

Change Initiation No.	Pre-change notification date	Tentative date for formal notification
CI/F/24/009	August 16, 2024	November 01, 2024

Subject : Use of new mdi facility for manufacturing of mdi Polypropylene cartridge filters and Microglassfiber cartridge filters

Scope : This change shall affect all mdi Polypropylene cartridge filters and Microglassfiber cartridge filters

Background and description of change:

This pre-change notification is initiated to pre-notify our customers regarding the new mdi manufacturing facility which shall be used for manufacturing, testing, packaging and labeling of mdi Polypropylene cartridge filters and Microglassfiber cartridge filters. The dispatch of these cartridge filters shall also be done from the new mdi facility after its incorporation. The mdi new facility at site-II shall be qualified prior to use. The address for the new mdi facility is:

Advanced Microdevices Pvt. Ltd.

Jawahargarh Road,

Village - Tepla, Ambala, INDIA

Different manufacturing facilities at the above mentioned site are already being used for manufacturing of multiple products including membrane capsule and cartridge filters, Stericheck, Funnels, Single Use Systems etc.

The new manufacturing facility for mdi Polypropylene cartridge filters and Microglassfiber cartridge filters shall replace the existing mdi manufacturing facility having below mentioned address:

Advanced Microdevices Pvt. Ltd.

21, Industrial area

Ambala cant, INDIA

Change impact assessment:

Aspects	Impact assessment	Justification/rationale
Product quality	No impact	All manufacturing processes shall be re-validated prior to routine use.
Equipment/machine	No impact	1. All machines and equipment shall be qualified prior to use. 2. The measuring instruments/equipment shall be calibrated prior to use.

The change will have no impact whatsoever on the product performance or its regulatory compliance.

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Implementation of Change:

The new **mdi** manufacturing facility shall be made functional after completion of all the requirements including qualification and validation. The final change notification shall be done only after completion of all qualification and validation activities and **mdi** Polypropylene cartridge filters and Microglassfiber cartridge filters shall be manufactured in the new facility, only after the completion of the notified implementation period.

We will continue to share further updates regarding this facility as we progress towards qualification and validation.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



Head - Quality Assurance
Advanced Microdevices Pvt. Ltd.