

**Product Name: Sputum™ Collection System**

**Catalogue No.: C200G**

This document replaces any previous version

## 1. Product Description:

- **Collection of biological samples:** Sterile, use to collect, carry and process samples. Base and funnel assembled with a removable sterile 50ml graduated tube with lip seal cap and patient ID label.

## 2. Packaging:

- **Case:** 72 units per case (individually wrapped)

## 3. Product Specifications:

- **Material:**
  - Polypropylene tube and collection unit;
  - Polyethylene cap.
- Base and funnel assembled with a 50ml tube with lip seal cap and patient ID label;
- Gamma radiation sterilized at a SAL of  $10^{-3}$ ; specified dose between 6.5 kGy and 12.5 kGy;
- Temperature range for the cap: -100°C to +90°C;
- Temperature range for the tube: -196°C to +121°C. Tube is autoclavable at 121°C, for up to 30 minutes;
- Tube is resistant to a maximum centrifuged of 3000 g.

## 4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resin conforms to FDA 21 CFR 177.1520
- **CONEG:** Plastics and colorants are in conformity with CONEG standards for heavy metals
- **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 inserted label 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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