**Edition Date:** 2013-02-28 Revision Date: 2017-11-28

Revised by: Annette Roy, QA Coordinator

Product Name: SpecTainer™ I Catalogue No.: C566-60Y

This document replaces any previous version

1. **Product Description:** 

> **▶** 60ml Urine Container: Disposable, non-sterile and assembled 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: yellow

> Gamma radiation resistant

> Temperature range: -90°C to +100°C

➤ Label to enter patient's name

➤ Cap configuration allows insertion of a Capinsert<sup>TM</sup> (T345 Series) for color-coding

#### **Standards and Conformity:** 4.

> 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 **≻** CE: Product is CE marked

#### 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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