

PRESS RELEASE

For Immediate Release

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ProMold Plastics Receives ISO 13485 Certification: Quality management system for medical devices

*Supports company's focus on delivering customers
the highest standard in quality*

(September 25, 2010, Portland CT...) ProMold Plastics, a contract manufacturer specializing in quality mold making and close tolerance injection molded components is pleased to announce they have just received ISO 13485 Certification.

"We are thrilled to have earned this recognition for all the hard work, dedication and commitment our employees have shown to make us a world class organization," states Richard Puglielli, President. "We sought and worked hard to earn the registration for the ISO 13485 Medical Device Standard not because we need to but because we believe that by having high standards for all of our business processes, our customers will benefit from our ability to consistently and reliably meet their expectations."

"We have been in business for over forty years and served many different industries with custom injection molds and precision molding," adds Mr. Puglielli. "Our success has been built on providing our customers and prospective customers with solutions to meet their

budgetary needs and time constraints, well before any commitment for an order is made.”

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 163 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. (ISO.org)

ISO 13485 is a quality management system that is oriented towards the design, development, production, and installation of medical devices and related services. ISO 13485 is not a product standard; it is a process standard. However, it is not enough to establish a quality management system that complies with the ISO 13485 standard, companies also need to comply with all relevant product and service oriented technical standards and regulations.

ISO 13485 requires the company to demonstrate the quality system is implemented and maintained. Some key points included in the ISO 13485 registration are:

- * the promotion and awareness of regulatory requirements as a management responsibility
- * controls in the work environment to ensure product conformity
- * focus on risk management activities and design transfer activities during product development
- * specific requirements for verification of the effectiveness of corrective and preventive actions

"The key objectives of ISO13485 are to maximize the probability that a medical device organization will meet regulatory quality management system requirements worldwide, will provide safe and effective medical devices, and will meet customer requirements," said Ed Kimmelman, Convener of the working group that developed the new standard. According to Ed Kimmelman, ISO 13485 is intended to be the vehicle for harmonizing quality management system regulations in the sector around the world. "Most of the industrialized countries around the world already have some form of quality management system regulation. For these countries, ISO 13485 should reflect their current



requirements and provide them with suggestions for improvements of these regulations. For those countries that are beginning to consider regulating medical device quality management systems, ISO 13485 is intended to serve as a model for such regulation." **
**[quotes by Mr. Kimmelman taken from www.iso.org Ref.: 872 Quality management systems for the medical industry]

About ProMold

ProMold Plastics is a full service company operating three shifts with in-house operations for Engineering and Design, Mold Making, Injection Molding and Secondary Operations. The company was founded in 1967 as a one-man Tool & Die shop by Riccardo Puglielli, an Italian immigrant, and since 1999 has been run by his son, Richard Puglielli. In 2008 the company moved to a new location in Portland, CT that more than doubled the company's floor space to 43,000 sq foot building.

ProMold Plastics is ISO 9001 and ISO 13485 Certified and a UL Recognized molder serving the medical, electronic and industrial market place and shipping products worldwide. Dedicated highly skilled craftsmanship and an unwavering commitment to their customers formed the foundation of the company and continue to serve as the principles guiding the company's growth. ProMold Plastics provides their customers with the best of both worlds in today's mold making industry by offering them the personal attention they expect from a family business, together with the structure and resources they expect from a larger corporation.

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