

Change Notice No.	Notification date	Implementation date
CN/A/24/005	November 26, 2024	December 26, 2024

Subject : Addition of expiry in product label of mdi non sterile AseptiLiner and Single Use Assembly.

Scope : This change will affect the products with catalog number A#####1## (# can be any alphabet or numeral).

Background:

This change notification has been initiated to notify our customers about the additions made in the product label of mdi AseptiLiner and Single Use Assembly. The expiry year and month of mdi non sterile AseptiLiner and Single Use Assembly with catalog numbers as mentioned in scope shall be incorporated/added in product label.

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

Need for Change:

The customers/users require information regarding the expiry of mdi non sterile products. The expiry of mdi non sterile AseptiLiner and Single Use Assembly is 2 years and 6 months from manufacturing. The manufacturing year and month are traceable through a unique product lot number which includes codes for the month and year of manufacturing.

The expiry of mdi non sterile AseptiLiner and Single Use Assembly is also mentioned on the Certificate of Quality (CoQ).



In order to communicate the product expiry to the customer/user in a better way, same (Year and month of expiry) shall be added/incorporated in product label of mdi non sterile products with catalog numbers as mentioned above.

No change shall be done in any materials of construction or performance parameters or any critical dimensions or manufacturing process or packaging.

How Does It Affect the User:

From the user point of view, this is only a paper change in which product labels for above mentioned products shall be changed in terms of addition of expiry. All product specifications including material of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product labels (as shown in pictures below).

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EXISTING LABEL (WITHOUT EXPIRY)	PROPOSED LABEL (WITH EXPIRY)
<p>mdi Single Use Assembly</p> <p>Cat. No. : A5673XXXXXC101 Rev. No. : 03 Quantity : 1 Nos. Lot No. : AS1734F</p>  <p>ADVANCED MICRODEVICES PVT. LTD. www.mdimembrane.com</p>	<p>mdi Single Use Assembly</p> <p>Cat. No. : A4319XXXXXC101 Rev. No. : 01 Quantity : 1 Nos. Lot No. : AS1234A</p>  <p>⌚ 2026 - 07</p> <p>ADVANCED MICRODEVICES PVT. LTD. www.mdimembrane.com</p>

Expiry year and month

Implementation of Change:

mdi non sterile AseptiLiner and Single Use Assembly with catalog numbers as mentioned above, released by QA after the implementation date will have the said changes in product labels. However, the available stock of the non sterile products without expiry mentioned on the product labels 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'.



**Head - Quality Assurance Single Use Assembly
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