mdi
Membrane Technologies

# 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 KSO-γ* PES Membrane Capsule Filters

Catalog No. : LKOX5401EERT101
Type : LKSO
Pore Size : 0.2 µm (0.45 µm + 0.2 µm)
Lot Number : LK5547I Sl.No. 005

**SPECIFICATION**

| | |
|---|---|
| **Length** | 10” |
| **Filter Media** | Polyethersulfone Membrane |
| **Drainage Layers** | Polypropylene |
| **Housing** | Polypropylene |
| **Differential Pressure** | < 4Kg/cm² at 30 °C |
| **Maximum Operating Temperature** | 80 °C @ < 2 Kg/cm² |
| **Sterilization** | Can be sterilized by Gamma Irradiation upto 50 kGy |

**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: ≤ 30 ml/min @ 2.60 kg/cm²
Bubble point value with DI water was: ≥ 50 psi (3.44 Bars)
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 ≥ 16 psi (1.10 Bars)

**Water Flow Rate** : ≥ 25 lpm @ 0.70 Kg/cm² @ 27 ºC

**Microbial Challenge Test** : Retains ≥ $10^7$ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

**VALIDATED FOR**

**Autoclavability** : Autoclavable once at 125 °C for 30 minutes after gamma irradiation @ 50 kGy.

**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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**An ISO 9001 Company**