Total Scope

The Leader in Medical Device Repair & Services

TOTAL SCOPE IS

ISO 13485-2016 CERTIFIED

How does ISO 13485 directly affect repair and service quality?

- Total Scope must be positive it can meet all customer requirements prior to the on boarding process
- All parts and suppliers undergo an annual review to ensure all parts are equal to or superior to the manufacturer
- Master device record containing device specifications and process requirements are established and maintained for each medical device
- Repairs undergo an internal audit to validate conformance to set procedures
- Before departure, scopes go through the three phases of QC process to ensure all scopes match OEM specifications
- Verified and authorized batch records must be maintained
- Device history is kept on all medical devices, which includes a lot numbering system for recall purposes. Device history is also available on your TSI Web Portal
- Satisfaction levels are monitored and evaluated through gold card surveys, new customer surveys, and our annual survey

WHICH COMPANY WILL YOU ENTRUST WITH YOUR SCOPE?

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