ZEON Medical Acquires Certification for Both ISO 9001:2000 and ISO 13485:2003

May 20, 2004

ZEON Medical Inc. (Shuwa Shiba Park Building, 2-4-1 Shiba Kohen, Minato-ku, Tokyo; President: Toshikazu Onuki) acquired certification for ISO 9001:2000, an international standard for quality management systems on April 16, 2004, and at the same time acquired certification for ISO 13485:2003, a sector-specific standard for medical devices.

With these certifications, ZEON Medical will further promote quality control under its established quality management system for the design, development, production, sales, and associated services in the medical device field, to provide better products that meet customer needs.

ZEON Medical Inc., a wholly owned subsidiary of ZEON Corporation (2-6-1 Marunouchi, Chiyoda-ku, Tokyo; President & CEO: Naozumi Furukawa), has recorded achievements in the development of circulatory system products, including the development of the world's first ventricular artificial hearts and IABP (intra-aortic balloon pumping), as well as products related to endoscopic treatment instruments such as bipolar snares and basket catheters. The company has recently expanded into coronary interventions, including the development and sales of the PCTA balloon catheter that treats coronary lesions using a small balloon. ZEON Medical is supporting the development of specialists in this field and works to fully comprehend the demands of doctors and needs of the market by staying in close contact with actual medical procedures.

Supplementary explanation

ISO 13485:2003 is a sector-specific standard for medical devices based on ISO 9001:2000 and includes requirements specifically related to medical devices. This standard does not incorporate all the content of ISO 9001:2000. It excludes customer satisfaction and continuous improvement, which are not associated with the regulation of medical devices, but does address sterilization concerns that are specific to medical devices.

For further information

ZEON Medical Inc., Quality Assurance Department

Tel: +81-3-3578-7722

Zeon Corporation,
Department of Corporate Communications

Tel: +81-3-3216-2747

Contact form