



ISS Achieves ISO 9001:2000 Certification

CHAMPAIGN, ILLINOIS —September 1, 2005—ISS just received certification for the ISO9001:2000 Quality System. The Quality Management System adopted by ISS for the Design and Manufacture of Scientific and Medical Instrumentation has been audited and certified by TÜV Rheinland of North America.

“The path to ISO certification has, at times, seemed to be a long and arduous road.” said Mr. Richard Wynn, ISO Management Representative of ISS. “ISS’ management and staff embarked upon a journey knowing that there would be twists and turns, and even a few detours along the way. The contributions of our dedicated staff members have brought us to this place, which is really just a “jumping-off” point for the next step in the process. I am quite sure that with commitment and cooperation our staff has shown during the ISO process, the next stage in the journey will be even smoother.”

“This is an important milestone for our company” Dr. Beniamino Barbieri, President of ISS, said. “By establishing a quality management system we have committed ISS to providing the highest level of customer satisfaction; by increasing the interactions with our customers, by keeping an open communication with them and by listening to their requirements we plan to constantly improve our quality products and services. At the same time, we intend to build an organization that provides, through team work and training, a rigorous professional development and personal growth for each employee. Our vision is for ISS to maintain the world leadership in fluorescence analytical instrumentation; also, we intend to expand our medical division by introducing novel photonics instrumentation that will improve the quality of health care and the well being of patients.”

The development of OxiplexTS™, a non-invasive tissue oximeter, played an important role in the march towards ISO certification. In the next few weeks, ISS will file a 510(k) pre-market notification with the Food and Drug Administration (FDA) seeking approval for the use of OxiplexTS™ as a medical device in assessing the stages of peripheral vascular disease (PVD). In the countries of the European Union (EU) ISS will seek the CE-mark for Class IIA devices, a registration required to sell to hospitals there. Both these steps required ISO certification for the company.

OxiplexTS™, a non-invasive tissue oximeter capable of determining the absolute concentrations of oxy- and deoxy-hemoglobin in tissues, has met great success in the medical research field. More than fifty units have been installed worldwide since its introduction. Now, ISS plans to access the clinical market, that is the about 8,000

hospitals providing health care in the United States and an additional 9,000 hospitals in countries of the European Union. ISS is continuing the search for the novel applications of OxiplexTS™. Currently, ISS has an active grant awarded by the National Institutes of Health (NIH) for the study of sleep apnea using the non-invasive tissue oximeter. The Principal Investigator of the grant is Dr. Antonios Michalos. Data is collected at Carle Clinic in Urbana, Illinois, and at The Medical School of the University of Illinois at Chicago. ISS also maintains collaboration with Prof. Fady Charbel, Head of the Department of Neurosurgery at The University of Illinois at Chicago, for the development of applications of OxiplexTS™ to neurosurgery.

OxiplexTS™ is an instrument born by the ideas of Prof. Enrico Gratton and his collaborators at The Laboratory for Fluorescence Dynamics at The University of Illinois at Urbana-Champaign. ISS has a long history of collaboration with the University. ISS has also received grants from the National Institutes of Health in order to design and build a suitable commercial instrument. “Whenever we will be able to sell the instrument as a clinical device we will have fulfilled our dream of transforming the inventions conceived in the academic world into products that will have a large impact on the outside world”, Dr. Barbieri said, “thus bridging the world of a great research institution with the role of a company like ISS.” ISO is an important step in this process.

“What is the strength of ISS? We are fortunate and privileged to live close to a great research institution like The University of Illinois at Urbana-Champaign that is source of both innovation and inspiration for us working in the high-tech world. I also need to recognize the instrumental role of IMEC, the Illinois Manufacturing Extension Center, and the Illinois Department of Commerce and Economic Opportunity: both institutions provided financial support and precious advice and support through the process conducive to ISO certification. Finally, I have to thank ISS wonderful employees: we have a dedicated and passionate workforce without which our dream could not come through”