



NEWS ANNOUNCEMENT

FOR IMMEDIATE RELEASE

SkyWater Achieves ISO 13485 Quality Certification for Medical Devices

Accelerates customers' migration to production in the fast-growing biochip market

BLOOMINGTON, MN April 18, 2019 – [SkyWater Technology Foundry](#), the trusted innovation partner for tomorrow's most advanced technology solutions, today announced its certification to the ISO 13485 standard which specifies requirements for a comprehensive quality management system that supports the design and manufacture of medical devices. The ISO 13485 standard outlines business process requirements for manufacturers supplying solutions into medical applications and serves to verify compliance with quality standards which minimize risks potentially affecting patient health or safety that stem from manufacturing quality issues. By achieving this standard, SkyWater is well-positioned to meet the increasing demand for semiconductor content in this rapidly accelerating market. In addition, SkyWater's geographic location in the Twin Cities, known as a healthcare technology hub, provides direct access to several leaders in this field.

The ISO 13485 certification provides confirmation of quality processes SkyWater has developed in-house to support its focus on medical device fabrication such as DNA sequencing and other applications in the design and development stage. The new certification will streamline customers' development cycles and accelerate their migration to production for a wide range of emerging biomedical market segments including implantable, wearable and rapid medical diagnostic devices. According to Inkwood Research, the global biochips market is estimated to generate net revenue of approximately \$62.82 billion by 2027 growing at a CAGR of 20.63% during the forecast period 2019-2027.

"Obtaining ISO 13485 compliance certification marks an additional commitment to our growing customer base. The certification was quickly achieved by leveraging many processes already in place which support our existing quality management certifications including those critical to servicing the automotive industry," said Thomas Sonderman, President, SkyWater Technology Foundry. "Our business is focused on streamlining the product development process for customers across our business units. Adding this qualification strengthens our ability to extend more of our innovation services into medical markets."

About SkyWater Technology Foundry

SkyWater is a solely U.S.-based and owned, DMEA-accredited Technology Foundry, providing custom design and development services, exclusive design IP, and volume manufacturing for integrated circuits and micro devices. The Company's world-class operations and unique processing capabilities enable mixed-signal CMOS, rad-hard and ROIC solutions. SkyWater's Innovation Engineering Services empower development of superconducting and 3D ICs, along with carbon nanotube, photonic and MEMS devices. SkyWater serves customers in growing markets such as aerospace & defense, automotive, cloud & computing, consumer, industrial, IoT and medical. For more information, please visit: www.skywatertechnology.com/.

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