

# Solos Endoscopy Reports Results From Stage 2 of Its ISO 13485 Audit With TUV SUD America

BOSTON, MA--(Marketwired - Oct 17, 2013) - Solos Endoscopy, Inc. (OTC Pink: SNDY) is pleased to announce that the Company has passed its Stage 2 audit with Notified Body and registrar TUV SUD for registration to ISO 13485:2003. The Stage 2 audit was conducted August 15 - 16, 2013. TUV SUD found no non-conformities to Solos Endoscopy's Quality Management System requirements in the audit.

Solos Endoscopy is now in the process of drafting Technical Files and associated documents for the MammoView® devices the company intends to sell in Europe. TUV SUD will review the Technical Files for Solos Endoscopy's sterile devices in the MammoView® system. Since the Ductoscope is a Class I device in the European Union, Solos Endoscopy will prepare the required documentation and self-certify without the need for Notified Body review.

Once the documentation has been prepared and TUV SUD reviews and approves the required documentation for the sterile devices, TUV SUD will certify Solos Endoscopy to ISO 13485:2003 and provide certificates for CE Marking for Solos Endoscopy's sterile MammoView® system devices. CE Marking will allow Solos Endoscopy to sell its endoscopic instruments, including the MammoView® devices to the European Union. The Company expects the entire process to be concluded by the end of the year. Solos Endoscopy plans to market and sell its instruments internationally in 2014.

"Solos Endoscopy is committed to the worldwide distribution of its endoscopic instruments. We believe this dedication will result in increased sales and profits for the Company and its shareholders," stated Robert Segersten, Solos Endoscopy CEO.

Solos Endoscopy retained Emergo Europe to act as the official Authorized Representative in Europe. Emergo will provide Solos assistance related to communications with authorities and importation of Solos instruments in Europe. Emergo Group will register Solos instruments with the Competent Authorities (Ministry of Health) as required, including the Dutch Ministry of Health. Emergo will act as a liaison for Solos Endoscopy between the European Commission and national Competent Authorities. Emergo Europe consultants will assist Solos with a wide variety of regulatory, quality assurance, and distribution.

The Solos MammoView® Breast Endoscopy System employs advanced microendoscopes and optical technology, which gives physicians sharp images of the milk ducts where the majority of breast cancer arises. This allows physicians to detect breast cancer significantly faster than the traditional mammography. Solos Endoscopy instruments are FDA approved. Upon Solos Endoscopy's receipt of its ISO 13485 Certification, the Company will be able to place the CE Mark on its entire MammoView® instrument line which will allow the instrument line to be sold globally.

## **About Solos Endoscopy, Inc.:**

Solos Endoscopy is celebrating its 25<sup>th</sup> Year of providing quality innovative healthcare instruments to Hospitals across the Country. For more than 25 Years, from medical schools to hospitals, surgeons have trusted Solos Endoscopy to develop and market breakthrough technology, applications, medical devices, and procedural techniques for the screening, diagnosis, treatment and management of disease and medical conditions.

For more information on TUV SUD America visit [www.tuvamerica.com](http://www.tuvamerica.com). For more information on Emergo Group visit [www.emergogroup.com](http://www.emergogroup.com).

Certain statements in this news release may contain forward-looking information within the meaning of Rule 175 under the Securities Act of 1933 and Rule 3b-6 under the Securities Exchange Act of 1934, and are subject to the safe harbor created by those rules. All statements, other than statements of fact, included in this release, including, without limitation,

statements regarding potential future plans and objectives of the company, are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Technical complications that may arise could prevent the prompt implementation of any strategically significant plan(s) outlined above. The company cautions that these forward-looking statements are further qualified by other factors including, but not limited to, those set forth in the company's Annual Report filing and other filings with the OTC Markets Group (available at [www.otcmarkets.com](http://www.otcmarkets.com)). The company undertakes no obligation to publicly update or revise any statements in this release, whether as a result of new information, future events, or otherwise.

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