

Product Name: SpecTainer™ II

Catalogue No.: C567-120CYS

This document replaces any previous version

1. Product Description:

- **120ml Urine Container:** Disposable, sterile and assembled with screw cap

2. Packaging:

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

3. Product Specifications:

- **Material:**
 - Container: Polypropylene
 - Cap: Polyethylene
- 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
- Tamper evident label for sterility assurance
- 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
- **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 (equivalent of 95KPa)

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 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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