

Change Notice No.	Notification date	Implementation date
CN/F/24/011	October 20, 2024	November 20, 2024

Subject : Addition of expiry in product label of mdj non sterile products

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

- AK#####1##
- AN#####1##
- ASPT#####1##
- AW#####1##
- C#####1##
- D#####1##
- E#####1##
- F#####1##
- G#####1##
- H#####1##
- I#####1##
- K#####1##
- L#####1##
- M#####1##
- N#####1##
- P#####1##
- Q#####1##
- R#####1##
- S#####1##
- T#####1##
- V#####1##

Background:

This change notification has been initiated to notify our customers about the additions made in the product label of mdj products. The expiry year and month of mdj non sterile products with catalog numbers as mentioned above have been incorporated/added in product label.

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

Need for Change:

The customers/users require information regarding the expiry of mdj non sterile products. The expiry of mdj non sterile products is 5 years from manufacturing and 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 mdj non sterile products 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) has been added/incorporated in product label of mdj non sterile products with catalog numbers as mentioned above.

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

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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 have been changed in terms of addition of expiry. All product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product labels.

EXISTING LABEL (WITHOUT EXPIRY)	PROPOSED LABEL (WITH EXPIRY)
<p>mdi AseptiCap KL PES Capsule Filter</p> <p>Cat. No. : DKLX5201EEXX101 Type : DKL Pore Size : 0.2 µm Size : 2" Lot No. : DK3894J SI.No. : 035</p>  <p>ADVANCED MICRODEVICES PVT. LTD. www.mdimembrane.com</p>	<p>mdi AseptiCap KL PES Capsule Filter</p> <p>Cat. No. : DKLX5201EEXX101 Type : DKL Pore Size : 0.2 µm Size : 2" Lot No. : DK3894J SI.No. : 035</p>  <p>2029 - 10</p> <p>ADVANCED MICRODEVICES PVT. LTD. www.mdimembrane.com</p>

Expiry year and month

Implementation of Change:

mdi non sterile products 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'.



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