



Contact: Tessa Berkley
Phone: (503) 213 4269
Email: tessa.berkley@lumencor.com

LUMENCOR ACHIEVES ISO 13485:2003 CERTIFICATION

Beaverton, Oregon (October 2016) — Lumencor, Inc., an industry leader in the photonics market for the life sciences, announced today that the company recently received their certificate of registration to ISO 13485:2003. “We are pleased that Lumencor has just been ISO 13485:2003 certified by the British Standards Institution (BSI) for the design, development, manufacture, distribution and servicing of light engines and high throughput scanners,” stated Claudia Jaffe, Ph.D., Executive Vice President of Business Development. “This achievement is one that we are particularly proud of as it demonstrates our commitment to providing the highest quality products and services to our customers. It further establishes Lumencor as a leader in the life sciences for the manufacture of tools for bioanalysis as well as for medical devices.”

ISO 13485:2003 is the internationally recognized standard which specifies requirements for a comprehensive quality management system in which an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

“Our decision to adopt the ISO 13485:2003 standard is a direct reflection of our commitment to the safety and quality of our products,” said Dr. Jaffe. “Our vision for medical device manufacturing was there since the inception of the company. Our journey toward achieving ISO 13485:2003 certification began in earnest in early 2016. Before presenting ourselves to the certification agency, we undertook countless hours of work and preparation. We performed internal audits, updated internal policies and processes and underwent a thorough employee training program. It took a lot of effort to fully align with the ISO 13485:2003 requirements, however, the certification is a gratifying reward.”

Adopting the ISO 13485:2003 standard provides a practical foundation for manufacturers to address the international regulations and responsibilities as well as demonstrating a commitment to safety and quality of medical devices.

Lumencor’s certification of compliance recognizes that our policies, practices and procedures ensure consistent quality in the services and products that we deliver.

“At Lumencor, producing high quality work is a top priority. Successfully completing the certification process to the ISO 13485:2003 standard aligns with our commitment to excellence and demonstrates just how dedicated we are to ensuring the best quality of work for all of our customers and we’re proud of what we’ve achieved,” stated Kasey Griffin, Director of Quality and Regulatory.

###

For more information on the topic, please contact Kasey Griffin, Director of Quality and Regulatory at (503) 992 6960 or kasey.griffin@lumencor.com.