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

Revised by: Annette Roy, Regulatory

Catalogue No.: T101-2 Product Name: BioTube™ Rack

This document replaces any previous version

1. **Product Description:**

> **➤** BioTube[™] Rack: sterile, disposable Rack containing 96 individual 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 10⁻³; 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

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

Material is Latex Free > LATEX: ➤ 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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Document Template: FRM-106 Rev01 Technical Data Sheet

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

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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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Document Template: FRM-106 Rev01 Technical Data Sheet

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