Edition Date: 2020-12-10 **Revision Date:** None

Revised by: Annette Roy, QA Coordinator

Product Name: CytoSep™ Cytology Funnel Catalogue No.: M967-10FW

This document replaces any previous version

1. **Product Description:**

> > Cytology Funnel: Disposable single funnel pre-assembled with white paper filter paper

> > and cap included

2. Packaging:

> Case: 2 inner boxes of 24 / case of 48

3. **Product Specifications:**

➤ Compatible with the Unitech (Wescor) Cytopro® Cytocentrifuge System

➤ Material:

• Funnel: Polypropylene

• Cap: Polyethylene

• Filter: White Cellulose filter board

4. **Standards and Conformity:**

> > ISO 2859-1: Sampling and inspection procedures

> FDA: Paper conforms to 21CFR 176.170 & 21CFR

176.180

Plastic conforms to FDA 21 CFR 177.1520

CE: Product is CE marked > LATEX: Material is Latex Free ➤ BSE / TSE: Material is BSE / TSE Free

5. **Quality Assurance:**

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

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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 in at room temperature in normal warehouse conditions
- > Avoid temperature variations and humidity
- > Protect from any possible contamination

8. **Recommended Use:**

> For use in Shandon Cytopspin® Cytocentrifuge automated equipment, follow the equipment manufacturer's instructions for use

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