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Revised by: Rossano Morgan-Cavallaro,

Regulatory Documentation &

Quality Agent

Technical Data Sheet

Product Name: CytoSep™ Catalogue No.: M963 Series

This document replaces any previous version

Product Description: 1.

Available components:

- M963-1 Non-Sterile, Disposable Cytology Funnel, 1 ml fluid chamber
- M963C Non-Sterile, Disposable Cap only
- M963B Non-Sterile, Disposable Base Holder only
- M963FW Non-Sterile, Disposable White Filter Paper with Square Hole only.

Compatible with:

Sakura Cyto-Tek® Cytocentrifuge and equivalent systems

2. Packaging:

➤ M963-1: 4 packages of 50 units / 200 units per case ➤ M963C: 4 packages of 50 units / 200 units per case ➤ M963B: 4 packages of 50 units / 200 units per case

➤ M963FW: 200 units per case

3. **Product Specifications:**

> Material:

- M963-1: Polypropylene (PP)
- M963C: High Density Polyethylene (HDPE)
- M963B: Polypropylene (PP)
- M963FW: White, smooth surface, Cellulose

4. **Standards and Conformity:**

> FDA: PP & HDPE Resins conform to FDA 21 CFR 177.1520

CE: Product is CE Marked

CONEG / RoHS: Supplier certifies resins are in conformity with CONEG / RoHS standards

for heavy metals

➤ REACH (SVHC): Supplier certifies the resins are in conformity to REACH standards > EU Reg. 2019/1021 (POPs): Supplier certifies the resins are in conformity with EU 2019/1021 (POP)

> Toxic Substance Control Act: Supplier certifies the resins are in conformity with US TSCA

> PFAS: Supplier certifies the resins are PFAS-Free **▶** BSE/TSE: Supplier certifies the resins are BSE/TSE-Free

Bisphenols: Supplier certifies the resins are free from Bisphenols & their compounds

> Phthalates: Supplier certifies the resins are Phthalate Free > LATEX: Supplier certifies the resins are Latex Free

Conflict Minerals Reporting: Supplier certifies the resins are in conformity with CMR standards

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5. **Quality Assurance:**

- No presence of contamination in plastic
- Visual attributes
- > Assembly and fit
- Closure verification

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 damage to the packaging

8. Recommended Use:

- Follow chemical resistance chart recommendations
- Check cap closure when using biohazard material and / or chemical reagents
- > For use in Sakura Cyto-Tek® Cytocentrifuge automated equipment, follow the equipment manufacturer's instructions for use

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