Tic tac, tic tac… Time is not only melting for medical device manufacturers, but also for all other economic operators

Recently, I had a conversation with a distributor of several medical device manufacturers, who was not aware of the new medical device regulation. I highlighted to him the requirements, that particularly affect him as a distributor. His comment was that the distributors he knows will wait for the information from the manufacturers asking them specifically what to do.

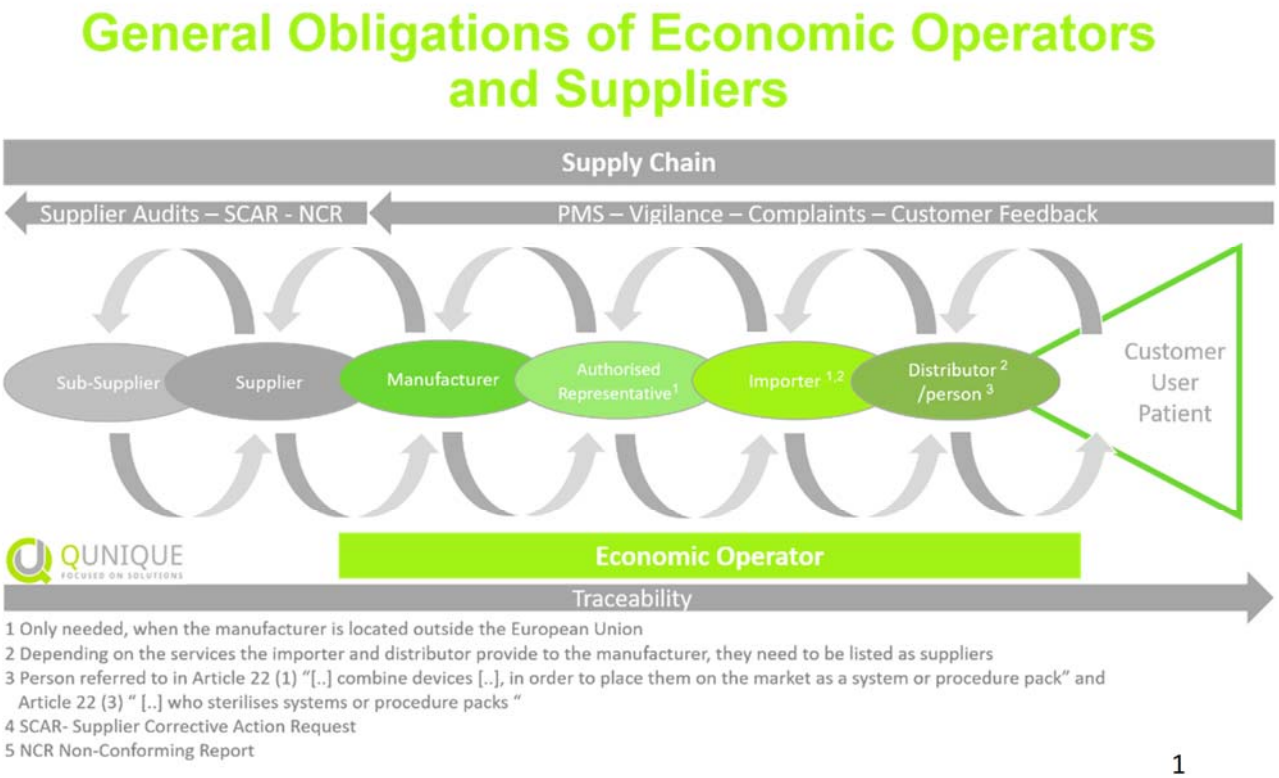
Therefore, I decided to create an overview to make it easier for manufacturers and other economic operators understand their new responsibilities, as required by the medical device regulation.

According to the medical device regulation (Article 2 (35)), economic operators are the following entities:

- Manufacturer
- Authorised Representative
- Importer
- Distributor or the person refered to in Article 22(1) and 22 (3)

Since the implementation of the new medical device regulation the economic operators have gained additional responsibilities.

The following illustration gives a non-concluding summary of the main activities and processes required to be performed by the supply chain members in order to achieve an appropriate level of traceability of devices in both directions : upstream and downstream.



The following table will help you identify the economic operators that are relevant for your business and the requirements they are expected to fulfill.

QUNIQUE	Manufacturer outside EU	Manufacturer inside EU
Authorised Representative	✓ Verifies that conformity assessment has been performed ✓ Keeps a copy of the evidence documents (TD, ER checklist, DOC and certificates) ✓ Able to identify who supplied them specific device ✓ Able to identify to whom they have supplied a specific device ✓ Verifies that Manufacturer complies with registration obligations and UDI requirements ✓ Cooperates and supports Corrective Actions for relevant devices ✓ Immediately informs manufacturers about customer feedback, complaints and adverse events ✓ Legally liable for defective devices ✓ Identifies a person responsible for regulatory compliance	X No Authorised Representative needed
Importer	✓ Verifies that conformity assessment has been performed, manufacturer is identified and authorized representative is designated ✓ Verifies correctness of labeling ✓ Verifies that Manufacturer complies with registration obligations and UDI requirements ✓ Keeps a copy of DOC and relevent certificates ✓ Ensures appropriate storing and transport conditions ✓ Immediately informs manufacturers and authorizes representative about customer feedback, complaints and adverse events ✓ Keeps a register of complaints and supports all other economic operators with any information requested by them for the purpose of inverstigating complaints ✓ Cooperates and supports Corrective Actions for relevant devices	X No Importer needed
Distributor	✓ Verifies that conformity assessment has been performed, manufacturer is identified and authorized representative is designated ✓ Verifies correctness of labeling ✓ Verifies that Manufacturer complies with registration obligations and UDI requirements ✓ Keeps a copy of DOC and relevent certificates ✓ Ensures appropriate storing and transport conditions ✓ Immediately informs manufacturers and if applicable authorized representative about customer feedback, complaints and adverse events ✓ Keeps a register of complaints and supports all other economic operators with any information requested by them for the purpose of inverstigating complaints ✓ Cooperates and supports Corrective Actions for relevant devices	

Manufacturers should involve their Economic Operators in their MDR readiness preparations in order to ensure that they have enough time to implement the required processes and train personnel on the new requirements. Consider updating the quality agreements to ensure documented evidence of fulfillment of the MDR requirements.

Taking into account the requirements listed above, the economic operators will also be acting as service providers for the manufacturer, thus, they need to be treated as suppliers as well. Manufacturers should add their economic operators to the list of suppliers and audit them accordingly.

Economic Operators on the other hand, should proactively approach manufacturers and be part of their readiness plan. This will help them identify early enough whether their manufacturer is going to be MDR certified, thus avoid undesired surprises later on.

Therefore, it is recommended, that besides the manufacturers, the other economic operators start to get familiar with the requirements of the medical device regulation in order to be able to acquire the needed know-how and implement appropriate processes before the clock strikes twelve.

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About QUNIQUE GmbH
QUNIQUE stands for Quality & Uniqueness. We focus on high quality and exceptionally customer oriented consulting services for the medical device industry. QUNIQUE is an international operating consulting company with the head office in Switzerland.

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