

# Telarc.



**ISO 13485**  
**Medical Devices Quality Management System**



# ISO 13485

**Safety and quality are  
non-negotiable in the  
medical devices  
industry.**

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Regulatory requirements are increasingly stringent throughout every step of a product's life cycle, including service and delivery.

Increasingly, organisations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do.

This internationally recognised standard sets out the requirements for a quality management system specific to the medical devices industry.



# Medical

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## Who is it for?

ISO 13485 is intended for any organisation involved in the design, production, installation, and servicing of medical devices and related services.

It can also benefit suppliers and external parties that provide product, including quality management system-related services to such organisations.

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## About the standard.

ISO 13485 is the internationally recognised standard for quality management systems in the design and manufacture of medical devices. It outlines specific requirements that help organisations ensure their medical devices meet both customer and regulatory demands for safety and efficacy.

ISO 13485 is crucial for manufacturers and suppliers of medical devices as it establishes a framework to ensure consistent design, development, production, and delivery of medical devices that are safe for their intended purpose. It aids in meeting rigorous regulatory requirements and managing risk, while ensuring best practices in the manufacture of medical devices. This standard not only facilitates market access across different countries but also enhances trust among stakeholders through demonstrated commitment to safety and quality.



# Medical

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## Benefits of ISO 13485

**Risk management enhancement.** Provides systematic methods to identify and mitigate risks throughout the product lifecycle, ensuring patient and user safety.

**Regulatory compliance.** Helps organisations meet strict regulatory requirements specific to medical device manufacturing, crucial for market access and global trade.

**Operational efficiency.** Streamlines processes to improve overall efficiency and effectiveness, reducing waste and increasing productivity.

**Market access.** Facilitates entry into global markets with standardised compliance, enhancing competitive advantage.

**Enhanced reputation.** Builds credibility and trust with stakeholders, including regulators, customers, and end-users, through proven adherence to a globally recognised quality standard.

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## Our approach to your certification.

We always work to ensure the auditing process both assists with compliance and improves the efficiency and viability of our customer's businesses. After a Telarc audit you'll receive an independent, authoritative and impartial report. This will help you to maintain the standards required by your chosen criteria, appropriate for your organisation.

As New Zealand's largest auditing body we can also conduct audits covering multiple standards and specifications, and we also routinely offer integrated audits. With this approach we can ensure the most cost-effective and time-efficient results for our clients.