

Product Name: Cryovial®

Catalogue No.: T309-4A

This document replaces any previous version

1. Product Description:

- **4 ml Cryogenic Vial with Cap:** Sterile, disposable, self-standing, external threaded design assembled with lip-seal cap.

2. Packaging:

- **Case:** 10 bags of 100 units / 1 000 units per case

3. Product Specifications:

- **Material:**
 - Tube: Polypropylene
 - Cap: Polypropylene
- RNase, DNase, Pyrogen and DNA Free
- Gamma radiation sterilized at a SAL of 10^{-3} ; specified dose between 6.5 kGy and 13.5 kGy
- Temperature range: -196°C to +121°C. Autoclavable at 121°C for up to 30 minutes
- Tubes have printed graduations and writing area
- Insertion of a Capinsert™ (T312 Series) allows for color coding identification

4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resin conforms to FDA 21 CFR 177.1520
- **USP:** Resin conforms to USP Class VI
- **CONEG / RoHS:** Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals
- **REACH (SVHC):** Plastic is in conformity to REACH standards
- **LATEX:** Material is Latex Free
- **BSE / TSE:** Material is BSE / TSE Free
- **CE:** Product is CE marked

5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg
- Gas phase of Liquid Nitrogen resistance.

6. Traceability:

- **Lot No. Composition:** 8 or 9 digits
- **The lot number can be found in one or all of these locations:**
 1. On exterior case label
 2. On label inserted inside the master case
 3. On the inner bag

7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Avoid temperature variations and humidity
- Protect from any possible contamination
- Protect from any damage to the packaging, which could compromise the product sterility

8. Recommended Use:

- Verify proper cap closure when using biohazard material and / or chemical reagents
- Follow chemical resistance chart recommendations
- For use in automated equipment, follow the equipment manufacturer's instructions
- Should be used only in the gas phase of Liquid Nitrogen

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