

# Certificate of Quality



Part Number	<b>MFLX06427-16</b>
Lot Number	<b>28368193</b>
Part Description	<b>TUBING MFLEX C-FLEX NO. 16 400FT</b>
Expiration Date	<b>15JAN2027</b>
Country of Origin	<b>USA</b>

## Inspection & Testing

- It is the responsibility of the user to conduct tests that are deemed necessary to determine the suitability of this product for any particular use.

## Product Specifications & Compliance

- Compound: R70-001-000
- Product is manufactured in accordance with quality regulation CFR Title 21, Part 820 Quality System Requirements (GMP).
- Thermoplastic Elastomer used to produce C-Flex® products meets standard physical property requirements as tested on ASTM slabs.
- Thermoplastic Elastomer used to produce C-Flex® products satisfies the requirements of the following tests:
  - European Pharmacopeia 6.0, 2008: Chapter 3.2.9 Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze-dried Powders
  - Hemolysis Study - ISO 10993-4, 2002, Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, Hemolysis - Rabbit Blood, Indirect Contact
  - Physicochemical Total Extractables - USP 32, NF 27, 2009; <381> Elastomeric Closures for Injections
  - Rabbit Pyrogen Test (Material Mediated)
  - ISO 10993-11, 2006, Biological Evaluation of Medical Devices- Part 1: Tests for Systemic Toxicity
  - USP 32, National Formulary 27, 2009. <151> Pyrogen Test
  - Physicochemical - USP 32, National Formulary 27 (USP) General Chapter <661>, Container-Plastics (2009) (i.e Heavy Metals)
  - Thermoplastic Elastomer used to produce C-Flex® products are Animal Derived Component Free (ADCF).
  - USP Class VI Post-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo. ISO 10933-5, Tests for Vitro Cytotoxicity
  - USP Class VI Pre-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo
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## **Storage**

- Storage in original packaging, at ambient conditions and away from direct sunlight, is recommended.

## **Certificate Approval**

- This certificate was issued and approved by the Avantor Fluid Handling Quality and Regulatory Departments and is valid without signature.