

# Medical Silicone Compliance: Why It Matters

Healthcare-grade silicone elastomers must meet strict standards for purity, clarity, durability, and biocompatibility. Momentive’s Silopren™ LSR 4000 series is engineered to comply with these requirements, making it ideal for both disposable and reusable medical devices.

## Key Compliance Features

- **Biocompatibility:** Safe for contact with body fluids and medications.
- **Regulatory Standards:** Meets stringent healthcare regulations and ISO, USP Class VI compliance, and FDA requirements.
- **Sterilization Resistance:** Maintains performance after repeated autoclave, gamma, or EO sterilization.
- **Primerless Adhesion:** Bonds to substrates like PC, PBT, and copolyesters without post-curing.
- **Aging and Chemical Stability:** Withstands harsh environments and extreme temperatures.

# Medical Silicone Specification Checklist

When selecting silicone for healthcare applications, ensure your material meets the critical specifications below.

Requirement	Silopren™ LSR 4000 Series Advantage
Biocompatibility	Compliant with ISO, USP Class VI, and FDA standards
Sterilization Durability	Stable after multiple sterilization (autoclave, gamma, or EO) cycles
Transparency & Clarity	High optical clarity for diagnostic devices
Durometer Range	Wide Shore A hardness (~30A) options
Fast Cure & Tear Strength	Supports high-speed injection molding processes
Self-Bonding Capability	Primerless adhesion to plastics and metals
Design Flexibility	Enables soft-hard overmolding and insert molding

## Applications in Healthcare

Silopren™ LSR 4000 grades are used in the following:

- **General Medical Parts:** O-rings, gaskets, seals, valves, diaphragms
- **Drug Delivery Systems:** Catheters, tubing, dosage control devices
- **Respiratory & Surgical:** Masks, valves, wound drains
- **Dental & Orthopedic:** Impression molds, prosthetic components

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