Carolina Components Group FlowLinX
Filling Needle Products Regulatory Overview

Date	February 19, 2024
Subject	Regulatory Compliance Statement
Parts Affected	FlowLinX Filling Needles
Resin Material Type	316L SS and Makrolon RX2530 Polycarbonate
Revision Date	June 11, 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.

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MATERIALS OF CONSTRUCTION:

FlowLinX filling needles manufactured from the following materials:

- 316L Stainless Steel Cannula
  - Cleaned, electropolished, and citric passivated per A967 (Citrisurf2250)
  - Straightness ≤ 2mm/1mm
  - Outer Surface Finish Ra max = 0.4
  - Inner Surface Finish Ra max = 1.6
  - Concentricity ≤10% of tube thickness
- Makrolon Rx2530 Polycarbonate Needle Hub

BIOCOMPATIBILITY:

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

The resin material used to manufacture FlowLinX filling needles are certified to meet USP <87>, Biological Reactivity Tests, Class VI, In Vitro.

USP <788> PARTICULATE MATTER IN INJECTIONS:

FlowLinX filling needles meet specifications per USP <788>, Particulate Matter In Injections. The number of particles ≥ 10um and 25um in each milliliter of the product shall not exceed 25 and 3, respectively.

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USP <85> BACTERIAL ENDOTOXIN:

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

PHYSIOCHEMICAL:

The resin material used to manufacture FlowLinX filling needles 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 filling needles.

NITROSAMINES:

Nitrosamines are not intentionally added in the formulation or manufacture of FlowLinX products.

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 filling needle products are compliant with REACH/RoHS requirements as indicated in the SVHC Table update 08JUL2021.

CONFLICT MINERALS:

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

STERILIZATION/SANITIZATION:

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

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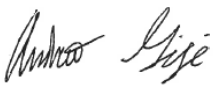
GAMMA-IRRADIATION COMPATIBILITY:

FlowLinX filling needles 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: 06/11/2024