TECHNICAL DATASHEET:
MEDICAL GRADE SILICONE SHEETING
Medical-Grade Solid Silicone Sheet — 10–70 Durometer

PRODUCT DESCRIPTION

Medical Grade Silicone Sheeting is a solid silicone elastomer formulated from domestically produced silicone rubber for use in medical devices and implant applications up to 29 days in the human body. The material meets USP Class VI, European Pharmacopeia, ISO 10993, and FDA Title 21 CFR 177.2600 standards, and is free of organic plasticizers, phthalates, and peroxides. Available from 10 to 70 Shore A durometer in gloss or matte finish, in thicknesses from .010" to .500" and widths up to 60"; this is a made-to-order product with an operating range of -80°F to +450°F (500°F intermittent).

TYPICAL APPLICATIONS

- Medical device seals and gaskets
- Short-term implantable components (up to 29 days)
- Surgical instrument sealing and insulation
- Pharmaceutical processing seals and gaskets
- Die-cut medical-grade gasketing and sheeting

PRODUCT FEATURES & BENEFITS

- Suitable for implant applications up to 29 days
- Temperature resistance: -80°F to +450°F (500°F intermittent)
- Fabricated from domestically produced silicone rubber
- No smell or odor; contains no organic plasticizers; phthalate and peroxide free
- Safe for steam and gamma sterilization
- Available in gloss or matte finish
- Wide durometer range (10–70 Shore A)
- USP Class VI compliant
- European Pharmacopeia compliant
- ISO 10993 compliant
- FDA Title 21 CFR 177.2600 compliant

Property	Test Method	ESS30HC	ESS40HC	ESS50HC	ESS55HC	ESS60HC	ESS65HC	ESS70HC
Durometer, Shore "A"	ASTM D2240	30 ±5	40 ±5	50 ±5	55 ±5	60 ±5	65 ±5	70 ±5
Tensile Strength, psi	ASTM D412	1100	1100	1250	1300	1300	1350	1300
Elongation, %	ASTM D412	900	850	850	700	800	700	600
Tear, ppi Die "B"	ASTM D624	170	170	205	180	205	185	185

Specifications are believed to be accurate at the time of publication and are subject to change without notice. It is the responsibility of the end-user to test and determine suitability of this material for a particular application. H-O will provide samples for this purpose at no charge. **REV. 0**