

## Indian Certification of Medical Devices Scheme launched

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Indian Certification of Medical Devices Scheme (ICMED)" - country's first indigenous quality assurance system for India manufactured medical devices was launched in the presence of top representatives from government, healthcare industry and quality council fraternity.

ICMED - the first home developed international class certification scheme for the medical devices in the country - is an initiative of Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB). ICMED is aimed at enhancing patient safety, to provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers and users. This Scheme is intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

For manufacturers, it aims to bring down the substantial time and cost-run to obtain globally accepted quality certification for Indian companies and eliminate the malpractices of sub-standard or fraudulent certification or quality audits, thereby ensuring substantial savings, enhanced credibility and increased competitiveness.

As currently, there is no India-specific official quality assurance system, due to which Indian medical device manufacturer's encountered loss of competitiveness to foreign companies while consumers ended up paying extra premium with no concomitant benefits, ICMED also fills a big regulatory void.

"The scheme fills a big regulatory vacuum in quality certification space for medical devices in the country and will enhance the competitiveness and profitability of Indian medical device industry," said Dr V K Subburaj, secretary, Dept of Pharmaceuticals, Gol while launching the scheme.

AIMED has termed it a significant milestone due to multiple benefits it would assure to different stakeholders.

"The Scheme is a significant milestone for both consumers as well as manufacturers as it brings quality, accountability and competitiveness in the system," said Mr Rajiv Nath, forum coordinator, AIMED and chairman, Technical Committee, QCI-AIMED Voluntary Initiative on Medical Devices.

The Certification Scheme being launched has presently two options for certification, one being 'ICMED 9000 Certification (an ISO 9001 plus additional requirements)' and other being 'ICMED 13485 (An ISO 13485 Plus additional requirements). A third level, which would additionally prescribe medical device specifications developed by NHSRC of the Ministry of Health and Family Welfare is still under development and would be launched later.

"QCI is happy to lend a helping hand to the medical device industry in India to showcase its strength in terms of meeting the highest international standards. We have already devised such schemes for ayurvedic products, ready mix concrete plants and yoga professionals and this would be a valuable addition to our portfolio. It would go a long way in contributing to the success of govt's flagship Make in India programme," said Mr Adil Zainulbhai, chairman, QCI.

According to Dr Dr M K Bhan, ex secretary to the Government of India, Department of Biotechnology, Ministry of Science and Technology, "For a country like India, the twin challenge is to ensure availability of quality healthcare products at reasonable cost so that overall healthcare cost remains reasonable. In this direction, the launch ICMED is a significant collaborative initiative and will go a long way to ensure realization of these objectives."

It may be added that NABCB has already secured international equivalence for most of its accreditation programmes and it would facilitate international acceptance of Indian medical devices.

"NABCB is accrediting certification and inspection bodies and its accreditation programmes are internationally equivalent placing it on par with European and American accreditation bodies. This equivalence would help facilitate acceptance of ICMED certification in overseas market," pointed out Mr Anil Jauhri, CEO, NABCB.

The manufacturers would need to approach any one of the certification bodies approved by QCI under the Scheme for obtaining certification. The certification bodies shall be under the oversight of NABCB, which as the national accreditation body, would accredit these certifying bodies as per applicable international standards.

Among the dignitaries present during the launch function of ICMED included: Mr Amitabh Kant, CEO, NITI Ayog; Mr C Viswanath, secretary, Department of Consumer Affairs; Mr Wajahat Habibullah, chairman, PSAIIF & the Jury; Mr Samir Behl, regional president, Amway, Europe, Africa and India; Mr Bejon Misra, founder, Consumer Online Foundation and Mr G Gurucharan, special secretary, Department of Consumer Affairs.

ICMED Backgrounder:

ICMED is the fructification of a MoU was signed between QCI and AIMED on 30 Oct 2014 to fill the regulatory vacuum in quality certification space for medical devices in the country. The scheme has been developed involving various stakeholders with a Steering Committee chaired by Dr MK Bhan, former secretary, Biotechnology, at the helm, supported by a Technical Committee and a Certification Committee constituted for this purpose.

More than twenty government and non-government organizations including Department of Commerce, National Health System Resource Centre (NHSRC), Bureau of Indian Standards (BIS), Central Drug Standard Control Organization (CDSCO), Engineering Export Promotion Council (EEPC), prominent industry bodies like AIMED and Confederation of Indian Industry (CII), Center for Biomedical Engineering, IIT Delhi, Indian Medical Association (IMA), etc. participated in various committees.