**Edition Date:** 2004-01-20 Revision Date: 2017-09-05

Revised by: Annette Roy, QA Coordinator

Product Name: Histosette® I Catalogue No.: M499-X Series

This document replaces any previous version

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

- > Biopsy Cassette with Attached Lid: Non-sterile, disposable cassette with attached lid that is easily separated from base
- > 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:

3 dispenser boxes of 500 units / case of 1500 cassettes Case:

- 3. **Product Specifications:** 
  - Material:
    - Acetal
  - Writing surface angle: 45°

### 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

Material is Latex Free > LATEX: **≻** CE: Product is CE marked

### 5. **Quality Assurance:**

- Clear, no presence of contamination in plastic
- Visual attributes
- Lid closure verification

Page 1 / 2 Issue Date: 2017-06-15

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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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