



MIRTLE MEDICAL RECEIVES ISO 13485 CERTIFICATION

May 10, 2021 – North Andover, Massachusetts – MiRTLE Medical LLC, a medical device company focused on patient monitoring and safety during an MRI, today announced that the Company has earned ISO 13485:2016 certification for its quality management system.

ISO 13485:2016 is a globally recognized quality management standard developed and published by the International Organization for Standardization (ISO). The certification provides a model for companies of all types and sizes to use in building an effective quality management system. The standard is based on several quality management principles, including having a strong customer focus, involvement of high-level company management, an outlined process-based approach, and ongoing improvement of the aforementioned approach.

MiRTLE Medical's certification scope includes design, development, manufacture, and service of MRI-compatible ECG monitors. Activities at MiRTLE Medical's corporate headquarters, 1600 Osgood St. Suite 2017, North Andover, MA 01845 USA, are included in the scope of certification.

"Every MiRTLE MRI-Compatible ECG Monitor is designed and built to the highest quality standards," said MiRTLE Medical CEO Jim Robertson. "Our ISO 13485:2016 accreditation is confirmation of our demonstrated and ongoing commitment to reliability, quality assurance, and safety."

About MiRTLE Medical LLC

MiRTLE Medical is a privately funded medical device company founded in 2012. MiRTLE Medical designs and manufactures MRI-compatible 12-lead ECG monitors and software to enable cardiac monitoring inside an MRI to expand clinical and operational procedures to improve patient outcomes.

For more information, please visit www.mirtlemed.com or contact:

Jim Robertson
CEO
jim.robertson@mirtlemed.com
978.918.7223 x112