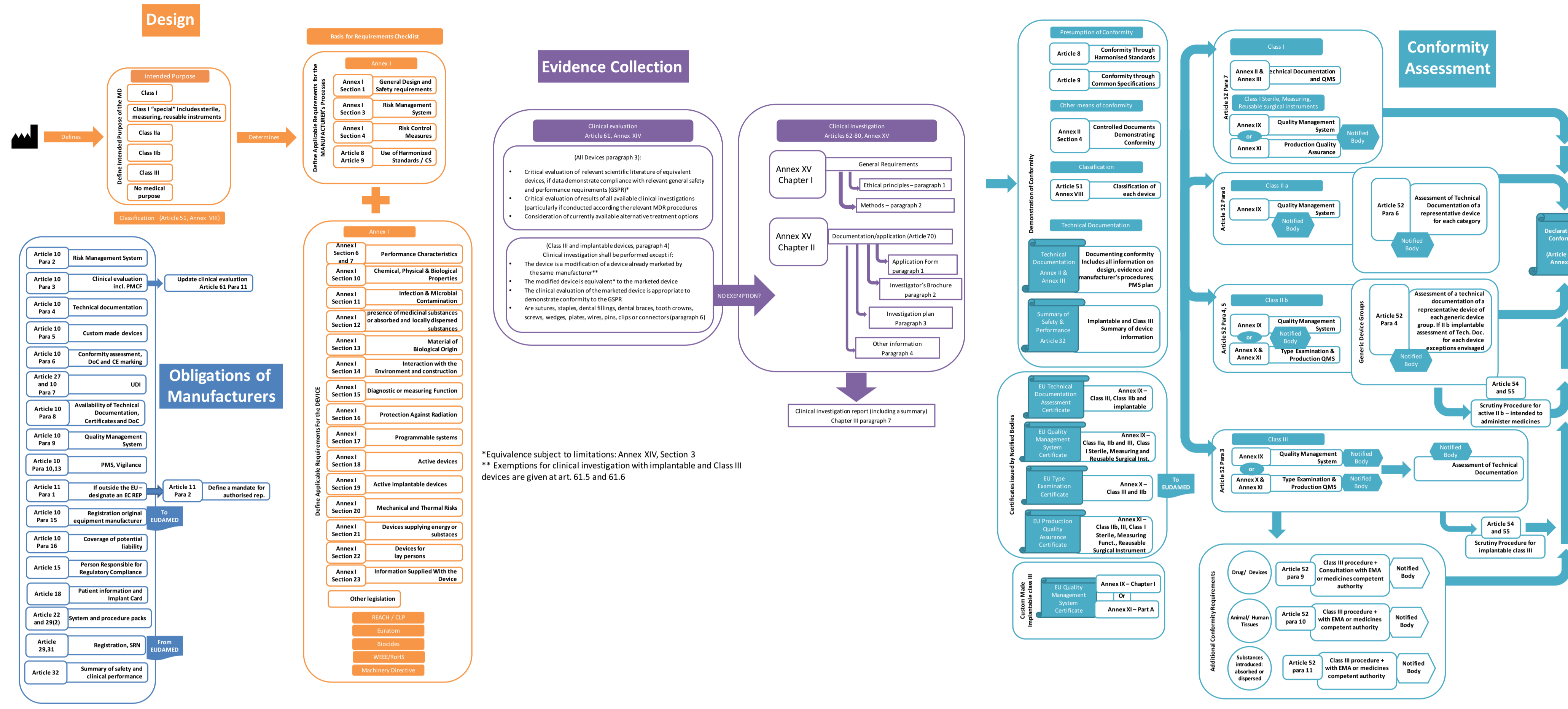


**Overview of requirements under the Medical Devices Regulation**  
Regulation 2017/745/EU on Medical Devices

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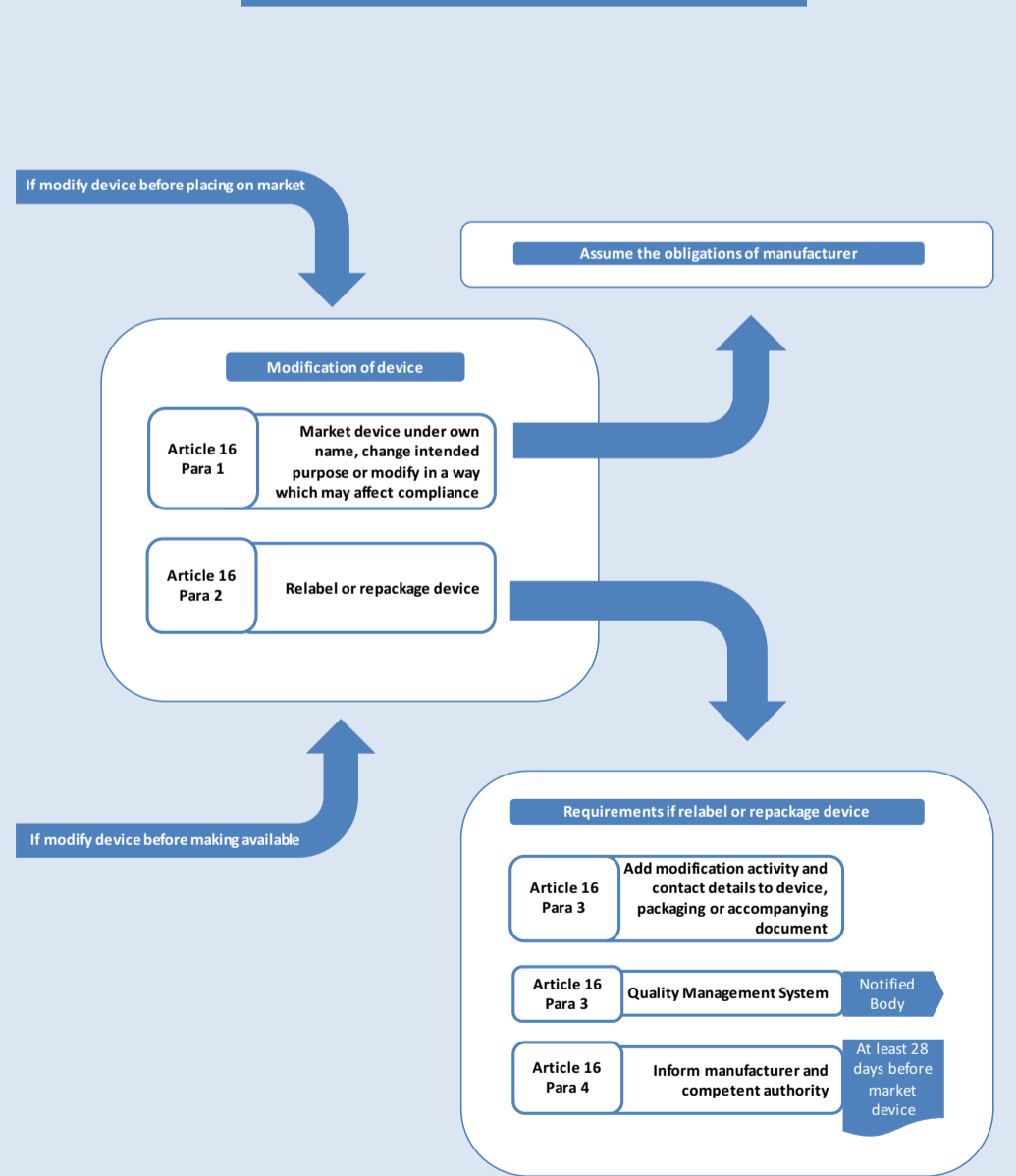
**Obligations of Manufacturers**

Article 10 Para 2	Risk Management System	Update clinical evaluation incl. PMCF
Article 10 Para 3	Clinical evaluation	
Article 10 Para 4	Technical documentation	
Article 10 Para 5	Custom-made devices	
Article 10 Para 6	Conformity assessment, DoC and CE marking	
Article 27 and 10 Para 7	UDI	
Article 10 Para 8	Availability of Technical Documentation, Certificates and DoC	
Article 10 Para 9	Quality Management System	
Article 10 Para 10, 11	PMS, Vigilance	
Article 11 Para 1	If outside the EU - designate an EC REP	
Article 10 Para 15	Registration original equipment manufacturer	EUDAMED
Article 10 Para 16	Coverage of potential liability	
Article 15	Person Responsible for Regulatory Compliance	
Article 18	Patient information and Implant Card	
Article 22 and 28(2)	System and procedure packs	
Article 29, 31	Registration, SRN	From EUDAMED
Article 32	Summary of safety and clinical performance	

Annex I Section 6 and 7	Performance Characteristics and Chemical, Physical & Biological Properties
Annex I Section 10	Infection & Microbial Contamination
Annex I Section 11	presence of medicinal substances or absorbed and locally dispersed substances
Annex I Section 12	Material of Biological Origin
Annex I Section 13	Interaction with the Environment and construction
Annex I Section 14	Diagnostic or measuring Function
Annex I Section 15	Protection Against Radiation
Annex I Section 16	Programmable systems
Annex I Section 17	Active devices
Annex I Section 18	Active implantable devices
Annex I Section 19	Mechanical and Thermal Risks
Annex I Section 20	Devices supplying energy or substances
Annex I Section 21	Devices for lay persons
Annex I Section 22	Information Supplied With the Device
Annex I Section 23	Other legislation

\*Equivalence subject to limitations: Annex XIV, Section 3  
\*\* Exemptions for clinical investigation with implantable and Class III devices are given at art. 61.5 and 61.6

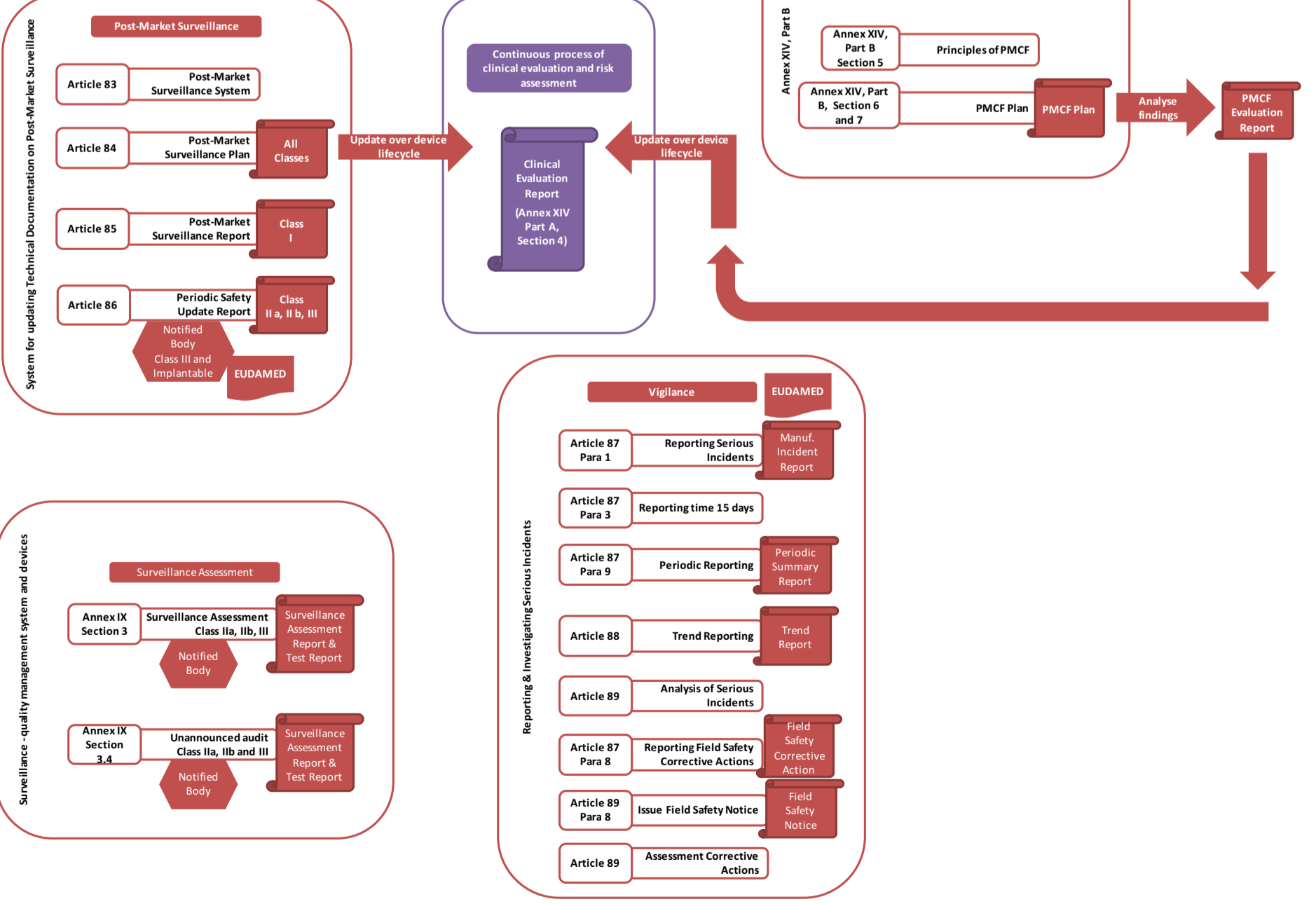
**Obligations of Representatives, Importers and Distributors**



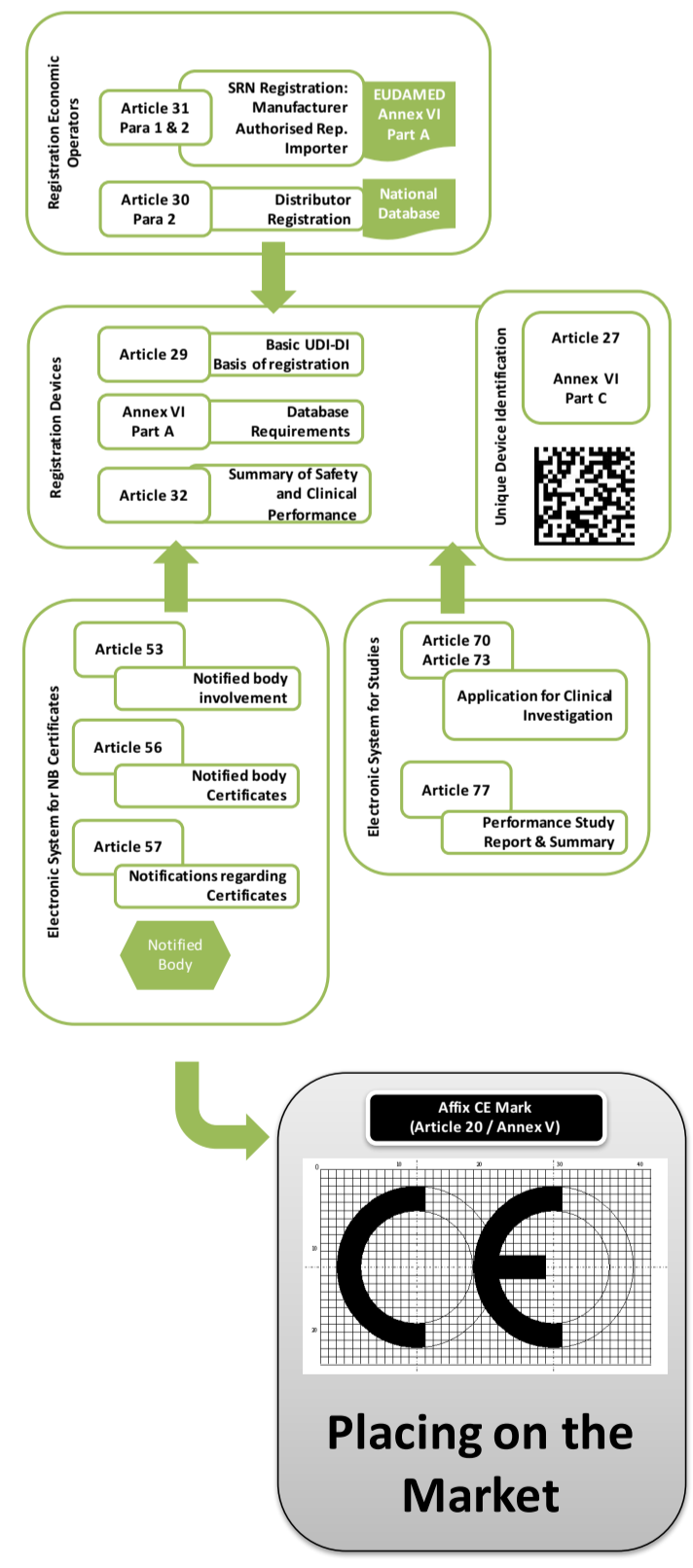
Article 11 Para 2, 3	Mandate
Article 11 Para 5	Liability
Article 11 Para 6	Termination of mandate if manufacturer acts illegally
Article 12	Change of authorized representative
Article 15 Para 6	Person responsible for regulatory compliance
Article 30 and 31	Registration, SRN

\*for Manufacturer Obligations see slide 1

**Post-Market and Vigilance**



**Registration**



# Overview of Regulation 2017/745/EU on Medical Devices