

Certificate of Compliance

Part Number	100S10-49
Description	10mL Stability Vials PET
Lot Number	1002731
Lot Quantity	4 EA
Manufacture Date	15 April 2025
Expiration Date	15 April 2030
Customer Purchase Order	22551

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 - 50 kGy
- Irradiation Date: 29 Apr 2025 Report Number: 2133-10216A
- 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: 18 June 2025

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