

Change Notice No.	Notification date	Implementation date
CN/16/01	18 <sup>th</sup> February 2016	18 <sup>th</sup> March 2016

**Subject** : Inclusion of Bubble Point Specification with 50% Isopropyl alcohol/water solution in Certificate of Quality (CoQ) for Polyethersulfone Membrane Inline Filters

**Scope** : This change notification will affect the Certificate of Quality (CoQ) of products with following catalog numbers: (\* can be any alphabet or numeral):

- IGK21001\*\*\*\*\*
- IGKS1001\*\*\*\*\*
- IKGX0801\*\*\*\*\*
- IKGX0802\*\*\*\*\*
- IKGX1001\*\*\*\*\*
- IKLX0601\*\*\*\*\*
- IKLX1001\*\*\*\*\*
- IKLX1002\*\*\*\*\*
- IKS50601\*\*\*\*\*
- IKSX0601\*\*\*\*\*
- IKSX1001\*\*\*\*\*
- VK2X1001\*\*\*\*\*
- VKLO1001\*\*\*\*\*
- VKLX1001\*\*\*\*\*
- VKS51001\*\*\*\*\*
- VKS51002\*\*\*\*\*
- VKSX1001\*\*\*\*\*
- VKXG1001\*\*\*\*\*
- VKXL1001\*\*\*\*\*
- VKXX1001\*\*\*\*\*

**Background:**

To incorporate Integrity test specifications with low surface tension reference fluid (as suggested by PDA Technical report No. 26, Revised 2008 on Sterilizing Filtration of Liquids) for preliminary trouble shooting in case of integrity failure with purified water, certain changes have been made in the Certificate of Quality (CoQ) for Polyethersulfone membrane Inline filters with above mentioned catalog numbers.

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**Need for Change:**

According to PDA Technical report No. 26, Revised 2008 on Sterilizing Filtration of Liquids, if a sterilizing filter fails integrity test, it could be damaged, but there may be other causes for the failure that include incorrect assembly (incomplete sealing) and incomplete/improper wetting. Filter damage or other possible reasons may be distinguished by retesting of failed filter after rewetting as per the specification or apply more aggressive wetting conditions e.g. increased flush volume/time, increased pressure, etc. or wetting of filter with lower surface tension reference fluid e.g. Isopropyl alcohol. If filter passes integrity test at any point mentioned above, it can be considered integral.

**How Does It Affect the User:**

From a practical point of view it is only a 'paper change' and in no way will affect the properties and performance characteristics of the product under actual conditions of use. All performance specification and attributes remains unchanged.

Certificate of quality (CoQ) for above mentioned products will now have Bubble Point specification with 50% Isopropyl alcohol/water solution in addition to integrity test specification with purified water.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



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**Advanced Microdevices Pvt. Ltd.**