



FOR IMMEDIATE RELEASE – Dec. 16, 2004
(ISSYS) Achieves ISO 9001:2000 Certification

YPSILANTI, Mich. - Integrated Sensing Systems, Inc. (ISSYS) has met the standards and requirements of the ISO 9001:2000 certification program and has been registered as an ISO 9001:2000 compliant company. This registration was made through BSI Management Systems, the world's first national standards body and founding member of the International Organization for Standardization (ISO). This achievement represents ISSYS' commitment to manufacturing excellence and to continuous quality improvement. Achieving ISO 9001:2000 certification required ISSYS to conform to high quality standards, including: a focus on providing and measuring customer satisfaction; adherence to a process model closely aligned to business practices; and a process for continual improvement.

ISO certification is a key step for ISSYS towards marketing its first medical device in the drug delivery field. Doug Sparks, executive vice president of operations, said, "Additionally, ISSYS is currently running its manufacturing infrastructure according to ISO-13485 and FDA GMP compliant manufacturing. We expect certification for these standards to be awarded shortly after the sales of ISSYS' first medical products (drug delivery systems)."

Drug administration errors are responsible for tens of thousands of injuries and deaths in the United States each year, according to ISSYS. Earlier this year, ISSYS completed development of its lead medical device that monitors the flow of intravenous drug infusion systems, and that may help to reduce a significant portion of those injuries and deaths. ISSYS plans to seek FDA approval to market this first medical device in the first quarter of 2005.

About ISO

ISO, the International Organization for Standardization (<http://www.iso.org/>), was established in 1947 and is a worldwide federation of national standards bodies from more than 140 countries. Its work results in international agreements that are published as international standards. The ISO family of standards represents an international consensus on good management practices with the aim of ensuring that organizations can consistently deliver products or services that meet clients' crucial quality requirements.

About ISSYS

ISSYS (<http://www.mems-issys.com/>) is a leader in advanced micromachining technologies for medical devices, microfluidic and scientific analytical sensing applications. Founded in 1995 by world-renowned leaders in MEMS technology, ISSYS is one of the oldest independent MEMS companies in the United States. ISSYS designs, develops and manufactures system-level products based on MEMS technology, and operates a state-of-the art bio-MEMS fabrication facility in Michigan.

About the registrar, BSI Management Systems

Founded in 1901, BSI has issued more than 35,500 registrations in over 90 countries. As the world's first national standards body, and a founding member of the ISO, BSI facilitated and published the first commercial standards to address quality management systems, environmental management systems, occupational health and safety management systems and project management. (<http://www.bsiamericas.com/>)