Stages	Activity	Responsibility	Duration
Step 01	Appoint Medical Device Regulatory Consultant.	Client	7 Days
Step 02	Identify the models and variants.	Consultant	
Step 03	Identify product standards and International standards	Consultant + Client	
Step 04	Determination of Intended use	Client	15-20 Days
Step 05	Production, Process, Sterilization, Environment requirements	Consultant	
Step 06	Risk Analysis	Consultant + Client	
Step 07	Identification of HARMONIZD Standards and Testing Laboratories	Consultant + Client	
Step 08	Collection of data related to device functionality and Shelf life	Client	
Step 09	Biocompatibility and sterilization related documents	Client	
Step 10	Clinical Evaluation	Consultant	
Step 11	Vigilance and Post market documents	Consultant	
Step 12	Technical File preparation	Consultant	
Step 13	Submission of Technical file to Notified Body	Consultant + Client	30-45 Days
Step 14	Review of Technical file	Notified Body	7-10 Days
Step 15	Supplementary Document Submission if requested by Notified Body	Consultant + Client	30-60 Days
Step 16	Onsite Audit (ISO 13485 + MDD)	NB + Client	02 - 04 Days
Step 17	Closure of NC's	Consultant + Client	02 - 04 Days
Step 18	Affix CE Mark	Client	-

Medical Device CE Marking Process