

## **EMIT Corporation Awarded CE-Mark For HypothermX® Intravenous Fluid and Blood Warming Devices with Sterile Fluid Paths**

### **Company Also Earns ISO 13485:2003 and EN ISO 13485:2012 Quality Certification**

HOUSTON, Aug. 28, 2014 /PRNewswire/ -- EMIT Corporation announced today that it has received CE-Mark for its HypothermX® Intravenous Fluid and Blood Warming Devices with sterile fluid paths, allowing for sales expansion into the European and other OUS markets. EMIT Corporation also announced that it has been awarded ISO 13485:2003 and EN ISO 13485:2012 quality certification from SGS United Kingdom Ltd, a quality management system registrar.

The HypothermX® Intravenous Fluid and Blood Warming Devices are indicated for use in warming blood, blood products and intravenous fluids prior to administration and are used by healthcare professionals in clinical and field environments. "The documented improvement in clinical outcomes with first responder administration of blood, plasma, and blood products at the point of injury, as quickly as possible, is enabled with our product," said Jeffery Sheldon, Chairman and CEO of EMIT Corporation. Mr. Sheldon also stated further that: "The product's ease of use and ability to warm sufficient resuscitative fluid volume over unmatched timeframes makes it ideal for military, air medical transport, mobile, remote, austere, and power challenged environments."

European Union regulations require that medical device manufacturers who wish to sell products in Europe apply for and obtain a CE-Mark. The CE-Mark for the HypothermX® now positions EMIT Corporation for European sales initiation. Sales in Europe will be accomplished through a network of distributors. "We are currently engaged in contract negotiations with distributors in several key European, Middle-Eastern, and other markets, but remain interested in expanding our network," said Mr. Sheldon.

ISO 13485:2003 and EN ISO 13485:2012 are internationally recognized quality management system standards developed by the International Organization for Standardization. To be certified to the standards, companies must implement a quality management system embracing the activities from product design & manufacturing to customer service & sales. Certification to ISO 13485:2003 and EN ISO 13485:2012, through an independent third-party, provides acknowledgement that EMIT Corporation operates a quality management system in accordance with the standard. As part of the evaluation process SGS United Kingdom Ltd performed on-site facility assessments, examined documented procedures, and audited EMIT Corporation's overall operations. "Certification exemplifies our commitment to providing high quality products to our customers and our desire to improve patient clinical outcomes," said Mr. Sheldon. He added, "Obtaining quality management system certification and product CE-Mark represents a significant milestone for EMIT Corporation, made possible only through the dedication and hard work of our employees, advisors and investors."

#### **About EMIT Corporation**

EMIT Corporation designs, develops, manufactures, and sells devices for the treatment and prevention of hypothermia caused by traumatic, environmental, and procedural related occurrences. The HypothermX® products are patent protected, FDA 510(k) cleared, CE-Marked, fast, simple, portable, compact, light-weight, fully-disposable, long-term use systems. The device utilizes a flameless hydrocarbon combustion process fueled with Isobutane/Propane for warming, thereby eliminating the need for generated power to operate. EMIT Corporation's technology was exclusively licensed from The University of Texas Health Science Center at Houston and The University of Texas at Austin following initial research and development funding provided by the United States Army Telemedicine and Advanced Technology Research Center. CitareTx Investment Partners, a Houston based Venture Capital fund with integrated business incubation, also co-founded by Mr. Sheldon,

provided all of EMIT Corporation's product development and commercialization funding since inception. EMIT Corporation plans to launch several new products in 2015. For more information about EMIT Corporation, please call (281) 984-7355, email [jsheldon@emitcorp.com](mailto:jsheldon@emitcorp.com) or visit us on the web at [www.emitcorp.com](http://www.emitcorp.com)  
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