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BIO-TECHNE ACHIEVES ISO 13485 CERTIFICATION FOR ITS WALLINGFORD, CT MANUFACTURING FACILITY

MINNEAPOLIS, Oct. 16, 2023 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH), a leading provider of proteins, antibodies and Immunoassays today announced that its Wallingford, CT facility has received ISO 13485:2023 certification for its quality management system (QMS), demonstrating the company's commitment to producing products for clinical applications. The company's Wallingford site manufactures Bio-Techne's cartridge-based Simple Plex™ immunoassays for its automated Ella™ multiplexing immunoassay platform, a rapid and hands-free precision biomarker detection system.

ISO 13485 is an internationally recognized quality standard for medical device and in vitro diagnostic (IVD) manufacturing. The standard creates a robust and reproducible quality system framework for the design, development, and manufacturing of medical devices to ensure the safety and effectiveness of their intended purposes. To be certified, organizations must demonstrate that critical components and processes are designed and manufactured to meet exacting customer and regulatory requirements.

Simple Plex assays are run on the Ella platform, with all critical components pre-validated within each cartridge. This design ensures consistency, minimizes errors, and eliminates the tedious manual preparation that comes with running a traditional immunoassay, enabling the high level of reproducibility and data quality critical for translational and clinical utility. Validated for over 250 protein targets and growing, Simple Plex assays are powered by R&D Systems, the recognized 30-year global leader for high-quality antibodies, proteins, and ELISA kits.

"This certification is a testament to Bio-Techne's relentless pursuit of excellence and our unwavering commitment to providing innovative, reliable, and safe medical and diagnostic solutions to healthcare providers worldwide," said Will Geist, President of Bio-Techne's Protein Sciences Segment. "We are proud of the systems we have built to achieve this important certification and look forward to expanding our support of regulated applications across research, diagnostics, and therapeutics."

About Bio-Techne

Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities. Bio-Techne products assist scientific investigations into biological processes and the nature and progress of specific diseases. They aid in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With thousands of products in its portfolio, Bio-Techne generated approximately \$1.1 billion in net sales in fiscal 2023 and has approximately 3,200 employees worldwide. For more information on Bio-Techne and its brands, please visit <http://www.bio-techne.com>

[About Bio-Techne Corporation](#) (NASDAQ: TECH)


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