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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	

DOMINIQUE DUTSCHER SAS

1. Product Description:

- **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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