

# 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.	: LBKO5601EEXT301
Type	: LBKSO-S
Pore Size	: 0.2 μm
Lot Number	: LK9931B      SI.No. 012
Ster. No.	: R111
Date of Sterilization	: 2021 - 02
Expiry Date	: 2023 - 02

### SPECIFICATION

<b>Length</b>	30"
<b>Filter Media</b>	Polyethersulfone Membrane
<b>Drainage Layers</b>	Polyethylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Housing</b>	Polypropylene
<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 filters have been tested for integrity by Air Diffusion test and Bubble point test using DI water.  
Diffusion flows were: ≤ 100 ml/min @ 1.54 kg/cm<sup>2</sup>  
Bubble point was: ≥ 30 psi (2.07 Bar)
- Typical Water Flow Rate** : 105 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>.
- 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.**  
21, Industrial Area, Ambala Cantt, INDIA,  
Tel: +91-171-2699290/ 2699274  
Website: www.mdimembrane.com  
Email: info@mdimembrane.com

**An ISO 9001 Company**