DOCUMENT CREATION FOR UL CERTIFICATION

Our customer is a global leader in medical technology. They develop new technologies and solution-oriented applications to support doctors. The company is known for its innovative products that enable more precise diagnostics and more effective treatments, particularly in microsurgery.

Preparation of a list of critical components
For UL certification, we supported the customer by creating the List of Critical Components. This defines all the safety-critical components that are required for use in medical devices in compliance with IEC 60601-1. By preparing and expanding the previous internal List of Safety Relevant Components, we were able to run tests using another product with the same assemblies and the resulting changes were communicated to the relevant project team. The customer benefited from this resource-saving approach.

Change coordination ++
konplan has been supporting this entire project for several years. Our specialists have developed so much know-how that they were able to compile the necessary lists and perform the associated system data comparisons with the stored data sheets for the safety-related components – all under critical time constraints. Thanks to the Medical Change Management team's broad expertise, a comprehensive, effective, and efficient approach was possible, going beyond mere change coordination tasks.

Result
- Approval-related Regulatory Compliance

Methodology & Technologies
- MS Office: Excel
- SAP

Scope of Services
- System Data Comparison
- LSRC Review
- LoCC Preparation

3 months

2 employees – konplan
3 employees – customer

Conception, operation

ılk developing together