**Edition Date:** 2006-03-28 **Revision Date:** 2018-06-19

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

Product Name: Cultubes<sup>™</sup> 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: PolystyreneCap: PolyethyleneTwo-position snap cap:

- Sealed position for anaerobic cultures
- Loose position for aerobic work
- Certified Pyrogen Free
- ➤ Gamma radiation sterilized at a SAL of 10<sup>-3</sup>; specified dose between 6.5 kGy and 12.5 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

Document Template: FRM-106 Rev01 Technical Data Sheet

Issue Date: 2017-06-15

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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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Document Template: FRM-106 Rev01 Technical Data Sheet

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