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# **Bio-Techne Announces ISO 13485:2016 Certification for the Woburn, MA Manufacturing Facility**

MINNEAPOLIS, Oct. 15, 2020 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH), a leading provider of proteins, antibodies and cytokines today announced that its Woburn, Massachusetts site received ISO 13485:2016 certification for Medical Device and Quality Management Systems. Bio-Techne's Woburn facility produces Cloudz™ Cell Activation Kits, a magnetic-free bead-based technology for the robust and reliable expansion of immune cells, including T cells and NK cells, representing a pivotal component of the cell and gene therapy workflow. This certification is widely recognized internationally as a standard for quality management systems related to medical devices and related services. This achievement provides additional assurances to our customers that critical components for their processes are designed and manufactured to meet their exacting requirements.

ISO 13485:2016 is an internationally recognized quality standard intended to ensure the consistent design, development, production, installation, and sale of medical devices that are safe for their intended purposes. To be certified, organizations must demonstrate that their Quality Management Systems are able to provide medical devices and related services that consistently meet customer and regulatory requirements.

"The implementation of ISO 13485:2016 demonstrates that Bio-Techne and the Cloudz reagents are produced under the strict standards of the medical devices industry," said Dave Eansor, President, Protein Sciences "This certification is an important milestone for our company and reflects our commitment to delivering safe, high-quality products for cell and gene-modified cell-based therapies."

"Quality is in everything that we do," said Chuck Kummeth, Bio-Techne's President and Chief Executive Officer. "This certification reflects our commitment to delivering high quality state-of-the-art technologies addressing the needs of our customers and ultimately the patients that they serve."

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

Contact: David Clair, Senior Director, Corporate Development  
[david.clair@bio-techne.com](mailto:david.clair@bio-techne.com)  
612-656-4416

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