

Certificate of Quality

The Cellulose Nitrate Membrane Disc Filters with **Ink grid** have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

Pre-sterilized Cellulose Nitrate Membrane Disc Filters with Ink Grid

Catalog No.	: RGCN0902XXXX204
Type	: RGCN-S
Pore Size	: 0.45 μ m
Diameter	: 47 mm
Lot Number	: 4487G
Ster. No.	: 055
Expiry Date	: 2020 - 07

LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

Mean Membrane Thickness	: 135 μ m
Integrity Test	: The membrane filter lot has been tested for integrity by Bubble point Test using Purified water. Bubble point was: \geq 30 psi (2.07 Bars)
Water Flow Rate	: \geq 50 ml/min/cm ² @ 0.70 Kg/cm ² @ 27 °C
Wettability of Membrane	: \leq 5 Seconds
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	: Exhibits \geq 90% recovery versus spread plate for <i>E. coli</i> ATCC 8739, when challenged with \approx 100 cfu.
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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An ISO 9001 Company