

# 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 KSPES Membrane Capsule Filters**

Catalog No. : LKSX5401QQXX101  
 Type : LKS  
 Pore Size : 0.2  $\mu\text{m}$  (0.45  $\mu\text{m}$  + 0.2  $\mu\text{m}$ )  
 Lot Number : LK8827G      SI.No. 004

### SPECIFICATION

<b>Length</b>	10"
<b>Filter Media</b>	Polyethersulfone 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>
<b>Sterilization</b>	25 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 and Bubble Point test using DI water.  
 Diffusion flows with DI water were:  $\leq 30 \text{ ml/min @ } 2.60 \text{ kg/cm}^2$   
 Bubble point value with DI water was:  $\geq 50 \text{ psi (3.44 Bar)}$   
 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  $\geq 16 \text{ psi (1.10 Bar)}$

#### Water Flow Rate

:  $\geq 30 \text{ lpm @ } 0.70 \text{ Kg/cm}^2 \text{ @ } 27 \text{ }^\circ\text{C}$

#### 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

#### Heat Stability

: Maintains integrity after 25 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>.

#### Cytotoxicity

: Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.

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

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**An ISO 9001 Company**