Custom Silicone Parts from ProMed Meet Rigorous Standards for Medical Device Manufacturing

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ProMed continues to deliver custom silicone parts designed to meet the demanding requirements of medical device manufacturing, supporting OEMs and product teams that require precision, consistency, and regulatory alignment. With decades of experience in silicone molding and cleanroom manufacturing, ProMed provides elastomer components that perform reliably in applications where tolerances, material integrity, and compliance directly affect patient safety and device function.

Custom silicone parts play a critical role in modern medical devices, ranging from drug delivery systems and diagnostic equipment to implantable and wearable technologies. These components must maintain dimensional accuracy, withstand sterilization, and remain stable over extended use. ProMed?s manufacturing approach reflects these realities, emphasizing controlled processes, validated materials, and detailed documentation throughout the production lifecycle.

At the core of ProMed?s capabilities is expertise in liquid silicone rubber (LSR) and high consistency rubber (HCR) molding. Both materials are widely used in medical applications due to biocompatibility, chemical resistance, and durability, but each presents different manufacturing considerations. LSR is often selected for complex geometries, tight tolerances, and high-volume production using injection molding, while HCR is commonly used for larger components or applications where compression or transfer molding is more efficient. ProMed supports both processes, allowing material and process selection to align with functional and regulatory requirements rather than manufacturing constraints.

Precision is a defining requirement for custom silicone parts used in regulated environments. ProMed operates molding equipment capable of producing components across a wide size range, including micro-molded parts with features measured in fractions of a millimeter. Dimensional control is supported through process validation, statistical monitoring, and in-house metrology, helping ensure parts remain within specification across production runs. This consistency is especially important for sealing components, drug-contact parts, and assemblies where silicone interfaces with rigid substrates.

Cleanroom manufacturing is another key element of ProMed?s medical device support. Production of custom silicone parts takes place in ISO Class 7 cleanroom environments, depending on application needs. These controlled spaces limit particulate contamination during molding, secondary operations, and assembly, supporting compliance with FDA and international standards. Environmental monitoring, gowning protocols, and documented cleaning procedures help maintain conditions suitable for patient-contact and combination device components.

Material selection is closely tied to regulatory expectations. ProMed works with medical-grade silicone materials that meet USP Class VI and ISO 10993 requirements, with testing available for cytotoxicity, sensitization, and irritation as needed. Full material traceability links raw material lots to finished components, providing documentation often required for regulatory submissions and audits. Compatibility with common sterilization methods, including gamma, ethylene oxide, and autoclave, is evaluated early in development to reduce downstream risk.

Beyond molding, ProMed supports secondary operations that are frequently required for finished medical components. These include deflashing, post-curing, surface treatment, and assembly performed within controlled environments. Overmolding capabilities allow silicone to be bonded directly to materials such as PEEK, stainless steel, titanium, and electronic substrates, reducing assembly steps and improving component integrity. Plasma treatment and priming processes are used to enhance adhesion when bonding silicone to low-surface-energy materials.

Quality systems underpin every stage of production. ProMed maintains ISO 13485 certification and FDA registration, with quality processes structured to support device manufacturers navigating audits, inspections, and submissions. Validation activities, including IQ, OQ, and PQ, are integrated into new programs, and corrective and preventive action systems are used to address process variation before it affects product performance. Advanced inspection tools, such as CT scanning and optical measurement systems, provide non-destructive insight into internal features that cannot be verified through traditional methods.

The ability to scale production is another factor influencing medical device manufacturing success. ProMed supports programs from early prototyping through commercial production, using tooling and automation strategies appropriate for each phase. Single-cavity tools may be used during development or clinical builds, with the option to transition to multi-cavity or automated cells as volumes increase. This approach helps maintain design intent and process knowledge as programs mature, reducing the risk associated with supplier changes or late-stage process transfers.

Custom silicone parts manufactured by ProMed are used across a broad range of medical applications, including implantable devices, diagnostic equipment, respiratory systems, and combination drug-device products. Each application presents unique challenges related to material behavior, tolerance requirements,

and regulatory expectations. Addressing these challenges requires coordination between engineering, manufacturing, and quality teams, as well as clear communication with device developers throughout the project lifecycle.

As medical devices continue to evolve toward smaller, more complex, and more integrated designs, the role of precision silicone components becomes increasingly important. ProMed?s focus on controlled manufacturing environments, validated processes, and material expertise positions the company as a reliable supplier for organizations seeking consistent, compliant custom silicone parts. The emphasis remains on meeting technical and regulatory requirements with clarity and discipline, supporting medical device programs where performance and quality cannot be compromised.

About ProMed:
Since 1989, ProMed has been recognized as a leading Contract Manufacturer of complex, intricately designed molded silicone and plastic components and assemblies for highly regulated industries. ProMed?s expertise extends across applications for short-term and long-term implantable devices, single use devices, drug-releasing combination devices, and specialized materials and processes for defense applications. They collaboratively work with our customers from prototype through production, providing over 30 years of experience related to design for manufacturability, material selection, tool and fixture design, process development, manufacturing, and other value-added services that result in cost-effective solutions with superior quality.
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