



MEDICAL DEVICE

ITA Group is a leading company in the Medical Devices (MD) sector, providing regulatory consultancy and support throughout the compliance and registration process of MDs. Our highly qualified technical team, both locally and internationally, offers specialized regulatory expertise.

The regulations governing the safety of medical devices include:

Scope Extension

These regulations define the types of medical devices subject to regulatory rules and requirements. Product Traceability Process: The regulations mandate that medical devices are traceable throughout their entire lifecycle, from production to distribution and end-use.

Structure and Content of Technical Documentation

The regulations establish requirements for the technical documentation of medical devices, including clinical data, compliance testing, and safety information.

Strengthening of Market Surveillance System

The regulations require a market surveillance and monitoring system to ensure the ongoing safety of medical devices. This includes conducting clinical investigations and extending obligations to importers and distributors.

The ISO 13485:2016 standard defines requirements for the quality management system of organizations involved in the design, production, and delivery of services related to medical devices. This standard covers various stakeholders, including medical device manufacturers, logistics service providers, distributors, and importers. Additionally, the standard places particular emphasis on the usability of medical devices and a risk-based approach to process management.

The U.S. Food and Drug Administration (FDA) is working to harmonize the Code of Federal Regulations (CFR) Title 21 Part 820 with the ISO 13485 standard to modernize and standardize industry regulations. Discover our services for the medical devices sector and learn how we can support you throughout the compliance and registration process of MDs.

We offer regulatory consultancy, technical support, and in-depth knowledge of industry regulations to ensure the success of your projects.