

**Overview of requirements under the IVD Regulation**

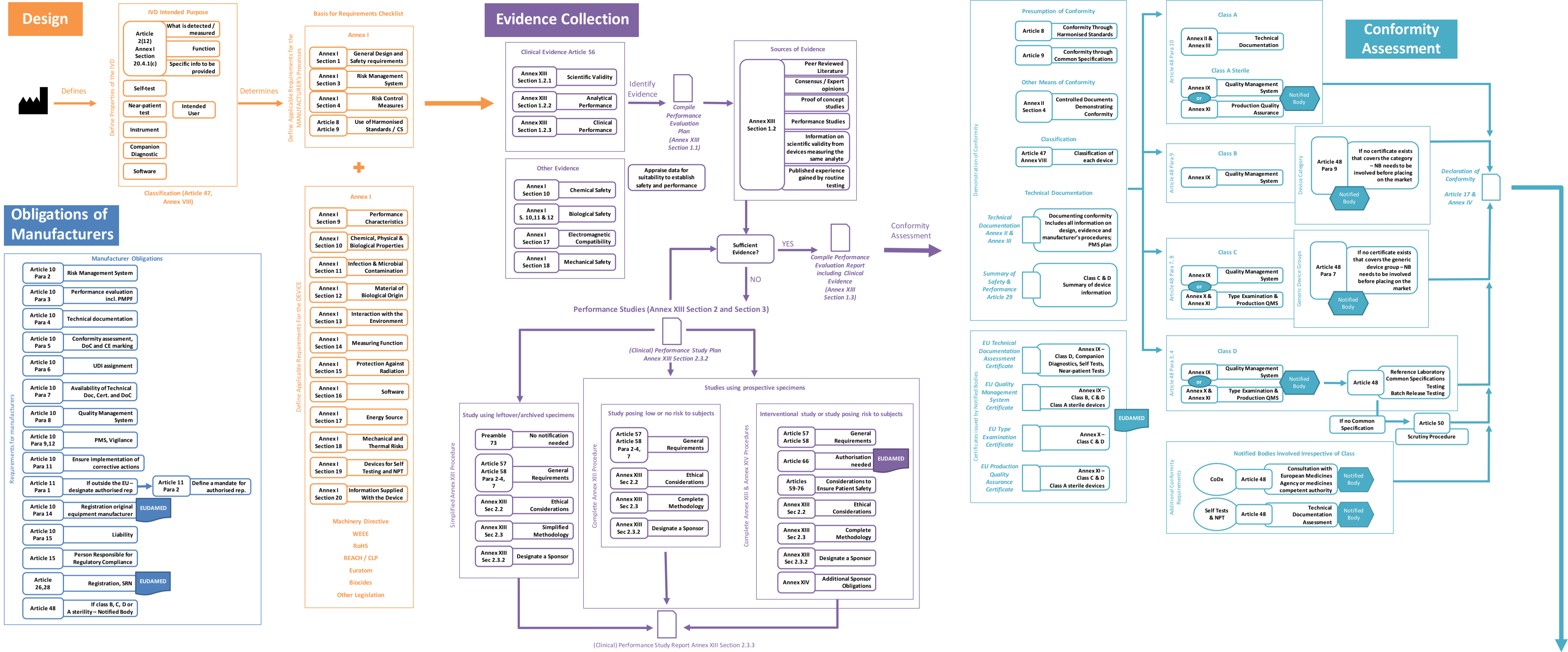
Regulation 2017/746/EU on In Vitro Diagnostic Medical Devices

December 2017

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**Obligations of Manufacturers**

**Manufacturer Obligations**

- Article 10 Para 2: Risk Management System
- Article 10 Para 3: Performance evaluation incl. PMPF
- Article 10 Para 4: Technical documentation
- Article 10 Para 5: Conformity assessment, DoC and CE marking
- Article 10 Para 6: UDI assignment
- Article 10 Para 7: Availability of Technical Doc, Cert. and DoC
- Article 10 Para 8: Quality Management System
- Article 10 Para 9, 12: PMS, Vigilance
- Article 10 Para 11: Ensure implementation of corrective actions
- Article 11 Para 1: If outside the EU - designate authorised rep. → Article 11 Para 2: Define a mandate for authorised rep.
- Article 10 Para 14: Registration original equipment manufacturer (EUDAMED)
- Article 10 Para 15: Liability
- Article 15: Person Responsible for Regulatory Compliance (EUDAMED)
- Article 26, 28: Registration, SRN (EUDAMED)
- Article 48: If class B, C, D or A sterility - Notified Body

**Obligations of Importers and Distributors**

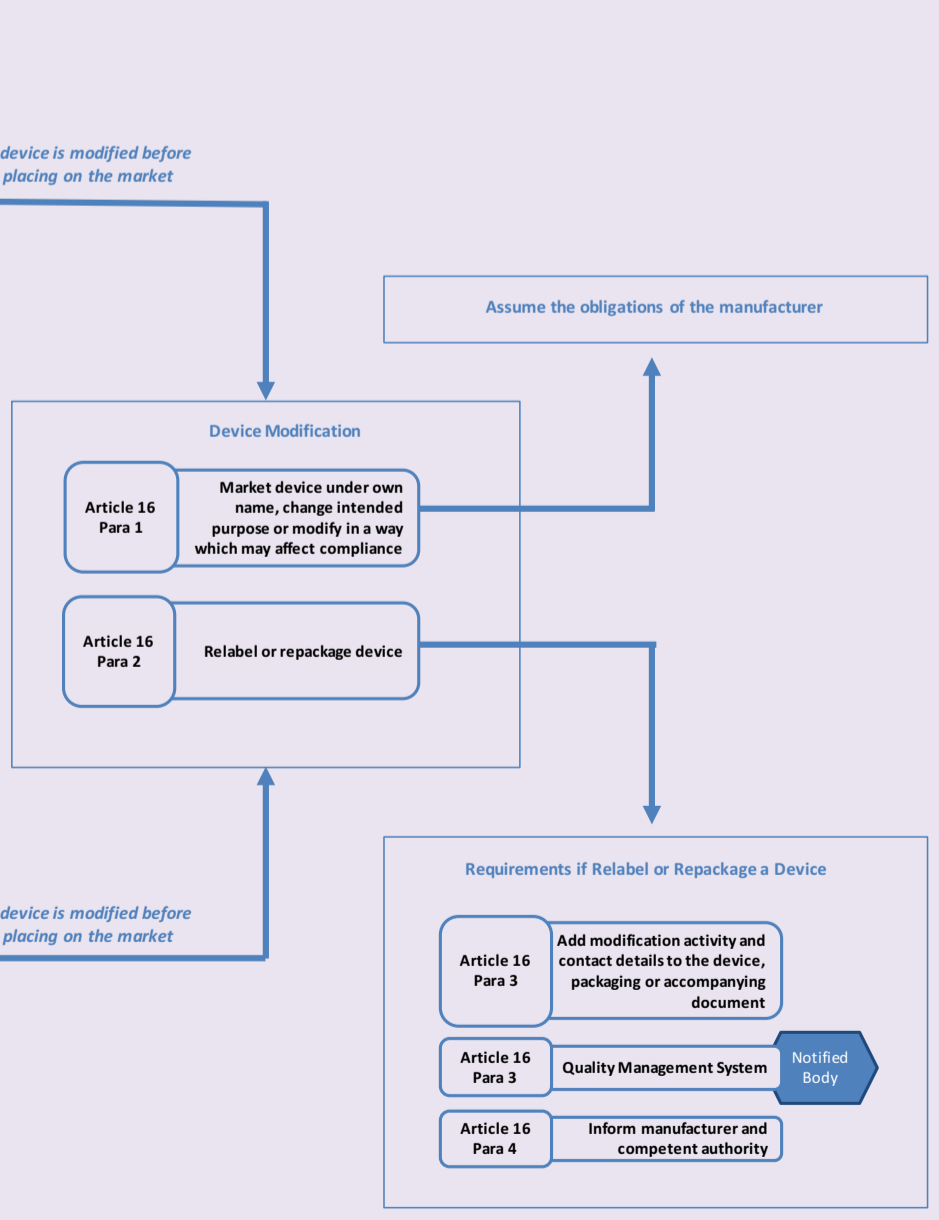
**Importer Obligations**

- Article 13 Para 1, 2: Verify device compliance
- Article 13 Para 3: Add contact details to device or packaging or accompanying document
- Article 13 Para 4: Verify device registration, add own details (EUDAMED)
- Article 13 Para 5: Safeguard storage and transport conditions
- Article 13 Para 6: Keep register of complaints, non-conforming devices, etc.
- Article 13 Para 7: Inform of non-conformities and serious risk
- Article 13 Para 7: Ensure implementation of corrective actions
- Article 13 Para 8: Inform of complaints & suspected incidents
- Article 13 Para 9: Keep Declaration of Conformity and certificates (EUDAMED)
- Article 13 Para 10: Cooperation with Competent Authorities
- Article 22: Identification within the supply chain
- Article 24 Para 8: Storage of UDI data
- Article 27 Para 3: Verify registration of manufacturer or authorised representative; add own details (EUDAMED)
- Article 28: Registration of the importer (EUDAMED)
- Article 90 Para 3: Application of corrective actions

**Distributor Obligations**

- Article 14 Para 2: Verify device compliance (Sampling method)
- Article 14 Para 3: Safeguard storage and transport conditions
- Article 14 Para 4: Inform of non-conformities and serious risk
- Article 14 Para 4: Ensure implementation of corrective actions
- Article 14 Para 5: Inform of complaints & suspected incidents
- Article 14 Para 6: Keep register of complaints, non-conforming devices, etc.
- Article 14 Para 6: Cooperation with Competent Authorities
- Article 22: Identification within the supply chain
- Article 24 Para 8: Storage of UDI data
- Article 27 Para 2: Distributor Registration (National Database)
- Article 90 Para 3: Application of corrective actions

**Obligations of Authorised Representatives, Importers and Distributors**



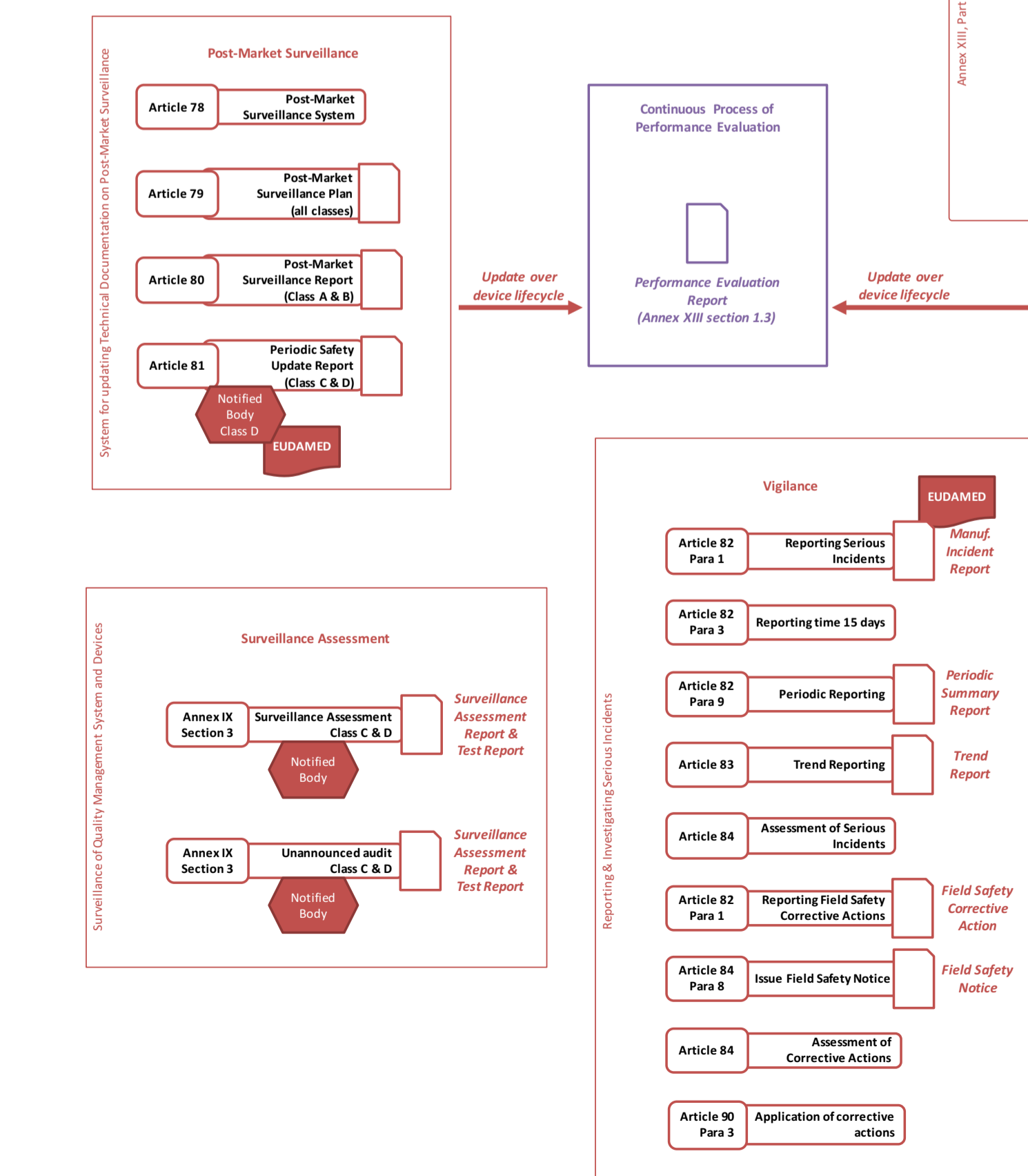
**Authorised Representative Obligations**

- Article 11 Para 2, 3, 4: Mandate
- Article 11 Para 5: Liability
- Article 11 Para 6: Termination of mandate if manufacturer acts illegally
- Article 12: Change of authorised representative
- Article 15 Para 6: Person responsible for regulatory compliance
- Article 24 Para 8: Storage of UDI data
- Article 28: Registration, SRN (EUDAMED)
- Article 90 Para 3: Application of corrective actions

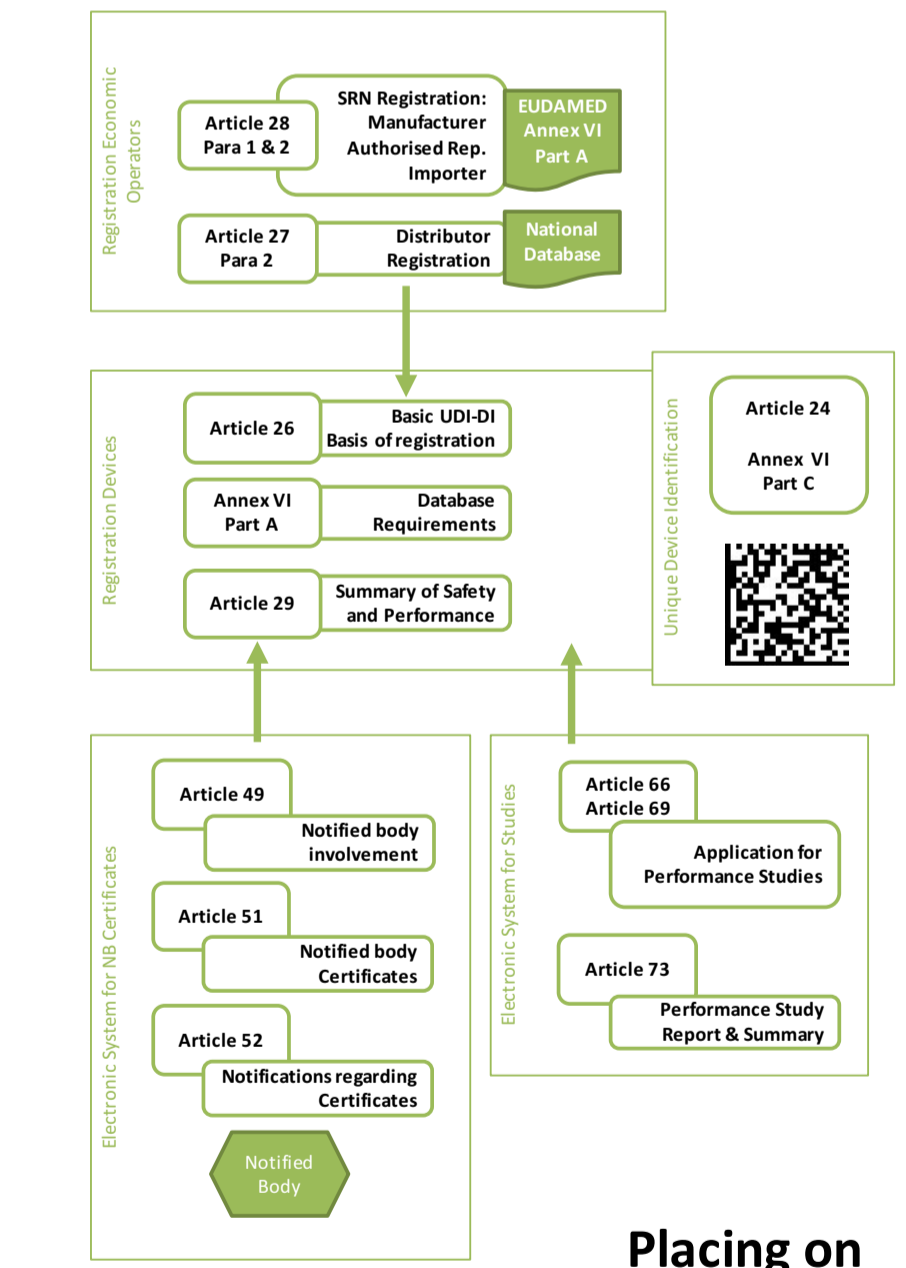
**Authorised Representative Mandate - Minimum Requirements**

- Article 11 Para 3: Verify declaration of conformity, technical doc., conformity assessment
- Keep available copy of technical doc., declaration of conformity, certificates
- Registration, verify device and UDI registration (EUDAMED)
- Device information to competent authority upon request
- Samples and access to device
- Preventive or corrective actions
- Inform of complaints and suspected incidents
- Terminate mandate if manufacturer acts illegally

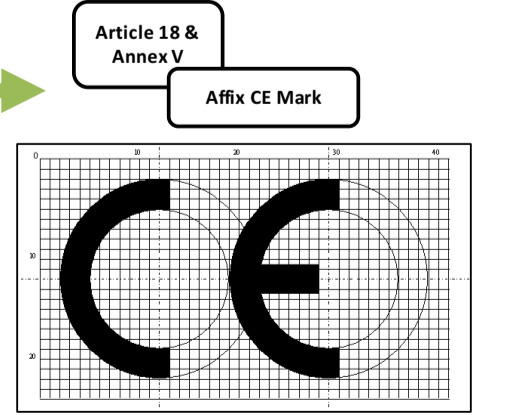
**Post-Market Surveillance and Vigilance**



**Registration**



**Placing on the market**



# Overview of Regulation 2017/746/EU on *In Vitro* Diagnostic Medical Devices