

# 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**.

## BioPro KSO-γ PES Membrane Capsule Filters

Catalog No. : DBKO5701DDXX301  
 Type : DBKSO-S  
 Pore Size : 0.2 μm  
 Lot Number : DK9863E      SI.No. 056  
 Ster. No. : R5623  
 Date of Sterilization : 2023 - 05  
 Expiry Date : 2025 - 05

### SPECIFICATION

<b>Length</b>	8"
<b>Filter Media</b>	Polyethersulfone Membrane
<b>Drainage Layers</b>	Polypropylene
<b>Housing</b>	Polypropylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Maximum Operating Temperature</b>	80 °C @ < 2Kg/cm <sup>2</sup>
<b>Sterilization</b>	Pre sterilized by Gamma Irradiation dose between 25 kGy to 40 kGy

### LOT RELEASE CRITERIA

**100% Integrity Tested** : The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point was: ≥ 30 psi (2.07 Bar).  
**Typical Water Flow Rate** : 13 lpm @ 0.70 Kg/cm<sup>2</sup> @ 27 °C

### VALIDATED FOR

**Sterility** : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10<sup>-6</sup> in accordance with ISO 11137.  
**Microbial Challenge Test** : Retains ≥ 10<sup>5</sup> organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge.  
**Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.  
**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).  
**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 μS/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/004-02



Head of Quality Assurance

### 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**