

SAINT-GOBAIN MEDICAL

BIO-SIL® 1350

Tubing for Medical Device Manufacturers

Bio-Sil® 1350 platinum-cured silicone tubing is engineered for ultrapure fluid transfer in medical applications where flexibility, precision, and pump performance are essential. With a Shore A hardness of 50, it combines high compressibility with resilience, supporting stable flow rates in peristaltic pump systems. The formulation minimizes wear over extended use, helping maintain dimensional integrity and functional performance through repeated pump cycles.

BIOCOMPATIBILITY CHARACTERISTICS

Bio-Sil 1350 is manufactured from raw materials that meet the requirements of USP<88> and can be classified as USP Plastic Class VI. Finished tubing is tested to ISO 10993 standards for genotoxicity (ISO 10993-3), hemolysis (ISO 10993-4), and cytotoxicity (ISO 10993-5). Testing is conducted on tubing sterilized by ethylene oxide (EtO), gamma irradiation (25–40 kGy), and steam autoclaving at 121°C to confirm compatibility with common medical sterilization methods.

IDEAL CHOICE FOR MEDICAL APPLICATIONS

The 50 Shore A durometer provides a balance of flexibility and compressibility for consistent pumping performance. The smooth bore and low friction surface reduce mechanical stress on pump components, while the material's resilience supports extended tubing life. These characteristics make Bio-Sil 1350 suitable for hemodialysis systems, anesthesia delivery, respiratory therapy devices, and diagnostic instruments requiring accurate, repeatable fluid control.

Manufactured in France, Bio-Sil 1350 is ideally positioned to support the European medical device market with localized production and supply chain advantages.

Product recommendations are based on a combination of industry knowledge, material science expertise, and/or material testing data. Contact Saint-Gobain Medical for further tubing recommendation information.



Bio-Sil®



Bio-Sil® 1350

FEATURES/BENEFITS

- Tubing has met ISO 10993-3/4/5 criteria
- Bio-Sil 1350 raw material has met USP <88> Class VI criteria
- Compatible with EtO, gamma (25–40 kGy), and steam sterilization
- Designed and manufactured without the intentional addition of animal-derived materials
- Custom sizes available

TYPICAL APPLICATIONS

- Diagnostic and analytical instruments
- Dialysis and blood filtration
- Drug delivery and infusion therapy
- Peristaltic pump systems
- Respiratory and anesthesia equipment



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BIO-SIL® 1350 TUBING MANUFACTURED SIZES

Part Number	I.D.		O.D.		Wall Thickness		Length	
	inches	mm	inches	mm	inches	mm	feet	m
BS1350-0076-0165	0.03	0.76	0.065	1.65	0.018	0.44	50	15
BS1350-0079-0239	0.031	0.79	0.094	2.39	0.032	0.80	50	15
BS1350-0102-0216	0.04	1.02	0.085	2.16	0.023	0.57	50	15
BS1350-0147-0196	0.058	1.47	0.077	1.96	0.010	0.24	50	15
BS1350-0160-0241	0.063	1.60	0.095	2.41	0.016	0.41	50	15
BS1350-0160-0318	0.063	1.60	0.125	3.18	0.031	0.79	50	15
BS1350-0198-0318	0.078	1.98	0.125	3.18	0.024	0.60	50	15
BS1350-0239-0396	0.094	2.39	0.156	3.96	0.031	0.79	50	15
BS1350-0264-0488	0.104	2.64	0.192	4.88	0.044	1.12	50	15
BS1350-0318-0478	0.125	3.18	0.188	4.78	0.032	0.80	50	15
BS1350-0318-0635	0.125	3.18	0.25	6.35	0.063	1.59	50	15
BS1350-0335-0465	0.132	3.35	0.183	4.65	0.026	0.65	50	15
BS1350-0396-0556	0.156	3.96	0.219	5.56	0.032	0.80	50	15
BS1350-0478-0635	0.188	4.78	0.25	6.35	0.031	0.79	50	15
BS1350-0478-0795	0.188	4.78	0.313	7.95	0.063	1.59	50	15
BS1350-0478-0953	0.188	4.78	0.375	9.53	0.094	2.37	50	15
BS1350-0478-1113	0.188	4.78	0.438	11.13	0.125	3.18	50	15
BS1350-0635-0795	0.25	6.35	0.313	7.95	0.032	0.80	50	15
BS1350-0635-0953	0.25	6.35	0.375	9.53	0.063	1.59	50	15
BS1350-0635-1113	0.25	6.35	0.438	11.13	0.094	2.39	50	15
BS1350-0635-1270	0.25	6.35	0.5	12.70	0.125	3.18	50	15

Custom hardness and dimensions available.

BIO-SIL® 1350 TUBING STERILIZATION METHODS

Physical properties are not significantly impacted by the following sterilization methods:

- Autoclavable (30 min at 250°F/121°C)
- EtO (Ethylene Oxide)
- Gamma irradiation (up to 4 Mrad (40 kGy))

BIO-SIL® 1350 TUBING TYPICAL PHYSICAL PROPERTIES*

Property	ISO	Value or Rating
Durometer Hardness, Shore A (+/-3)	48-4	53
Color	Translucent	
Tensile Strength, psi (MPa)	37	1427 (9,84)
Ultimate Elongation, 100%	37	923
Tear Resistance, Die B, ppi (kN/m)	34-1	166 (27,27)
Specific Gravity	1183	1.13

* Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strips, 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

BIO-SIL® 1350 TUBING CHARACTERISTICS**

Method Description	Reference Standard	Result
USP Class VI (raw material)	USP <88>	Meets Criteria
Genotoxicity (Ames)***	ISO 10993-3	Meets Criteria
Hemolysis (direct and indirect)	ISO 10993-4	Meets Criteria
Cytotoxicity (L929)	ISO 10993-5	Meets Criteria

**After gamma, steam and EtO sterilization.

***EtO results in progress.

NOTE: The information provided pertains only to product manufactured at the Saint-Gobain Saint-Quentin-Fallavier facility (France). Saint-Gobain Performance Plastics France ("Saint-Gobain") products that are used as components in the manufacture of medical devices (as defined by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices) are sold by Saint-Gobain only and exclusively to medical devices manufacturers for use in the manufacture, assembly or distribution of their medical devices. This product is not a finished medical device and is not intended for direct use by end users, consumers or patients. Medical device manufacturers, to whom Saint-Gobain acts as a supplier or a subcontractor for finished products, are solely responsible for determining whether their finished products qualify as a medical device and for ensuring compliance with the appropriate certifications and registrations, or other regulatory requirements relevant to their intended markets.

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