Certificate of Quality

Part Number	**MFLX06436-26**
Lot Number	**27039716**
Part Description	**TUBING MFLEX CFLEX NO 26**
Expiration Date	**18NOV2025**
Country of Origin	**USA**

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 Phamacopeia 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
- 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.

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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.