



Certificate of Conformance

Inventory ID: XXXXXXXX

QC Order No.: XXXXXXXXXXXXX

Item Description: CCST-XXXX-XXXX | Platinum Silicone Tubing XXXX ID x XXXX OD

Test date: MM/DD/YYYY

Certificate of Conformance Statement

This document certifies that Carolina Components Group Silicone Tubing is manufactured in an ISO 14644-1 Class 7 clean room, adhering to current Good Manufacturing Practices (cGMP) and within an ISO 9001 quality management system.

The tubing is constructed from platinum-cured F-HCR-022520 silicone.

CCG Silicone Tubing meets the biocompatibility testing criteria of USP <88>, USP <87>, and ISO 10993-4, 10, and 11. Additionally, it complies with the testing standards of USP <85>, USP <788>, USP <661>, and EP 3.1.9.

The raw material supplier confirms that no animal-derived ingredients are present or intentionally added during the manufacturing process and asserts compliance with REACH and ROHS requirements.

The tubing may be sterilized/sanitized by autoclaving and may be exposed to Gamma-Irradiation to a total of 45kGy. It should be stored away from exposure to direct sunlight within its original product packaging under ambient temperature and humidity conditions.

Lot #	XXXXXX	Manufacturing Date:	DD/MM/YYYY	Best by Date:	DD/MM/YYYY
<u>CHARACTERISTICS</u>	<u>SPECIFICATION (Min, Norm, Max)</u>	<u>VALUE</u>	<u>RESULT</u>		
Modulus	350.000 < 450.000 < 550.000	XXXXXX	P		
Elongation	250.000 < 300.000 < 1,000.000	XXXXXX	P		
Tensile	1,200.000 < 1,200.000 < 2,500.000	XXXXXX	P		
Compression Set	0.000 < 20.000 < 30.000	XXXXXX	P		
Tear B PPI	70.000 < 70.000 < 500.000	XXXXXX	P		
Appearance			P		
Shore A	60.000 < 65.000 < 70.000	XXXXXX	P		
Specific Gravity	1.150 < 1.150 < 1.190	XXXXXX	P		

Released By: Lindsay Staten

Date: 05/28/2024