

| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/F/21/004 | March 15, 2021 | April 15, 2021 |

Subject: Improvement in the methodology used for microbial recovery testing of M-Funnels with black membranes

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

- FMCB0902#####

Background:

This change notice has been initiated to notify our customers/users about updated information regarding the products they are using. The Certificate of Quality (CoQ) of M-Funnels with catalog number as mentioned above has been updated with regards to Microbial Recovery testing. The change will have no impact whatsoever on the product performance or its regulatory compliance.

Need for Change:

MDI M-Funnels with black membranes are mainly used for enumeration of microorganisms such as *Candida albicans*, *Streptococcus pyogenes* and *Listeria monocytogenes* which have light colored colonies making these difficult to observe and enumerate against the white background of the commonly used M-Funnels with white membranes.

Although, the MDI M-Funnels with catalog number as mentioned above are tested on lot basis for microbial recovery with *Escherchia coli* (ATCC 8739), it has been decided to align the methodology used for microbial recovery testing of M-Funnels with black membrane in line with the intended use/application through use of test organism *Candida albicans* (ATCC 10231) instead of *Escherchia coli* (ATCC 8739) for routine testing. However, the acceptance criteria for microbial recovery testing shall remain the same. No change has been done in any product performance parameter or materials of construction or manufacturing process of MDI M-Funnels with black membrane.

How Does It Affect the User:

This change re-defines the test organism used for microbial recovery testing of M-Funnels with black membrane from existing *Escherchia coli* (ATCC 8739) to *Candida albicans* (ATCC 10231) to bring it in line with actual use conditions. All product specifications including materials of construction as well as performance specifications shall remain unchanged. The said change will be reflected in the accompanying Certificate of Quality (CoQ).

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Implementation of Change:

MDI M-Funnels with catalog numbers as mentioned above, manufactured/tested after the implementation date will have the said changes in the Certificate of Quality (CoQ). However, the available stock of the same having Certificate of Quality (CoQ) with microbial recovery of M-Funnels with *Escherchia coli* (ATCC 8739) will be supplied 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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