

# Annette Roy, Regulatory

### Product Name: Micrewtube® Catalogue No.: T335-6SPR

### This document replaces any previous version

#### 1. **Product Description:**

$\triangleright$	2ml Micrewtube®:	Sterile, printed, self-standing tube with Silicone washer seal, flat
		top screw cap. Caps are screwed on.

#### 2. Packaging:

> Case: 10 packages of 50 units / 500 units per case

#### 3. **Product Specifications:**

- > Material:
  - Tube: Polypropylene
  - Cap: Polypropylene
  - Washer Seal: 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 a white marking area
- Centrifuge resistant at up to 17 000 g

#### 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

#### 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



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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
- > 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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