

Edition Date: 2021-12-17 Revision Date: 2025-05-29

Revised by: Rossano Morgan-Cavallaro,

Regulatory Documentation &

Quality Agent

Technical Data Sheet

Product Name: CytoSep™ Catalogue No.: M965 Series

This document replaces any previous version

Product Description: 1.

Available Variations and/or Components:

- M965-1 Non-Sterile, Disposable Cytology Single-Funnel, 0.5 mL Fluid Chamber
- M965-1D Non-Sterile, Disposable Cytology Double-Funnel, 0.25 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
- M965B Non-Sterile, Reusable Clip for M965 Series Single and Double Cytology Funnels only
- M965-10FT Non-Sterile, Disposable, Pre-Assembled Single-Funnel (0.4 mL Fluid Chamber) with **Brown Filter Paper & Cap**
- M965-10FW Non-Sterile, Disposable, Pre-Assembled Single-Funnel (0.5 mL Fluid Chamber) with White Filter Paper & Cap
- M965-20FW Non-Sterile, Disposable, Pre-Assembled Double-Funnel (0.25 mL Fluid Chamber each) with White Filter Paper & Cap
- M965-40 CYTOSEP™ Mega Funnel & Cap

Compatible with:

Shandon Cytospin® Cytocentrifuges and equivalent systems

2. Packaging:

➤ M965-1: 50 units per pack / 500 units per case ➤ M965-1D: 50 units per pack / 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

➤ M965B: 50 units per pack / 500 units per case

12 inner boxes of 40 units / 480 units per case ➤ M965-10FT: ➤ M965-10FW: 12 inner boxes of 40 units / 480 units per case ➤ M965-20FW: 12 inner boxes of 40 units / 480 units per case ➤ M965-40: 12 inner boxes of 40 units / 480 units per case

Document Template: FRM-106 Rev01 Technical Data Sheet

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3. **Product Specifications:**

➤ Material:

M965-1: Polypropylene (PP) M965-1D: Polypropylene (PP)

M965C: High Density Polyethylene (HDPE) M965FW: White, smooth surface, Cellulose M965FWD: White, smooth surface, Cellulose M965FWDV: White, smooth surface, Cellulose Brown, smooth surface, Cellulose M965FT:

M965B: Polypropylene (PP)

M965-10FT: PP funnel; HDPE cap; Brown, smooth surface, Cellulose filter paper **M965-10FW:** PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper M965-20FW: PP funnel; HDPE cap; White, smooth surface, Cellulose filter paper

M965-40: Polypropylene (PP) funnel and base, High Density Polyethylene (HDPE) cap

4. **Standards and Conformity:**

➤ FDA: PP & HDPE Resins conform 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 resin is 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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