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Quality Agent

Technical Data Sheet

Product Name: CytoSep[™] Catalogue No.: M966 Series

This document replaces any previous version

1. Product Description:

- > Available Variations and/or Components:
 - M966-1 Non-Sterile, Disposable Cytology Single-Funnel, 1 mL Fluid Chamber
 - M966-2 Non-Sterile, Disposable Cytology Single-Funnel, 2 mL Fluid Chamber
 - M966-4 Non-Sterile, Disposable Cytology Single-Funnel, 4 mL Fluid Chamber
 - M966-8 Non-Sterile, Disposable Cytology Single-Funnel, 8 mL Fluid Chamber
 - M966FW Non-Sterile, Disposable White filter paper for Single-Funnel, 1 to 4 mL Fluid Chamber
 - M966FW8 Non-Sterile, Disposable White filter paper for Single-Funnel, 8 mL Fluid Chamber
- Compatible with:
 - Hettich Cyto-System and equivalent systems
- 2. Packaging:

M966-1: 10 units per pack / 50 units per case
M966-2: 10 units per pack / 50 units per case
M966-4: 10 units per pack / 50 units per case
M966-8: 10 units per pack / 50 units per case
M966FW: 100 units per pack / 200 units per case
M966FW8: 200 units per pack / 200 units per case

3. Product Specifications:

> Material:

M966-1: Polypropylene (PP)
M966-2: Polypropylene (PP)
M966-4: Polypropylene (PP)
M966-8: Polypropylene (PP)

M966FW: White, smooth surface, Cellulose
 M966FW8: White, smooth surface, Cellulose

4. Standards and Conformity:

> FDA: Polypropylene 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 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

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> 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
- 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 Hettich Cyto-System automated equipment, please follow the equipment manufacturer's instructions for use

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