

## Certificate of Compliance

Part Number	105000-01
Description	5L PET PharmaTainer™
Lot Number	SAMPLE
Lot Quantity	1 EA
Manufacture Date	12 March 2025
Expiration Date	12 March 2030
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<sup>-6</sup> (Vdmax 25kGy)
- This product has been irradiated by Gamma or X-ray Irradiation between 25 - 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

Certified by:



Quality Department

Date: 12 March 2025

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