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ISO 13485:2016 | QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES CERTIFICATION

SKU: ISO13485certification

ISO 13485:2016 | Quality Management Systems for Medical Devices

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WHAT IS ISO 13485:2016?

ISO 13485 is the internationally recognised standard for **quality management systems (QMS) specific to medical devices**. First published in 2003 and most recently revised in 2016, the standard outlines the processes, documentation, and controls needed to design, produce, store, distribute, install, and service safe and effective medical devices.

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