QUALITY MANAGEMENT SYSTEM - MEDICAL DEVICES

CERTIFICATION SCHEME

Enhance Patient's Confidence With Quality Assurance

Make your mark in the global medical devices market. SIRIM QAS ensures that your company meets international standards of quality based on the ISO 13845 requirements. Establish and maintain quality management systems to improve competitiveness and ease of access into this highly lucrative industry.

Ensuring Optimum Quality – ISO 13485 Quality Management System Medical Devices Sector

ISO 13485 is an international standard that proves itself useful for all aspects of the device production and can be implemented at any point in the supply chain. It applies to an array of industries involved in the:

1) Supply of raw materials
2) Design and development of medical equipment
3) Installation of medical equipment
4) Servicing of medical devices (calibration maintenance and sterilization services)
5) Storage and distribution of medical devices
6) Final decommissioning and disposal of medical devices

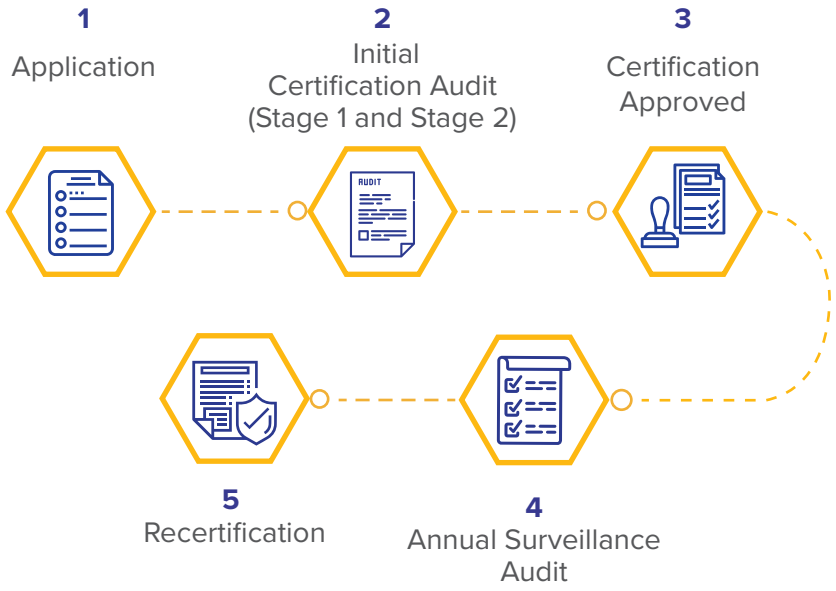
The Ministry of Health (MOH) has adopted this standard as a measure of controlling the quality and standards that the medical device industry must hold itself up to. This is crucial for their consumers, who stake their security and peace of mind on the competence of medical device manufacturers and distributors. No one wants to be the victim of a faulty mammography machine or defective colonoscope. It is a standard that the medical device industry must uphold with integrity and pride.

Regulators worldwide have adopted the standard to easily facilitate the process of license application that every medical device manufacturer must go through. Ideally, this would streamline the quality of devices that are faced with different system requirements and give manufacturers the space and time needed to incorporate new, potentially life-saving innovations in their products.

Why Get Certified

- Expand reach and distribution with more credibility and ease.
- Gain access to the wider market as you can apply for a medical device export permit.
- Enhance trust through certification that proves your competence and quality control.
- Improve competency by adhering to technical requirements of the certification.

Certification Process



SIRIM QAS – Reputation Built Upon Expertise

SIRIM QAS is an internationally recognised Conformity Assessment Body with years of experience in providing testing, inspection and certification services to both local and international customers. We are backed by a team of highly-trained and experienced auditors in the medical devices sector.

SIRIM QAS has been approved and registered by the Medical Device Authority (MDA) division under the Ministry of Health Malaysia (MOH) as a Conformity Assessment Body (CAB) to assess and certify quality management systems for traders of medical devices based on GDPMD requirements.

We are accredited by the Department of Standards Malaysia (STANDARDS MALAYSIA) and the United Kingdom Accreditation Service (UKAS), demonstrating the credibility of our processes. SIRIM QAS is also a member of the International Certification Network (IQNet), which facilitates acceptance of our certifications globally. Leverage on SIRIM QAS's well-established global presence and make your mark in the market, today.

For more information, contact us at:

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