

# Certificate of Quality

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

## M – Funnel NXT

Catalog No.	: FXCN0902XXXX212
Type	: M - Funnel NXT
Pore Size	: 0.45 µm
Lot Number	: 9965L
Ster. No.	: 969
Date of Sterilization	: 2025 - 12
Expiry Date	: 2028 - 12

## 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

<b>Typical Water Flow Rate</b>	: 250 ml/min at Vacuum of 250 mm of Hg
<b>Microbial Recovery of <i>E. coli</i></b>	: Exhibits greater than 70% recovery for <i>E. coli</i> (ATCC 8739).

## VALIDATED FOR

<b>Sterility</b>	: The sterilization process has been validated to assure Sterility Assurance Level (SAL) of $10^{-6}$ in accordance with ISO 11135.
<b>Microbial Recovery Test</b>	: Passes Test as per ISO 7704: Water Quality – Evaluation of membrane filter used for microbiological analysis.
<b>Inhibitory Effect of Ink Grids</b>	: Passes test as per ASTM D 4200-82: Standard test method for evaluating inhibitory effect of ink grids on membrane filters.
<b>Package Integrity Test</b>	: Passes as per ASTM F1929-98: Standard test method for detecting seal leaks in porous medical packaging by Dye Penetration Test.
<b>EO Residual Level</b>	: $\leq 6$ ppm

T. No.: COQ/FUN/016-00

Head of Quality Assurance  
Issue Date: 08-Dec-25

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**An ISO 9001 Company**