

Keep your patients protected with an ISO-certified biomedical equipment provider

What is ISO 13485:2016?

It's a customer patient-focused quality management system to help ensure medical devices support patient safety and quality standards. It outlines requirements that organizations need to adhere to in order to demonstrate their ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Who needs to follow it?

Organizations involved in the design, production, installation and servicing of medical devices and related services.

What are some of the requirements?

Requirements in maintaining the effectiveness of a quality management system include:

- Documented procedures to maintain an effective quality management system
- Maintaining records throughout the medical device life cycle
- Taking a risk-based approach to servicing activities
- Documented training program for technicians and support staff
- Continuous improvement through customer feedback



McKesson Biomedical Solutions™

is proud to be a 13485:2016 certified service provider for medical devices such as enteral pumps, infusion devices and ventilators. And we'll take the stocking, servicing and tracking of those devices off of your plate as well. That means that you can enjoy a worry-free equipment experience while ensuring your patients stay protected.

- *Comprehensive, patient-ready inventory*
- *Dependable equipment service*
- *Inventory management solutions like McKesson OneTrack®*
- *Supply chain management*

Contact your McKesson Medical-Surgical Account Manager to learn more.

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