**Edition Date:** 2020-05-08 **Revision Date:** None

Revised by: Annette Roy, Regulatory

Product Name: BioTube™ Rack Catalogue No.: T101-4

This document replaces any previous version

1. **Product Description:** 

> **➤** BioTube<sup>™</sup> Rack: sterile, disposable Rack containing 8 strips of 12 tubes.

2. Packaging:

> Case: 10 units per case

# **Product Specifications:**

- Material:
  - Rack: Polypropylene • Tube: Polypropylene
- 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 13.5 kGy
- > Temperature range: -196°C to +121°C
- > Autoclavable at +121°C for up to 30 minutes
- > Footprint conforms to SBS standards

### 4. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures > FDA: Resin conforms to FDA 21 CFR 177.1520

> CONEG / RoHS: Plastics and colorants are in conformity with CONEG

/ RoHS standards for heavy metals

Plastic is in conformity to REACH standards > REACH (SVHC):

> LATEX: Material is Latex Free ➤ BSE / TSE: Material is BSE / TSE Free

### 5. **Quality Assurance:**

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

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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 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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