

Edition Date: **Revision Date :** Revised by:

2013-02-27 2020-08-25 Annette Roy, Regulatory

# Product Name: Cryovial®

Catalogue No.: T309-1A

This document replaces any previous version

# 1. Product Description:

- > 1.2ml 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<sup>-3</sup>; specified dose between 6.5 kGy and 13.5 kGy

Sampling and inspection procedures

Resin conforms to USP Class VI

Material is Latex Free

Product is CE marked

Material is BSE / TSE Free

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

- 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>TM</sup> (T312 Series) allows for color coding identification

#### 4. Standards and Conformity:

- > ISO 2859-1:
- ➢ FDA:
- ➤ USP:
- **CONEG / RoHS**:
- **REACH (SVHC):**
- $\succ$  LATEX:
- **BSE / TSE:**
- ➤ CE:



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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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