

Edition Date: Revision Date : Revised by: 2013-05-28 2020-08-25 Annette Roy, Regulatory

Product Name: Cryovial[®] Catalogue No.: T310-2A

This document replaces any previous version

- **1. Product Description:**
 - 2 ml Cryogenic Vial with Cap: Sterile, disposable, , self-standing, external threaded design assembled with washer seal cap
- 2. Packaging:
 - Case: 10 bags of 100 units / 1 000 units per case

3. Product Specifications:

- > Material:
 - Tube: Polypropylene
 - Cap: Polypropylene
 - Washer Seal: White Silicone
- Certified RNase, DNase, Pyrogen and DNA Free
- Samma 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 marking area
- > Cap configuration allows insertion of a Capinsert[™] (T312 Series) for color-coding

4. Standards and Conformity:

- ISO 2859-1: Sampling and inspection procedures
- > FDA:
- > USP:
- > CONEG / RoHS:
- **REACH (SVHC):**
- ➤ LATEX:
- > BSE / TSE:
- ➤ CE:

Resin conforms to FDA 21 CFR 177.1520 Resin conforms to USP Class VI Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals Plastic is in conformity to REACH standards Material is Latex Free Material is BSE / TSE Free Product is CE marked



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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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