

Certificate of Quality

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

AseptiSure KSPES Membrane Cartridge Filters

Catalog No. : CPKX5436A0SS101
 Type : CPPKS
 Pore Size : 0.1 μm (0.45 μm + 0.1 μm)
 Lot Number : CK8530C SI.No. 004

SPECIFICATION

Length	10"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm ² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm ²
Reverse Pressure	< 0.7 Kg/cm ² at 25°C
Sterilization	25 Autoclave/ Steam sterilization cycles at 121°C for 30 minutes each

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The Cartridge filters have been tested for integrity by Air Diffusion Flow Test using purified water and Bubble Point Test using 50% IPA/Water solution.
 Diffusion flows were: ≤ 29 ml/min @ 3.52 kg/cm²
 Bubble point with was: ≥ 31 psi (2.14 Bar).
- Water Flow Rate** : ≥ 18 lpm @ 0.70 Kg/cm² @ 27 °C
- Microbial Retention** : Retains $\geq 10^7$ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

- Heat Stability** : Maintains integrity after 25 autoclave/ Steam sterilization cycles at 121°C for 30 minutes each.
- 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.
- 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