Edition Date: 2004-02-05 Revision Date: 2021-06-10

Revised by: Annette Roy, QA Coordinator

Catalogue No.: T335-5STP Product Name: Micrewtube®

This document replaces any previous version

1. **Product Description:**

> > 1.5ml Micrewtube®: Sterile, conical bottom with a Silicone washer seal, flat-top, tamper

> > evident screw cap. Caps are slightly screwed on.

2. Packaging:

> Case: 1 pk of 1000 units per case

3. **Product Specifications:**

- ➤ Material:
 - Polypropylene tube
 - Polypropylene cap
 - Silicone washer seal
- 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
- Centrifuged up to 20 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: 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

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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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