

## **IRADIMED CORPORATION Announces 510(k) Clearance of Invasive Blood Pressure Module for use with its MRI-Compatible Patient Vital Signs Monitor**

WINTER SPRINGS, Fla., Dec. 19, 2018 — IRADIMED CORPORATION (NASDAQ:IRMD), a leader in the development of innovative magnetic resonance imaging (“MRI”) medical devices, today announced FDA 510(k) clearance of its 3883 MRI-compatible invasive blood pressure module for use with its 3880 MRI compatible patient vital signs monitoring system.

“This newly cleared device represents a feature extension to the 3880 MRI-compatible patient monitoring system, which we launched in the U.S. just over a year ago. With the invasive blood pressure module, we now offer advanced monitoring capabilities to our customers,” said Roger Susi, President and Chief Executive Officer of the Company.

The 3883 MRI-compatible invasive blood pressure module is available as an option to the 3880 MRI-compatible patient vital signs monitor.

“Customers can now provide a more comprehensive suite of vital signs monitoring while transporting patients from hospital critical care departments to the MRI scanner room and back to critical care while maintaining continuous vital signs monitoring,” said Susi.

### About the 3880 MRI Compatible Patient Vital Signs Monitoring System

IRADIMED designed the 3880 MRI-compatible patient vital signs monitoring system using non-magnetic components and other special features enabling the safe and accurate monitoring of a patient’s vital signs during various MRI procedures. The IRADIMED 3880 MRI-compatible patient vital signs monitoring system has an easy-to-use design and allows for the effective communication of patient vital signs information to clinicians.

Additionally, the IRADIMED 3880 MRI-compatible vital signs monitoring system’s compact and lightweight design enables uninterrupted monitoring during transport, resulting in increased patient safety and decreasing the amount of time critically ill patients are away from critical care units.

Available features of the IRADIMED 3880 system include:

- Wireless ECG with dynamic gradient filtering;
- Wireless SpO2 using Masimo® SET algorithms;
- Non-magnetic respiratory CO2;
- Non-invasive blood pressure;
- Invasive blood pressure;
- Patient temperature;
- Advanced Masimo® multi-gas anesthetic agent unit featuring continuous Minimum

Alveolar Concentration measurements.

The IRADIMED 3880 system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room.

## **About IRADIMED CORPORATION**

IRADIMED CORPORATION is a leader in the development of innovative magnetic resonance imaging ("MRI") compatible medical devices. We are the only known provider of a non-magnetic intravenous ("IV") infusion pump system that is specifically designed to be safe for use during MRI procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI-compatible IV infusion pump system has been designed with a non-magnetic ultrasonic motor, uniquely-designed non-ferrous parts and other special features to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated to remain immobile during an MRI scan.

For more information please visit [www.iradimed.com](http://www.iradimed.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Act of 1995, particularly statements regarding our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. These statements relate to future events or our future financial performance or condition and involve unknown risks, uncertainties and other factors that could cause our actual results, level of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. The risks and uncertainties referred to above include, but are not limited to, risks associated with the Company's ability to receive FDA 510(k) clearance for new products; unexpected costs, delays or diversion of management's attention associated with the design, manufacture or sale of new products; the Company's ability to implement successful sales techniques for existing and future products and evaluate the effectiveness of its sales techniques; additional actions by or requests from the FDA; our significant reliance on a single product; unexpected costs, expenses and diversion of management attention resulting from the FDA warning letter; potential disruptions in our limited supply chain for our products; a reduction in international distribution; actions of the FDA or other regulatory bodies that could delay, limit or suspend product development,

manufacturing or sales; the effect of recalls, patient adverse events or deaths on our business; difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services; changes in laws and regulations or in the interpretation or application of laws or regulations. Further information on these and other factors that could affect the Company's financial results is included in filings we make with the Securities and Exchange Commission from time to time. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements.

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