

## **PRODUCT CERTIFICATE**

Catalog Number: **8600-0070**  
Lot Number: **J000001254-0-01**  
Date of Manufacture: **12/13/2023**  
Description: **Nalgene Pharma-Grade Platinum-Cured Silicone Tubing -**  
Size Description: **1/4" ID x 7/16" OD**  
Manufacturing Tolerances: **Close**

Products and Materials meet or exceed:

- FDA Regulations CFR 177.2600 Contact with food
- USP 35 <661> Physicochemical Tests – Plastics
- European Pharmacopoeia, Section 3.1.9 Silicone Elastomer for Closures and Tubing
- ISO 10993-3 Mutagenicity / Genotoxicity
- ISO 10993-4 Hemolysis
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation / Intracutaneous (USP Class VI)
- ISO 10993-11 Systemic (USP Class VI)

Thermo Fisher Scientific certifies this material supplied has been manufactured with Platinum-Cured Silicone Elastomer in conformance with cGMP guidelines in a Class 7 manufacturing environment:

Material Properties:

| Property                   | Specification |
|----------------------------|---------------|
| Hardness/Durometer Shore A | 45-55         |
| Tensile Strength psi       | 900 minimum   |
| Elongation %               | 350% minimum  |
| Tear Strength, Die B, ppi  | 75 minimum    |

Product defined above was produced and inspected in the USA, in accordance and in compliance with established manufacturing procedures and quality acceptance requirements.

***This material is not intended for implantation.***

Sincerely,

*Tammy Parmelee*

Tammy Parmelee  
Quality Systems Administrator  
Thermo Fisher Scientific  
Labware and Specialty Plastics