Edition Date: 2005-10-08 **Revision Date:** 2020-06-25

Revised by: Annette Roy, Regulatory

Product Name: Micrewtube® Catalogue No.: T338-4S

This document replaces any previous version

1. Product Description:

> 1.5ml Micrewtube®: Sterile, self-standing tube with lip seal screw

cap. Caps screwed on.

2. Packaging:

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

3. Product Specifications:

Material:

- Polypropylene tube
- Polyethylene cap
- 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 +100°C
- > Tubes have white marking areas
- Centrifuged 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 FreeBSE / 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 to 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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