

The M – Funnel has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## M – Funnel

Catalog No. : FMCN0902XXXX212  
Type : M - Funnel  
Pore Size : 0.45 µm  
Lot Number : 5577G  
Ster. No. : 006  
Expiry Date : 2020 - 07

### SPECIFICATION

Membrane : Cellulose Nitrate Membrane with Ink grid  
Plastic Components  
    Funnel Cover : Acrylic  
    Funnel & Base : Polypropylene  
    Plug : LDPE  
Filter Diameter : 47 mm  
Funnel capacity : 100 ml  
Sterilization : Pre sterilized with EO

### LOT RELEASE CRITERIA

**Water Flow Rate** :  $\geq 200$  ml/min at Vacuum of 250 mm of Hg  
**Sterility Test** : The test samples have been sterilized using validated EO sterilization process. Biological Indicators ( $10^6$  spores) showed no growth/ turbidity for a total of 7 days after inoculation as per USP < 55 >.

### VALIDATED FOR

**Microbial Recovery Test** : Passes Test as per ISO 7704: Water Quality – Evaluation of membrane filter used for microbiological analysis.  
**Inhibitory Effect of Ink Grids** : Passes test as per ASTM D 4200-82: Standard test method for evaluating inhibitory effect of ink grids on membrane filters.  
**Package Integrity Test** : Passes as per ASTM F1929-98: Standard test method for detecting seal leaks in porous medical packaging by Dye Penetration Test.  
**EO Residual Level** :  $\leq 6$  ppm



Head of Quality Assurance

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