



September 9, 2020

## MedicaMetric Announces ISO 13485:2016 Certification

### **MedicaMetric achieves important milestone on its path to commercialize ProstaMetric and SureSet medical devices**

**BOSTON, MASSACHUSETTS** (September 9, 2020) – MedicaMetric, LLC, a prostate disease management and securement devices medical device company announced today that the company received ISO 13485:2016 certification for Medical Device and Quality Management Systems. This ISO certification indicates that the company's quality management system meets the most current regulatory requirements specific to the medical device industry. "We are very proud of this certification and it demonstrates the commitment of our global team to quality, and to meeting customer and international regulatory expectations," said Satish Vankayalapati, Co-Founder and Chairman of MedicaMetric.

"This certification is further evidence of our unwavering commitment to quality and enables MedicaMetric to continue to develop ProstaMetric and SureSet devices in compliance with the highest standards for safety, product performance and reliability," said Robert Rudelius, CEO for MedicaMetric. "Maintaining a world-class quality management system is a key goal for MedicaMetric."

ISO 13485:2016 is an internationally recognized quality standard for a quality system to ensure customer and regulatory requirements are consistently met throughout the lifecycle of the medical device product. "This certification represents an important milestone for our company and reflects our rigorous and risk-based approach to development and commercialization," said Christopher LaFarge, MedicaMetric' COO and Global Head of Quality.

#### **About MedicaMetric**

MedicaMetric develops innovative technologies and device solutions that transform the healthcare status quo, leading to better medical outcomes, streamlined care and enhanced patient experience.

We are leading the development of a new paradigm that transforms the diagnosis, treatment, and management of prostate health by filling the gap between PSA testing and imaging / biopsies. The ProstaMetrix system is a minimally invasive medical device designed to accurately measure the volume of the prostate gland early in the diagnostic process. ProstaMetrix helps physicians assess a patient's prostate status to better plan and monitor diagnostic procedures, treatments, drug therapies, and guide recommendations for active surveillance versus prostate biopsies.

MedicaMetrix is planning on releasing a number of devices including our SureSet™ Securement device, which secures the catheter hub and infusion tube with a single site bandage and organizes the tubing for easy access and removal. This one simple device streamlines infusion set-up, allows safe and easy access, while reducing variation and improve safety.

### **Cautionary Statements Concerning Forward-Looking Statements**

This press release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements related to the expected impact of COVID-19 on our business, statements regarding our growth, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative

only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise.

**MedicaMetrix, LLC**

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