# Certificate of Conformance

**Part No:**
**Revision:**
**Description:**
**Lot Number:**

**Manufactured Date:**
**Expiration Date:**
**Irradiation Dose:** **25.0 – 45.0 kGy**

Sample

**Biological:** The fluid path of this single use fluid transfer system has passed USP Class VI (USP<88>) and/or ISO 10993 testing.

**TSE/BSE:** The fluid path of this single use fluid transfer system conforms to European guidance EMA/410/01.

**Endotoxin:** The fluid path of a representative single use system is routinely tested in periodic validations for the presence of endotoxin in accordance with current USP Bacterial Endotoxin Test (USP<85>). Aqueous extracts contained <0.25 EU/mL as determined by the Limulus Amebocyte Lysate test (LAL).

**Particulate:** The fluid path of a representative single use system is routinely tested in periodic validations in accordance with current USP Particulate Matter in Injections Light Obscuration Particulate Count Test (USP<788>).

**Sterility:** The fluid path of the single use system has been validated following ANSI/AAMI/ISO 11137 guidelines for $VDmax^{25}$ to provide a minimum Sterility Assurance Level (SAL) of $10^{-6}$ for an established irradiation dose.

**Inspection:** This lot has been 100% visually inspected for acceptance in accordance with product specifications and Repligen Quality Control procedures.

**Manufacturing:** Repligen is an ISO 9001 certified company and products are manufactured meeting Repligen's quality management system.
This product was assembled in an ISO Class 7 cleanroom.

**Storage:** Store in original packaging at ambient conditions protected from moisture, extreme temperatures, and light.

**Quality Assurance** **Issue Date**



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