

2010-10-25 2022-08-08 Annette Roy, QA Coordinator

# Product Name: SecurTainer<sup>™</sup> I Catalogue No.: C575-40MA

## This document replaces any previous version

## **1. Product Description:**

> 40ml Specimen Container: Disposable and non-sterile with tamper evident leakproof screw cap

## 2. Packaging:

Case: 5 packs of 100 units / 500 units per case

#### 3. Product Specifications:

- > Material:
  - Container: Polypropylene
  - Cap: Polyethylene
  - Cap Color: magenta
- > Caps packaged separately in bags of 100
- Gamma radiation resistant
- Temperature range: -90°C to +100°C
- ➤ Cap configuration allows insertion of a Capinsert<sup>TM</sup> (T345 Series) for color-coding

#### 4. Standards and Conformity:

- ISO 2859-1: Sampling and inspection procedures
- FDA: Resins conform to FDA 21 CFR 177.1520
- RoHS Plastics and colorants are in conformity with
- RoHS standards for heavy metals
- **REACH (SVHC):** Plastics are in conformity to REACH standards
- > LATEX: Materials are Latex Free

# 5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Dimension and volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg



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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
- Protect from any possible contamination
- 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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