

2004-01-19 2019-07-19 Annette Roy, QA Coordinator

Product Name: Histosette[®] II

Catalogue No.: M486-XSL Series

This document replaces any previous version

1. **Product Description:**

- Biopsy Cassette in plastic sleeve with Separate 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: 10 QuickLoad[™] plastic sleeves of 75 cassettes and 10 bags of 75 lids / 750 units per case

Product Specifications: 3.

- ➤ Material:
 - Cassettes and lid: Acetal resin
 - Sleeve: PVC Plastic
- ➢ Writing surface angle: 45°
- Temperature range: -80°C to +30°C

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 Plastic is in conformity to REACH standards
- **REACH (SVHC):**
- > 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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