



# Carolina Components Group FlowLinX Clamp Regulatory Overview

Date	April 25, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX
Resin Material Type	F-POK-301C
Revision Date	October 3, 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 8 Clean room facility (certified operational) in accordance with ISO 14644 principles.

## **MATERIALS OF CONSTRUCTION:**

FlowLinX clamp products are manufactured from F-POK-301C resin.



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### **BIOCOMPATIBILITY:**

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

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

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

Tallow derived may be used in the manufacture of this FlowLinX clamp product. Tallow derived materials used in this product are certified as BSE free by EU standards and processed in full compliance with EMEA/410/01 Rev. 4 Sec 6.4.

### **CONFLICT MINERALS:**

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

### **STERILIZATION/SANITIZATION:**

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

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

FlowLinX clamp 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 5 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: 10/03/2023