



## Modulated Imaging Receives ISO 13485 Certification

IRVINE, CA, May 1, 2018 – [Modulated Imaging](#), the leader in optical imaging solutions powered by Spatial Frequency Domain Imaging (SFDI) for noninvasive assessment of tissue health, has been awarded International Organization for Standardization (ISO) 13485:2016 certification for its medical device Quality Management System.



Modulated Imaging's FDA-cleared medical device, Ox-Imager CS<sup>®</sup>, helps clinicians identify patients with compromised circulation, which is critical in the management of patients with diabetes, peripheral vascular disease, peripheral neuropathy, chronic kidney disease, burns, and decubiti. This platform technology helps providers and healthcare organizations improve care and workflow while reducing costs.

ISO 13485 certification is another major milestone for Modulated Imaging, following the company's successful recent series A funding round.

About Modulated Imaging's ISO 13485 certification:

- ISO certification assures healthcare providers and patients that the company is adhering to the best quality management and regulatory compliance procedures to develop, manufacture, and test its products and services.
- ISO certification builds on the FDA's quality management system principles and is recognized internationally.
- Based in Geneva, Switzerland, the International Organization for Standardization (ISO) is an independent, non-governmental international organization with a membership of 162 national standards bodies.

- ISO 13485:2016 is the latest update to ISO requirements for a comprehensive quality management system for the design and manufacture of medical devices. This long-awaited revision expands risk management, adds new safeguards, and outlines new policies for quality control in supply chain management.

"Our technologies and products are focused on early detection and prevention of complications from circulatory compromise," said Charles Gropper, the Management Representative for the Quality System at Modulated Imaging. "Having a certified ISO 13485 compliant quality system means that we rigorously follow validated processes throughout our design and manufacturing approach. This empowers us to innovate at the speed required to *safely* bring new optical imaging applications to market that will help healthcare providers realize better patient outcomes, greater operational efficiencies, and reduced cost of care."

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#### About [Modulated Imaging](#):

Modulated Imaging leverages medical photonics and informatics to help clinicians assess tissue health. Powered by Spatial Frequency Domain Imaging (SFDI), the company's disruptive technology identifies compromised circulation and perfusion by measuring microvascular tissue oxygenation and hemoglobin concentration and distribution. As a result, the company's optical imaging system can identify patients with tissue health problems early enough for clinicians to intervene. With widespread adoption, this approach could save thousands of limbs and lives, not to mention billions of dollars in treatment costs.

Spatial Frequency Domain Imaging was invented by researchers at UC Irvine's Beckman Laser Institute, including Dr. David Cuccia, CEO/CTO of Modulated Imaging. Dr. Cuccia and Dr. Amaan Mazhar, VP Research & Development, are renowned experts in medical photonics.

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