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Revised by: Annette Roy, Regulatory

Product Name: Micrewtube® Catalogue No.: T334-5S

This document replaces any previous version

1. **Product Description:** 

> > 1.5ml Micrewtube<sup>®</sup>: Sterile, conical bottom tube with Silicone washer seal screw cap.

> > Caps are screwed on.

2. Packaging:

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

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

- ➤ Material:
  - Polypropylene tube and cap
  - Silicone washer seal
- 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
- Centrifuge resistant at up to 20 000 g

### 4. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures Resin conforms to FDA 21 CFR 177.1520 > FDA:

Resin conforms to USP Class VI ➤ USP:

> CONEG: Plastics and colorants are in conformity with

CONEG 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

Document Template: FRM-106 Rev01 Technical Data Sheet Page 1 / 2 Issue Date: 2017-06-15

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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

### 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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