**Edition Date:** 2018-01-31 **Revision Date:** 2020-08-25

**Revised by:** Annette Roy, Regulatory

Product Name: Cryovial® Catalogue No.: T310-2

This document replaces any previous version

# 1. Product Description:

**2 ml Cryogenic Vial with Cap:** Sterile, disposable, , round bottom, external threaded design

assembled with washer seal cap

2. Packaging:

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

#### 3. Product Specifications:

➤ Material:

Tube: PolypropyleneCap: Polypropylene

• Washer Seal: White Silicone

- > Certified 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 marking area
- ➤ Cap configuration allows insertion of a Capinsert<sup>TM</sup> (T312 Series) for color-coding
- > 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

➤ LATEX: Material is Latex Free
 ➤ BSE / TSE: Material is BSE / TSE Free
 ➤ CE: 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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