

# 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. : CPN55301E0SS101  
 Type : CPNS  
 Pore Size : 0.2  $\mu\text{m}$  (0.8  $\mu\text{m}$  + 0.2  $\mu\text{m}$ )  
 Lot Number : CN9287G      Sl.No. 004

### 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:  $\leq 15$  ml/min @ 2.60 kg/cm<sup>2</sup>  
 Bubble point was:  $\geq 50$  psi (3.44 Bar)  
 The capsule filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.  
 Bubble point with 50% IPA/Water solution is  $\geq 17$  psi (1.17 Bar)
- Water Flow Rate** :  $\geq 12$  lpm @ 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

- Extractable** : Within limits as specified in USP.
- 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).

### CUSTOMER SUPPORT

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



Head of Quality Assurance

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**An ISO 9001 Company**