

# Certificate of Quality

The Nylon-66 Membrane Disc Filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## Pre-sterilized Nylon-66 Membrane Disc Filters

Catalog No. : HNNX0901XXXX204  
Type : HNN-S  
Pore Size : 0.2  $\mu$ m  
Diameter : 47 mm  
Lot Number : 2287G  
Ster. No. : 012  
Expiry Date : 2020 - 07

### 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** :  $\geq 12$  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.
- HPLC Test** : The filter did not add artifacts to the sample when tested with HPLC.
- Sterility** : Samples passed the sterility test in accordance with U.S. Pharmacopoeia.

### VALIDATED FOR

- Fiber/Particle release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Extractables** : Within limits as specified in USP.



Head of Quality Assurance  
Issue Date: 24-Jul-17

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**An ISO 9001 Company**