ECM’s On-Time Service Accelerates Med Device Go To Market

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Miami, FL, May 1, 2019-- ECM (Ente Certificazione Macchine) a modern, agile, global Notified Body (NB) (#1282) and an accredited ISO 13485 Certification Body, today announced that it will be exhibiting at FIME, booth #X23, June 26-28 in Miami Beach, FL with a spotlight on the company’s latest On-Time service.

As complexities and EU MDR regulatory demands are coming into force and rapid advancements are taking place, medical manufacturers face challenges for accelerated growth. ECM’s introduction of the On-Time Service is tailored to reduce process times to help clients with timely CE Marking and ISO 13485 regulatory approvals.

To help manufacturers keep pace, the On-Time Service offers two simple phases;
Phase 1: On-Site Technical Documentation Review
Phase 2: On-Site Audit

Both phases work in parallel to streamline the CE and ISO 13485 certification process in a well-planned timeframe. According to Andrea Secchi, President of ECM, “ECM’s team of experts work onsite to review documentation and discuss findings in real time, engaging in a dynamic discussion with the client’s team to identify any non-conformities. Working on-site enhances collaboration and productivity to accelerate regulatory approvals and market access.”

“We are committed to changing the blueprint for our customers, helping clients quickly meet EU directives and get certifications. This On-Time Service further advances innovation, bringing safe and high-quality medical devices to market faster and more efficiently,” concluded Secchi.

ECM (Ente Certificazione Macchine) is an experienced and professional Notified Body (NB) (#1282) and an accredited ISO 13485 Certification Body with a broad portfolio for medical device and other industries. In addition, our application under the Medical Device Regulation (MDR) 2017/745 has been filed to further support European market access.

Our team of experts (comprised of over 65% of engineers) are dedicated in supporting manufacturers through ECM’s efficient testing and certification programs. As a modern NB, we redefine the concept of certification process in-line with evolving requirement dynamics and market expectations, defining new regulatory approval processes.

ECM is headquartered in Italy with offices, laboratories and extensive partner networks throughout Asia, America, Europe, and the Middle East delivering reliable, efficient and responsive services. Learn more at ecmmedicaldevices.com.

Contact Information
For more information contact Roy Strunin of http:// (http://)

781-738-7180

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