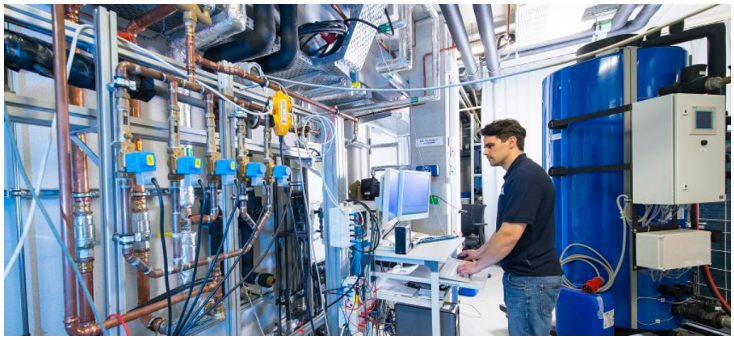
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

TUV Rheinland opens NABL accredited Biomaterial and EMC testing lab in India

23 October 2020 | News

The new facility promotes affordable healthcare by reducing the cost of medical devices, reducing reliance on imports, and delivering quality medical devices to the domestic market.



TUV Rheinland, a global leader in independent technical services on 23 Oct 2020 announced the opening of its Biomaterial and EMC (Electro Magnetic Compatibility) Testing Laboratories located at Andhra Pradesh MedTech Zone (AMTZ), Visakhapatnam, Andhra Pradesh, India.

These newly opened laboratories, housed within the 'TUV Rheinland Medical Device Centre of Excellence' have been accredited in accordance with International Standard ISO/IEC 17025:2017 for Medical, Non-Medical Devices and EMC Testing Services by the National Accreditation Board for Testing and Calibration Laboratories (NABL). The EMC Testing Laboratory has also been accredited by the American 'Association for Laboratory Accreditation' (A2LA).

This accreditation demonstrates TUV Rheinland's technical competence for a defined scope to serve a diverse range of product categories and the operation of a laboratory quality management system which will enable customers to gain entry into domestic and international markets.

At the 'Medical Device Centre of Excellence', TUV Rheinland offers an extensive list of services which includes Regulatory Compliance, Product Performance, Engineering Analysis and Reliability Services for various active and non-active medical devices such as Medical Ventilators, Face mask, X-ray Systems, Infant Care Devices, Health Monitoring Devices and Medical Implants. It also offers a variety of testing services for IT and Telecom products with speciality in Electronic Subassemblies for vehicle usage.

TUV Rheinland's state-of-the-art Biomaterial Testing Laboratory is equipped to analyse and test the nature of biomaterial along with physiochemical, histopathological, and mechanical strength evaluation -- both post and pre-implantation, sterility and other related tests. To ensure safe and effective biomaterial products, the Biomaterial Testing facility offers a wide range of analytical capabilities to determine the identity, purity and biosafety of a growing number of biomaterials using the latest testing methodologies to meet safety and quality standards as per local and global regulations. It is also equipped with advanced technology to perform tests on medical textiles including surgical and N95 masks in order to support customers with their regulatory and non-regulatory testing requirements.

To prevent electromagnetic interference and susceptibility, electrical devices have to adhere to Electromagnetic Compatibility (EMC) guidelines. TUV Rheinland's "Medical Device Centre of Excellence" offers a fully equipped EMC testing facility as a

one-stop-solution for all immunity tests as per medical and non-medical product categories. Its 10-metre and 3-metre Anechoic EMI EMC Test Laboratory is the only internationally certified facility in India that is accredited up to 40 GHz. It performs tests such as Radiated Emission, Conducted Emission, Radiated & Conducted Susceptibility, Electrostatic Discharge, Surge, Electrical Fast Transients (EFT) and many more. The laboratory has a wide range of environmental test facilities such as Combined Shock and Vibration as well as Thermal Shock Chambers to support manufacturers with their product validations.

The "A2LA accreditation for EMC Services" helps to perform tests locally and is a full-service-solution for entry into international markets. The semi-anechoic chamber housed in this facility is the largest within TUV Rheinland globally.

TUV Rheinland India operates its one-of-a-kind "Medical Device Centre of Excellence" as per ISO standards as well as guidelines set by the National Health Systems Resource Centre, Government of India to support affordable healthcare by reducing the cost of medical devices, reducing reliance on imports and delivering quality medical devices to the domestic market, with a larger goal of garnering a bigger share of the medical devices export market.