Press Release

American Association for Laboratory Accreditation (A2LA) ISO/IEC 17025:2017 Accreditation

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New Biology and Chemistry Laboratory Gets Accredited under ISO/IEC 17025:2017

New Brighton, MN. TÜV SÜD America Inc., a leading provider of certification, auditing and testing services, has been accredited under American Association for Laboratory Accreditation (A2LA) ISO/IEC 17025:2017 Accreditation. The new laboratory conducts biological and chemical testing of medical devices and is part of TÜV SÜD's ongoing commitment to providing high-quality medical device services that deliver precision with purpose to its customers. The methods and building products used to construct the lab meet or exceed Minnesota state guidelines for energy efficiency and sustainable building practices.

The laboratory enables domestic and international medical device companies to accelerate their research and development by providing testing services in the areas of microbiology, reusable device testing, chemistry, biocompatibility and packaging.

In order to manufacture and sell medical devices, including in vitro diagnostic products (IVDs), international regulations and standards need to be met. ISO/IEC 17025:2017 is the international standard for testing and calibration laboratories, and it outlines the requirements for the competence, impartiality, and validity of laboratory results. This accreditation confirms that the New Brighton Laboratory has been recognized to meet these rigorous standards and has demonstrated technical competence in all areas of medical device testing.

A wide range of testing is covered including Chemistry, Microbiology, Water Testing, Bioburden, Biocompatibility, and Cytotoxicity. The lab uses a variety of methods and techniques to conduct these tests, including Metals and Elements ICP-MS Targeted Method, SVOC by GCMS, Endotoxin Testing (Kinetic Chromogenic), Incubation and Enumeration, Microbial Characterization, ISO MEM Elution Assay, and Direct Contact Assay.

The accreditation process involved a thorough evaluation of the lab's testing procedures, equipment, and personnel by an independent accreditation body. The lab demonstrated its compliance with the strict requirements of ISO/IEC 17025, which ensures that the tests are conducted with accuracy, reliability, and consistency.

Our team of highly trained professionals uses state-of-the-art equipment and methods to ensure accurate and reliable testing results for a variety of medical devices, including implants, surgical instruments, and diagnostic equipment. With our ISO/IEC 17025:2017 accreditation, TÜV SÜD's customers can be confident that the company's testing services are performed at the highest level of quality and are in compliance with international standards. “This accreditation not only validates our technical competence, but also ensures our customers receive the highest level of service and accuracy. We will continue to uphold these standards and strive for excellence in all that we do,” said Dr Fabian Schober, CEO of TÜV SÜD America. “On the one hand, it gives our customers the confidence they need to bring their products to market, and on the other hand, it ultimately contributes to the highest possible patient safety.” Dr Julien Senac, Director of Medical & Health Services at TÜV SÜD America, states, "We are thrilled to have achieved this important milestone. This accreditation reinforces our commitment to providing the highest quality testing services for medical devices.“

The New Brighton laboratory was constructed following methods and building products that meet or exceed the state of Minnesota guidelines for energy efficiency and sustainable building practices. The laboratory will include a comprehensive rooftop solar installation, which will maximize energy offsets and reduce carbon emissions. The system size is approximately 500,000W DC, with an estimated energy production of 565,000 kWh annually. Based on historical power consumption and including the projected power consumption of the lab expansion, the solar (PV) power production potentially offsets 97% of our electricity needs at the lab. This leads to a potential CO2 emission avoidance of 10,000 metric tons over a period of 30 years.

The New Brighton laboratory is part of TÜV SÜD 's broader global strategy to help alleviate and address the market demand for quality testing driven by increased regulatory requirements, and to provide a future-forward approach to innovations in the medical device space. This includes the introduction of the Medical Device Regulation (MDR) and In vitro Diagnostic Regulation (IVDR), and to provide testing where and when it’s needed in the local language of TÜV SÜD’s customers. The company is committed to working closely with its customers and partners to understand their needs and develop solutions that are cost effective and have competitive turnaround times.

For more information about our New Brighton Laboratory and our testing services, please visit our website at https://www.tuvsud.com/en-us/about-us/north-america/new-brighton-mn-laboratory

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