

# Certificate of Quality



Part Number	<b>MFLX96423-14</b>
Lot Number	<b>29111046</b>
Part Description	<b>TUBING MFLEX SILICONE NO. 14 400FT</b>
Expiration Date	<b>09MAR2027</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: Tygon® 3350
- The components/materials used in the production of the product were manufactured in a manner compliant with good manufacturing practices.
- This product is manufactured in the USA.
- Shelf-life is five years.
- Meets or exceeds USP Class VI, USP 87 requirements, current revision.
- Meets or exceeds PFR CFR 177.2600 "Rubber articles intended for repeated use may be safely used in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section".
- ALSO Per 21 CFR 177.2600(G) "In accordance with GMP finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food. Listed materials are entirely non-toxic, non-hemolytic, non-pyrogenic."
- Meets or exceeds ISO 10993 testing requirements.
- Manufactured with Tygon brand platinum cured silicone elastomer.
- Meets or exceeds 3A standards.
- Meets or exceeds European Pharmacopoeia 3.1.9, Current Revision.
- Testing showed the quantity of Metals with Safety Concerns was below the Parenteral Exposure limits given in EMEA/CHMP/SWP/4446/2000.
- This material is NOT INTENDED FOR INVASIVE USE.

## 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.