

# Certificate of Quality

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

## Cellulose Nitrate Membrane Disc Filters

Catalog No. : CNXX1601XXXX103  
Type : CN  
Pore Size : 0.2  $\mu$ m  
Diameter : 142 mm  
Lot Number : CA897977G

### LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

- Integrity** : The membrane filter lot has been tested for integrity by Bubble point Test using DI water. Bubble point was:  $\geq 50$  psi (3.4 Bars)
- Water Flow Rate** :  $\geq 20$  ml/min/cm<sup>2</sup> @ 0.70 Kg/cm<sup>2</sup> @ 27 °C
- Microbial Challenge Test** : Retains  $\geq 10^7$  organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

### VALIDATED FOR

- Heat Stability** : Maintains integrity after autoclaving/steam sterilization cycles at 121 °C of 30 minutes.
- Fiber/Particle release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Extractables** : Within limits as specified in USP
- EXPIRY** : 3 Years when stored in a cool and dry place.



Head of Quality Assurance  
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**An ISO 9001 Company**