

# ADVANCED MICRODEVICES (PVT.) LTD.

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| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/17/20          | November 01, 2017 | December 01, 2017   |

## Subject : Addition of Bubble Point Test Specification to the Certificate of Quality (CoQ) of **mdi** Membrane Cartridge Filters with size 20" and 30"

- Scope : This change notification will affect the products with following catalog numbers: (# can be any alphabet or numeral):
  - CH2#55########
  - CHR#55#########
  - CKH755#########
  - CKH756#########
  - CNZ#55#########
  - CNZ#56########
  - CPH#55#########
  - CPH#56########
  - CPK#55#########
  - CPK#56########
  - CPM#55#########
  - CPM#56#########
  - CPN#55########
  - CPN#56########
  - CPT#55#########
  - CPT#56########

### **Background:**

In our efforts to provide the user/customer with updated and latest information with regards to filter integrity and performance, certain changes have been made to the contents of the CoQ of **mdi** Membrane Cartridge Filters with catalog numbers as mentioned above.

The CoQ for above mentioned product types will now have the Bubble Point Test specifications in addition to the Diffusion Flow Test specifications. This will enable the customer to perform the Integrity test of the filter by Bubble Point Test also.



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#### Need for Change:

**mdi** Membrane Cartridge Filters with catalog numbers as mentioned above can be tested for integrity with reference wetting fluid by subjecting the filters to both Diffusion Flow Test as well as Bubble Point Test. But, the specification of Bubble Point Test is not reflecting in current CoQ for cartridge filters of sizes 10" and 20" having large filtration area.

Existing Electronic Integrity Test equipments are capable to perform Integrity testing of large area filters by Bubble point test and require Bubble point test specification for these large area filters. To incorporate this information, the CoQ for **mdi** Membrane Cartridge Filters with catalog numbers as mentioned above has been updated with inclusion of Bubble Point Test specifications.

In addition to the above, for hydrophilic filters, the specification of minimum Bubble Point with lower surface tension refernce fluid (50% IPA/Water solution) as recommended by PDA Technical report No. 26, Revised 2008 on Sterilizing Filtration of Liquids for troubleshooting in case integrity failure with reference wetting fluid has also been added in CoQ for **mdi** Membrane Cartridge Filters with catalog numbers.

### How Does It Affect the User:

From a practical point of view this change only affect the CoQ of above mentioned product types by providing additional information in the form of Bubble Point Test specification to enable the customer to perform the integrity test of the cartridge filters by Bubble Point Test. All product attributes and performance specifications remain unchanged. The accompanying CoQ will reflect the said change.

- Hydrophilic Nylon Membrane Cartridge Filters addition of Bubble Point Test specifications with purified water and 50% IPA/Water solution (low surface tension reference fluid).
- Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters addition of Bubble Point Test specifications with purified water and 50% IPA/Water solution (low surface tension refernce fluid).
- Hydrophobic PTFE Membrane Cartridge Filters addition of Bubble Point Test specifications
  with 70% IPA/Water solution.



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### Implementation of Change:

**mdi** Membrane Cartridge Filters with catalog numbers as mentioned above, manufactured after the implementation date (**December 01, 2017**) will have the said changes. However, the available stock of **mdi** Membrane Cartridge Filters with catalog numbers as mentioned above having CoQ without Bubble Point Test Specification 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.