

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

This document replaces any previous version

- 1. Product Description:
  - ➢ BioTube<sup>™</sup> Rack: sterile, disposable Rack containing 96 individual tubes.
- 2. Packaging:
  - Case: 10 units per case

## 3. Product Specifications:

- > Material:
  - Rack: Polypropylene
  - Tube: Polypropylene
- Certified RNase, DNase, Pyrogen and DNA Free
- Samma 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:

$\triangleright$	ISO 2859-1:	Sampling and inspection procedures
$\triangleright$	FDA:	Resin conforms to FDA 21 CFR 177.1520
$\triangleright$	CONEG / RoHS:	Plastics and colorants are in conformity with CONEG
		/ RoHS standards for heavy metals
$\triangleright$	REACH (SVHC):	Plastic is in conformity to REACH standards
$\triangleright$	LATEX:	Material is Latex Free
$\triangleright$	BSE / TSE:	Material is BSE / TSE Free

## 5. Quality Assurance:

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



Edition Date: Revision Date : Revised by: 2020-05-08 None Annette Roy, Regulatory

# 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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