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Revised by: Annette Roy, Regulatory

Page 1 / 2

Product Name: BioTube[™] Rack Catalogue No.: T100-2 Series

This document replaces any previous version

1. Product Description:

➤ BioTubeTM Rack with tubes: Disposable, 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
- > Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy
- > 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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Page 2 / 2

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 possible contamination
- Protect from any damage to the packaging which could compromise the product 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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