Certificate of Compliance

Part Number	210000-01
Description	10L PC PharmaTainerTM
Lot Number	SAMPLE
Lot Quantity	1 EA
Manufacture Date	19 December 2024
Expiration Date	19 December 2029
Customer Purchase Order	SAMPLE

Quality Standards

This product has been manufactured, inspected, tested, and released in accordance with our Quality Management System certified to the current ISO 9001 Standard.

Sanisure has documentation confirming this lot conforms to our tolerances for configuration and quality.

Compliance/Biocompatibility

- Representative samples of finished product have been tested by an independent laboratory and determined to contain no detectable endotoxin. Testing is based on a validated assay method using a 5% rinse volume and detection limit of 0.001 EU/ml and complies with current USP <85> and EP Bacterial Endotoxin tests (BET) methodologies. The endotoxin test is carried out on a lot by lot basis
- A sterilization validation study has been performed assuring SAL of 10-6 (Vdmax 25kGy)
- This product has been irradiated by Gamma or X-ray Irradiation between 25.0 - 50 kGy
- Irradiation Date: Report Number:
- MATERIAL IS USP CLASS VI COMPLIANT
- Manufactured and/or packaged in an ISO 14644-1 Class 7 cleanroom environment
- Particulate Matter USP <788>: Contains ≤ 25 particles/mL for particulate sizes ≥10 µm; ≤ 3 particles/mL for particulate sizes ≥ 25 µm
- Assemblies are 100% integrity tested using the pressure decay method

Certified by: _____ Date: 28 April 2025

Quality Department

SaniSure make no warranty express or implied as to the merchantability of the product or its fitness for any specific purpose, unless the user is supplied with a separate written warranty for a particular use or purpose. No responsibility is accepted for alteration, abuse, or misuse of the product. SaniSure sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be defective of other than warranted.