

# Certificate of Conformance SAMPLE ONLY



CCG PART #: 00113919
CUSTOMER: SAMPLE
CUSTOMER PO #: XXXXXXXX

**CUSTOMER ITEM #:** 

QUANTITY: 1 UOM: EA

LOT #: XXXXXXXX

**DOM:** XX/XX/XXXX **EXPIRATION:** 2 Years from DOM

**DESCRIPTION:** F-PBCW-10-3TC-S | FlowLinX 10L Powder Handling Bag, 3" Sanitary Seal with

Wash Line - Sterile

#### **MATERIALS OF CONSTRUCTION:**

Manufactured from ULDPE film.

### **BIOCOMPATIBILITY:**

Meets USP 88 Biological Reactivity Tests, Class VI, In Vivo., Meets USP 87 Biological Reactivity Tests, In Vitro., Resin is non-mutagenetic in accordance with ISO 10993-3., Resin is non-hemolytic in accordance with ISO 10993-4., Resin is non-cytotoxic in accordance with ISO 10993-5., Resin is in accordance with ISO 10993-10., Resin is in accordance with ISO 10993-11.

## TSE/BSE/ADCF STATEMENT:

No animal products or by-products are used/added in mfg.

## **REACH/RoHS:**

Material is compliant with REACH/RoHS requirements.

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

Meets SAL 10-6 per ISO 11137

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

This product is certified to meet USP 85.

# PHYSIOCHEMICAL COMPATIBILITY:

Material is certified to meet USP <661>., Material is certified to meet EP 3.2.2.1.

#### MANUFACTURING ENVIRONMENT:

Manufactured in ISO 7 Cleanroom per ISO 14644.

Supplied By: Carolina Components Group, 1001 Hill Dr. Suite 110, Durham, NC 27703

**Quality Assurance,** Carolina Components Group Date: 10/11/2023