Edition Date: 2004-02-05 Revision Date: 2022-08-08

Revised by: Annette Roy, Regulatory

Catalogue No.: C571-1 **Product Name: Sample Tube**

This document replaces any previous version

1. **Product Description:**

> 50 ml Sample Tube with Cap: Disposable, sterile, self-standing conical bottom and skirted tube with cap.

2. Packaging:

Case: 20 packs of 25 units / 500 units per case

3. **Product Specifications:**

- Material:
 - Tube: Polypropylene • Cap: Polyethylene
- ➤ Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy
- > Temperature range: -90°C to +100°C
- Tubes have molded-in graduations from 10ml to 50ml with 5ml increments

4. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures ➤ FDA: Resins conform to FDA 21 CFR 177.1520 > CONEG / RoHS: Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals

Plastics are in conformity to REACH standards > REACH (SVHC):

> LATEX: Materials are Latex Free ➤ BSE / TSE: Materials are BSE / TSE Free

5. **Quality Assurance:**

- Clear, no presence of contamination in plastic
- Visual attributes
- Volume measurements
- Closure verification
- Gas phase of Liquid Nitrogen resistance

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Document Template: FRM-106 Rev01 Technical Data Sheet

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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
- > Follow the equipment manufacturer's instructions
- > Should be used only in the gas phase of Liquid Nitrogen

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Document Template: FRM-106 Rev01 Technical Data Sheet
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