Simport Scientific inc. Since 1975

Edition Date: 2022-04-05
Revision Date : 2025-05-29
Revised by: Rossano Morgan-Cavallaro, Regulatory Documentation & Quality Agent

Technical Data Sheet

Product Name: CytoSep™	**Catalogue No.: M968 Series**
This document replaces any previous version	

1. Product Description:

- **Available Variations and/or Components:**
  - **M968-1 –** Non-Sterile and Disposable Cytology Single-Funnel (⌀ 7 mm) for 50 to 400ul sample volumes
  - **M968FW –** Non-Sterile, Disposable White filter paper for single funnel
- **Compatible with:**
  - StatSpin® Cytofuge 2 Cytocentrifuge and equivalent systems

2. Packaging:

- **M967-10FW:** 48 units per case
- **M967FW:** 200 units per case

3. Product Specifications:

- **Material:**
  - **M968-1:** Polypropylene (PP)
  - **M968FW:** White, smooth surface, Cellulose

4. Standards and Conformity:

- **FDA:** Resin 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 resin is 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 resin is in conformity with EU 2019/1021 (POP)
- **Toxic Substance Control Act:** Supplier certifies the resin is in conformity with US TSCA
- **PFAS:** Supplier certifies the resin is PFAS-Free
- **BSE/TSE:** Supplier certifies the resin is BSE/TSE-Free
- **Bisphenols:** Supplier certifies the resin is free from Bisphenols & their compounds
- **Phthalates:** Supplier certifies the resin is Phthalate Free
- **LATEX:** Supplier certifies the resin is Latex Free
- **Conflict Minerals Reporting:** Supplier certifies the resin is in conformity with CMR standards

5. Quality Assurance:

- No presence of contamination in plastic
- Assembly and fit
- Visual attributes
- Dimension measurements

DOMINIQUE DUTSCHER SAS

Technical Data Sheet

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 StatSpin® Cytofuge 2 Cytocentrifuge automated equipment, please follow the equipment manufacturer's instructions for use

***OWNERSHIP OF MATERIALS**:*

*Materials and information contained in this document are **Simport Scientific**'s copyrighted and are protected by worldwide copyright laws and treaty provisions. They may not be copied, reproduced, modified, published, uploaded, posted, transmitted or distributed in any way.*

***Disclaimer**:*

The information contained in this document shall not constitute a representation or warranty of the suitability for any specific purpose. To the best of our knowledge, the information contained is reliable and true based on our internal and external testing as well as statements supplied to us by third party suppliers.

DOMINIQUE DUTSCHER SAS