**Edition Date:** 2004-02-05 **Revision Date:** 2021-07-20

**Revised by:** Annette Roy, Regulatory

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Product Name: Micrewtube<sup>®</sup> Catalogue No.: T336-6SPR

This document replaces any previous version

# 1. Product Description:

> 2.0 ml Micrewtube®: Sterile, Printed, Self-Standing with lip seal

screw cap and attachment loop. Caps are

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<sup>-3</sup> 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 71.3 cm 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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