# How Gynaecologic achieved MDSAP certification to maintain access to the Australian medical device market

**CASE STUDY**

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When Gynaecologic needed MDSAP certification to support Class IIa medical device registration with the Therapeutic Goods Administration (TGA), the company faced the challenge of becoming the legal manufacturer of its products after many years of relying on an external manufacturing partner. Working with SGS, regulatory consultants and key suppliers, Gynaecologic successfully achieved MDSAP and ISO 13485 certification, supporting continued supply into the Australian market.

## The challenge

Gynaecologic required MDSAP certification to support Medical Devices Class IIa registration with the Therapeutic Goods Administration (TGA) for continued supply into the Australian market.

For many years, the company relied on an Australian organisation to manufacture its products as the legal manufacturer. When that business was wound down, Gynaecologic explored alternative options before deciding to become the legal manufacturer itself.

As a small company with two products, pursuing MDSAP certification had previously appeared to be a significant undertaking. However, certification became necessary to support ongoing market access.

## The process

Once the decision was made to become a manufacturer, Gynaecologic worked with its regulatory consultants, critical suppliers and SGS throughout the implementation and audit process.

According to the company, the process was not as long or as complex as initially anticipated, and SGS provided support before and throughout the audit stages.

"Once we made the decision to become a manufacturer, the process was not as long or complex as I had anticipated. SGS were collaborative prior to and during the different audit stages, and I felt incredibly supported." Grace Carey, Managing Director, Gynaecologic.

### Primary driver

MDSAP certification to support Class IIa medical device registration with the TGA

### Key learning

Implementing MDSAP was less complex than initially expected

### Audit outcome

The audit highlighted areas where Gynaecologic was performing well while also providing opportunities to further strengthen supporting documentation

## What the audit revealed

For Gynaecologic, implementing a quality management system and progressing through the SGS audit process provided valuable insights into the company's quality practices. The experience helped strengthen key aspects of its quality management system while reinforcing existing processes.

**Key learnings**

- Improved documentation and process control
- Enhanced supplier management and oversight
- Improved traceability
- Reinforced risk-based approach to quality

> "Going through this process with SGS has been hugely beneficial in improving documentation and process control, enhancing supplier management and traceability, and has reinforced our risk-based approach to quality."
>
> *- Grace Carey, Managing Director, Gynaecologic.*

## What is ISO 13485?

ISO 13485 is the internationally recognised standard for medical device quality management systems (QMS). It provides medical device manufacturers with a framework to consistently meet customer and regulatory requirements while demonstrating a commitment to quality and patient safety. The standard applies across the product lifecycle, from design and development through to manufacture and servicing.

**Benefits of ISO 13485 certification**

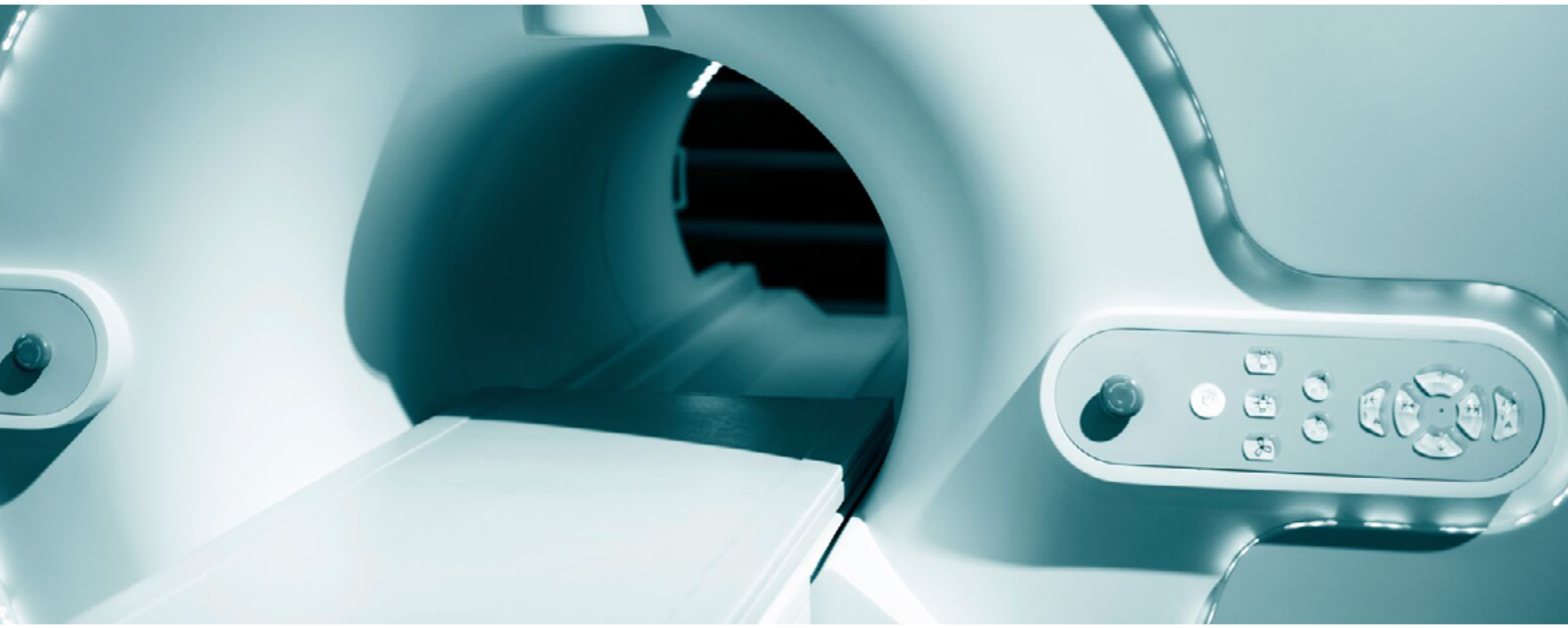
- Demonstrates compliance with medical device regulatory requirements
- Supports access to international markets
- Helps organisations demonstrate consistent product quality
- Builds confidence among regulators, customers and stakeholders
- Reinforces a commitment to quality and patient safety

## What is MDSAP?

The Medical Device Single Audit Program (MDSAP) enables medical device manufacturers to undergo a single audit that is accepted by multiple participating regulatory authorities. As an MDSAP Auditing Organisation, SGS can conduct audits that satisfy quality management system requirements for participating jurisdictions including Australia, Brazil, Canada, Japan and the United States.

**Benefits of MDSAP certification**

- Gain access to multiple markets through a single audit



- Minimise business disruption while optimising time and resources
- Achieve comprehensive coverage of participating regulatory requirements
- Leverage a single audit report across participating jurisdictions

## What is the certification process?

### ISO 13485 certification

SGS independently assesses quality management systems against ISO 13485 requirements and provides the certification required for market access.

The assessment focuses on:

- Management responsibility
- Resource management
- Product realisation
- Measurement, analysis and improvement

### MDSAP certification

1. **Proposal and Application**
   SGS reviews requirements and gathers information needed to plan the audit
2. **Stage 1 Audit – Documentation and Preparedness Review**
   Assessment of quality management system documentation and readiness for certification
3. **Stage 2 Audit**
   Evaluation of the effectiveness of the quality management system and compliance with applicable regulatory requirements
4. **Certification Review and Decision**
   Following successful completion of the audit process and certification review, certification is issued
5. **Ongoing Surveillance Audits**
   Annual audits verify continued compliance and maintenance of the quality management system

### ABOUT GYNAECOLOGIC

Gynaecologic Pty Ltd develops and manufactures anatomically designed pessaries used in the treatment of pelvic organ prolapse. Its products support both conservative clinical management and surgical outcomes, helping improve quality of life for patients living with this common condition.

**Primary driver**
TGA registration and market access

**Certification achieved**
MDSAP & ISO 13485

**Industry**
Medical Devices

**Location**
Melbourne, Australia

**Key learning**
Implementing MDSAP was less complex than anticipated

# When you need to be sure

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