Certificate of Quality

Part Number	**MFLX96404-16**
Lot Number	**H033P3H018**
Part Description	**TUBING MFLEX SILICONENO.16 20/CS**
Expiration Date	**25FEB2029**
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: Tubing:QCF7-5201 Proprietary BioMed Grd. Elastomer
- All raw materials used in these tubing products meet the requirements of the FDA 21, subchapter B, CFR 177.2600, Rubber Articles Intended for Repeated Use in Contact with Food (Food-Grade).
- Meets most criteria for selected tests of Dairy 3-A Sanitary Standards.
- These products have been manufactured in accordance with the principles of Good Manufacturing Practices in an ISO 14001:2004 Environmental Management System and ISO 9001 registered facility.
- The site is registered with the Department of Health and Human Services, Public Heatlh Service and Food and Drug Administration (FDA) and is inspected.
- Tubing is rigorously tested, fully traceable, comprehensively documented and thoroughly managed for contamination.
- The elastomer meets or exceeds the requirements of all USP Class V Extractables tests and exceeds the requirements for the USP Class VI Plastics Test.
- The elastomer has also been tested and meets the requirements for USP pyrogens, tissue culture tests. All tests passed according to protocol.
- The elastomer meets ICH Q3D permitted concentrations (ppm) for parenteral applications
- Meets European Pharmacopoeia 9th edition 3.1.9 * this only applies to the tubing and not the labeling ink.
- * Please Note & where applicable - This item is provided in bulk and individual packages will be labeled MFLX96410-xx. (where as xx represents the size). The compound and specifications are the same.
- Not to be used for any hospital or patient care use, such as for temporary insertion. Not to be used in human implantation, or human contraceptive, reproductive, obstetric or gynecological applications.
- 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.

Storage

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

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recommended.

Certificate Approval

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