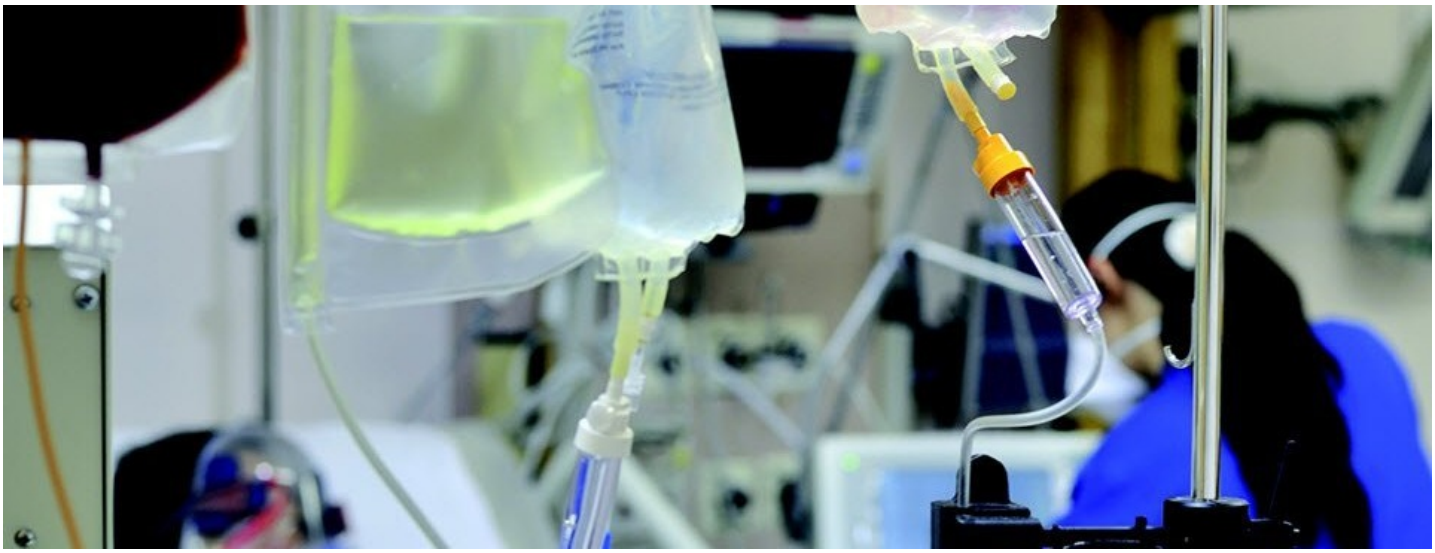
ISO 13485 Medical Devices



ISO 13485:2016 Medical Devices – quality management systems certification with Kiwa: ensure quality, build trust and comply with regulations in the medical devices sector.

Relevant to any organization in the medical devices sector.

People rely on medical devices to survive; if your organization operates in the medical devices field, quality is vital. ISO 13485 certification can help you demonstrate your ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
ISO 13485 specifies the requirements for a quality management system that any organization operating in the medical devices sector needs to demonstrate. Certification demonstrates your organization's reliability, proving your commitment and abilities to provide design, manufacturing, testing and sales services that consistently meet customer needs and regulatory requirements.

What you need to know

Based on the more general management standard ISO 9001, ISO 13485 is aimed specifically at organizations in the medical devices field, covering all stages, from design to installation and maintenance, and related services such as sterilization and testing. It sets out the specific requirements for a quality management system related to medical devices. In the EU, the requirements have been harmonized with those of several regulations, including the Medical Device Directive (93/42/EEC), the Directive for In Vitro Diagnostic Medical Devices (98/79/EC) and the Directive for Active Implantable Medical Devices (90/385/EEC).
ISO 13485 follows a structure that makes it easy to use alongside other management system standards, such as ISO 14001.

Getting certified with Kiwa

Safety and quality are non-negotiable in the medical devices industry – they can literally mean the difference between life and death. With increasingly strict regulatory requirements and expectations from customers and organizations throughout the supply chain, it is critical to demonstrate best practice in quality management processes – and ISO 13485 certification can do that.

Kiwa N.V.
info@kiwa.nl
+31 (0)88 998 44 00

By partnering with Kiwa, you can use ISO 13485 to ensure the products or services you offer in the medical devices field are in accordance with internationally accepted standards, helping you build trust with customers and meet legal requirements.
ISO 13485 was most recently updated in 2016; if you were previously certified, you have until March 2019 to transition to the new standard. Kiwa can help you make the change – contact us to find out more.

USPs/benefits

- *Win new business* – you can beat the competition in procurement processes when ISO 13485 certification is a requirement.
- *Improve processes* – with ISO 13485, you can identify areas for improvement in your management processes, ensuring they are internationally accepted.
- *Reduce costs* – by highlighting where your processes can be improved, ISO 13485 helps you cut operating, manufacturing and energy costs.
- *Meet customers' needs* – with a focus on customers, ISO 13485 lets you set out goals for meeting customer needs.
- *Demonstrate your commitment to quality* – ISO 13485 certification shows customers, partners and employees that you are committed to continuous improvement.
- *Improve competitiveness* – ISO 13485 certification helps you enter new global markets and supply chains and forge new partnerships.
- *Monitor and improve performance* – ISO 13485 helps you analyze your processes and monitor customer opinion.
- *Manage your supply chain* – ISO 13485 covers supply chain management, helping you improve your processes and maintain quality throughout the value chain.

ISO 13485 and the MDR

The ISO 13485 quality standard helps suppliers of medical devices and related services comply with the Medical Devices Regulation (MDR). The introduction of this new European regulation will bring major changes for both healthcare institutions and manufacturers of medical devices:

- Additional requirements for market operators;
- New risk classification and extension of scope;
- More transparency for patients and better traceability;
- Stricter rules for certain products.

MDR applicable from May 26, 2021

The introduction of the MDR was planned for May 2020. Due to the corona crisis, the introduction has been formally postponed by one year. The MDR is applicable from 26 May 2021.

Kiwa N.V.
info@kiwa.nl
+31 (0)88 998 44 00