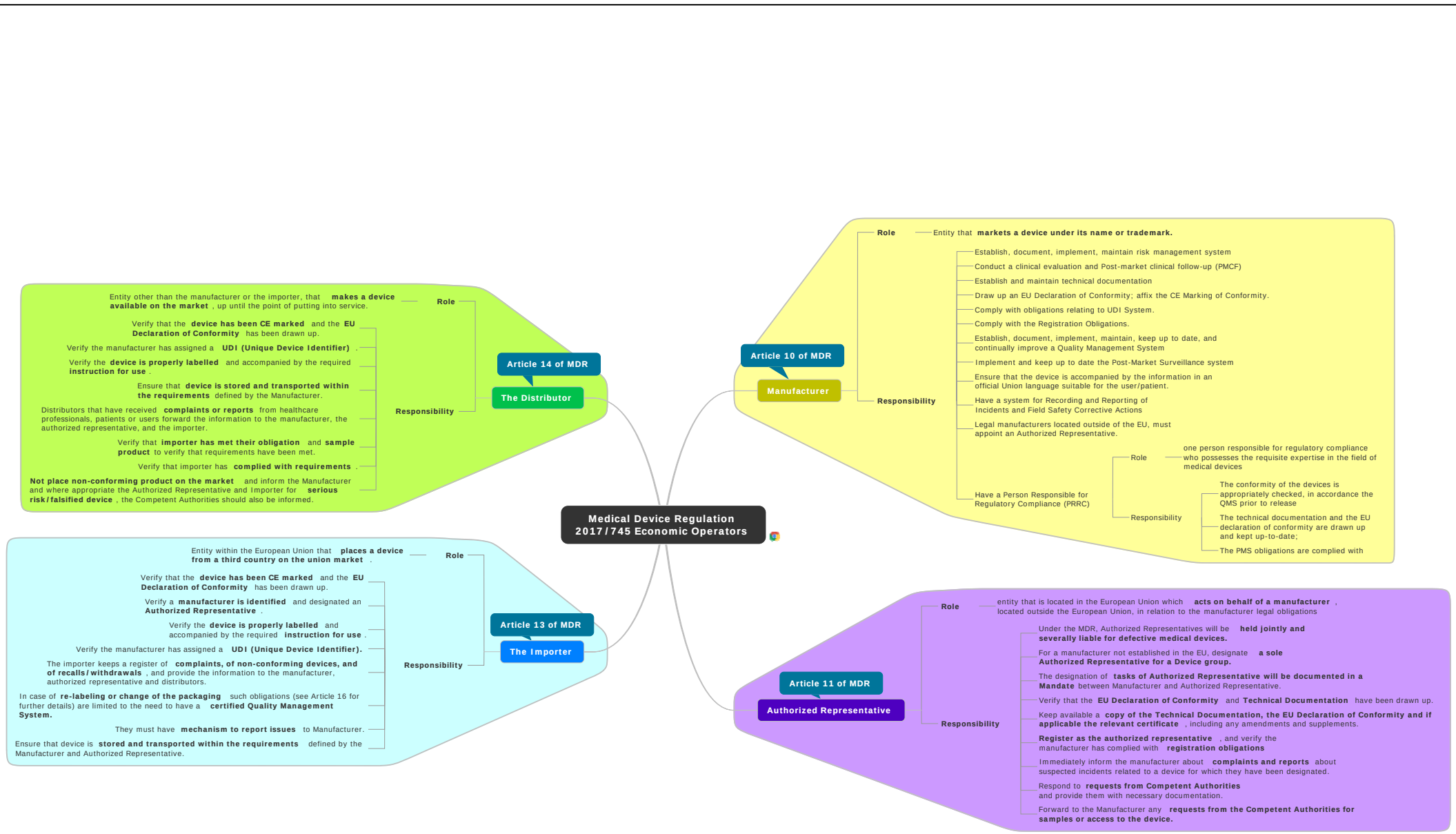
Medical Device Regulation 2017/745 Economic Operators
Article 14 of MDR
The Distributor
Role
Entity other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.
Responsibility
Verify that the device has been CE marked and the EU Declaration of Conformity has been drawn up.
Verify the manufacturer has assigned a UDI (Unique Device Identifier).
Verify the device is properly labelled and accompanied by the required instruction for use.
Ensure that device is stored and transported within the requirements defined by the Manufacturer.
Distributors that have received complaints or reports from healthcare professionals, patients or users forward the information to the manufacturer, the authorized representative, and the importer.
Verify that importer has complied with requirements.
Verify that importer has met their obligation and sample product to verify that requirements have been met.
Not place non-conforming product on the market and inform the Manufacturer and where appropriate the Authorized Representative and Importer for serious risk/falsified device, the Competent Authorities should also be informed.
Article 13 of MDR
The Importer
Role
Entity within the European Union that places a device from a third country on the union market.
Responsibility
Verify that the device has been CE marked and the EU Declaration of Conformity has been drawn up.
Verify a manufacturer is identified and designated an Authorized Representative.
Verify the device is properly labelled and accompanied by the required instruction for use.
Verify the manufacturer has assigned a UDI (Unique Device Identifier).
The importer keeps a register of complaints, of non-conforming devices, and of recalls/withdrawals, and provide the information to the manufacturer, authorized representative and distributors.
In case of re-labeling or change of the packaging such obligations (see Article 16 for further details) are limited to the need to have a certified Quality Management System.
They must have mechanism to report issues to Manufacturer.
Ensure that device is stored and transported within the requirements defined by the Manufacturer and Authorized Representative.
Article 10 of MDR
Manufacturer
Role
Entity that markets a device under its name or trademark.
Responsibility
Establish, document, implement, maintain risk management system
Conduct a clinical evaluation and Post-market clinical follow-up (PMCF)
Establish and maintain technical documentation
Draw up an EU Declaration of Conformity; affix the CE Marking of Conformity.
Comply with obligations relating to UDI System.
Comply with the Registration Obligations.
Establish, document, implement, maintain, keep up to date, and continually improve a Quality Management System
Implement and keep up to date the Post-Market Surveillance system
Ensure that the device is accompanied by the information in an official Union language suitable for the user/patient.
Have a system for Recording and Reporting of Incidents and Field Safety Corrective Actions
Legal manufacturers located outside of the EU, must appoint an Authorized Representative.
Have a Person Responsible for Regulatory Compliance (PRRC)
Role
one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices
Responsibility
The conformity of the devices is appropriately checked, in accordance the QMS prior to release
The technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;
The PMS obligations are complied with
Article 11 of MDR
Authorized Representative
Role
entity that is located in the European Union which acts on behalf of a manufacturer, located outside the European Union, in relation to the manufacturer legal obligations
Responsibility
Under the MDR, Authorized Representatives will be held jointly and severally liable for defective medical devices.
For a manufacturer not established in the EU, designate a sole Authorized Representative for a Device group.
The designation of tasks of Authorized Representative will be documented in a Mandate between Manufacturer and Authorized Representative.
Verify that the EU Declaration of Conformity and Technical Documentation have been drawn up.
Keep available a copy of the Technical Documentation, the EU Declaration of Conformity and if applicable the relevant certificate, including any amendments and supplements.
Register as the authorized representative, and verify the manufacturer has complied with registration obligations
Immediately inform the manufacturer about complaints and reports about suspected incidents related to a device for which they have been designated.
Respond to requests from Competent Authorities and provide them with necessary documentation.
Forward to the Manufacturer any requests from the Competent Authorities for samples or access to the device.