MUMBAI, March 7, 2017 /PRNewswire/ --

- The Accreditation Will Enable TÜV SÜD to Grant Certifications for ISO 13485, ICMED 9000 and ICMED 13485
- Manufacturers That Partner With TÜV SÜD Will now be Able to Seamlessly Export to Markets Such as the US, Canada, Brazil, Australia, Japan and the EU With a Single Audit (MDSAP)

Globally acclaimed German safety and quality expert, TÜV SÜD, today, received accreditation from National Accreditation Board for Certifying Bodies (NABCB) to grant certifications for ISO 13485, ICMED 9000 and ICMED 13485. NABCB is a part of Quality Council of India (QCI). TÜV SÜD is the first and only independent certification body till date in India to be accredited by NABCB to issue these certifications.

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ISO 13485 specifies requirements for a quality management system that can benefit an organization right from design to practical usage of medical devices and related services. ICMED 9000 certification comprises of ISO 9001 plus additional requirements, whereas, ICMED 13485 includes ISO 13485 plus additional requirements. These certifications are covered under the ICMED (Indian Certification for Medical Devices) Scheme, which was introduced by the Quality Council of India with an aim to bring down cost and turnaround.

TÜV SÜD will also offer the unique MDSAP (Medical Device Single Audit Programme). The programme aims to help manufacturers get their devices into multiple global markets through a single audit.

Commenting on the accreditation, Suresh Kumar, Vice President, Product Services TÜV SÜD South Asia said, "It is an honour for us to be the first certification body in India accredited by the NABCB to issue ISO 13485 and ICMED certifications. Global quality regulations for medical devices are among the most stringent as they safeguard patient interests. The ICMED Standard that TÜV SÜD offers is poised to build credibility of the manufacturers, secure user confidence that will subsequently uphold brand reputation. With our MDSAP services, we aim to provide manufacturers credibility, motivate them to increase their export footprint, empower them to gain easy access to exports and align with the government's 'Make in India' program."

In one of the most significant policy shifts this year, the government decided to move the medical device industry out of the pharmaceutical sector which has lent easy accessibility to important medical devices. These quality standards will help identify and eliminate trading of substandard quality of devices, thereby protecting patients from imminent harm. Industry reports suggest that India contributes just over 1.3% to the USD 335 billion global medical devices market. Only 5% of the 750 medical device manufacturing firms in India have established significant presence in export markets.

TÜV SÜD's ISO 13485; ICMED13485 and ICMED 9000 program adheres to guidelines as per ISO 17021: 2011 and ISO 17065: 2012 for certification bodies providing audit and certification of management systems.
About TÜV SÜD

TÜV SÜD is a leading international service organisation catering to the strategic business segments industry, mobility and certification. Headquartered in Munich, Germany and founded in 1866, it has over 24,000 employees representing more than 850 locations throughout the world. Optimising technology, systems and know-how, the interdisciplinary specialist teams act as process partners to strengthen their customers’ competitiveness.

About TÜV SÜD South Asia

TÜV SÜD South Asia is the leading consulting, testing, inspection and certification (TIC) company with presence across India, Bangladesh and Sri Lanka. With more than 1300 employees, TÜV SÜD South Asia has serviced over 10,000 clients to date through the past two decades. It is present at 32 locations including 19 labs across the three countries. Today, TÜV SÜD South Asia is internationally competent to provide TIC solutions cutting across a wide range of sectors that include management systems, conventional and renewable energy, water sanitation, environmental technology, infrastructure, transit systems, real estate, food, supply chain, agriculture, toys, consumer electronics, textiles, leather and related products, automobile and components, and technical as well as soft-skills training.

For further details visit http://www.tuv-sud.in/

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