Edition Date: 2013-05-28 **Revision Date:** 2020-08-25

Revised by: Annette Roy, Regulatory

Product Name: Cryovial® Catalogue No.: T310-1A

This document replaces any previous version

1. Product Description:

> 1.2 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

➤ 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

> 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: 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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