Type of Requirement	Required Documents
General	
☐Has my Organization generated, documented, implemented and maintains a Quality Management System (QMS)?	☐Consult Article 10 and ISO 13485
☐ Has my Organization established and documented an upto-date Risk Management System (RM)?	☐Consult Annex I, Chapter I
☐ Has my Organization established, implemented and maintains a dynamic Post Surveillance System (PMS)?	☐Consult Articles 84, 85, 86; Annex XIV, part B
☐ Has my Organization appointed a Person Responsible for Regulatory Compliance (PRRC)?	☐Consult Article 15
☐ Has my Organization identified and established EU Distributors and Importers?	☐Consult Articles 13, 14, 16, 30, 31
☐ Has a Notified Body (NB) been appointed with an agreed mandate for my Organization? – ☐ Has my Organization verified that the current NB is designated under MDR?	☐Consult Chapter 6; Annex VII
Clinical Evaluation	
☐ Has my Organization established a comprehensive Clinical Evaluation Plan (CEP) covering ALL the following:	○ Clinical Evaluation Plan (CEP ○ Clinical Evaluation Report (CER)

– ☐ Full identification of the device under evaluation (including regulatory information e.g. classification rationale, device description, clinical development plan, overview of sales) – ☐ State of the Art and current Standards of Care for the intended medical field of the device under evaluation – ☐ Benchmark devices of the device under evaluation – ☐ Identification of clinical claims – ☐ Presentation of current Labelling – ☐ Establishment of a Search plan (search periods/search terms/eligibility criteria) to identify and appraise clinical data on the intended medical field and benchmark devices and device under evaluation – ☐ Establishment of a Search plan for internal postmarket surveillance data (post-market clinical follow-up (PMCF) plan if applicable) – ☐ Establishment of a search plan for post-market vigilance data	□Consult Article 61; Annex XIV, part A
☐ Has my Organization established a comprehensive Clinical Evaluation Report (CER) covering ALL the following: – ☐ Full identification of the device (including regulatory information e.g. classification rationale, device description, clinical development plan) – ☐ Sales data – ☐ Discussion and corroboration of identified clinical claims	

– ☐ Discussion State of the Art and current Standards of Care for the intended field of the device under evaluation – ☐ Discussion/Analysis of clinical data for benchmark devices – ☐ Discussion/Analysis of clinical data for device under evaluation – ☐ Discussion/Analysis of clinical data for device under evaluation (including clinical investigations if applicable) – ☐ Discussion/Analysis of internal post-surveillance data (including PMCF studies if applicable) – ☐ Discussion/Analysis of Risk Management data – ☐ Discussion/Analysis of External Vigilance data – ☐ Discussion/Analysis of pre-clinical and technical data – ☐ Conclusion on Requirement for Safety – ☐ Conclusion on Requirement for Performance – ☐ Conclusion on Requirement for Acceptability of sideeffects – ☐ Conclusion on Requirement for Acceptability of Benefit/Risk profile – ☐ Presentation of Labelling (revised if required) – ☐ Statement on periodic update of the CER – ☐ Qualifications of Authors	
Clinical Investigation **(to be included in the CER if applicable)**	
☐ Has my Organization identified the need for a clinical investigation for the device under evaluation based on whether: – ☐ It is a new medical device – ☐ A class III medical device – ☐ A medical device with insufficient clinical data	o Clinical investigation plan o Investigator's brochure Informed consent o Application forms o Insurance arrangement Statement on performance & safety o Clinical Investigation Report

☐ If the answer is yes in the above question, has my Organization identified and implemented all requirements set in EU-MDR and ISO 14155 and GCP and ICH Guidelines?	□Consult: Articles 62- 82 ; Annex XV
Post-Market Surveillance (PMS)	
☐ Has my Organization reached a consensus on types of incidents it will be monitoring (customer complaints, trend reporting etc.)? ☐ Has my Organization identified the reporting requirements and adapted its internal procedures accordingly? ☐ Has my Organization reached a consensus on the need to initiate a post-market clinical follow-up (PMCF)? – ☐ If the answer is yes in the above question, is the PMCF integrated to the QMS management review?	○ PMS Plan ○ PMS Report ○ Periodic Safety Update Report (PSUR) (for class IIa, IIb, III devices) ○ Post-Market Clinical Follow-up (PMCF) Plan ○ Post-Market Clinical Follow-up (PMCF) Repot (if applicable) ○ Summary of safety and Clinical Performance (SSCP) (for class III and implantable devices) □Consult Articles 84, 85, 86; Annex XIV, part B
Vigilance Data	
☐ Has my Organization reached a consensus on types of incidents it will be providing periodic summary reports on (adverse events (AEs); field safety corrective actions (FSCA) etc.) and external resources it will be referring to? ☐ Has my Organization identified reporting requirements involving EUDAMED and adapted its internal procedures accordingly?	○ Field Safey Corrective Actions (FSCA) ○ Adverse Events Report □Consult Article 87
Risk Management	
☐ Has my Organization, – ☐ identified, – ☐ documented,	○ Risk Management Plan ○ Risk Management File(s) ○ Risk Management Report

– ☐ evaluated, – ☐ addressed and mitigated all risks related to the device under evaluation as far as possible for its entire lifetime – ☐ defined the benefit-risk ratio and residual risk	☐Consult Annex I, Chapter I
Unique Device Identification (UDI)	
☐ Has my Organization complied with obligations related to UDI System and Registration? ☐ Has my Organization included basic UDI device identifier(s) in the EU Declaration of Conformity? ☐ Has my Organization generated, implemented and maintained an up-to-date list of all UDIs assigned as part of the Technical Documentation? – ☐ Has my Organization a QMS-compliant system for storing and keeping UDIs of supplied devices?	☐Consult Article 27
Technical Documentation	
☐ Has my Organization generated, completed and maintains up-to-date a Technical Documentation, which includes detailed presentation/discussion of: – ☐ Device description and specifications – ☐ Labelling – ☐ Design & Manufacturing information – ☐ Conformity with GSPRs – ☐ Benefit- Risk Analysis and Risk Management data	☐Consult Annex II

– ☐ Post-Market Surveillance data – ☐ Verification and Validation Studies data	
☐ Has my Organization identified how the review of the Technical Documentation will proceed: – ☐ class I devices: Assessment of certain device features such as cleaning, disinfection, sterilization, maintenance, functional testing and IFU (all that is applicable) – ☐ class IIa devices: Assessment of at least one representative device for each category of devices – ☐ class IIb, III, implantable devices: Assessment of the Technical Documentation of every medical device	
Declaration of Conformity	
☐ Has my Organization identified and provided a corroborated rationale on risk classification for the device under evaluation?	☐Consult Article 10, 19, 20; Annex IV
☐ Has my Organization aligned Labelling against – ☐ Literature data – ☐ Post-market Surveillance Data – ☐ Risk Management Data – ☐ GSPRs	
☐ Is my Organization ready to assume full responsibility of the DoC content? – ☐ Is my Organization able to assume full responsibility for compliance with requirements of EU-MDR?	