



NEWS RELEASE

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DEVICIX AFFIRMS COMMITMENT TO QUALITY AND CUSTOMERS WITH ACHIEVEMENT OF ISO 13485 AND 14971 CERTIFICATIONS

FOR IMMEDIATE RELEASE

(Eden Prairie, MN, USA – Sept. 9, 2009) – Devicix LLC, a contract medical-device design and engineering firm, announced today that it has successfully completed the requisite steps to obtain the Medical Device ISO 13485 Quality Management System and the ISO 14971 Risk Management System certifications. Devicix has been accredited by BSI Management Systems America Inc., one of the foremost auditing bodies in the world.

These certifications are major milestones in Devicix's history and exemplify the firm's dedication to continual process improvement, risk management, compliance with regulatory requirements, and exceeding customers' expectations; they also position Devicix as one of a select number of firms that have attained both ISO 13485 and 14971 certifications.

ISO 13485:2003 defines the requirements for maintaining a regimented Quality Management System, assuring quality throughout the development process and it dictates that risk management is thoroughly documented and conducted throughout a product's entire lifecycle, from initial concept to delivery and post-delivery. However, the standard leaves the specifics to a related standard, ISO 14971: 2007, Application of

Risk Management for Medical Devices. While 13485 states that a manufacturer's management team is charged with the management of device-related risks and the development of risk management plans, 14971 defines the methodology to be taken by management in order to address and manage the risks inherent in medical devices.

"These certifications help ensure that our services and goals are aligned with all of our clienteles' demands and quality standards, as it provides them with the assurance that we can accelerate the delivery of high-quality devices for approval and market entry, regardless of the markets they are pursuing," says CEO and President of Devicix, Pete DeLange. DeLange thanks Robert Parsons, Devicix's Director of Quality and Regulatory, for designing and implementing the quality system as well as for educating and training the firm's talented and experienced staff; collaboratively resulting in the conscientious and successful adoption of the two systems.

About Devicix, LLC

Started in April of 2004, Devicix has grown from 4 to 30 employees, and is a leading provider of design and development-for-manufacturing services for the medical device industry, exclusively. The firm partners with start-ups, midsize and multi-national device manufacturers, affording innovative, value-added, outsourced solutions in software, electrical, mechanical and biomedical engineering and design. Devicix is one of only five firms to be ISO 14971 certified.

For more information visit ***www.devicix.com***.

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