Carolina Components Group FlowLinX
Bag Regulatory Overview

Date	March 3, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX
Resin Material Type	ULDPE
Revision Date	October 11th, 2023

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

MATERIALS OF CONSTRUCTION:

FlowLinX bag products are manufactured from ULDPE film.

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BIOCOMPATIBILITY:

The resin material used to manufacture FlowLinX bags is certified to meet USP <88>, Biological Reactivity Tests, Class VI, In Vivo.

The resin material used to manufacture FlowLinX bags is certified to meet USP <87>, Biological Reactivity Tests, In Vitro

The resin material used to manufacture FlowLinX bags is non-mutagenetic in accordance with ISO 10993-3.

The resin material used to manufacture FlowLinX bags is non-hemolytic in accordance with ISO 10993-4.

The resin material used to manufacture FlowLinX bags is non-cytotoxic in accordance with ISO 10993-5.

The resin material used to manufacture FlowLinX bags does not cause a reaction after implantation in accordance with ISO 10993-6.

The resin material used to manufacture FlowLinX bags does not cause irritation and skin sensitization in accordance with ISO 10993-10.

The resin material used to manufacture FlowLinX bags does not cause adverse systemic reactions in accordance with ISO 10993-11.

USP <85> BACTERIAL ENDOTOXIN:

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

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PHYSIOCHEMICAL:

The resin material used to manufacture FlowLinX bags is certified to meet USP <661>, Plastic Packaging Systems and Their Materials of Construction

The resin material used to manufacture FlowLinX bags is certified to meet EP 3.2.2.1, Plastic Containers for Aqueous Solutions for Infusion

TSE/BSE/ADCF STATEMENT:

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

REACH/RoHS:

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

STERILIZATION/SANITIZATION:

FlowLinX products may be Sterilized/sanitized by Gamma-Irradiation.

GAMMA-IRRADIATION COMPATIBILITY:

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

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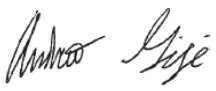
SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:

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: 10/11/2023