

2021-12-14 2022-09-20 Christine Laforge Technical Representative

Product Name: SpecTainer[™] Catalogue No.: C566-120AQSECO

This document replaces any previous version

1. Product Description:

Eco-Friendly, 120 ml Urine Container: Disposable, Sterile and assembled with tamper evident leakproof closure.

2. Packaging:

Case: 3 packs of 100 units / 300 units per case

3. Product Specifications:

- > Material:
 - Container: Specially formulated degradable Polypropylene
 - Cap: Specially formulated degradable Polyethylene
 - Cap Color: Aqua
- > Fully Biodegradable in 9 months to 5 years in organic environment.
- ➤ Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy
- 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:

- 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 which could compromise 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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