

Edition Date: Revision Date : Revised by: 2018-10-11 2018-10-31 Annette Roy, QA Coordinator

Product Name: Cryovial[®] Catalogue No.: T301-2

This document replaces any previous version

1. Product Description:

2 ml Cryogenic Vial with Cap: Sterile, disposable, , self-standing, internal threaded design assembled with a red O-ring seal cap. Tubes have printed graduations and marking area

Resin conforms to FDA 21 CFR 177.1520

Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals

Plastic is in conformity to REACH standards

Resin conforms to USP Class VI

Material is Latex Free

Material is BSE / TSE Free

Material has passed MEA testing

- 2. Packaging:
 - Case: 10 bags of 100 units / 1 000 units per case

3. Product Specifications:

- > Material:
 - Tube and cap: Polypropylene
 - O-ring Seal: Silicone
- Certified 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
- > Cap configuration allows insertion of a Capinsert[™] (T312 Series) for color-coding
- Leak proof tested in vacuum at 71.3cm Hg
- Gas phase of Liquid Nitrogen resistance

4. Standards and Conformity:

| ISO 2859-1: | Sampling and inspection procedures |
|---------------|------------------------------------|
| × 150 2055-1. | |

- > FDA:
- > USP:
- > CONEG / RoHS:
- **REACH (SVHC):**
- > LATEX:
- > BSE / TSE:
- > MEA:



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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

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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