Certificate of Conformance

Part No:
Revision:
Description:
Lot Number:

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

EXAMPLE CoC Supplied 16NOV2022

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>).
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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