**Edition Date:** 2004-02-05 **Revision Date:** 2016-10-25

**Revised by:** Annette Roy, QA Coordinator

Product Name: Micrewtube® Catalogue No.: T335-7SPR

This document replaces any previous version

# 1. Product Description:

2.0ml Micrewtube®: Sterile, conical bottom, printed graduated tube with Silicone washer

seal and flat-top screw cap. Caps are screwed on.

2. Packaging:

Case: 10 packages of 50 units / 500 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<sup>-3</sup>; specified dose between 6.5 kGy and 12.5 kGy;
- > Temperature range: -196°C to +121°C.
- Autoclavable at 121°C, for up to 30 minutes;
- Tubes have graduations and a white marking area;
- Flat caps have top writing surface;
- Centrifuged up to 20 000 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: Plastics and colorants are in conformity with CONEG standards for heavy metals

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> 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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