

Edition Date: Revision Date : Revised by:

# Product Name: Cryovial<sup>®</sup> Catalogue No.: T309-2

This document replaces any previous version

## **1.** Product Description:

- 2 ml Cryogenic Vial with Cap: Sterile, disposable, round bottom, 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<sup>-3</sup>; 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<sup>™</sup> (T312 Series) allows for color coding identification
- Centrifuge resistant at up to 17 000g

#### 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

Material is BSE / TSE Free

Product is CE marked

- Material is Latex Free
- BSE / TSE:
- ≻ CE:

► LATEX:



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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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