Mack Prototype earns quality gold standard for medical manufacturing

The quality management system of Mack Prototype Inc., a division of Mack Molding Co., has been independently audited and certified to be in compliance with the requirements of the ISO 13485 international quality standard for medical device manufacturing.

The International Organization for Standardization, or ISO, a prestigious network of national standards institutes from over 50 countries, created the standard to provide medical devices that consistently meet applicable customer and regulatory requirements. NSF International Strategic Registrations, or NSF-ISR, an accredited registrar, carried out the third-party assessment and certification.

"Achieving this quality hallmark uniquely positions us as a prototype house and low-volume manufacturer," said President Ric Perry, "as many manufacturers our size are not certified to this stringent medical standard. It will put us at the table with major medical OEMs, who require suppliers to be certified to ISO 13485 in order to quote new projects. I will assure customers we are continually driving toward quality system improvement. And based on customer needs, it will allow us to partner with Mack Holding, which is FDA registered and has been certified to ISO 13485 for several years, to provide a low-volume solution for major medical OEMS."

Mack Prototype is a low-volume manufacturing company that specializes in SLA rapid prototyping, CNC machining, LIM polyurethane and injection molding. The Gardner location houses eight injection presses, 10 to 230 tons each, for low volume, small-to-medium part molding.

Mack Prototype complements Mack's growing list of vertically-integrated services, which includes product design and development, custom injection molding, sheet metal fabrication, printed circuit board assembly and full product assembly and order fulfillment.