

Roncelli Plastics Earns Medical Device Quality Management Systems Registration from NSF International Strategic Registration, Ltd.

ISO 13485 registration demonstrates Roncelli Plastics' commitment to producing safer, high quality medical devices

Monrovia, Calif. (July 16, 2012) -- Roncelli Plastics, industry leader and diversified manufacturer of engineered plastics, has achieved ISO 13485:2003 registration for its Monrovia, Calif. facility. The facility includes CNC Fabrication and Mechanical Assembly of nonmetallic components. Earning ISO 13485 registration demonstrates Roncelli Plastics' commitment to design and manufacture high quality materials to better serve the medical device community.

ISO 13485 is an international standard, recognized throughout the world for establishing a business management system specific to the medical device industry. Created by the International Organization for Standardization, ISO 13485:2003 is based on eight quality management principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, fact based decision-making and mutually beneficial supplier relationships. When fully adopted, these principles have been proven to enhance organizational performance.

Roncelli Plastics' ISO 13485 registration complements their other quality management system registrations, including AS9100 and ISO 9001, reflecting the wide range of industries served by Roncelli Plastics such as aerospace, defense, electrical and semiconductor, as well as medical and pharmaceutical.

"For more than 40 years, we have been committed to quality. Our goal is consistent improvement of our processes to provide the highest quality products and materials to our clients. Our ISO 13485 registration from NSF-ISR is additional proof of the success of these efforts," said Riley Cole, President of Roncelli Plastics.

In order to earn ISO 13485 registration, **Roncelli Plastics** demonstrated its ability to meet customer and regulatory requirements, enhance customer satisfaction through effective application of their quality systems, as well as provide for continual improvement. NSF-ISR assessed Roncelli Plastic's quality management systems via a two-day comprehensive audit and found it to be in compliance with the ISO 13485 quality management system requirements.

"Registration to ISO 13485 shows Roncelli Plastics' continued dedication to quality," said Tony Giles, Director of Sales for NSF-ISR. "They clearly pursue excellence in all their quality programs and this latest certification to ISO 13485 is just one more example of the merit of their systems approach to maintaining superior performance."

NSF-ISR will audit Roncelli Plastics' facility annually to verify continued compliance with the ISO 13485 requirements. Roncelli Plastics' registration listing can be found on NSF-ISR's web site.

For more information about **Roncelli Plastics** quality registrations, visit <u>www.Roncelli.com</u> or contact Chris Cole at 626.359.2551 or <u>chris@Roncelli.com</u>.