Carolina Components Group FlowLinX
TPE Products Regulatory Overview

Date	February 19, 2024
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX
Resin Material Type	F-FLEX-22520
Revision Date	February 19, 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 8 Clean room facility (certified operational) in accordance with ISO 14644 principles.

MATERIALS OF CONSTRUCTION:

FlowLinX F-FLEX-22520 is manufactured from TPE.

Carolina Components Group FlowLinX
TPE Products Regulatory Overview

BIOCOMPATIBILITY:

The resin material used to manufacture F-FLEX-22520 products is certified to meet USP <88>, Biological Reactivity Tests, Class VI, In Vivo.

The resin material used to manufacture F-FLEX-22520 products is certified to meet USP <87>, Biological Reactivity Tests, Class VI, In Vitro.

The resin material used to manufacture F-FLEX-22520 products is non-hemolytic in accordance with ISO 10993-4.

The resin material used to manufacture F-FLEX-22520 products does not cause irritation and skin sensitization in accordance with ISO 10993-10.

The resin material used to manufacture F-FLEX-22520 products does not cause adverse systemic reactions in accordance with ISO 10993-11.

USP <788> PARTICULATE MATTER IN INJECTIONS:

FlowLinX F-FLEX-22520 meets specifications per USP <788>, Particulate Matter In Injections.

USP <85> BACTERIAL ENDOTOXIN:

The resin material used to manufacture F-FLEX-22520 products is certified to meet USP <85>, Bacterial Endotoxin.

Carolina Components Group FlowLinX
TPE Products Regulatory Overview

EUROPEAN PHARMACOPOEIA:

The resin material used to manufacture F-FLEX-22520 products is certified to meet EP 3.2.9, Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and or Freeze-Dried Powders.

PHYSIOCHEMICAL:

The resin material used to manufacture F-FLEX-22520 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 F-FLEX-22520.

LATEX:

Latex is not intentionally added in the formulation or manufacture of FlowLinX F-FLEX-22520 products.

PHTHALATES:

Material used to manufacture FlowLinX F-FLEX-22520 products are Phthalate-free.

Carolina Components Group FlowLinX
TPE Products Regulatory Overview

BPA / MELAMINE STATUS:

Neither BPA nor Melamine are used in the formulation or manufacture of the resin product used to manufacture FlowLinX F-FLEX-22520 products.

ALLERGENS:

The material used to manufacture 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.

GMO

Material used to manufacture FlowLinX F-FLEX-22520 products are GMO-free.

REACH/RoHS:

Material used to manufacture F-FLEX-22520 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 F-FLEX-22520 products has been tested for extractables per the recommended USP <665> guidelines. Results of the testing are available upon request.

Carolina Components Group FlowLinX
TPE Products Regulatory Overview

CONFLICT MINERALS:

Conflict minerals as defined by the Dodd-Frank Act, are not used in the manufacture of F-FLEX-22520.

STERILIZATION/SANITIZATION:

F-FLEX-22520 may be sterilized/sanitized by autoclaving (121°C for 20 minutes) and gamma-irradiation.

GAMMA-IRRADIATION COMPATIBILITY:

F-FLEX-22520 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.

Prepared By: Date: 02/19/2024