

# SynaLinX<sup>®</sup> B-Flex™ Thermoplastic Tubing

BioLink offers SynaLinX<sup>®</sup> B-Flex<sup>™</sup> Thermoplastic Tubing with imported selective medical-grade raw materials and a unique manufacturing process, aimed at helping biopharmaceutical companies reduce costs and increase efficiency. SynaLinX<sup>®</sup> B-Flex<sup>™</sup> Thermoplastic Tubing features low leachable, low toxicity, and low adsorption in terms of biocompatibility. It has passed tests for physical, chemical, and biological properties, is compliant with the requirements of USP Class VI, ISO 10993, and other standards, and has been certified by SGS testing.

#### SynaLinX<sup>®</sup> B-Flex<sup>™</sup> Thermoplastic Tubing – Product Features

- Resistant to sterilization by high temperature and pressure, ethylene oxide,
- and gamma irradiation
- Applicable at –45 to 135 °C
- Compatible with the TPE tubing of the mainstream brands available in the market
- Excellent tensile strength and elongation at break
- Manufactured in workshops of ISO Class 7 cleanliness
- Free of animal-derived component
- Free of silicone oil
- Good biocompatibility

## SynaLinX<sup>®</sup> B-Flex<sup>™</sup> Thermoplastic Tubing – Applications

- Aseptic welding and disconnection
- Feed liquid transfer
- Cell culture
- Tubing assembly

## Validation

Test Item	Reference Standard	Test Result
Hardness, shore A	ASTM D2240	60 ± 5
Tensile strength, Mpa	ASTM D412	8.1
Elongation at break, %	ASTM D412	680
Tensile modulus, 300%, psi	ASTM D412	630
Bacterial endotoxin	ChP <1143> (same as USP <85>)	< 0.25 EU/mL
Particulate matter	ChP <0903> (same as USP <788>)	Each mL contained not more than 25 particles that are equal to or greater than 10 μm and not more than 3 particles that are equal to or greater than 25 μm
	USP <87>	Pass
<b>Biocompatibility</b>	USP <88>	Pass
Biocompatibility	ISO 10993-4	Pass
	ISO 10993-10	Pass
Testing of plastic packaging system	USP <661>	Pass
Testing of elastomeric closures for injections	USP <381>	Pass
Extractable	BPOG & USP <665>	Pass
Chemical compatibility	ΝΑ	Please consult the local sales of BioLink (for validation guide)

#### **Ordering Information**

Cat. No.	ID*OD*WT (mm)	ID*OD*WT (inch)	Packaging Specification (meter/roll)
BFX-125-250	3.2*6.4*1.6	1/8*1/4*1/16	15
BFX-188-313	4.8*8.0*1.6	3/16*5/16*1/16	15
BFX-188-375	4.8*9.6*2.4	3/16*3/8*3/32	15
BFX-250-375	6.4*9.6*1.6	1/4*3/8*1/16	15
BFX-250-438	6.4*11.2*2.4	1/4*7/16*3/32	15
BFX-375-625	9.6*15.9*3.2	3/8*5/8*1/8	15
BFX-500-750	12.7*19.1*3.2	1/2*3/4*1/8	15
BFX-750-1000	19.1*25.4*3.2	3/4*1*1/8	15

# About BioLink

BioLink is a group of technology-driven businesses that provide process solutions in the life sciences industry. The company focuses on the development and production of the key processing equipment and consumables used in the manufacturing process of recombinant protein drugs, vaccines, antibodies, cell therapies, gene therapies, and other biological products. BioLink's portfolio of offerings covers the entire upstream and downstream bioprocess such as cell culture, single-use mixing and storage, chromatography, filtration (ultrafiltration/diafiltration, clarification, and virus removal), and hydration products, as well as process development services. BioLink is committed to providing customers with high-quality, innovative products and solutions and strives to build an efficient, safe and competitive biopharmaceutical supply chain eco-system.

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