

ADVANCED MICRODEVICES PVT. LTD.

20 - 21, INDUSTRIAL AREA, AMBALA CANTT – 133 001, INDIA Phone : + 91 - 171 - 2699290, 2699471, 2699274 Website: www.mdimembrane.com

Change Notice No.	Notification date	Implementation date
CN/19/007	June 10, 2019	July 10, 2019

Subject : Addition of Bacterial Retention test in Certificate of Quality for mdi 0.1µm rated Products

Scope : This change notification will affect the products with following catalog numbers: (# can be any alphabet or numeral):

- AK####36######
- CH2###36######
- CHR###36######
- CPH###36######
- CPK###36######
- CPM###36######
- DK####36######
- DN####36######
- DP####36######

- DW####36######
- HVF###36######
- IK####36######
- LK####36######
- LW####36######
- MD####36######
- NN####36######
- VK####36######

Background:

In our efforts to provide the user updated information regarding the products they are using, it has been decided to make certain addition in the contents of the Certificate of Quality (CoQ) for **mdi** Products with catalog numbers as mentioned above.

Need for Change:

mdi Products with catalog numbers as mentioned above have been validated for Bacterial Retention Test with *B. diminuta* (ATCC 19146) as per the methodology mentioned in ASTM F838-05 (Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration) and are being tested for the same on lot basis as well. But, the compliance to this test is not reflecting in current Certificate of Quality (CoQ). Hence, the Certificate of Quality (CoQ) for **mdi** Products with catalog numbers as mentioned above has been updated with inclusion of Bacterial Retention test as a lot release criteria. No change has been done in any other critical dimensions or materials of construction or manufacturing process of **mdi** 0.1µm rated products.



ADVANCED MICRODEVICES PVT. LTD.

20 - 21, INDUSTRIAL AREA, AMBALA CANTT – 133 001, INDIA Phone : + 91 - 171 - 2699290, 2699471, 2699274 Website: www.mdimembrane.com

Change Notice No.	Notification date	Implementation date
CN/19/007	June 10, 2019	July 10, 2019

How Does It Affect the User:

From a practical point of view this change specifically states the compliance to Bacterial Retention Test with *B. diminuta* (ATCC 19146) as per ASTM F838-05. The test was already being carried out but the compliance was not stated/reflected in the Certificate of Quality (CoQ). All product specifications including materials of construction as well as performance specifications remain unchanged. The accompanying product literature e.g. Certificate of quality, validation guide, product data sheet etc. will reflect the said change.

Implementation of Change:

mdi Products with catalog numbers as mentioned above, manufactured after the implementation date (**July 10, 2019**) will have the said changes. However, the available stock of **mdi** Products having Certificate of Quality (CoQ) without Bacterial Retention Test will be received by you till the stocks last.

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

Head - Quality Assurance Advanced Microdevices Pvt. Ltd.