mdi
Membrane Technologies

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 KS PES Membrane Cartridge Filters

Catalog No. : CPKX5436A0SS101

Type : CPPKS

Pore Size : 0.1 µm (0.45 µm + 0.1 µm)

Lot Number : CK8987G Sl.No. 011

SPECIFICATION

Length	10”
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm²
Reverse Pressure	< 0.7 Kg/cm² 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 has been tested for integrity by Air Diffusion flow test using DI water. Diffusion flows were: ≤ 29 ml/min @ 3.52 kg/cm²

Water Flow Rate : ≥ 7.5 lpm @ 0.70 Kg/cm² @ 27 ºC

VALIDATED FOR

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

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