



Medical device certification for a healthier business

The recent pandemic has intensified focus on medical devices and technology. For players within the medical devices supply chain, there is a pressing need to demonstrate competency to ensure the quality, safety and performance of medical devices under its care.



SIRIM QAS offers a solution for organisations looking to have a greater competitive edge within the medical device industry. The ISO 13485 Medical Devices is a standard requirement for quality management system (QMS) specific for medical device manufacturers.

Under the Medical Device Act 2012, all companies involved in the manufacture, storage, distribution, installation, servicing or disposal of medical devices must be ISO 13485 certified. More than that, compliance with the ISO 13485 standard provides:



- Increased credibility and brand image
- Improved decision-making on management of medical devices supply chain
- Assurance to stakeholders of compliance with standards
- Greater market access and a competitive edge

Promoting growth in the industry

SIRIM QAS has been appointed by the Medical Device Authority (MDA) – an agency

under the Ministry of Health as the Conformity Assessment Body for medical devices in Malaysia. As the country's leading testing, inspection and certification centre, SIRIM QAS is well-positioned to be your partner in assurance and safety.

Set the standard for good practices for medical devices with SIRIM QAS

Need help or have a question?

Helpline: +603 5544 6400

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About SIRIM QAS

SIRIM QAS International Sdn Bhd is an accredited testing, inspection and certification body with an established presence in over 37 countries worldwide. Together with our highly trained and experienced personnel, we are committed to provide our clients with the highest standards of service. With our wide range of services and stellar track record in the area of conformity assessment, we are your partners in assurance and quality.



[The IBR Asia Group](#), on behalf of SIRIM QAS, is glad to be of service in assisting with further enquiries. Email us at consulting@ibrasiagroup.com, or simply click on the "Enquire Here" button above and we will make sure to direct your questions to SIRIM QAS

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