TATA ELXSI

Case Study

Updating the CERs as per EU MDR guidelines (Class II and III) for a 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

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