

# Certificate of Quality

The Nylon-66 Membrane Cartridge Filter has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiSure NS Nylon-66 Membrane Cartridge Filter**

Catalog No. : CPNX5301E0SS101  
 Type : CPNS  
 Pore Size : 0.2 µm (0.45 µm + 0.2 µm)  
 Lot Number : CN6554L SI.No. 085  
 Manufacturing Date : 2024 - 12  
 Expiry Date : 2029 - 12

### SPECIFICATION

<b>Length</b>	5"
<b>Filter Media</b>	Nylon-66 Membrane
<b>Drainage Layers</b>	Polyester
<b>Plastic Components</b>	Polypropylene
<b>Differential Pressure</b>	< 3.5 Kg/cm <sup>2</sup> at 25°C
<b>Maximum operating Temperature</b>	80 °C at < 2 Kg/cm <sup>2</sup>
<b>Reverse Pressure</b>	< 0.7 Kg/cm <sup>2</sup> at 25°C

### LOT RELEASE CRITERIA

- 100% Integrity Tested** : The Cartridge filter has been tested for integrity by Air Diffusion test and Bubble point test using DI water.  
 Diffusion flow was: ≤ 15 ml/min @ 2.60 kg/cm<sup>2</sup>  
 Bubble point was: ≥ 50 psi (3.44 Bar)
- Typical Water Flow Rate** : 9 lpm @ 0.70 Kg/cm<sup>2</sup> @ 27 °C
- Microbial Challenge Test** : Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.
- VALIDATED FOR**
- Bubble point (50% IPA)** : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 17 psi (1.17 Bar)
- Sterilization** : In-line steam sterilizable/Autoclavable @ 121°C for 30 minutes @ differential pressure of < 3psi (< 0.2 Kg/cm<sup>2</sup>).
- Extractable Bacterial Endotoxin** : Within limits as specified in USP.  
 : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
- Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
- Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)1(i).
- Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).
- Total Organic Carbon** : Meets USP <643> limit of 500 ppb for total organic carbon after flushing specified volume of water for injection.
- Conductivity** : Meets USP <645> limit of 1.3 µS/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

### CUSTOMER SUPPORT

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

T. No.: COQ/CAR/002-02



Head of Quality Assurance

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### **Advanced Microdevices Pvt. Ltd.**

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**An ISO 9001 Company**