**Edition Date:** 

2021-10-27 **Revision Date:** 

Revised by:

Annette Roy, Regulatory

**Product Name: CytoSep™ filter paper** Catalogue No.: M963FW

This document replaces any previous version

- 1. **Product Description:** 
  - Filter paper for Cytology Funnel: Disposable White filter paper with square hole
- 2. Packaging:
  - Case: 200 per case
- 3. **Product Specifications:** 
  - ➤ Compatible with the Sakura Cyto-Tek® Cytology funnels
  - Material: White, smooth surface, Cellulose
- 4. **Standards and Conformity:**

> ISO 2859-1: Sampling and inspection procedures > FDA: Paper conforms to 21CFR 176.170

CE: Product is CE marked > LATEX: Material is Latex Free ➤ BSE / TSE: Material is BSE / TSE Free

- 5. **Quality Assurance:** 
  - ➤ No presence of contamination
  - > Assembly and fit
  - Visual attributes
  - Dimension measurements
- 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

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## 7. Storage Conditions:

- > Store in at room temperature in normal warehouse conditions
- > Avoid temperature variations and humidity
- > Protect from any possible contamination

## 8. Recommended Use:

For use in Sakura Cyto-Tek® Cytology funnels in automated equipment, follow the equipment manufacturer's instructions for use

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