**Edition Date:** 2007-07-04 Revision Date: 2018-09-27

Revised by: Annette Roy, QA Coordinator

Product Name: Histosette® I Catalogue No.: M491-X Series

This document replaces any previous version

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

> Biopsy Cassette with Attached Lid: on-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 boxes of 500 cassettes / 1 500 units per case

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

➤ Material: Acetal

Writing surface angle: 30°

#### 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

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