**Edition Date:** 2021-10-26

**Revision Date:** 

Revised by: Annette Roy, Regulatory

Product Name: BioTube<sup>™</sup> Rack Catalogue No.: T105-51

This document replaces any previous version

#### 1. **Product Description:**

**>** BioTube<sup>™</sup> Rack with tubes: Disposable, Sterile, rack with 96 square tubes.

#### 2. Compatible with:

> T105-26 tube mat cover

#### 3. Packaging:

Case: 2 packages of 5 units / 10 units per case

#### 4. **Product Specifications:**

- Material:
  - Polypropylene rack
  - PVC rack cover
  - Polypropylene tubes
- 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: -170° C to +121°C. (without the PVC cover)
- Autoclavable rack and tubes (without the PVC cover) for up to 30 minutes
- > Tubes total volume of 2.1 ml will hold 2.0 ml with tube's mat cover T105-26
- Note: These racks size are compatible with most robotic workstations

#### 5. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures SBS standard: Footprint conforms to SBS standard ➤ 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

#### 6. **Quality Assurance:**

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

#### Traceability: 7.

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**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

# 8. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Protect from any damage to the packaging which could compromise the product sterility

## 9. 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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