**Edition Date:** 2005-10-08 Revision Date: 2021-06-10

Revised by: Annette Roy, QA Coordinator

Product Name: Micrewtube®

Catalogue No.: T335-2SPRTP

This document replaces any previous version

1. **Product Description:** 

> > 0.5 ml Micrewtube®: Sterile, Printed, self-standing tube with Silicone washer seal, flat

> > top and tamperproof screw cap. Caps not assembled.

2. Packaging:

> Case: 1 000 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 a printed 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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# Traceability: 6.

**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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