Obelis GROUP

MDR COMPLIANCE ROADMAP: STEPS & TIMELINE

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#	STEPS	DURATION	CLASS I	CLASS Im, Is, Ir, IIa, IIb, III	Can Obelis assist you on this?
PHASE 1 - PLANNING					
STEP 1	Full gap analysis of QMS and technical documentation against MDR	2 weeks	✓	✓	**YES!**
STEP 2	Draft Clinical Evaluation Plan (incl. PMCF)	2 weeks	✓	✓	**YES!**
STEP 3	Clinical Evaluation – Assess existing data	8 weeks	✓	✓	**YES!**
STEP 4	Perform Clinical Investigations (if required)	6 months minimum (Depending on Class – Max 24 months)	✓	✓	**NO**
STEP 5	Update QMS & PMS (PMS plan, PSUR, Risk Management, Quality Manual, Vigilance, etc)	8 weeks minimum (more in case of QMS creation – Max 6 months)	✓	✓	**YES!**
STEP 6	Contract with UDI issuing entity	2 weeks minimum	✓	✓	**YES!**
Minimum Total without Investigation			**5.5 months**	**5.5 months**	
Minimum Total			**11.5 months**	**11.5 months**	

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PHASE 2 - DRAFTING					
STEP 7	Update Technical File to MDR (Including accompanying documents e.g. DoC, Labelling, Promotional material, website, etc.)	8 months minimum (longer in case of Clinical investigations)	✓	✓	**YES!**
STEP 8	Translate part of the Technical Documentation depending on countries Language Requirements (e.g. Labels, IFUs, DoC etc.)	4 weeks	✓	✓	**YES!**
Minimum Total			**10 months**	**10 months**	

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PHASE 3 - DESIGNATION					
STEP 9	Designate EU Representative	2 weeks	✓	✓	**YES!**
STEP 10	Designate PRRC within or outside the organization – depending on Company Size	2 weeks	✓	✓	**YES!**
STEP 11	Contract Product Liability Insurance Policy	2 weeks	✓	✓	**NO**
STEP 12	Select and designate a Notified Body for Certification	4 weeks minimum (depending on Device Type and class)	/	✓	**YES!**
STEP 13.1	Complete Notified Body ISO audit (optional for Class I)	6 months	/	✓	**NO**
STEP 13.2	Complete Notified Body CE audit		/	✓	**NO**
Minimum Total			**1.5 months**	**8.5 months**	

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PHASE 4 - EXECUTION					
STEP 14	Full documentation review by EAR	6 weeks	✓	✓	**YES!**
STEP 15	EUDAMED Registration (when available)	2 weeks	✓	✓	**YES!**
STEP 16	Any additional National Registration where applicable	6 weeks	✓	✓	**YES!**
STEP 17	Contact / Engage with your critical suppliers / importer & distributor to ensure MDR compliance and sign Quality Agreements	4 weeks	✓	✓	**YES!**
Minimum Total			**4.5 months**	**4.5 months**	

GRAND POSSIBLE TOTAL

Minimum	**21.5 months**	**28.5 months**

Any questions? Contact us at:

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