**Edition Date:** 2020-08-27

**Revision Date:** 

Revised by: Annette Roy, Regulatory

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Product Name: Culture Tubes | Catalogue No.: T417-4S

This document replaces any previous version

1. Product Description:

**8 ml Culture Tube:** Disposable, Sterile, 13 x 100 mm culture tube with screw cap.

2. Packaging:

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

3. Product Specifications:

> Material: Polystyrene tube and Polyethylene cap

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

> Temperature range: -80°C to +80°C

Non autoclavable

Certified Pyrogen Free

Centrifuge resistant up to 3 000 g

4. Standards and Conformity:

ISO 2859-1: Sampling and inspection procedures
FDA: Resin conforms to FDA 21 CFR 177.1640
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

## 5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes

> Dimension and volume measurements

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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
- 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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