GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES

CERTIFICATION SCHEME

Meet National Requirements for Medical Device Distribution After Wholesale and Imports

Partnering with SIRIM QAS allows your company to demonstrate consistent quality assurance. With best distribution practices in place, you can assure customers that medical devices are handled under suitable conditions to ensure product safety, quality and performance.

The Manual for Best Practices – Good Distribution Practice for Medical Devices

Good Distribution Practice for Medical Devices (GDPMD) outlines requirements for the establishment, implementation and maintenance of a quality management system for businesses involved in the distribution process of medical devices.

This is one of the requirements stipulated under the Medical Device Act 2012, in which importers and distributors need to implement GDPMD prior to obtaining their licence to trade in medical devices in Malaysia.

The objective of GDPMD is to ensure the quality, safety and performance of medical devices throughout the supply chain. Its requirements are not limited to procurement, logistics, storage and after-sales activities, but also covers competencies of personnel, tracking, documentation and record-keeping. With these controls in place, companies can ensure that products are consistently handled and managed under suitable and appropriate conditions.

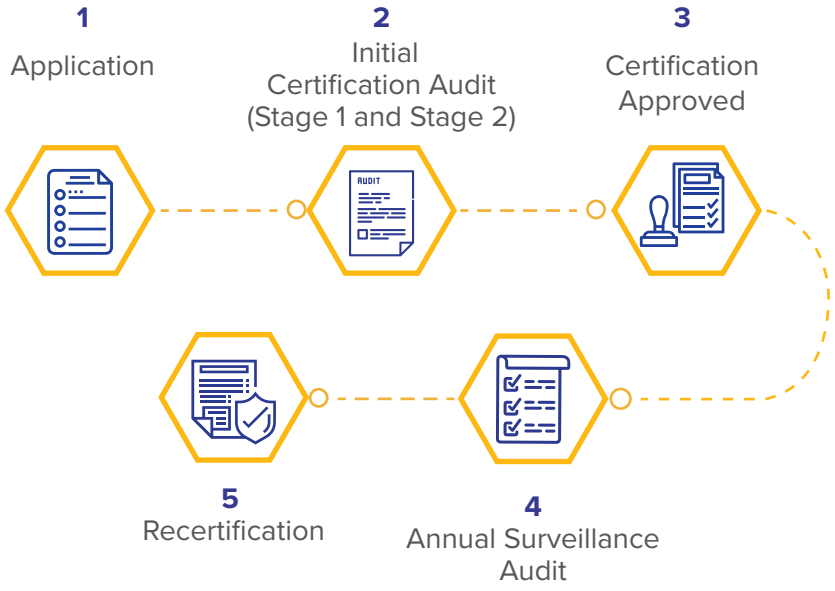
SIRIM QAS is an approved and registered Conformity Assessment Body (CAB) under the Medical Device Authority (MDA), a division under the Ministry of Health Malaysia (MOH). Our extensive experience in management system certifications positions us as a committed partner to the industry.

We can also help companies that are already certified to ISO 9001 to fill the gaps and reconcile requirements prior to undergoing audits for GDPMD.

Why Get Certified

- Provide independent assurance that regulatory and standard requirements are implemented and consistently maintained.
- Ensure quality of products under an effective system of supervision and control throughout the supply chain.
- Ensure that medical devices are consistently stored, transported and handled under suitable conditions, safeguarding the quality and safety of products.
- Facilitate market acceptance and access by demonstrating compliance to best industry standards.
- Enhance production efficiency through maintenance of a quality management system that addresses risks and deficiencies in processes.

Certification Process



SIRIM QAS – Supporting the Growth of the Medical Devices Industry

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.

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