

Change Notice No.	Notification date	Implementation date
CN/F/24/003	March 07, 2024	March 20, 2024

Subject : Tightening of 50% IPA/Water solution wetted minimum bubble point specification for **mdi** 0.2 µm Polyethersulfone (PES) and hydrophilic PVDF membrane filters

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

- CH2###01#####
- CHR###01#####
- CK#####
- CPH###01#####
- CPK###01#####
- CPM###01#####
- CW###01#####
- DK2###01#####
- DKL###01#####
- DKO###01#####
- DKS###01#####
- DKX7###01#####
- DP###01#####
- DW###01#####
- IHX###01#####
- IKD###01#####
- IKG###01#####
- IKL###01#####
- IKO###01#####
- IKS###01#####
- IKX7###01#####
- IPGX###01#####
- IW###01#####
- LKL###01#####
- LKO###01#####
- LKS###01#####
- LKX7###01#####
- LW###01#####
- MDKL###01#####
- VK2X###01#####
- VKG4###01#####
- VKL###01#####
- VKS###01#####
- VKX7###01#####
- VW###01#####

Background:

This advance change notification is initiated to provide the user updated information regarding the products they are using. The 50% IPA/Water solution wetted minimum bubble point specification (as mentioned in product related literature) of **mdi** 0.2 µm Polyethersulfone (PES) and hydrophilic PVDF membrane filters with catalog numbers as mentioned in the scope shall be upgraded/ tightened from existing 16 psi to 18 psi.

The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

mdi 0.2 µm Polyethersulfone (PES) and hydrophilic PVDF membrane filters with catalog numbers as mentioned in the scope are tested and certified/validated for integrity by bubble point test using 50% IPA/Water solution as wetting agent. The minimum specification of 16 psi is defined for 50% IPA/Water solution wetted bubble point and same is reflecting in different product related literature such as Certificate of Quality (CoQ), validation guide etc.

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Based on the trends analysis of data of these products, the minimum 50% IPA/water solution wetted bubble point has always been more than 18 psi. So, it has been decided to upgrade/tightens the specification for minimum bubble point with 50% IPA/water solution from existing 16 psi to 18 psi.

No changes have been made to the materials of construction or performance parameters or manufacturing process or critical dimensions or traceability.

How Does It Affect the User:

From a practical point of view this change will re-define the specification for minimum bubble point with 50% IPA/Water solution from existing 16 psi to 18 psi. All product attributes/specifications including materials of construction as well as other performance specifications remain unchanged. The said change will be reflected in the accompanying Certificate of quality.

The related product literature such as certificate of quality, validation guide, etc. will reflect the said changes.

Implementation of Change:

mdi 0.2 µm Polyethersulfone (PES) and hydrophilic PVDF membrane filters with catalog numbers as mentioned in the scope, released after the implementation date will have the said changes. However, the available stock of **mdi** 0.2 µm Polyethersulfone (PES) and hydrophilic PVDF membrane filters with catalog numbers as mentioned in the scope, having minimum bubble point specification of 16 psi with 50% IPA/Water solution mentioned in product related literature, 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'.



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