

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. : CGKX5304E0SS101
 Type : CPGK
 Pore Size : 0.5 µm (Nominal)
 Lot Number : CK9694L SI.No. 045
 Manufacturing Date : 2024 - 12
 Expiry Date : 2029 - 12

SPECIFICATION

Length	5"
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: ≤ 22 ml/min @ 0.21 kg/cm²

Typical Water Flow Rate : 22 lpm @ 0.70 Kg/cm² @ 27 °C

VALIDATED FOR

Sterillization : 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.

T. No.: COQ/CAR/004-04



Head of Quality Assurance

Issue Date: 17-Dec-24

Advanced Microdevices Pvt. Ltd.

Jawahargarh Road,
 Village-Tepla, Ambala, INDIA.
 Tel: +91-171-2699290/2699274
 Website: www.mdimembrane.com
 Email: info@mdimembrane.com

An ISO 9001 Company