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**Revised by:** Annette Roy, Regulatory

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Product Name: Cultubes<sup>™</sup> Catalogue No.: T425-6A

This document replaces any previous version

1. Product Description:

> 5ml Culture Tube with Cap: Disposable, sterile 12 x 75 mm culture tube, non-printed.

Without Cap.

2. Packaging:

Case: 20 bags of 125 units / 500 units per case

3. Product Specifications:

> Material: Polypropylene

Certified Pyrogen Free

➤ Gamma radiation sterilized at a SAL of 10<sup>-3</sup>; specified dose between 6.5 kGy and 13.5 kGy

> Temperature range tube: -80°C to +121°C

> Autoclavable

Centrifuge resistant at up to 3 000 g

# 4. Standards and Conformity:

➢ ISO 2859-1: Sampling and inspection procedures
➢ FDA: Resins conform to FDA 21 CFR 177.1520
➢ 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
- > Dimension and volume measurements
- Closure verification

# 6. Traceability:

**Lot No. Composition:** 8 or 9 digits

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## > 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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