



23 November 2011

Sphere Medical Holding plc

EN ISO13485 Scope Extension to include Manufacturing

Cambridge, UK, 23 November 2011: Sphere Medical Holding plc (AIM:SPHR.L) ("Sphere Medical" or the "Company"), a leading developer of innovative patient monitoring and diagnostic products for the critical care market, is pleased to announce that it has received formal certification by its Notified Body, TÜV SÜD Product Service GmbH, of the extension of its existing EN ISO13485 for Design and Development to include Production of Medical Monitoring Systems.

This extension now enables Sphere Medical to manufacture its monitoring and diagnostic medical devices, including its Proxima disposable patient-attached arterial blood analyser, at its manufacturing facility in Harston, Cambridge.

Commenting on the EN ISO13485 scope extension, Chief Executive Officer, Dr Stuart Hendry, said:

"The successful completion of the audit and certification by TÜV SÜD, our notified body, validates the excellent quality management system which we have at Sphere Medical. This scope extension is an important achievement and underpins our capability for commercial manufacture at our Harston facility."

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Notes for Editors

Sphere Medical is a UK based medical device company completing the development of a range of monitoring and diagnostic products designed to provide significant improvements in patient management in a number of hospital specialities. Sphere Medical's products are expected to allow near real time measurement of blood gases, various electrolytes and drug levels with laboratory accuracy, at the patient's bedside. This information can be used in a wide range of medical applications and is intended to enable faster clinical decision making and consequently to improve the management of patients.

Sphere Medical's two most advanced products, based on its proprietary microanalyser platform technology, are a disposable patient-attached arterial blood analyser for use in the Intensive Care Unit and Operating Room ('Proxima') and a device for continuous blood monitoring in the bypass circuit in patients undergoing cardiopulmonary bypass surgery



("CPB device"). Sphere Medical has also developed and is selling a device ('Pelorus 1000') that can measure blood levels of the intravenously administered anaesthetic drug, propofol. In each case, these products will ultimately target patients requiring close monitoring and frequent levels of blood testing.

Sphere Medical employs 43 staff in the areas of research and development, product development, sales and marketing and management and operations at its premises at Harston, Cambridge, UK.