**Edition Date:** 2004-01-01 **Revision Date:** 2017-08-28

Revised by: Annette Roy, QA Coordinator

Product Name: Histosette® II Catalogue No.: M493- Series

This document replaces any previous version

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

Biopsy Cassette with Assembled Lid: Disposable and non-sterile

- > 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 boxes of 500 cassettes / 1 500 units per case

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

- Material:
  - Acetal
- ➤ Writing surface angle: 45°
- Compatible with cassette printers

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

> ISO 2859-1: Sampling and inspection procedures > FDA: Resin conforms to FDA 21 CFR 177.2470 **➤ 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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