



## Carolina Components Group FlowTainer PET Media Bottle Overview

Date	August 3, 2023
Subject	Regulatory Compliance Statement
Parts Affected	Media Bottle
Resin Material Type	PET
Revision Date	January 30, 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:**

FlowTainer Media bottles are manufactured from PET.



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### **BIOCOMPATIBILITY:**

The resin material used to manufacture FlowTainer Media bottles is certified to meet USP <88>, Biological Reactivity Tests, Class VI, In Vivo.

The resin material used to manufacture FlowTainer Media bottles is certified to meet USP <87>, Biological Reactivity Tests, In Vitro

The resin material used to manufacture FlowTainer Media bottles is non-hemolytic in accordance with ISO 10993-4.

The resin material used to manufacture FlowTainer Media bottles is non-cytotoxic in accordance with ISO 10993-5.

The resin material used to manufacture FlowTainer Media bottles does not cause a reaction after implantation in accordance with ISO 10993-6.

The resin material used to manufacture FlowTainer Media bottles does not cause irritation and skin sensitization in accordance with ISO 10993-10.

The resin material used to manufacture FlowTainer Media bottles does not cause adverse systemic reactions in accordance with ISO 10993-11.

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

The resin material used to manufacture FlowTainer Media bottles is certified to meet USP <85>, Bacterial Endotoxin.



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

FlowTainer Media bottles meet specifications per USP <788>, Particulate Matter 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.

### **PHYSIOCHEMICAL:**

The resin material used to manufacture FlowTainer Media bottles is certified to meet USP <661>, Plastic Packaging Systems and Their Materials of Construction

### **LATEX:**

Latex is not intentionally added in the formulation or manufacture of FlowTainer Media bottles.

### **PHTHALATES:**

Material used to manufacture FlowTainer Media bottles are Phthalate-free.

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

No animal products, or by-products, are used in the manufacture of, nor intentionally added to FlowTainer Media bottles.



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### **NITROSAMINES**

Material used to manufacture FlowTainer Media bottles do not contain nitrosamines, and no nitrosamines are added or brought in during the production process.

### **MELAMINE**

Material used to manufacture FlowTainer Media bottles do not contain melamine, and no melamine is added or brought in during the production process.

### **ELEMENTAL IMPURITIES**

Material used to manufacture FlowTainer Media bottles caps do not contain elemental impurities, and no elemental impurities are added or brought in during the production process.

### **BISPHENOL-A**

Material used to manufacture FlowTainer Media bottles do not contain Bisphenol-A, and no Bisphenol-A is added or brought in during the production process.

### **REACH/RoHS:**

Material used to manufacture FlowTainer Media bottles are compliant with REACH/RoHS requirements as indicated in the SVHC Table update 08JUL2021.



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### **CONFLICT MINERALS:**

Conflict minerals as defined by the Dodd-Frank Act, are not used in the manufacture of FlowTainer Media bottles.

### **STERILIZATION/SANITIZATION:**

FlowTainer Media bottles may be sterilized/sanitized by gamma-irradiation.

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

FlowTainer Media bottles may be exposed to Gamma-Irradiation up to a total of **45kGy**.

### **SHELF-LIFE AND STORAGE CONDITIONS STATEMENT:**

Non-Sterile and Non-Irradiated FlowTainer Media bottle 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 2 Year Shelf Life.

Prepared By:

Date: January 30, 2024