

# Certificate of Quality



Part Number	<b>MFLX06422-02</b>
Lot Number	<b>28578306</b>
Part Description	<b>TUBING CFLEX 1/16IN ID 25FT</b>
Expiration Date	<b>03APR2027</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: R70-082-000
- 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:
- 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
- European Pharmacopeia 3.2.9 Testing of Rubber Closures for Containers
- Rabbit Pyrogen Test (Material Mediated)
- ISO 10993-11, 2006, Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity
- ISO 10993-11, 2007, USP 32, National Formulary 27, 2009. <151> Pyrogen Test
- USP Class VI Post-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo
- USP Class VI Pre-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo
- Physicochemical - USP 32, National Formulary 27 (USP) General Chapter <661>, Container-Plastics (2009) (i.e Heavy Metals)
- Note - for product sku 06422-21 The internal number of 082-750-6 will be listed on the internal package. These internal numbers relate directly to their respective Avantor part numbers as indicated.
- Note - for product sku 06422-23: The internal number of 082-1000-6 will be listed on the internal package. These internal numbers relate directly to their respective Avantor part numbers as indicated.

## Storage

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

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## **Certificate Approval**

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