

Edition Date: Revision Date : Revised by: 2004-01-01 2017-08-28 Annette Roy, QA Coordinator

Product Name: Histosette[®] II C

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:
- > FDA:
- CONEG / RoHS:
- > REACH (SVHC):
- > LATEX:
- ≻ CE:

Sampling and inspection procedures Resin conforms to FDA 21 CFR 177.2470 Plastics and colorants are in conformity with CONEG / RoHS standards for heavy metals Plastic is in conformity to REACH standards Material is Latex Free 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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