

2012-01-12 2018-06-12 Annette Roy, QA Coordinator

Product Name: CytoSep[™] Cytology Funnel Catalogue No.: M965-20FW

This document replaces any previous version

1. Product Description:

Cytology Funnel: Disposable Double funnel pre-assembled with white paper filter and cap included

2. Packaging:

Case: 12 inner boxes of 40 / case of 480

3. Product Specifications:

- > Compatible with the Shandon Cytopspin[®] Cytocentrifuge:
- > Material:
 - Funnel: Polypropylene
 - Cap: Polyethylene
 - Filter: White Cellulose filter board

4. Standards and Conformity:

\triangleright	ISO 2859-1:	Sampling and inspection procedures
\triangleright	FDA:	Paper conforms to 21CFR 176.170 & 21CFR
		176.180
\triangleright		Plastic conforms to FDA 21 CFR 177.1520
\triangleright	CE:	Product is CE marked
\triangleright	LATEX:	Material is Latex Free
\triangleright	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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