

PRODUCT CERTIFICATE

May 4, 2022

Catalog Number: **8600-0200**
Lot Number: **14142008**
Date of Manufacture: **03/23/2022**
Description: **Nalgene Pharma-Grade Platinum-Cured Silicone Tubing -**
Size Description: **1/2" ID x 3/4" 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
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