Carolina Components Group FlowLinX Polypropylene Fitting (PF511) Regulatory Overview

Date	February 20, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX Products
Resin Material Type	Pro-fax PF511
Resin Manufacturer	LyondellBasell
Revision Date	February 20, 2022

USE OF THIS REGULATORY INFORMATION

The information provided as requested is intended to be used for informational purposes only. Carolina Components Group relies on information provided by its suppliers. Carolina Components Group makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of compound under end-use conditions prior to specification is essential. Customers must make their own determination that use of this product is safe, lawful, and technically suitable for the intended use.

MANUFACTURING ENVIRONMENT:

ISO 8 Clean room facility (certified operational) in accordance with ISO 14644 principles.

MATERIALS OF CONSTRUCTION:

FlowLinX products are manufactured from Pro-fax PF511 polypropylene resin, a drug master file listed (# 26106) resin.

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BIOCOMPATIBILITY:

The resin material used to manufacture FlowLinX products is 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 USP <87>, Biological Reactivity Tests, In Vitro.

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 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

ALLERGENS:

The material used to manufacture FlowLinX products does not contain allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the manufacture or formulation of this product.

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LATEX:

Latex is not intentionally added in the formulation or manufacture of FlowLinX products.

PHTHALATES:

Material used to manufacture FlowLinX products is Phthalate-free.

BPA / MELAMINE STATUS:

Neither BPA nor Melamine are used in the formulation or manufacture of the resin product used to manufacture FlowLinX products.

REACH/RoHS:

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

CONFLICT MINERALS:

Conflict minerals as defined by the Dodd-Frank Act, are not used in the manufacture of FlowLinX products.

STERILIZATION/SANITIZATION:

FlowLinX products may be Sterilized/sanitized by Autoclaving (121°C for 20 minutes) and Gamma-Irradiation.

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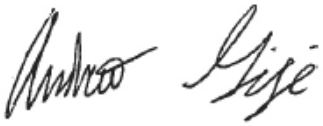
GAMMA-IRRADIATION COMPATIBILITY:

FlowLinX products may be exposed to Gamma-Irradiation up to a total of **45kGy**.

SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:

Non-Sterile and Non-Irradiated FlowLinX Product Shelf Life is 3 Years from Date of Manufacture when stored away from exposure to direct sunlight within its original product packaging under ambient temperature and humidity conditions. Gamma irradiated product, when stored under the same conditions, will have a 2 Year Shelf Life.

Prepared By:  Date: 09/27/2023

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