**Edition Date:** 2013-11-06 Revision Date: 2020-08-25

Revised by: Annette Roy, Regulatory

**Product Name: Transport Tube** Catalogue No.: T307-5A

This document replaces any previous version

1. Product Description:

> 5 ml Q-Swab<sup>™</sup> Transport Tube with External Thread: Disposable, Sterile, self-standing and non-

graduated

2. Packaging:

Case: 50 units per package / 500 units per case

3. Product Specifications:

Material:

• Tube and Cap: Polypropylene

• Washer Seal: Silicone

• Tipped Applicator: Polyester tip on polypropylene shaft

➤ Gamma 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

➤ Cap configuration allows insertion of a Capinsert<sup>TM</sup> (T312 Series) for color-coding

## 4. Standards and Conformity:

> ISO 2859-1: Sampling and inspection procedures ➤ FDA: plastics conform to FDA 21 CFR 177

> CONEG / RoHS: Plastics and colorants are in conformity with

CONEG / RoHS standards for heavy metals

> REACH (SVHC): Materials conform to REACH regulations

> LATEX: Materials are Latex Free ➤ BSE / TSE: Materials are BSE / TSE Free

### 5. Quality Assurance:

Clear, no presence of contamination in plastic

- Visual attributes
- Volume measurements
- Closure verification
- ➤ Leak proof testing in vacuum at 71.3cm Hg
- > Gas phase of Liquid Nitrogen resistance

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## 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 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
- > Should be used only in the gas phase of Liquid Nitrogen

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