

2008-01-29 2017-10-03 Annette Roy, QA Coordinator

# Product Name: Swingsette<sup>™</sup>

## Catalogue No.: M516-X Series

This document replaces any previous version

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

- > Biopsy Cassette with Assembled Lid: Non-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 inner packs of 500 units / 1 500 units per case

Sampling and inspection procedures

Material is Latex Free

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

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

- > Material:
  - Acetal
- Writing surface angle: 45°

## 4. Standards and Conformity:

- ISO 2859-1:
- > FDA:
- CONEG / RoHS:
- > REACH (SVHC):
- > LATEX:
- 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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