

# Certificate of Quality



Part Number	<b>MFLX06432-50</b>
Lot Number	<b>NA</b>
Part Description	<b>TUBING C-FLEX 1/8X1/4IN 50FT</b>
Expiration Date	<b>31DEC2049</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: R70-374-000
- 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 meet standard physical property requirements as tested on ASTM slabs.
- Thermoplastic Elastomer used to produce C-Flex® are Animal Derived Component Free (ADCF).
- Hemolysis Study- ISO 10993-4, 2002, biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-11, 2007, USP 32, National Formulary 27, 2009. <151> Pyrogen Test. FDA 21 CFR, Part 610.13, 2002
- European Pharmacopeia Section 3.2.9 Rubber Closures for Containers for Aqueous Parenteral Preparations
- Class VI Plastics - Biologic Reactivity Tests, In Vivo: Post-Gamma Irradiation Samples, USP <88>
- Biological Reactivity Tests, In Vitro, ISO 10993-5

## 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.