

Change Notice No.	Notification date	Implementation date
CN/F/24/001	February 20, 2024	March 20, 2024

Subject : Change in lot release criteria for **mdi** Hydrophilic membrane filters

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

- CGK###01#####
- CH2###01#####
- CHR###01#####
- CHR###02#####
- CK#####
- CNZ#####
- CPH###01#####
- CPH###02#####
- CPK###01#####
- CPK###02#####
- CPM###01#####
- CPM###02#####
- CPN###01#####
- CPN###02#####
- CW###01#####
- CW###02#####
- DGN###01#####
- DK2###01#####
- DKL###01#####
- DKL###02#####
- DKO###01#####
- DKO###02#####
- DKS###01#####
- DKS###02#####
- DKX7###01#####
- DN###01#####
- DN###02#####
- DP###01#####
- DP###02#####
- DW###01#####
- DW###02#####
- IGK###01#####
- IHX###01#####
- IKD###01#####
- IKG###01#####
- IKG###02#####
- IKL###01#####
- IKL###02#####
- IKO###01#####
- IKS###01#####
- IKS###02#####
- IKX7###01#####
- IN###01#####
- IN###02#####
- IW###01#####
- IW###02#####
- LKL###01#####
- LKL###02#####
- LKO###02#####
- LKS###01#####
- LKS###02#####
- LKX7###01#####
- LKX7###02#####
- LN###01#####
- LN###02#####
- LW###01#####
- LW###02#####
- VGK###01#####
- VK2X###01#####
- VKG4###01#####
- VKG4###02#####
- VKL###01#####
- VKL###02#####
- VKS###01#####
- VKS###02#####
- VKX7###01#####
- VN###01#####
- VN###02#####
- VW###01#####
- VW###02#####

Background:

This advance change notification is initiated to provide the user correct information regarding the products they are using. The lot release criteria, with respect to bubble point with 50% IPA/Water solution, specified in the Certificate of Quality (CoQ) of **mdi** hydrophilic membrane filters **having** catalog numbers as mentioned in the scope has been changed/updated.

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

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Need for Change:

The integrity testing (100%) of **mdi** hydrophilic membrane filters having catalog numbers as mentioned in the scope is performed by subjecting the water wetted filters to bubble point test. The water wetted bubble point values are specified as lot release criteria in the CoQ of these products.

In addition to 100% bubble point testing with water, these filters are also certified/validated for integrity by bubble point test using 50% IPA/Water solution as wetting agent. However, this is not a 100% testing and not a lot release criteria. The way it is mentioned in CoQ giving information that it is a part of 100% integrity testing.

To correct this misinterpretation, the COQ for **mdi** hydrophilic membrane filters having catalog numbers as mentioned in the scope shall be updated/corrected.

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 bubble point with 50% IPA/Water solution as a validation activity and corrects the wrong interpretation regarding the same. All product 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.

Implementation of Change:

mdi hydrophilic membrane filters having catalog numbers as mentioned in the scope, released after the implementation date, will have an updated COQ having bubble point using 50% IPA/Water solution mentioned as a validation activity. However, the available stock of **mdi** hydrophilic membrane filters with catalog numbers as mentioned in the scope and with CoQ having bubble point with 50% IPA/Water solution mentioned as a lot release criteria 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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