



Carolina Components Group FlowLinX Silicone Molded Products Regulatory Overview

Date	April 20, 2022
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX
Resin Material Type	F-LIM-22520
Revision Date	November 9, 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 silicone molded products are manufactured from platinum cured F-LIM-22520.



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BIOCOMPATIBILITY:

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

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

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

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

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

USP <85> BACTERIAL ENDOTOXIN:

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

EUROPEAN PHARMACOPOEIA:

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



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PHYSIOCHEMICAL:

The resin material used to manufacture FlowLinX silicone molded products 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 molded products.

FOOD CONTACT APPLICATIONS:

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

REACH/RoHS:

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

LEACHABLES/EXTRACTABLE (L/E) PROFILE:

The F-LIM-22520 resin used to manufacture FlowLinX silicone molded products has been tested for extractables per the recommended guidelines of the BioPhorum Operations Group (BPOG). Results of the testing are available upon request.



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CONFLICT MINERALS:

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

STERILIZATION/SANITIZATION:

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

GAMMA-IRRADIATION COMPATIBILITY:

FlowLinX silicone molded 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 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.

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Date: November 9, 2023