ISO 13485:2016

Medical devices — Quality management systems — Requirements for regulatory purposes

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

The ISO 13485:2016 certification is a proof of Quality Management System compliance to the standard for organizations involved in the Medical Device industry. This approach is not only followed by Medical Device Manufacturers but also supporting organizations such as Subcontractors, Suppliers, European Authorized Representatives, specialized Consulting firms etc…

Note that ISO 13485:2016 expands the profile of companies and organizations to which the standard can apply: Organizations involved in one or several stages of a Medical Device Lifecycle or a Supplier or other External Parties providing such organizations with products for example.

Organizations involved in one or more stages of the medical device lifecyle	Suppliers or External Parties who provide products to such Organizations
• Design and Development • Production • Storage • Distribution • Installation • Servicing	• Raw materials • Components • Sub-assemblies • Medical devices • Sterilization services • Calibration services • Distribution services • Maintenance services

In addition, the ISO 13485 standard requires that the organization identifies its role(s) in connection with the regulatory requirements (e.g. Manufacturer, Representative, Importer and / or Distributor), and determines the applicable regulatory requirements depending on the role(s), then integrates the regulatory requirements in the QMS.