**Edition Date:** 2012-01-12 **Revision Date:** 2018-06-12

Revised by: Annette Roy, QA Coordinator

**Product Name: CytoSep™ Cytology Funnel** Catalogue No.: M965-10FW

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:

> 12 inner boxes of 40 / case of 480 Case:

3. **Product Specifications:** 

➤ Compatible with the Shandon Cytopspin® Cytocentrifuge:

➤ 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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Document Template: FRM-106 Rev01 Technical Data Sheet

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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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Document Template: FRM-106 Rev01 Technical Data Sheet

Issue Date: 2017-06-15