

SIGN Fracture Care International Receives ISO 13485:2003 Certification From Intertek



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Boxborough, MA —Intertek, (LSE: ITRK), a leading provider of quality and safety solutions serving a wide range of industries around the world, announced that it has certified SIGN Fracture Care International's (SIGN) quality management system to ISO 13485:2003. This certification affirms that the company's operations adhere to the internationally-recognized standard for quality management and that SIGN has implemented a system to provide medical devices that consistently meet regulatory requirements applicable to medical devices.

"Our goal is to build orthopedic capacity in developing countries where the epidemic of road traffic and other accidents is steadily rising. According to the WHO, millions of people are injured each year, 90 percent of the injured are in the developing world. But 80 percent of the orthopedic surgeons who could provide healing surgery are in developed countries. We address this inequality by providing training and implants to the local surgeons so they can perform immediate and effective surgery to the injured poor. These patients cannot afford to purchase the implants needed for these surgeries, so we donate them to their hospitals. The surgeons are grateful for the donated materials, but need assurance that the products are of good quality. Obtaining the ISO 13485 certification gives the surgeons and their patients the assurance that the implants used to fix their fractures are produced under a quality management system that meets the same requirements as other implants made in North America and Europe. We are proud to work with Intertek to further our goal of creating equality of fracture care worldwide. ." said Jeanne Dillner, CEO of SIGN Fracture Care International.

We chose Intertek because they were recommended to us by a large international medical manufacturing company that supports SIGN. They were very impressed with the service provided by the field auditors. We also found working with Intertek to be both a professional and an exceptionally educational experience. The Intertek staff, including the office and the field auditors, were always personable, professional and patient with the services they provided. We are pleased with our decision and plan to continue our relationship to maintain our ISO 13485 certification and to achieve CE marking for our products" said Doug Donnelly, Quality Assurance Manager for SIGN Fracture Care International. ISO 13485:2003 is the international standard that sets requirements for a quality management system with a focus on the provision of safe and effective medical devices. Regulatory authorities in most major markets require, or strongly prefer, that manufacturers marketing medical products in their countries have a third-party audited and certified quality management system in place.

"As soon as we understood what SIGN Fracture Care's International's mission was, we were excited that there was a way for us to partner with them by using our expertise and becoming a corporate donor. We are proud to be a global player in the medical device sector, where our clients make direct contributions to the improvement of health care, in this case a very visible one," said Christine Forcier, Medical Program Manager for Intertek's Business Assurance group.

“Intertek is honored to be a corporate donor for SIGN Fracture Care International. SIGN’s mission to support surgeons in developing nations is something Intertek is proud to say we are a part of. We look forward to the continued partnership between Intertek and SIGN in the coming years,” said Calin Moldovean, President of Intertek’s Business Assurance group.

Contacts

For further information, please contact

For Market Inquiries:

Lauren Reidy
Marketing Manager, Americas Region
Direct +1 978.929.2111
Email: lauren.reidy@intertek.com

For Media Inquiries:

Cassie Biscanin
PR Manager, Intertek Group, Americas Region
Direct: +1 713.543.3775
Email: cassandra.biscanin@intertek.com

About Intertek

Intertek (www.intertek.com) is a leading provider of quality and safety solutions serving a wide range of industries around the world. From auditing and inspection, to testing, quality assurance and certification, Intertek people are dedicated to adding value to customers’ products and processes, supporting their success in the global marketplace. With a network of more than 1,000 laboratories and offices and over 33,000 people in more than 100 countries, Intertek helps its clients to meet end users’ expectations across increasingly diverse quality, health, environmental, safety and social accountability aspects in virtually any market around the world.

View the original article at: <http://intertek-france.com/news/2012/08-16-sign/>