



*ExtruMed LLC announces ISO 13485:2003 Certification for the Manufacture and Distribution of Custom, High-Precision Plastic Tubing for Medical Applications.*

Placentia, Calif., July 7, 2008 - ExtruMed LLC, a global market leader in precision medical tubing, announced today that it has achieved ISO 13485:2003 certification for the Manufacture and Distribution of Custom, High-Precision Plastic Tubing for Medical Applications from TUV SUD America, Inc. for both of its Southern California facilities, [Placentia and Temecula](#).

The [ISO 13485:2003](#) standard, published by the International Organization for Standardization, is a globally recognized standard of quality control covering management, training, supplier management, product realization, production control, and customer satisfaction. ISO 13485:2003 specifies requirements for quality management systems in which organizations demonstrate the ability to provide medical devices and related services that consistently meet both customer and regulatory requirements.

Upon obtaining the certification, [Bill Ellerkamp](#), President and CEO commented, "We are very pleased to have our quality management system be recognized by TUV SUD America as meeting ISO 13485:2003 standards. Our precision tubing products are found in the most critical implant, interventional and minimally invasive catheters and devices in the market today. Voluntarily upgrading to this standard demonstrates our commitment to supporting our customers as they deliver more sophisticated diagnostic and therapeutic devices to their patients and as they come under increasingly strict regulatory scrutiny with respect to the use of contract manufacturers."

ExtruMed is one of only a very few dedicated precision medical tubing contract manufacturers to be ISO 13485:2003 certified. This certification affirms to the medical device community that ExtruMed has quality people and processes in place, procedures are consistently executed in daily operations, and that the system is effective at assuring the quality, consistency and reliability of products which are supplied to customers. ExtruMed's Director of Quality, [Scott Dudevoir](#), says "This certification reflects the current state of an aggressively evolving quality management system. This system provides the platform from which ExtruMed can readily satisfy the most stringent quality and reliability requirements of our customers. Ultimately, the certification increases the customer's confidence in the products that we deliver and our value to the medical device community."

### **ExtruMed Quality Policy**

[ExtruMed](#) is committed to providing the highest quality precision tubing for use in medical devices. We will strive to exceed our customer's expectations for [products](#) and [services](#), on-time delivery, reliability, and integrity. We will continually evaluate, invest in, and improve our processes, technology, and personnel, in order to maintain technical competence, an effective quality system, and market leadership. We will seek opportunities to build quality into all phases of design and manufacturing. We will maintain the highest ethical standards in all business practices by fostering an environment of trust, safety, teamwork, and open communication.

### **About ExtruMed LLC**

[ExtruMed](#) provides [precision tubing](#) solutions for catheter based delivery systems used in minimally invasive, interventional and implantable therapies. The Company serves a diverse customer base including many of the world's leading medical device OEMs as well as high-profile venture-backed medical device companies. The Company offers a complete range of tubing services including design, engineering, material selection, prototyping, volume manufacturing, and supply chain management. For more information about ExtruMed visit <http://www.extrumed.com/aboutus.html>.

#### *Contact:*

ExtruMed, LLC

Bill Ellerkamp

President and CEO

Tel: (714) 993-4100

e-mail: [bellerkamp@extrumed.com](mailto:bellerkamp@extrumed.com)