

# Certificate of Quality

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

## **AseptiCap NNZ Nylon-66 Membrane Capsule Filters**

Catalog No. : DNNZ5101AAXX101  
 Type : DNNZ  
 Pore Size : 0.2 µm  
 Lot Number : DN8567G      Sl.No. 005

### SPECIFICATION

<b>Length</b>	1"
<b>Filter Media</b>	Positively charged Nylon-66 Membrane
<b>Drainage Layers</b>	Polyester
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Housing</b>	Polypropylene
<b>Maximum Operating Temperature</b>	80 °C @ < 2 Kg/cm <sup>2</sup>

### LOT RELEASE CRITERIA

- 100% Integrity Tested** : The capsule filter has been tested for integrity by Bubble point Test using 50% IPA/Water solution. Bubble point was:  $\geq 17$  psi (1.17 Bar)
- Water Flow Rate** :  $\geq 600$  ml/min @ 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**