

Edition Date: Revision Date : Revised by:

# Product Name: UNISETTE

# Catalogue No.: M526-XT Series

This document replaces any previous version

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

- > Biopsy Cassette with Attached Lid in taped stacks: 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:

25 QuickLoad<sup>™</sup> Stacks of 40 taped cassettes / 1 000 units per case

- **3.** Product Specifications:
  - > Material:
    - Acetal
  - Writing surface angle: 45°
  - Temperature range: -80°C to +30°C

### 4. Standards and Conformity:

- ➢ ISO 2859-1:
- > FDA:
- Resin conforms to FDA 21 CFR 177.2470 Plastics and colorants are in conformity with
- ➢ REACH (SVHC):

> CONEG / RoHS:

CONEG / RoHS standards for heavy metals Plastic is in conformity to REACH standards

Sampling and inspection procedures

- 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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