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**Revised by:** Annette Roy, Regulatory

Product Name: BioTube<sup>™</sup> Rack Catalogue No.: T100-1 Series

This document replaces any previous version

# 1. Product Description:

➤ **BioTube<sup>TM</sup> Rack with tubes:** Disposable, Non-Sterile, rack with 96 individual tubes. Caps are

sold separately

- Rack is made of 3 components:
  - A white base
  - A removable grid plate that can hold individual or strips of tubes
  - A translucent cover with alphanumerical grid
- Available colors of the removable Grid plate:
  - Blue, Green, Red and Yellow
- 96 individual tubes
- One alphanumerical grid ID card included for each unit
- 2. Packaging:

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

## 3. Product Specifications:

- Material:
  - Polypropylene rack (base, lid and grid plate)
  - Polypropylene tube
- Certified RNase, DNase, Pyrogen and DNA Free
- > Temperature range: -80° C to +121°C. Autoclavable at 121°C, for up to 30 minutes
- Cover has easy to read alphanumerical dots
- > The unique grid can stand alone when removed from the base to a counter
- Tubes total volume of 1.2 ml will hold 1.1 ml with cap
- Note: These racks size have a standard microtiter configuration

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## 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

LATEX: Material is Latex FreeBSE / TSE: Material is BSE / TSE Free

## 5. Quality Assurance:

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

## 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
- Protect from any damage to the packaging

#### 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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