



# Certificate of Quality

## Product Information

Product :

Pleated Cartridge Filter

Description:

30" cartridge filter PES- 0.45

micron ,226Fin ,Silicone

Lot No:

KY25A05C0304001

Pore Size: 0.45um

Quantity: 50

Date of Manufacture: 040225

Expiration: 040128

## ISO 9001 Quality Standard

This product was manufactured in a facility whose Quality Management System has certified to the ISO 9001 Quality Systems Standard.

## Integrity Testing

This product has passed a non-destructive integrity test in the process of manufacture to the specification of

**Minimum Bubble Point in water:**

1800mbar

## Biosafety

All materials of this product meet the criteria of the USP<88>Biological Reactivity Test for Class VI Plastics and ,FDA Indirect Food Additive requirements cited in 21CFR177.2910, 21CFR177-182.

## Non-Fiber Releasing

This product meet the criteria of “non-fiber releasing” filter that defined in 21CFR.210.3 (b) (6).

## Oxidizable Substances

Effluent of sterilized sample filters was negative after a water flushing 1000 ml per 10”.

## Extractable Substances

Sample filters were immersed in DI Water for 24 hours at 25°C. Extractable substances were equal to or less than 15mg per 10”.

## Thermal Stress

Sample filters maintained integrity following multiple cycles of in-situ steam.

30 cycles 121°C, 30min,