



Certificate of Conformance

DATE: MM/DD/YYYY
 CUSTOMER: XXXXXXXXX
 CUSTOMER PO #: XXXXXXXXX
 CUSTOMER PART #: XXXXXXXXX
 QUANTITY: XXXXXXXXX
 LOT #: XXXXXXXXX
 DOM: MM/DD/YYYY
 EXPIRATION: MM/DD/YYYY

COUNTRY OF ORIGIN:

FlowLinX fittings are manufactured within the United States of America.

MATERIALS OF CONSTRUCTION:

FlowLinX TC products are manufactured from P5M6K-080 polypropylene resin, a drug master file listed (#9988) resin.

BIOCOMPATIBILITY:

The resin material used to manufacture FlowLinX products has been certified to meet USP <88>, Biological Reactivity Tests, Class VI, In Vivo. The resin material used to manufacture FlowLinX products is non-cytotoxic in accordance with ISO 10993-5.

USP<85> BACTERIAL ENDOTOXIN:

The resin material used to manufacture FlowLinX products is certified to meet USP <85>, Bacterial Endotoxin.

TSE/BSE/ADCF STATEMENT:

No animal products, or by-products, are used in the manufacture of, nor intentionally added to FlowLinX polypropylene products.

FOOD CONTACT APPLICATIONS:

FlowLinX products which are intended for the application of food and beverage processes are compliant to the extractable limits specified in FDA 21 CFR 177.1520 (c) 3.1a.

REACH/RoHS:

Material used to manufacture FlowLinX products are compliant with REACH/RoHS requirements as indicated in the SVHC Table update 08JUL2021.

GAMMA-IRRADIATION COMPATIBILITY:

FlowLinX products may be exposed to Gamma-Irradiation to a total of 50kGy.

Quality Assurance,

Date:

Flow Through Us



+31 (0)85 043 31 10

info@romynox.nl

www.romynox.nl