

Product Name: **SpecTainer™ II**

Catalogue No.: **C567-60CYS**

This document replaces any previous version

1. Product Description:

- **60ml Urine Container:** Sterile, assembled with leak proof screw cap.

2. Packaging:

- **Case:** 5 packages of 100 units / 500 units per case

3. Product Specifications:

- **Material:**
 - Polypropylene container;
 - Polyethylene cap;
 - Color cap: cyan.
- Gamma radiation sterilized at a SAL of 10^{-3} ; specified dose between 6.5 kGy and 12.5 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:** Resin conforms to FDA 21 CFR 177.1520
- **RoHS** Plastics and colorants are in conformity with RoHS standards for heavy metals
- **REACH (SVHC):** Plastic is in conformity to REACH standards
- **LATEX:** Material is 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.

6. Traceability:

- **Lot No. Composition:** 8 to 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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