January 24, 2012

CardioComm Solutions, Inc. Passes Canadian Medical Devices Conformity Assessment System ISO 13485:2003 Audit

Follows FDA Clearance for Over-the-Counter (OTC) Sales & Marketing of the Consumer-based, HeartCheck™ Pen Handheld ECG.

January 24, 2012 - - TORONTO, CANADA - - CardioComm Solutions, Inc. (CardioComm Solutions) received confirmation from the Canadian Medical Devices Conformity Assessment System (CMDCAS) that it had cleared an ISO audit performed by DQS Medizinprodukte GmbH. CardioComm Solutions is registered under Health Canada's Therapeutic Products Programme (TPP) according to ISO 13485:2003 and CMDCAS as well as MDD regulations, for the 'Manufacturing and Distribution of Health Management Software Systems and Distribution of Health Monitoring Devices.' The mission of the TPP, and the purpose of the audit, is to ensure that drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

The audit reported that management review, resource planning processes and corrective action loops "are very well implemented" and that the design and development process is "fully implemented and very well documented." In addition, the following responsibilities were audited: Production and Process Controls; Customer Related Processes; Implementation of Applicable Canadian Medical Devices Regulations, Part 1 Requirements; Implementation of Regulatory Requirements of the Directive 93/42/EEC; and Document Control Processes.

The audit concluded that the requirements of all applicable ISO 13485:2003 standards as well as Canadian regulatory requirements are fulfilled, that CardioComm Solutions' quality system is well established and that no nonconformities were found.

"This is excellent news for CardioComm Solutions", stated Etienne Grima, CardioComm Solutions' CEO, "especially in light of the rally in our stock price and brisk trading. The recent market response provides a clear signal that our shareholders and corporate partners understand the significance of the FDA's permission for CardioComm Solutions to sell the HeartCheck™ Pen with our GEMS™ Home software. The results of this ISO audit demonstrates that what differentiates CardioComm Solutions in the marketplace is our design excellence and compliance pedigree as an ISO-certified, FDA-compliant software engineering and solutions company."

CardioComm Solutions achieved their first FDA clearance in January 1999 and their GEMS™ software platform has been FDA cleared as a Class II Medical Device since 2002.

"These 10-plus years operating in the highly regulated medical software market has allowed us to become a trusted and preferred provider in the prescribed ECG services market," added Grima. "Our GEMSTM medical customer base includes Toronto-based St. Michael's Hospital and the Hospital for Sick Children, the Ottawa Heart Institute, the Calgary Foothills Hospital in Alberta, as well as US-based clients such as the Mayo Clinic Health System Hospitals and Kaiser Permanente. Additionally, CardioComm Solutions has a customer footprint covering more than 20 countries and has contractual relationships with clients such as AstraZeneca, GE HealthCare and the Philips Remote Cardiac Services."

CardioComm Solutions is now preparing for its move into the consumer medical market. "Our target is to reach the 3C market (Consumers with Chronic Conditions)," explained Grima, "as well as those interested in primary disease prevention. The HeartCheck™ PEN, together with GEMS™ Home and our C4 medical call service will serve to connect the 3C consumer to healthcare practitioners using a solution that is globally expandable."

"The FDA clearance was a material announcement and marks the first phase of the pre-launch plans for the HeartCheck™ PEN distribution and sales. Passing the 2012 ISO Audit confirms we are in excellent shape to proceed to next steps, which will involve confirming sales channels and agency representation across several global markets, finalizing technology infrastructure for placement of multicountry C4 locations to honor the requirements to house medical data in the country of service, and to confirm production timelines" stated Grima. "We have been on a progressive and consistent path and believe that this is CardioComm Solutions' time. It is our 2012

goal to connect consumers' health in a way that has never been done before – we are truly at the door step of exciting innovation and service."

More Information

For more information on the Assessment Audit, the HeartCheck™ Pen or any CardioComm Solutions product or service, call the sales and marketing group at 1-877-977-9425 toll free in the U.S. and Canada, or email sales@cardiocommsolutions.com.

About CardioComm Solutions, Inc.

CardioComm Solution's patented and proprietary technology is used in products for recording, viewing, analyzing and storing electrocardiograms (ECGs) for diagnosis and management of cardiac patients. Products are sold worldwide through a combination of an external distribution network and a North Americanbased sales team. The company has earned the ISO 13485 certification, is HPB approved, HIPAA compliant, and has received FDA market clearance for its software devices. CardioComm Solutions, Inc. is headquartered in Toronto, Canada, with offices in Victoria, B.C.

Contact

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