

Change Notice No.	Notification date	Implementation date
CN/18/09	September 10, 2018	October 10, 2018

Subject : Change in lot release criteria for mdi 0.8µm rated Products

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

- CN####03#####
- CP####03#####
- DK####03#####
- DN####03#####
- DP####03#####
- GC####03#####
- GM####03#####
- HN####03#####
- NN####03#####
- PL####03#####
- RG####03#####

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, data sheet etc. of **mdi** Products with catalog numbers as mentioned above. The Microbial Challenge Test (Microbial Retention Test) has been removed from lot release criteria and will be performed at the time of validation only.

Need for Change:

mdi Products with catalog numbers as mentioned above have been validated for Microbial Retention Test with *Staphylococcus aureus* (ATCC 6538) and are being tested for the same on lot basis as well. Since these products are used for bio burden reduction only, Microbial Challenge Testing with *Staphylococcus aureus* (ATCC 6538) on every lot is an overkill. Hence, it has been decided that the Microbial Challenge Test with *Staphylococcus aureus* (ATCC 6538) shall be removed from lot release criteria of **mdi** Products 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.

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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 *Staphylococcus aureus* (ATCC 6538). 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, product data sheets etc.

Implementation of Change:

mdi Products with catalog numbers as mentioned above, manufactured after the implementation date (**October 10, 2018**) will have the said changes. However, the available stock of **mdi** products with catalog numbers as mentioned above having Microbial Challenge Test with *Staphylococcus aureus* (ATCC 6538) 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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