Edition Date: 2013-02-28 Revision Date: 2022-08-08

Revised by: Annette Roy, Regulatory

Product Name: Eco-Friendly SpecTainer™

Catalogue No.: C567-60DOECO

This document replaces any previous version

1. **Product Description:**

> 60 ml Biodegradable Urine Container: Disposable, Non-Sterile and assembled with leakproof

screw cap

2. Packaging:

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

Product Specifications: 3.

- Material:
 - Container: Specially formulated degradable Polypropylene
 - Cap: Specially formulated degradable Polyethylene
 - Cap Color: Gold
- > Fully Biodegradable in 9 months to 5 years in organic environment.
- > Gamma radiation resistant
- > Temperature range: -90°C to +100°C
- ➤ Label to enter patient's name
- Cap configuration allows insertion of a Capinsert[™] (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 Plastics and colorants are in conformity with ➤ RoHS:

RoHS standards for heavy metals

Plastics are in conformity to REACH standards > REACH (SVHC):

> 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
- > 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

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