



FOR: CARDIOCOMM SOLUTIONS, INC.  
TSX VENTURE SYMBOL: EKG

**December 12, 2018**

**CARDIOCOMM SOLUTIONS SECURES MDSAP ISO CERTIFICATION FOR THE MANUFACTURING,  
MARKETING AND SALE OF CONSUMER AND Rx MEDICAL DEVICES INTO THE USA AND CANADA**

MDSAP Certification Completion Will Expand Market Access to CardioComm's Medical Devices and Software

**TORONTO, ONTARIO - CardioComm Solutions, Inc.** (TSX VENTURE: EKG) ("**CardioComm**" or the "**Company**"), a leading global provider of consumer heart monitoring and electrocardiogram ("**ECG**") acquisition and management software solutions, has completed its ISO 13485:2016 ("**ISO**") certification in compliance with the Medical Device Single Audit Program ("**MDSAP**"), which is now mandatory under Health Canada requirements and recommended by the USA Food and Drug Administration ("**FDA**").

CardioComm completing MDSAP for both Canada and the USA, solidifies the Company's abilities to continue to produce and sell its Global ECG Management System ("**GEMS™**") software globally. CardioComm is also a preferred importer, distributor and reseller of hospital and consumer ECG medical devices for organizations based outside of Canada such as the USA, China and Singapore.

Manufacturers of Class II, III, and IV medical devices, whether based in Canada or elsewhere, must report to the Canadian Medical Devices Bureau that they have either passed, or initiated the transition to an MDSAP audit by December 31, 2018. Failure to do so will result in manufacturers losing their medical device licences and the rights to have their products imported into or sold into Canada. As of November 14, 2018, only two-thirds of the medical device companies that sell into Canada have signed up for MDSAP (*Quality Digest*, 11/14/2018). This situation may cause a shortage of medical products available to health care providers and consumers in Canada (*Globe and Mail* 05/09/2018).

With ISO under MDSAP, CardioComm has confirmed that it may contract with other medical devices makers that sell into Canada, but have decided not to renew their ISO medical device certification under the more stringent and costly MDSAP standard. Under this scenario, CardioComm can place non-MDSAP ISO-certified devices under the Company's own MDSAP certification for a fee, gaining sole distribution rights for device sales in Canada and ensuring that established and emerging sales channels have continued access to needed medical devices. One such example involves the recent application for FDA 510(k) clearance of the HeartCheck™ CardiBeat by CardioComm on behalf of the original equipment manufacturer. While ISO under MDSAP is not required in the USA, CardioComm's Canadian/USA MDSAP certification is accepted by the FDA and removes the need for routine FDA inspections. This certification will also help newly FDA-cleared products when applying for Health Canada medical device clearances.

To learn more about CardioComm's products and for further updates regarding HeartCheck™ ECG device integrations, please visit the Company's websites at [www.cardiocommsolutions.com](http://www.cardiocommsolutions.com) and [www.theheartcheck.com](http://www.theheartcheck.com).

**About CardioComm Solutions**

CardioComm Solutions' patented and proprietary technology is used in products for recording, viewing, analyzing and storing electrocardiograms for diagnosis and management of cardiac patients. Products are sold worldwide through a combination of an external distribution network and a North American-based sales team. CardioComm Solutions has earned the ISO 13485:2016 certification, is HIPAA compliant and holds clearances from the European Union (CE Mark), the USA (FDA) and Canada (Health Canada).

FOR FURTHER INFORMATION PLEASE CONTACT:

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**Forward-looking statements**

This release may contain certain forward-looking statements and forward-looking information with respect to the financial condition, results of operations and business of CardioComm Solutions and certain of the plans and objectives of CardioComm Solutions with respect to these items. Such statements and information reflect management's current beliefs and are based on information currently available to management. By their nature, forward-looking statements and forward-looking information involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements and forward-looking information.

In evaluating these statements, readers should not place undue reliance on forward-looking statements and forward-looking information. The Company does not assume any obligation to update the forward-looking statements and forward-looking information contained in this release other than as required by applicable laws, including without limitation, Section 5.8(2) of National Instrument 51-102 (*Continuous Disclosure Obligations*).

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