

ISO 13485 – Medical devices

Quality management system certification for organisations working in the design, development, production, installation or sale of medical devices and related services.



Quality management system certification for organisations working in the design, development, production, installation or sale of medical devices and related services. The certification of quality management systems for medical devices supports organisations in this sector to achieve regulatory compliance and to meet the needs of their clients, both for companies and for related services.

What is ISO 13485 certification?

The ISO 13485 standard shares its structure with that of ISO 9001 and includes important factors such as sterile manufacturing, traceability and risk assessment. This permits the monitoring of the full healthcare-product production process, from design conception to end destination.

ISO 13485 compliance enables organisations to meet quality system requirements around the world, including those set by the FDA in the United States, the Canadian authorities and the European Union.

Key benefits

- Ensures compliance with international regulatory schemes
- Ensures compliance with client requirements
- Enables the full monitoring of products, from design conception to end destination
- Fosters recognition and confidence in the medical device industry
- Provides access to national and global markets



- Increases efficiency
- Enhances the company's reputation

Why certify with Applus+ Certification?

Applus+ Certification is a prestigious independent body that was established to help organisations achieve their aim of continuous improvement. We assess the specific needs of our clients so that our auditors, who specialise in the sectors in question, can add maximum value while evaluating an organisation's compliance.

Our teams of professionals draw up customised certification plans taking into account client structures, processes and areas of activity. Our global presence, extensive product portfolio and wide-ranging accreditations enable us to provide our clients with a comprehensive, expert and tailor-made service.