

A close-up photograph of a surgeon in a blue surgical gown and a green face mask, wearing blue gloves. The surgeon is focused on a patient, whose arm is visible in the foreground. The background is blurred, showing other medical staff in a sterile operating room environment. An orange geometric shape is in the top left corner.

Medsalv: Driving quality, safety & sustainability with ISO 13485 certification

CASE STUDY



The background

Meeting the need for safer, more sustainable healthcare

Single use medical devices are a major source of both financial strain and environmental waste in hospitals. Medsalv, a mission driven healthcare company operating across New Zealand and Australia, saw an opportunity to tackle this challenge through remanufacturing.

By collecting used devices, restoring them to meet strict performance and safety standards and returning them to hospitals for reuse, Medsalv provides a sustainable, cost effective alternative.

To ensure these operations meet global expectations for safety, consistency and compliance, Medsalv committed to implementing a Quality Management System (QMS) certified to ISO 13485 as part of it's ongoing commitment to regulatory excellence and patient safety.

"Achieving ISO 13485 certification demonstrates our commitment to patient safety, regulatory compliance and operational excellence," said Oliver Hunt, Founder at Medsalv. "It provides assurance to hospitals and

regulators that we meet the highest international standards."

milestone in its regional growth strategy.

The implementation

A two-country, multi-year certification journey.

Medsalv began its ISO 13485 journey in New Zealand, spending several years developing and refining its QMS to meet the requirements. Certification was achieved on 24 November 2021. As the company expanded into Australia, it undertook a further 12 month integration project to bring the new site under the same quality framework. This involved:

- Aligning operations and procedures across both countries
- Managing regulatory differences between jurisdictions
- Ensuring consistent risk management and traceability across the supply chain

On 24 November 2024, Medsalv successfully extended its ISO 13485 certification to cover both of it's remanufacturing sites, in New Zealand and Australia, a key

"The certification journey was straightforward and consistent, with the rigour demanded by SGS helping make our Medsalv stronger and setting our operations up for further scaling"

- Oliver Hunt, Founder, Medsalv

Strengthening systems and unlocking value

The SGS certification audit process helped Medsalv:

- Reinforce its risk based approach to quality and compliance
- Enhance supplier management and traceability

- Improve documentation and process control
- Streamline reporting and operational efficiency

"The SGS Audit reinforced the value of our strong QMS, which extends throughout our operations - and supports our high standards of delivery for our customers, as we grow rapidly." affirmed Oliver.

SGS auditors also commended Medsalv's robust inspection and testing protocols, strong commitment to staff training and continual improvement and proactive focus on sustainability, patient safety and regulatory engagement.

Market confidence and future growth

With ISO 13485 certification in place, Medsalv has:

- Built greater trust with hospitals, clinicians and procurement teams
- Positioned itself to expand into new healthcare markets
- Strengthened its brand as a leader in sustainable healthcare innovation
- Demonstrated that remanufactured medical devices can meet and exceed global expectations and regulatory requirements

WHY SGS

SGS is the world's leading Testing, Inspection and Certification company. We operate a network of over 2,500 laboratories and business facilities across 115 countries, supported by a team of 99,500 dedicated professionals.

We can help you to understand the requirements through our internationally recognised ISO 13485 training courses, confirm that your medical device products meet the requirements of the standard, provide proof of compliance with our independent assessment and certification and gain the quality assurance required to meet the demands of stakeholders at every level.

CASE STUDY OVERVIEW

Client: Medsalv

Industry: Healthcare / Medical device remanufacturing

Certification: ISO 13485

Certification body: SGS

Locations covered: Australia and New Zealand

When you need to be sure

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