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## Mack Prototype makes medical standard

By IMM Staff

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The quality management system of [Mack Prototype Inc.](#) (Gardner, MA) has obtained ISO 13485 certification, the international quality standard for medical device manufacturing. "Achieving this quality hallmark uniquely positions us as a prototype house and low-volume manufacturer," says 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." It will also allow Mack Prototype to partner with parent company [Mack Molding Co.](#) (Arlington, VT), which is FDA registered and has been certified to ISO 13485 for several years, to provide a low-volume solution for major medical OEMs. Just last month the company formed a medical products group, called MackMedical, to more directly address the needs of 30% of its business.

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 (10-230 tons) 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. —[immeditorial@cancom.com](mailto:immeditorial@cancom.com)

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