

Change Notice No.	Notification date	Implementation date
CN/F/20/002	March 20, 2020	May 20, 2020

Subject : Rationalization of Minimum Acceptable Bubble Point specification of Hydrophobic PTFE Membrane Disc Filters type TF2

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

- TF2###01####1##
- TF2###01####2##

Background:

In our efforts to inform the user updated information regarding the products they are using, certain changes have been done in the minimum acceptable Bubble Point specification of MDI Hydrophobic PTFE Membrane Disc Filters type TF2 having catalog numbers as mentioned above. The specification for minimum acceptable Bubble Point has been re-defined from 28 psi (1.93 bar) to 22 psi (1.52 bar).

Need for Change:

The specification for minimum acceptable Bubble point of MDI Hydrophobic PTFE Membrane Disc Filters type TF2 with catalog numbers as mentioned above is specified as 28 psi (1.93 bar) in the certificate of Quality (CoQ). However, the specification for minimum acceptable Bubble point of other MDI Hydrophobic PTFE Membrane products (e.g capsule filters, cartridge filters, Inline filters etc.) is specified as 22 psi (1.52 bar). The MDI products with minimum Bubble point of 22 psi (1.52 bar) are validated to retain $\geq 10^7$ organisms/cm² of *B. diminuta* (ATCC 19146) challenge as per ASTM F838-05 methodology.

To overcome this discrepancy, the specification for minimum acceptable Bubble point of MDI Hydrophobic PTFE Membrane Disc Filters type TF2 with catalog numbers as mentioned above has been re-defined to 22 psi (1.52 bar), same as that of the rest of the products manufactured using the Hydrophobic PTFE Membrane. The change will be reflected in the Certificate of Quality (CoQ) of MDI Hydrophobic PTFE Membrane Disc Filters type TF2 with catalog numbers as mentioned above. No change has been done in materials of construction, manufacturing process, test methodology and product attributes (including Bacterial Retention). The change will have no impact whatsoever on the product regulatory compliance.

Change Notice No.	Notification date	Implementation date
CN/F/20/002	March 20, 2020	May 20, 2020

How Does It Affect the User:

From the user point of view, this change only re-defines the Bubble point of Hydrophobic PTFE Membrane Disc Filters type TF2 to 22 psi (1.52 bar) and aligned the specifications with the specification of other products manufactured using the Hydrophobic PTFE Membrane. All other product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product's Certificate of quality (CoQ).

Implementation of Change:

MDI Hydrophobic PTFE Membrane Disc Filters type TF2 with catalog numbers as mentioned above, released after the implementation date will have the said changes in the CoQ. However, the available stock of MDI Hydrophobic PTFE Membrane Disc Filters type TF2 with catalog numbers as mentioned above having CoQ with specification for minimum acceptable Bubble point as 28 psi (1.93 bar) 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.