

Edition Date: 2020-12-10 **Revision Date:** 2025-05-29

Revised by: Rossano Morgan-Cavallaro,

Regulatory Documentation &

Quality Agent

Technical Data Sheet

Product Name: CytoSep[™] Catalogue No.: M967 Series

This document replaces any previous version

1. Product Description:

- > Available Variations and/or Components:
 - M967-10FW Non-Sterile, Disposable, Pre-Assembled Single-Funnel (0.5 mL Fluid Chamber) with White Filter Paper & Cap
 - M967-20FW Non-Sterile, Disposable, Pre-Assembled Double-Funnel (0.25 mL Fluid Chambers) with White Filter Paper & Cap
 - M967FW Non-Sterile, Disposable White filter paper for Single-Funnel, 0.5 mL Fluid Chamber
 - M967FWD Non-Sterile, Disposable White filter paper for Double-Funnel, 0.25 mL Fluid Chambers
- Compatible with:
 - ELITechGroup Cytopro® Cytocentrifuge and equivalent systems
- 2. Packaging:

M967-10FW:
 M967-20FW:
 2 inner boxes of 24 units / 48 units per case
 2 inner boxes of 24 units / 48 units per case

M967FW: 100 units per caseM967FWD: 100 units per case

3. Product Specifications:

➤ Material:

M967-10FW: Polypropylene (PP) Funnel, Polyethylene (PE) Cap
 M967-20FW: Polypropylene (PP) Funnel, Polyethylene (PE) Cap

M967FW: White, smooth surface, Cellulose
 M967FWD: White, smooth surface, Cellulose

4. Standards and Conformity:

FDA: 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 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-FreeBSE/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

Document Template: FRM-106 Rev01 Technical Data Sheet

Issue Date: 2017-06-15

Page 1 / 2



Edition Date: 2020-12-10 Revision Date: 2025-05-29

Revised by: Rossano Morgan-Cavallaro,

Regulatory Documentation &

Quality Agent

Technical Data Sheet

5. **Quality Assurance:**

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

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 ELITechGroup Cytopro® 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.

Document Template: FRM-106 Rev01 Technical Data Sheet Page 2 / 2

Issue Date: 2017-06-15