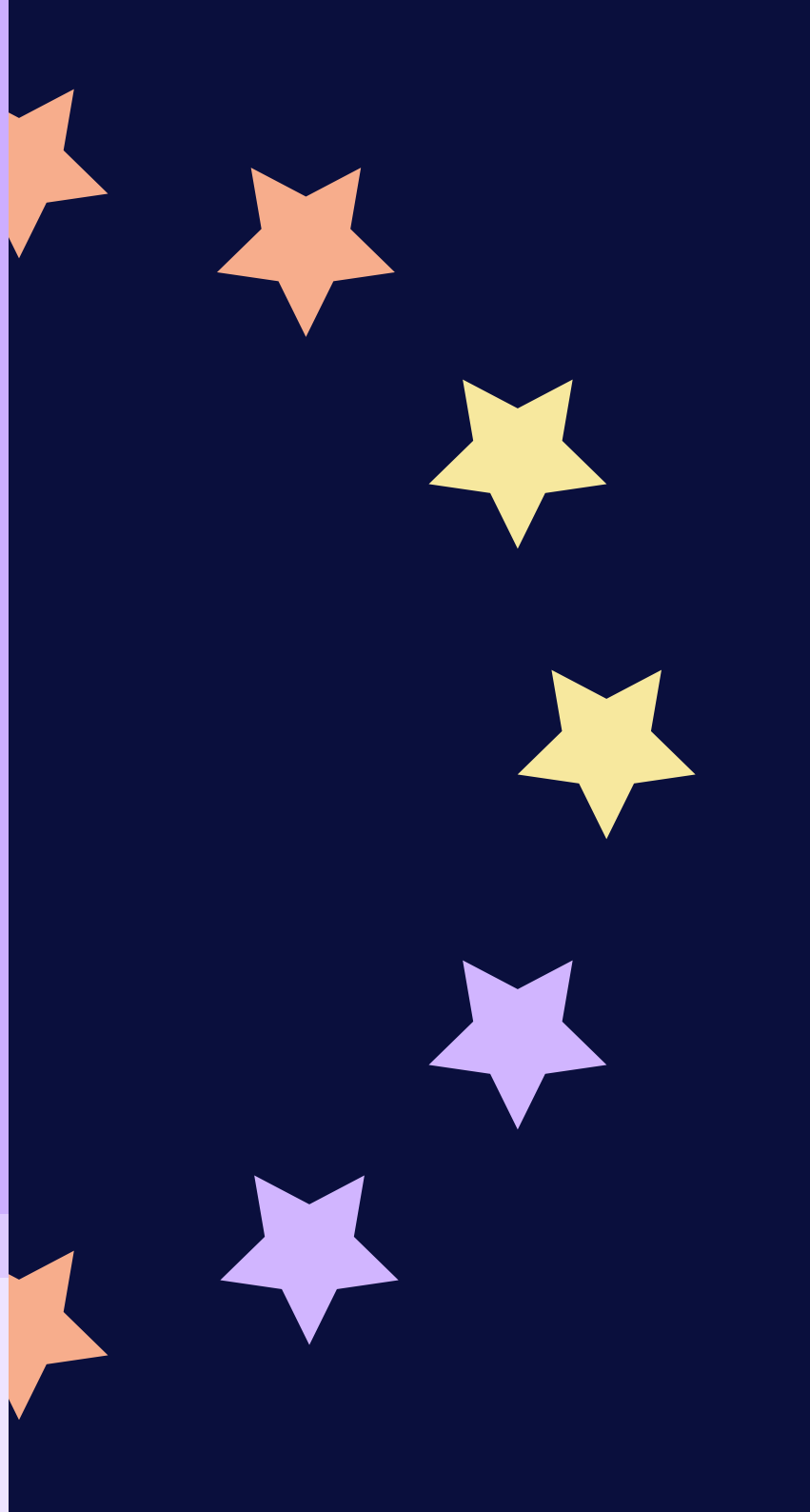
EU MDR

European Union Medical Device Regulation 2017/745

Checklist Implementation



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EU MDR
Checklist

		Reuirement/Details	EU MDR Text	ISO 13485:2016 Relevant clauses	Comments
	1	A stratergy for regulatory compliance	A strategy for regulatory compliance, including compliance with conformity assessmentpro-cedures and procedures for management of modifications to the devices covered by the system Article 10 (9 (a))	4.1	
	2	Safety and Performance	Identification of applicable general safety and performance requirements and exploration of options to address those requirements Article 10 (9 (b))	7.5	
	3	Management Responsi-biliy	Responsibility of the management Article 10 (9 (c))	5.1, 5.5	
	4	Resource Management	Resource management, including selection and control of suppliers and sub-contractors Article 10 (9 (d))	7.4	
	5	Risk Management	Risk management as set out in Section 3 of Annex I Article 10 (9 (e)) Section 3 of Annex I	7.3	

	Reuirement/Details	EU MDR Text	ISO 13485:2016 Relevant clauses	Comments
6	Clinical Evaluation	Clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF Article 10 (9 (f)) Article 61, Annex XIV	7.3	
7	Clinical Evaluation	Product realisation, including planning, design, development, production and service provi-sion Article 10 (9 (g))	7	
8	Verification of Unique Device Identity assignment	Verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29 Article 10 (9 (h)) Article 27 (3) Article 29”	7.5.8 7.5.9	
9	Post-marketing surveillance system	Setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83 Article 10 (9 (i)) Article 83	8.2.1 8.2.2	
10	Communication with authorities	Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakehol-ders Article 10 (9 (j))	8.2.3	

	Reuirement/Details	EU MDR Text	ISO 13485:2016 Relevant clauses	Comments
11	Incident reporting	Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance Article 10 (9 (k))	8.2.3	
12	Corrective and Preventive Actions (with verification of effectiveness)	Management of corrective and preventive actions and verification of their effectiveness Article 10 (9 (l))	8.5.2 8.5.3	
13	Monitoring and Measurement, data analysis, and product improvement	Processes for monitoring and measurement of output, data analysis and product improvement Article 10 (9 (m))	8.2	

Doubts?

Let us know if we can help you

Let’s chat