Treatment Facility – Program Quality Overview

FDA Registration

 All containers are cleared for commercial distribution via the 510K pre-market notification process.

Quality System Regulation Compliance

 GMPs from 21 CFR Part 820 are followed to create Standard Operating Procedures.

Process Validations

- Protocols developed by an independent medical device testing lab using the latest AAMI guidelines.
- PLC, Installation, Operational and Performance Qualifications are conducted.

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Rachel S Tattersall

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