Obligations of the Economic Operators under the new MDR 2017/745 – a generic overview

The new European Medical Device Regulation (MDR) 2017/745 introduces the concept of the Economic Operators. Organizations shall identify their roles undertaken in Europe. These roles can include

- Manufacturer,
- Authorized representative,
- Importer or
- Distributor.

These terms were already introduced within the ISO 13485:2016.

Articles 9 to 12 of the proposed MDR defines the obligations of these Economic Operators. The following table provides a rough and generic overview of these obligations:

Task	Manufacturer	Authorized Representative	Importer	Distributor
Quality Management System	x	-	-	-
Risk Management System	x	-	-	-
Clinical Evaluation	x	keep available	-	-
Technical Documentation	x	keep available	-	-
Conformity Assessment Procedure	x	verify DoC and assessment	verify DoC	verify DoC
UDI System	x	verify	verify	verify
Post Market Surveillance System	x	participate	participate	participate
IFU / Labeling	x	x	x and verify	verify
Vigilance	x	inform manufacturer	inform manufacturer /representative	inform manufacturer /representative/ importer
Traceability of devices	x	x	x	x
Escalation to authorities	x	x	x	x
Samples free of charge	x	communicate	x	x
Storage and Transport	x	-	x	x
Registration Eudamed	x	x and verify	x and verify	(if required local law)
Liability for products	x	x	(import)	-
Person responsible for regulatory compliance	x	x	-	-

Please note that there are more details for each obligation to be considered. It also need to be understood that both importers and distributors may have the same obligations as a manufacturer if they perform activities changing or modifying medical devices (for example in Articles 14 and 15).

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