

# Certificate of Quality

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

## AseptiCap Nano PES Membrane Capsule Filters

Catalog No. : DKNX52S7DDXX101  
 Type : DKN  
 Pore Size : Sterilizing Grade  
 Lot Number : DK9883L SI.No. 063  
 Manufacturing Date : 2023 - 12  
 Expiry Date : 2028 - 12

### SPECIFICATION

<b>Length</b>	2"
<b>Filter Media</b>	Polyethersulfone Membrane
<b>Drainage Layers</b>	Polyester
<b>Housing</b>	Polypropylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Maximum Operating Temperature</b>	80 °C @ < 2 Kg/cm <sup>2</sup>
<b>Sterilization</b>	3 autoclaving cycles at 125 °C of 30 minutes each

### LOT RELEASE CRITERIA

#### 100% Integrity Tested

: The capsule filter has been tested for integrity by Air Diffusion Flow test using DI water. Diffusion flow with DI water was:  $\leq 1.2 \text{ ml/min @ } 1.41 \text{ kg/cm}^2 \text{ (20 psi)}$

#### Typical Water Flow Rate

: 3.0 lpm @ 0.70 Kg/cm<sup>2</sup> @ 27 °C

#### Microbial Challenge Test

: LRV > 7 for *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

### VALIDATED FOR

#### Bacterial Endotoxin

: Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.

#### Heat Stability

: Maintains integrity after 3 autoclaving cycles at 125 °C of 30 minutes each.

#### Extractable

: Within limits as specified in USP.

#### Oxidizable matter

: Passes test as per 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).

#### 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  $\mu\text{S/cm}$  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/CAP/001-02



Head of Quality Assurance

Issue Date: 30-Dec-23

### Advanced Microdevices Pvt. Ltd.

Jawahargarh Road,  
 Village-Tepla, Ambala, INDIA.  
 Tel: +91-171-2699290/2699274  
 Website: www.mdimembrane.com  
 Email: info@mdimembrane.com

**An ISO 9001 Company**