Ocutech, Inc. Achieves ISO 13485:2016 Certification

March 04, 2026

Chapel Hill, North Carolina - March 04, 2026 -
Ocutech, Inc. announced that it has achieved ISO 13485:2016 certification, an internationally recognized standard for quality management systems in the medical device industry. The certification reinforces Ocutech?s commitment to quality, regulatory compliance, and patient safety in the design and manufacture of its low vision aid devices.

ISO 13485:2016 establishes requirements for organizations involved in the design and manufacture of medical devices, with an emphasis on risk management, process control, and quality system oversight throughout the product lifecycle. Certification to this standard indicates that an organization has implemented documented procedures and controls intended to support consistent product quality and compliance with applicable regulatory expectations.

?Achieving ISO 13485:2016 certification is an important milestone for Ocutech,? said Henry A. Greene, OD, FAAO, Co-founder and President of Ocutech. ?It reflects our team?s dedication to disciplined processes and supports our mission to deliver high-quality solutions that help individuals with visual impairment enhance their independence.?

Ocutech designs and manufactures low vision bioptic telescope systems and visual field assistive aids that are prescribed by low vision specialists to support individuals with visual impairment. These devices are used by eye care professionals in clinical settings to help patients improve functional vision and engage more effectively in daily activities. The company?s products are prescribed by clinicians worldwide who specialize in low vision care.

The ISO 13485:2016 certification applies to Ocutech?s quality management system governing its design and manufacturing operations. As part of the certification process, the company?s systems and procedures were evaluated against the requirements of the standard, including controls related to design activities, manufacturing processes, documentation, and ongoing quality monitoring. Maintaining certification requires continued adherence to these requirements and periodic external audits.

Ocutech was founded with the goal of developing optical solutions for individuals with visual impairment, and quality management has remained a core element of the organization?s operations. The company?s approach emphasizes structured processes intended to support consistency, traceability, and reliability in the production of its medical devices. Achieving ISO 13485:2016 certification represents a formal recognition of these practices within an internationally accepted framework.

Dr. Greene, who co-founded Ocutech, is a Fellow of the American Academy of Optometry and has been involved in the field of low vision care for decades. His clinical and professional background has informed the company?s focus on designing devices that align with the needs of low vision specialists and their patients. Under his leadership, Ocutech has continued to expand its product offerings while maintaining an emphasis on quality system development and regulatory alignment.

ISO 13485:2016 is widely recognized within the medical device industry as a benchmark for quality management systems. Organizations certified to the standard are expected to demonstrate ongoing commitment to maintaining effective processes and addressing risk throughout the product lifecycle. For manufacturers of medical devices, certification may support engagement with regulatory bodies, clinical partners, and other stakeholders who rely on documented quality system controls.

Ocutech stated that it will continue to maintain its ISO 13485:2016 certification through ongoing evaluation and continuous improvement of its quality management system.

For more information about Ocutech, Inc., visit www.ocutech.com.

About Ocutech, Inc.

Ocutech, Inc. designs and manufactures low vision medical devices intended to support individuals with visual impairment. The company specializes in bioptic telescope systems and visual field assistive aids prescribed by eye care professionals and is headquartered in Chapel Hill, North Carolina.

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For more information about Ocutech, contact the company here:OcutechTina Woods1-919-967-6460bioptics@ocutech.com105 Conner Drive, Suite 2105Chapel Hill, NC, 27514 USA

Ocutech

Ocutech is a global leader in telescopic low vision aids and develops innovative bioptic glasses that empower individuals with vision impairments to regain visual independence.

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