

# Device Adhesives and Encapsulants

To assure consistent quality for medical device and pharmaceutical applications, elastomers from Dow Corning are manufactured, packaged, and tested at the Healthcare Industries Materials Site utilizing principles of GMP guidelines for both Active Pharmaceutical Ingredients (APIs) and Medical Devices.

## Regulatory Status

Ph. Eur. (EP) Monograph 3.1.9. Silicone Elastomer for Closures and Tubing  
 Volatile Matter  
 Substances Soluble in Hexane  
 FDA Regulation 21 CFR 177.2600 (Food Grade)

## Biocompatibility Tests

Cytotoxicity  
 Mutagenicity/Genotoxicity  
 Hemolysis  
 Skin Sensitization  
 Pyrogenicity (USP)  
 90-day Implant (exceeds USP Class VI)  
 30-day Implant (exceeds USP Class VI)  
 USP Class V and VI

## BioMedical Grade Low Consistency Rubber

*Silastic*® MDX4-4210  
 Medical Grade Elastomer

## RTV Adhesive

*Silastic*® Medical Adhesive Silicone, Type A

## Description Typical Applications

Two-part (10:1 by weight), platinum-catalyzed, low-temperature-curing and pourable silicone elastomer  
 • Medical device encapsulating and moldmaking  
 • Drug matrix for pharmaceutical applications

One-part, low-slump, translucent silicone material; solventless; cures at room temperature between 50-60% relative humidity  
 • Assembling and sealing medical device components  
 • Encapsulating and insulating electrical components for medical devices

## Typical Properties†

Durometer Hardness, Shore A	Tensile Strength, Die C		Relative Density
	MPa (psi)	%	
30	5.0 (730)	470	1.11
35	3.3 (480)	450	1.06

## Regulatory Status

FDA Drug Master File

## Soft Filling Elastomer

*Dow Corning*® 7-9600 A & B  
*Dow Corning*® 7-FC9600 A & B

## Description Typical Applications

Two-part (1:1 by weight), platinum-catalyzed, unfilled silicone elastomer  
 • Filling material for external form prostheses and pressure cushions

As Supplied†	Cure Rate, Viscosity at Room Temperature		After Curing for 60 min at 140°C†	Penetration (62.5 g probe weight)	
	Viscosity at 25°C	After 120 min		Appearance	mm/10
	mPa·s	mPa·s			
	470	≤4000 <sup>1</sup>		Clear	260
	480	>6500		Clear to Straw	260

† Specifications Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office prior to writing specifications on these products.

