

Certificate of Quality

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

ClariSure GK Membrane Prefilter Cartridge

Catalog No. : CGKX5504A0SS101
 Type : CPGK
 Pore Size : 0.5 µm (Nominal)
 Lot Number : CK8567G SI.No. 005

SPECIFICATION

Length	20"
Filter Media	Polyethersulfone Membrane with Microglassfiber Prefilter
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

LOT RELEASE CRITERIA

100% Integrity Tested : The cartridge filters have been tested for integrity by Air Diffusion flow test using 50% IPA/Water solution. Diffusion flows were: ≤ 90 ml/min @ 0.21 kg/cm²

Water Flow Rate : ≥ 70 lpm @ 0.70 Kg/cm² @ 27 °C

VALIDATED FOR

Sterilization : 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>.

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