

Govt to introduce 'Indian Certification for Medical Devices Scheme' to ensure quality of medical devices

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In order to bring down cost and time run to obtain globally accepted certification for Indian companies, the Quality Council of India (QCI), India's apex quality facilitation and national accreditation body, is likely to introduce voluntary certification scheme named Indian Certification for Medical Devices Scheme (ICMED) in one month's time.

Though the scheme is voluntary, it intends to enable the medical device industry to demonstrate adherence to the best international standards and enhance its credibility in the world market and on the other hand take care of Indian scenario too. ICMED 9000 will cover Class A category having low risk devices and ICMED 13485 will cover Class B, C, D having moderate to high risk devices.

The scheme is a joint voluntary initiative of QCI and Association of Indian Medical Device Industry (AIMED). Under this scheme, 3 types of certification criteria will be available- ICMED 9000 which is based upon ISO 9001 plus additional requirements, ICMED 13485 based upon ISO 13485 plus additional requirements and ICMED 13485 plus based upon ICMED 13485 plus Product specification as per ministry of health and family welfare technical specifications.

It is necessary to have an institutional mechanism for operating Voluntary Certification Scheme based on international best practices and sound technical standards and using competent certifiers, which can promote medical devices manufactured in India as high quality products and bring esteem to the Indian industry.

QCI and AIMED had signed an MoU on October 30, 2014 to develop and operate voluntary certification programmes for medical devices in order to enable medical device industry to demonstrate adherence to the best international standards and enhance its credibility in the world market.

While QCI and AIMED are the joint Scheme owners, the governing structure of the initiative is under a multi stakeholder Steering Committee and the initiative would be operated on a non-profit but self- sustaining basis. It would have a defined consensus based technical criteria laid down for the medical devices which would be evaluated by competent third party certification bodies.

This ICMED Standard specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of this ICMED Standard is to facilitate harmonized medical device regulatory requirements for quality management systems.

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