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December 30, 2014

Dear Valued Customer;

Lake Region Medical's Quality Management System (QMS), is focused on meeting customer requirements and continual improvement. The QMS supports our business objective of providing services to the medical device industry that result in safe and effective components and finished devices. The Lake Region Medical Quality Management System is designed to satisfy International Standards ISO 9001:2008, ISO 13485:2003, and EN ISO13485:2003/AC:2012, and is compliant to U.S. Food & Drug Administration (FDA) 21 CFR Part 820 – Quality System Regulation. For specific customer needs, our quality management systems can be supplemented to meet other regulatory requirements (CMCAS, MDD, JPAL, etc.).

All of the Lake Region Medical facilities have been certified to both ISO 13485:2003 and EN ISO13485:2003/AC:2009. Some facilities also possess additional quality system certifications, based upon business needs. Copies of the current certificates for each Lake Region Medical location can be found on our website (www.lakeregionmedical.com) under 'About Us.'

If you need additional information or have any questions, please feel free to contact me.

Sincerely,

Graciela Denis
Director of Quality Assurance and Regulatory Affairs
Global Quality Systems

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