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Technical Data Sheet

Product Name: CytoSep™	**Catalogue No.: M964 Series**
This document replaces any previous version	

1. Product Description:

➢ Available Variations and/or Components:

- **M964-1 –** Non-Sterile, Disposable Cytology Single-Funnel, 1 mL Fluid Chamber
- **M964-1D –** Non-Sterile, Disposable Cytology Double-Funnel, 0.5 mL Fluid Chamber each
- **M965C –** Non-Sterile, Disposable Cap only for M964-M965
- **M965FW –** Non-Sterile, Disposable White filter paper for single funnel
- **M965FWD –** Non-Sterile, Disposable White filter paper for double funnel
- **M965FWDV –** Non-Sterile, Disposable White filter paper for TPX double funnel
- **M965FT –** Non-Sterile, Disposable Brown filter paper for single funnel
- **M964B –** Reusable Clip for M964 Series Single and Double Cytology Funnels only
- **M964-10FT –** Non-Sterile, Disposable, Pre-Assembled Single-Funnel (1 mL Fluid Chamber) with Brown Filter Paper & Cap
- **M964-10FW –** Non-Sterile, Disposable, Pre-Assembled Single-Funnel (1 mL Fluid Chamber) with White Filter Paper & Cap
- **M964-10FW1 –** Individually Wrapped, Non-Sterile, Disposable, Pre-Assembled Single-Funnel (1 mL Fluid Chamber) with White Filter Paper & Cap
- **M964-20FW –** Non-Sterile, Disposable, Pre-Assembled Double-Funnel (0.5 mL Fluid Chamber each) with White Filter Paper & Cap
- **M964-20FW1 –** Individually wrapped, Non-Sterile, Disposable, Pre-Assembled Double-Funnel (0.5 mL Fluid Chamber each) with White Filter Paper & Cap

➢ Compatible with:

- Epredia™ (formerly Shandon) Cytospin® Cytocentrifuges and equivalent systems

2. Packaging:

- ➢ **M964-1:** 500 units per case
- ➢ **M964-1D:** 500 units per case
- ➢ **M965C:** 50 units per pack / 500 units per case
- ➢ **M965FW:** 200 units per pack
- ➢ **M965FWD:** 200 units per pack
- ➢ **M965FWDV:** 200 units per pack
- ➢ **M965FT:** 200 units per pack
- ➢ **M964B:** 6 units per case
- ➢ **M964-10FT:** 50 units per pack / 500 units per case
- ➢ **M964-10FW:** 50 units per pack / 500 units per case
- ➢ **M964-10FW1:** 100 units per pack / 500 units per case
- ➢ **M964-20FW:** 50 units per pack / 500 units per case
- ➢ **M964-20FW1:** 100 units per pack / 500 units per case

3. Product Specifications:

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- **Material:**
  - **M964-1:** Polypropylene (PP)
  - **M964-1D:** Polypropylene (PP)
  - **M965C:** High Density Polyethylene (HDPE)
  - **M965FW:** White, smooth surface, Cellulose
  - **M965FWD:** White, smooth surface, Cellulose
  - **M965FWDV:** White, smooth surface, Cellulose
  - **M965FT:** Brown, smooth surface, Cellulose
  - **M964B:** Stainless Steel
  - **M964-10FT:** PP funnel; HDPE cap; Brown, smooth surface, Cellulose filter paper
  - **M964-10FW:** PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper
  - **M964-10FW1:** PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper
  - **M964-20FW:** PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper
  - **M964-20FW1:** PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper

4. Standards and Conformity:

- **FDA:** PP & HDPE Resin conforms to FDA 21 CFR 177.1520
  Filter Papers conform to FDA 21 CFR 176.170 and 21 CFR 176.180
- **CE:** These Products are 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

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

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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 Shandon Cytospin® Cytocentrifuges and Shandon Cytospin® Cytocentrifuges using TPX double funnels automated equipment, follow the equipment manufacturer's instructions for use

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