



FOR IMMEDIATE RELEASE:

## Xhale Assurance Receives ISO 13485 Certification

GAINESVILLE, FL April 1, 2014 – Xhale Assurance, Inc.

Xhale Assurance, Inc., developer of the Assurance® [Alar One-Sense™](#) pulse oximetry sensor, today announced it has received ISO 13485 certification, an internationally recognized quality standard for the establishment of Quality Management Systems for manufacturers of medical devices.

The scope of Xhale's ISO 13485 certification covers the design, development, manufacture, servicing and distribution of monitors and sensors for pulse oximetry and respiratory rate.

ISO (the [International Organization for Standardization](#)) is the world's largest developer and publisher of International Standards. ISO 13485 registration is a step for medical device companies to take in order to meet global quality system requirements. Although implementing ISO 13485 is voluntary, applying this standard demonstrates compliance with the continually changing customer and regulatory requirements within the medical device industry.

### **About Xhale, Inc., Xhale Assurance, Inc. and Xhale SMART, Inc.**

*Xhale, Inc. is a medical technology company developing and commercializing patient-centric monitoring solutions for the healthcare industry. Xhale, Inc. is focused on developing two broad technology platforms. Through its Xhale Assurance, Inc. subsidiary, Xhale, Inc. is developing a patient monitoring technology designed to improve and expand the use of conventional pulse oximetry used in hospitals and other clinical settings to monitor critical patient parameters, as well as to increase the number of parameters which can be measured. Xhale, Inc.'s first product based on this technology, the Assurance® Alar One-Sense™ pulse oximetry sensor, received marketing clearance in the United States in April 2013. The Assurance® Alar One-Sense™ pulse oximetry sensor is a disposable sensor placed on a patient's nasal ala which transmits heart rate and blood oxygenation information to an oximetry monitor. Through its Xhale SMART, Inc. subsidiary, Xhale, Inc. is developing a medication adherence monitoring technology which focuses on monitoring patient adherence to medication regimens established in protocols for investigation drugs in clinical trials.*

For more information, please visit <http://www.xhale.com> or contact the company at [info@xhale.com](mailto:info@xhale.com) or 352-371-8488.