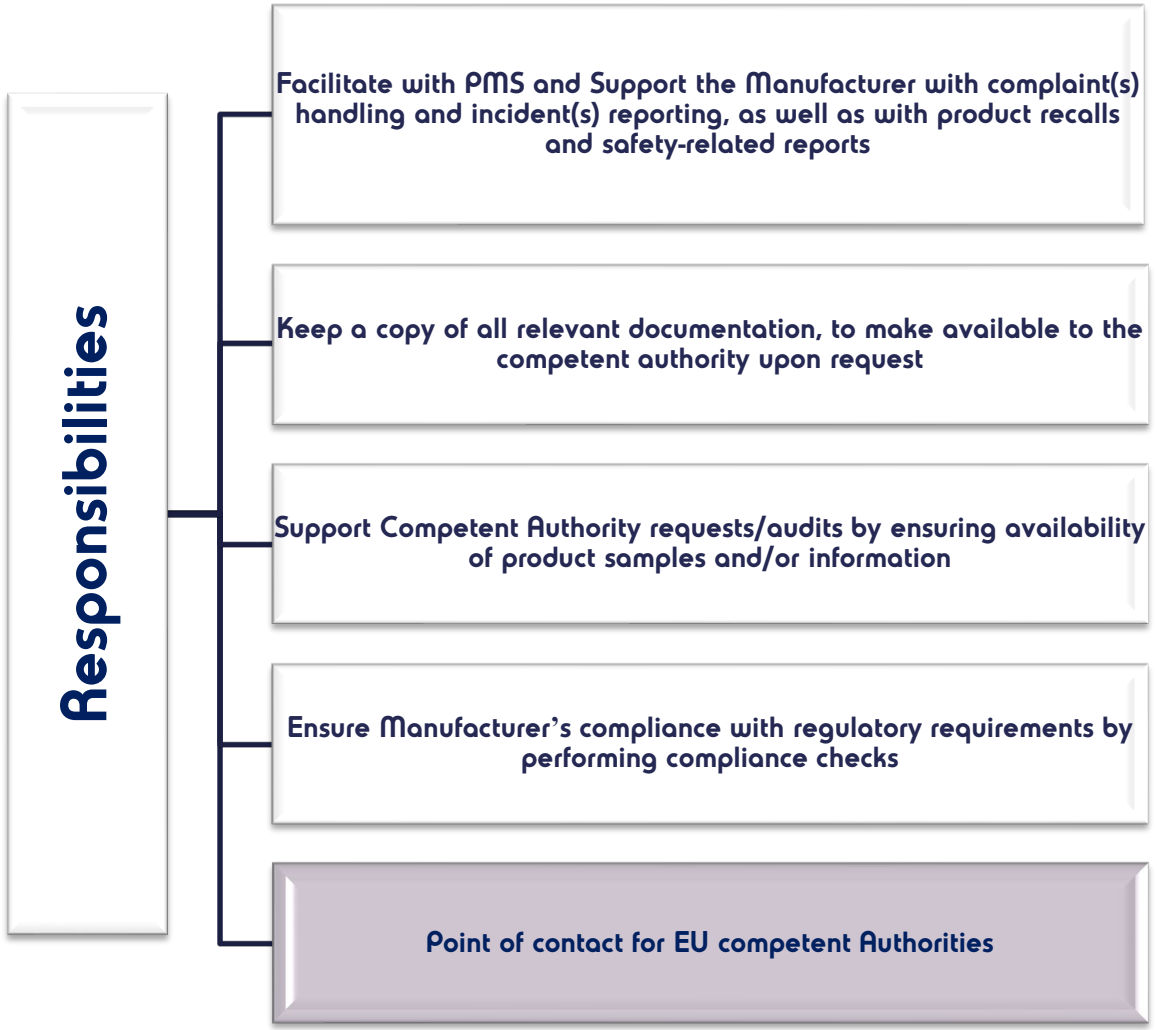
Authorized Representative

Article 11

An EU AR should be placed in the EU (physical presence in one of the Member States) and will represent the Manufacturer in all interactions with the EU competent authorities, including device registration for new products.

Article 11.5

The EU Authorised Representative is accountable (jointly with the Manufacturer) for any defective devices that enter the EU market.



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Person Responsible for Regulatory Compliance

Art. 15

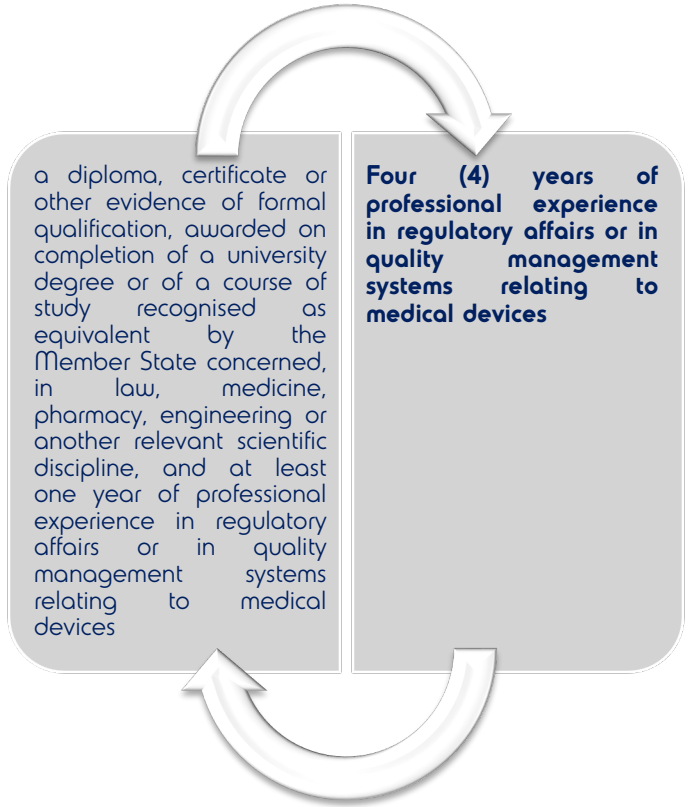
- EU-MDR 2017/745 mandates that MedTech companies have a regulatory expert, who will be ensuring that the company conforms with the certain requirements.
- Manufacturers and ARs are mandated to have at least on PRRC
- Also refer to MDCG 2019-7 for further guidance

15 (3)

Responsibilities

- the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released
- the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date
- the post-market surveillance obligations are complied with in accordance with Article 10(10)
- the reporting obligations referred to in Articles 87 to 91 are fulfilled
- in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued

15 (1) Profile – Qualifications**



** manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing

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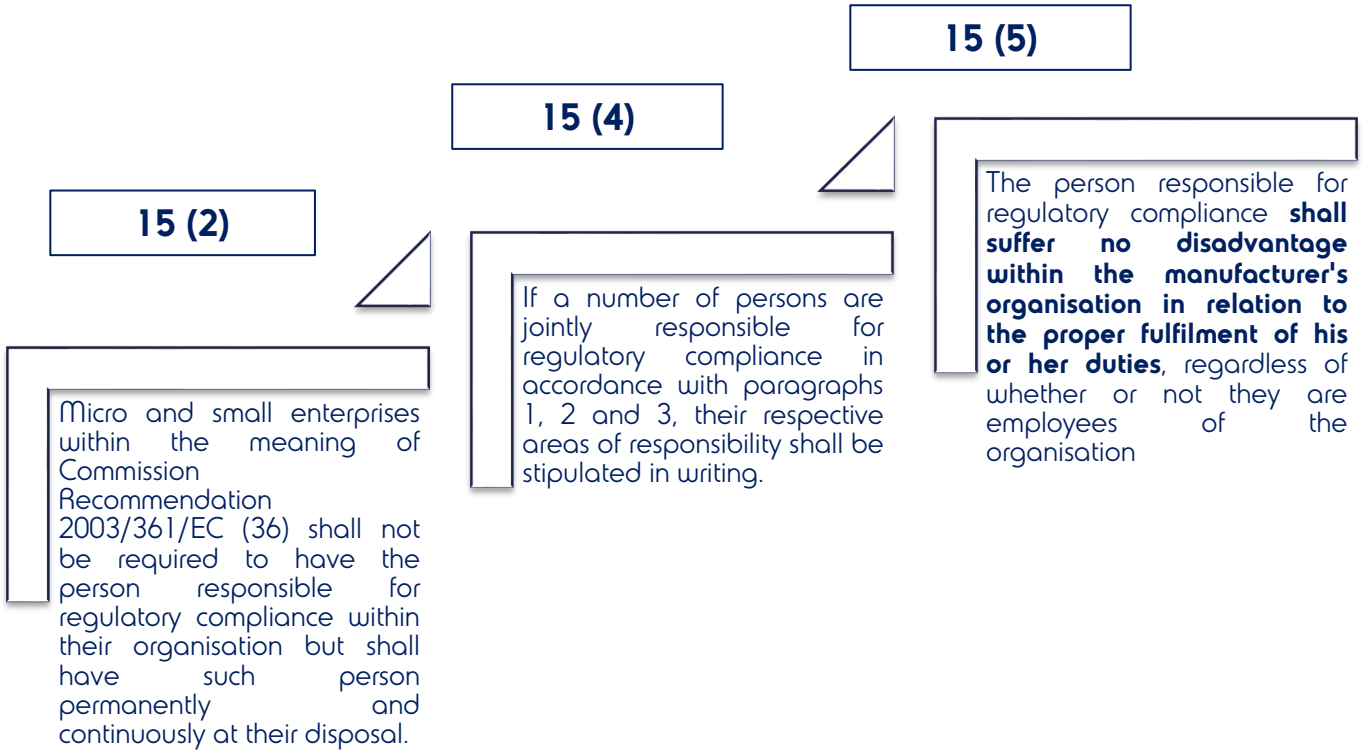
Person Responsible for Regulatory Compliance



PRRC and Authorized Representative

- When the manufacturer is headquartered outside of the EU and an Authorized Representative (AR) is required, the PRRC performs additional controls in order to confirm regulatory compliance

- The PRRC of an AR should be responsible for ensuring that the tasks of an AR as specified in the given mandate, in accordance with Article 11(3), are fulfilled.

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