

Annette Roy, Regulatory

# Product Name: BioTube<sup>™</sup> Rack

## Catalogue No.: T100-50 Series

## This document replaces any previous version

## **1.** Product Description:

**BioTube<sup>™</sup> Rack :** Disposable, Non-Sterile, storage box with 96 position rack.

#### • 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
- 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)
- 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
- > Note: These racks size have a standard microtiter configuration

#### 4. Standards and Conformity:

- 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 Free
- **BSE / TSE:** Material is BSE / TSE Free

## 5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Volume 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
- Protect from any damage to the packaging

#### 8. Recommended Use:

- > Follow chemical resistance chart recommendations
- > For use in automated equipment, follow the equipment manufacturer's instructions

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