

# 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 NS Nylon-66 Membrane Capsule Filters**

Catalog No. : DNSX5701BBXX101  
 Type : DNS  
 Pore Size : 0.2 µm (0.45 µm + 0.2 µm)  
 Lot Number : DN8567G      SI.No. 045

### SPECIFICATION

<b>Length</b>	8"
<b>Filter Media</b>	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 DI water. Bubble point value with DI water was: ≥ 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 ≥ 17 psi (1.17 Bar)

#### **Water Flow Rate**

: ≥ 14 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 F838-05 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**