**Edition Date:** 2008-07-18 Revision Date: 2019-07-19

Revised by: Annette Roy, QA Coordinator

**Product Name: UNISETTE** Catalogue No.: M506 Series

This document replaces any previous version

#### 1. **Product Description:**

Biopsy Cassette with Attached Lid: Non-Sterile, disposable cassette

- > Available Colors:
  - White, Pink, Green, Yellow, Blue, Peach, Tan, Gray, Lilac, Orange and Aqua
  - Fluorescent Pink, Green and Yellow also available, minimum order quantity required
- 2. Packaging:

Case: 3 inner packs of 500 units / 1 500 units per case

### 3. **Product Specifications:**

Material:

Acetal

➤ Writing surface angle: 35°

> Temperature range: -80°C to +30°C

### 4. **Standards and Conformity:**

Sampling and inspection procedures > ISO 2859-1: Resin conforms to FDA 21 CFR 177.2470 > FDA: > CONEG / RoHS: Plastics and colorants are in conformity with CONEG / 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
- ➤ Lid closure verification

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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

### 8. Recommended Use:

- Verify proper lid closure of the cassette before using
- > Avoid picric acid, prolonged use in this acid will cause degradation
- > Follow chemical resistance chart recommendations
- > For use in automated equipment, follow the equipment manufacturer's instructions

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