

Change Notice No.	Notification date	Implementation date
CN/17/26	November 15, 2017	December 15, 2017

Subject : Change in lot release criteria for nominally rated **mdi** Capsule filter types *BioPro* KS and *BioPro* KSO

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

- DBKO##01#####
- DBKS##01#####
- DBKS##36#####
- LBKO##01#####
- LBKS##01#####

Background:

In our efforts to convey the user/customer updated information regarding the products they are using, certain changes have been done in respective product literature such as CoQ, validation guide, data sheet etc. of **mdi** Capsule filters with catalog numbers as mentioned above. The frequency of Microbial Challenge Test (Microbial Retention) has been changed from a lot release activity to validation activity.

Need for Change:

mdi capsule filters with catalog numbers as mentioned above have been validated for Microbial Retention Test with *B. diminuta* ATCC 19146 and are being tested for the same on lot basis as well. Since these capsule filters are nominally rated filters and used for bio burden reduction only, Microbial Challenge Testing with *B. diminuta* ATCC 19146 on every lot is an overkill. Hence, it has been decided that the Microbial Challenge Test with *B. diminuta* ATCC 19146 shall be removed from lot release criteria of **mdi** Capsule filters with catalog numbers as mentioned above. However, the same will be carried out during validation and will be reflected as validation activity in respective documents. No change has been done in any critical dimensions or materials of construction or manufacturing process or other performance parameters.

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

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How Does It Affect the User:

From a practical point of view this change only re-defines the lot release criteria in terms of Microbial Challenge Testing with *B. diminuta* ATCC 19146 based on criticality of use. All other product specifications including materials of construction as well as other performance specifications remain unchanged. The said changes will be reflected in the accompanying product literature e.g. Certificate of quality, validation guide, etc.

Implementation of Change:

mdi Capsule filters with catalog number as mentioned above, manufactured after the implementation date (**December 15, 2017**) will have the said changes. However, the available stock of **mdi** Capsule filters with catalog numbers as mentioned below having Microbial Challenge Testing with *B. diminuta* ATCC 19146 as 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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