

Transasia Bio-Medicals receives ICMED 13485 certification

14 June 2018 | News

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Transasia Bio-Medicals Ltd., India's leading In-vitro Diagnostic Company, has been recently certified by ICMED 13485 - Indian Certification for Medical Devices (ICMED) Certification Scheme. This is in addition to the latest ISO 9001:2015 certification. The company has been audited and registered by UL India Private Limited.

ICMED is the country's first indigenous quality assurance system for India manufactured medical devices. It 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, by providing the product credentials to manufacturers and is intended to significantly eliminate trading of sub-standard products or devices.

Transasia received the ICMED 13485 certification for its manufacturing facilities at Mumbai, Daman and Baddi. All the three facilities were successfully audited for quality compliance for the design, development, manufacture, installation and service of IVD analyzers and reagents used in diagnosis.

"We are glad that alongwith all existing national and international quality certifications we are now also certified by India's very own QA system. We are committed to always deliver innovative products of the highest quality and consistent efficiency. The ICMED 13485 alongwith the latest ISO 9001:2015 certification is an assurance of our focus on continuous improvement of our systems and processes, leading to greater customer satisfaction." said Transasia's Chairman & Managing Director, Suresh Vazirani.

He further added, "The Indian medical device industry has long needed its own quality assessment system. I am grateful to AIMED, QCI and NABCB for their joint efforts in making ICMED 13485 a reality. It a boon for IVD manufacturers like us, as it will bring down the substantial time and monetary investment to obtain globally accepted quality certifications. It will also give

a boost to the 'make in India' focus on this industry. From the customer's perspective, it will help in assuring standardized products."

For over three decades, Transasia has been delivering the highest quality of IVD instruments and reagents, not just in India but also globally. Infact it was the first company to attain the CE certification and enter the European market, way back in the 1990s. Over the years, Transasia has been successfully certified as compliant and adherent to all international regulatory norms, and has well established documentation and procedures.