



Sphere Medical Holding PLC

Sphere Medical achieves EN ISO 13485 certification for the Design and Development of Medical Monitoring Systems

Sphere Medical Holding PLC ('Sphere Medical' or 'Sphere'), the Cambridge, UK, based medical microtech company is pleased to announce that it has achieved EN ISO 13485:2003 for the Design and Development of Medical Monitoring Systems certified by TÜV SÜD Product Service GmbH.

EN ISO 13485 is the international quality management standard for the medical device industry and is based on ISO 9001. It takes a process based approach to quality management to ensure that organisations function effectively, and certification is essential for companies developing medical devices for the market.

Dr Stuart Hendry, Sphere Medical's CEO, said "A robust quality management system is an essential element of any medical device company particularly one such as Sphere functioning in the Critical Care space. This is a major step in our company's development, underlining our commitment to product quality and providing a clear foundation for our vision to become a global provider of Critical Care Monitoring products. I am proud of the company and what we have achieved in reaching this certification and I look forward to building on this success."

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About Sphere Medical

Sphere Medical is developing highly innovative monitoring products to provide clinical and economic benefits in the critical care environment, based on the company's proprietary technology. The products allow minimally invasive, real time measurement of clinical chemistry parameters and therapeutic drug concentrations, giving healthcare professionals the information they require to more effectively manage therapy and optimise patient outcomes. Sphere Medical was founded in 2002 and is based in Cambridge, UK.

For further information please see www.spheremedical.com