

Certificate of Quality



Part Number	MFLX96102-15
Lot Number	28666297
Part Description	TUBING MFLEX PHARMED NO.15 5'
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: PharmedBPT (tubing), Polypropylene (overmolded)
- This assembly meets the requirements of the USP, Biological Test for Plastics, Class VI.
- This product is either animal derivative content free (ADCF) or compliant with EMA/410/01 Rev.3.
- Tubing Material grade: PharmMed®BPT, Fitting End material - POLYPROPYLENE COPOLYMER (13R9A).
- Product produced in an ISO-9001 facility.
- "Fitting Ends - European Union (EU) Food Contact:
- POLYPROPYLENE COPOLYMER 13R9A does not meet the requirements of EU Regulation 10/2011 for food contact as it contains an additive not included in Annex 1."
- Fitting Ends - This product does not pass the EP 3.1.3 or 3.1.6 monographs for Polyolefins and Polypropylenes due to the type and/or amount of additives in this product's formulation.
- Fitting Ends - The resin does pass all other testing of the 3.1.3 and 3.1.6 monographs.
- Fitting Ends - This product has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, In Vivo). Physicochemical (USP<661>) and Endotoxin (USP<85>) testing have also been performed.
- 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 recommended.

Certificate Approval

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