



# Carolina Components Group FlowLinX Silicone Tubing Products Regulatory Overview

Date	February 8, 2024
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX
Resin Material Type	Platinum Cured Silicone F-HCR-22520
Revision Date	August 14, 2024

## **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 silicone tubing is manufactured from platinum cured silicone.



## **Carolina Components Group FlowLinX Silicone Tubing Products Regulatory Overview**

### **BIOCOMPATIBILITY:**

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

The resin material used to manufacture FlowLinX silicone tubing is certified to meet USP <87>, Biological Reactivity Tests, Class VI, In Vitro.

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

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

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

### **USP <788> PARTICULATE MATTER IN INJECTIONS:**

FlowLinX tubing meets specifications per USP <788>, Particulate Matter In Injections. The number of particles  $\geq 5\mu\text{m}$ ,  $10\mu\text{m}$  and  $25\mu\text{m}$  in each milliliter of the product shall not exceed 100, 25 and 3, respectively.

### **USP <85> BACTERIAL ENDOTOXIN:**

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



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### **EUROPEAN PHARMACOPOEIA:**

The resin material used to manufacture FlowLinX silicone tubing is certified to meet EP 3.1.9, Silicone Elastomer for Closures and Tubing

### **PHYSIOCHEMICAL:**

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

### **TSE/BSE/ADCF STATEMENT:**

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

### **FOOD CONTACT APPLICATIONS:**

FlowLinX silicone tubing which is intended for the application of food and beverage processes are compliant to the extractable limits specified in FDA 21 CFR 177.2600

### **LATEX:**

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



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### **PHTHALATES:**

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

### **LEACHABLES/EXTRACTABLE (L/E) PROFILE:**

The resin used to manufacture FlowLinX silicone tubing products has been tested for extractables per the recommended USP <665> guidelines. Results of the testing are available upon request.

### **CONFLICT MINERALS:**

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



## **Carolina Components Group FlowLinX Silicone Tubing Products Regulatory Overview**

### **STERILIZATION/SANITIZATION:**

FlowLinX silicone tubing may be sterilized/sanitized by autoclaving (121°C for 20 minutes) and gamma-irradiation.

### **GAMMA-IRRADIATION COMPATIBILITY:**

FlowLinX silicone tubing 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 10 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 5 Year Shelf Life.

Prepared By:

Date: 08/14/2024