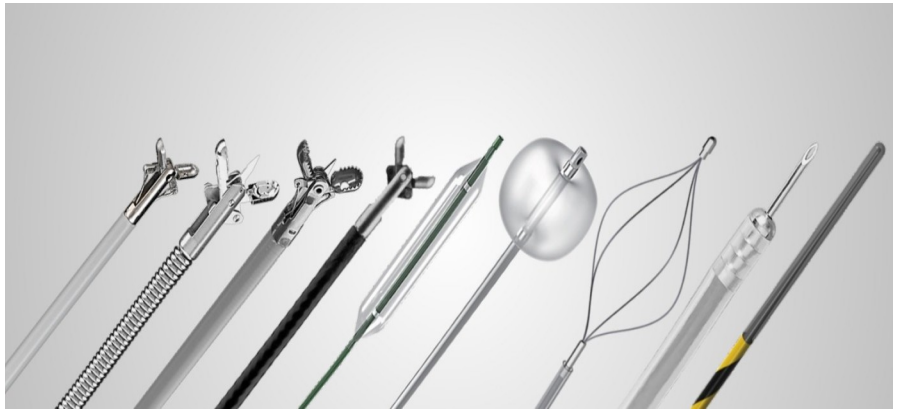
Updating the CERs as per EU MDR guidelines (Class II and III) for US based client

Successfully delivered more than 35+ CERs for Endoscopic instruments (catheters, wire guides, Dilators etc.), Retractors, Stents, Peritoneal Dialysis set and trays

Scope:

- Gap analysis w.r.t EU MDR
- Creation of templates for CEP, CER, PMCF plan & PSUR
- Prepare clinical evaluation plan | PMCF plan & report | Literature review plan, strategy & report & CER as per the new template
- Update Risks, Biocompatibility, Lifetime & Reprocessing data to the CER
- Update the Post market Surveillance data
- Update data for clinical investigations conducted



Team Size	Model	Performance	Business Impact	Risk Classes
9 (2 months)	Output based	Standardization across various manufacturing sites + CER updates as per MDR compliance	Submissions initiated to Notified Body	Class II and Class III

Reference mockup image