

Change Notice No.	Notification date	Implementation date
CN/F/24/006	April 27, 2024	May 04, 2024

Subject : Change in micro-organism used for microbial/bacterial retention test of 0.1µm rated membrane filters

Scope : This change will affect the 0.1µm rated membrane filters with following catalog numbers:
(# can be any alphabet or numeral):

- HVFX##36#####
- NNXX##36#####
- PLXX##36#####

Background:

In our efforts to improve/strengthen the product testing, a change has been initiated for microbial/bacterial retention test of **mdj** 0.1µm rated membrane filters having catalog numbers as mentioned in the scope. The microbial/bacterial challenge test shall be performed with *Acholeplasma laidlawii* (ATCC 23206) as challenge organism instead of existing *B. diminuta* (ATCC 19146). This advance change notification is initiated to provide the advance notification to the user.

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

Need for Change:

Every lot of **mdj** 0.1µm rated membrane filter is sampled and tested for microbial/bacterial retention of $> 10^7$ organisms/cm² of *B. diminuta* (ATCC 19146).

As, these membranes have already been validated for retention of high challenge level ($> 10^7$ organism/cm²) of *Acholeplasma laidlawii* (ATCC 23206) which is smaller in size. So, it has been decided to discontinue the microbial/bacterial retention testing with *B. diminuta* (ATCC 19146) and implement the lot basis microbial/bacterial retention testing with *Acholeplasma laidlawii* (ATCC 23206).

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

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How Does It Affect the User:

From a practical point of view this change will re-defines the challenge organism used for microbial/bacterial retention test of **mdi** 0.1µm membrane filters with catalog number as mentioned in the scope. All product specifications including materials of construction as well as performance specifications remain unchanged. The said changes will be reflected in the accompanying product literature e.g. Certificate of quality, product data sheets, validation guides etc.

Implementation of Change:

mdi products with catalog numbers as mentioned in the scope, manufactured after the implementation date will be tested for microbial/bacterial retention with *Acholeplasma laidlawii* (ATCC 23206) and compliance to the same will be reflected in accompanying product literature.

However, the available stock of **mdi** 0.1µm membrane filters with catalog number as mentioned in the scope and having microbial/bacterial retention test with *B. diminuta* (ATCC 19146) as challenge organism will be supplied til 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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