

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. : CPK15036E0SS101
Type : CPPKS
Pore Size : 0.1 μ m (0.2 μ m + 0.1 μ m)
Lot Number : CK8887G Sl.No. 005

SPECIFICATION

Length	2.5"
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 Bubble Point Test using 50% IPA/Water solution.
Bubble point with was: \geq 31 psi (2.14 Bar).

Water Flow Rate : \geq 4.0 lpm @ 0.70 Kg/cm² @ 27 °C

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

Issue Date: 22-Jul-17

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An ISO 9001 Company

Certificate of Quality

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AseptiSure KS PES Membrane Cartridge Filters

Catalog No. : CPKX5301G0XX101
Type : CPPKS
Pore Size : 0.2 μ m (0.45 μ m + 0.2 μ m)
Lot Number : CK5547I SI.No. 012

SPECIFICATION

Length	5"
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 filter has been tested for integrity by Air Diffusion Flow test and Bubble Point test using DI water.
Diffusion flows with DI water were: ≤ 15 ml/min @ 2.60 kg/cm²
Bubble point value with DI water was: ≥ 50 psi (3.44 Bars)
The cartridge 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

: ≥ 7.0 lpm @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test

: 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.

Extractable

: Within limits as specified in USP.

Oxidizable matter

: Passes test as per USP.

Bacterial Endotoxins

: Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.

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).

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Issue Date: 11-Sep-17

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