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2017-09-13 2021-04-28 Annette Roy, QA Coordinator

# Product Name: BioTube<sup>™</sup> Rack Catalogue No.: T101-1 This document replaces any previous version 1. **Product Description:** Rack with 1.2 ml tubes: Disposable, non-sterile, rack pre-filled with 96 plain individual tubes. Caps sold separately. Rack Made of 3 Components: • A white base with alphanumerical grid • A translucent cover with alphanumerical grid • 96 individual tubes > Compatible with: T100-28 Individual Plug Caps 2. Packaging:

Case:

2 packages of 5 units / 10 units per case

## **3.** Product Specifications:

- Material:
  - Polypropylene
- Certified RNase, DNase, Pyrogen and DNA Free
- Temperature range: -80°C to +121°C
- Autoclavable at +121°C, for up to 30 minutes
- > Cover and rack have easy to read alphanumerical dots
- Tubes total volume of 1.2 ml will hold 1.1 ml with cap
- > Note: These racks size have a standard microtiter configuration

## 4. Standards and Conformity:

- > ISO 2859-1:
- FDA:
- CONEG / RoHS:
- Resin conforms to FDA 21 CFR 177.1520 Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals

Plastic is in conformity to REACH standards

Sampling and inspection procedures

- REACH (SVHC):
- ► LATEX:

- Material is Latex Free Material is BSE / TSE Free
- 5. Quality Assurance:

BSE / TSE:



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- > Clear, no presence of contamination in plastic
- Visual attributes
- Gas phase of Liquid Nitrogen resistance

## 6. Traceability:

- Lot No. Composition: 8 or 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

#### 8. Recommended Use:

- > Follow chemical resistance chart recommendations
- > For use in automated equipment, follow the equipment manufacturer's instructions
- > Should be used only in the gas phase of Liquid Nitrogen

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