Edition Date: 2006-03-28 Revision Date: 2020-08-26

Revised by: Annette Roy, Regulatory

Product Name: Cultubes™ Catalogue No.: T415-3

This document replaces any previous version

1. **Product Description:**

> 5ml Culture Tube with Cap: Disposable, sterile 12 x 75mm culture tube with graduations and

white marking area with cap

2. Packaging:

> Case: 8 bags of 125 units / 1 000 units per case

3. **Product Specifications:**

Material:

• Tube: Polystyrene • Cap: Polyethylene > Dual-position snap cap:

- Sealed position for anaerobic cultures
- Loose position for aerobic work
- Certified Pyrogen Free
- ➤ Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy
- > Temperature range for tube: -80°C to +80°C
- Not autoclavable
- > Centrifuge resistant up to 1 400 g

4. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures

> FDA: Resins conform to FDA 21 CFR 177.1640 & CFR 177.1520

> CONEG / RoHS: Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals

> REACH (SVHC): Plastics are in conformity to REACH standards

> LATEX: Materials are Latex Free

5. **Quality Assurance:**

- > Clear, no presence of contamination in plastic
- Visual attributes
- > Dimension and volume measurements
- Closure verification

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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 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

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