IRADIMED CORPORATION Expects Minor Impact to 2019 Revenue After Temporarily Suspending Shipments of MRI Compatible Patient Vital Signs Monitoring Systems in European Markets

- Action being taken after CE mark expiration
- Expects negative impact to full-year 2019 revenue of approximately two percent

WINTER SPRINGS, Fla., Jan. 22, 2019 — IRADIMED CORPORATION (NASDAQ: IRMD), a leader in the development of innovative magnetic resonance imaging ("MRI") medical devices today announced that it temporarily suspended sales of its 3880 MRI compatible patient vital signs monitoring systems in European Commission ("EC") markets due to the expiration of its CE Mark on January 17, 2019.

Our products are regulated in Europe by the U.K. Notified Body, UL International Ltd. ("UL"), who provides Certification allowing use of the CE Mark and permitting shipments of products into EC markets. Maintaining Certification and use of the CE Mark requires manufacturers to routinely undergo periodic re-certification, which typically involves the re-review of a product technical file. Our 3880 MRI compatible patient vital signs monitoring system, originally cleared by UL and added to our EC Certificate in June 2017, was recently subjected to such re-review.

On January 16, 2019, we were notified by UL that their recent technical file review of our 3880 MRI compatible patient vital signs monitoring system could not be completed as aspects of clinical evaluation reporting, as required by newly issued guidance from the European Union, was not acceptable, resulting in a technical non-conformity. Accordingly, UL is issuing a temporary EC Certificate that excludes our 3880 patient vital signs monitoring system. This temporary EC Certificate will extend for six months, during which time we expect to cure the non-conformity and be permitted to again use the CE Mark on our 3880 patient vital signs monitoring system. In full compliance with this notification, we immediately suspended shipments of our 3880 patient vital signs monitor to all markets requiring a CE Mark.

Key points to note resulting from the notification and subsequent temporary suspension of shipments include:

- This action is not the result of safety, effectiveness or performance issues with our 3880 patient vital signs monitoring system.
- This action does not impact sales of our 3880 patient vital signs monitoring system in the U.S. or in other markets that do not require a CE Mark for importation purposes.
- This action does not impact shipments of our MRI compatible IV infusion pump and related accessories, disposables or services.

“Despite the retrospective application of new guidance to our previously cleared 3380 MRI compatible patient vital signs monitoring system, we are fully cooperating and in direct discussions with UL to agree upon the necessary and proper application of the new guidance. We believe that data collection, documentation and UL’s review of the required information will take between three to four months, after which time we believe UL will renew the EC Certificate, once again permitting use of the CE Mark on our MRI compatible patient vital signs monitoring system. We expect to fully resolve this matter prior to the end of our second quarter,” said Roger Susi, President and Chief Executive Officer of the Company.

“We expect this action may reduce full-year 2019 revenue by approximately two percent. After considering this impact, we still expect mid 20 percent revenue growth in 2019. We will provide our full-year 2019 revenue, GAAP and non-GAAP earnings guidance in our fourth quarter earnings release,” said Susi.

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.

Our 3880 MRI compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features to safely and accurately monitor a patient’s vital signs during various MRI procedures. 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. The IRADIMED 3880 has a compact, lightweight design allowing it to travel with the patient from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. The features of the IRADIMED 3880 include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; non-invasive blood pressure; patient temperature,

and; optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. 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.

For more information please visit 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 an EC Certificate or CE Mark for our existing products, 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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