

Change Notice No.	Notification date	Implementation date
CN/F/21/001	February 20, 2021	March 20, 2021

Subject : Addition of manufacturing date and expiry date in Certificate of Quality (CoQ) of MDI non sterile products

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

- A#####1##
- C#####1##
- D#####1##
- E#####1##
- F#####1##
- G#####1##
- H#####1##
- I#####1##
- L#####1##
- M#####1##
- N#####1##
- P#####1##
- Q#####1##
- S#####1##
- T#####1##
- V#####1##

Background:

This change notice has been initiated to notify our customers about the additions made in the Certificate of Quality (CoQ) of MDI products with catalog numbers as mentioned above. The manufacturing date and expiry date of MDI products with catalog numbers as mentioned above have been added in CoQ. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

1. The customers/users require information regarding manufacturing date of MDI non sterile products. The manufacturing date of MDI non sterile products is traceable through unique product lot number which includes codes for month and year of manufacturing. But, same needs to be established using the explanation of product lot number mentioned in respective product insert. In order to communicate the product manufacturing date to the customer/user in a better way, same (month and year of manufacturing) has been added in Certificate of Quality (CoQ) of MDI products with catalog numbers as mentioned above.

Change Notice No.	Notification date	Implementation date
CN/F/21/001	February 20, 2021	March 20, 2021

2. The defined shelf life (expiry of the product) of MDI pre-sterilized products is already mentioned in respective Certificate of Quality (CoQ). But, the defined shelf life of MDI non sterile products is not reflecting in current Certificate of Quality (CoQ). However, the product shelf life (expiry of the product) of non sterile products is traceable through unique product lot number mentioned on CoQ and product label. In order to communicate the product shelf life (expiry of the product) of non sterile products to the customer/user, same (month and year of expiry) has been added in Certificate of Quality (CoQ) of MDI products with catalog numbers as mentioned above.

How Does It Affect the User:

From the user point of view, this is only a paper change in which CoQ for above mentioned products has been changed in terms addition of manufacturing date and expiry date. 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 Certificate of quality (CoQ).

Implementation of Change:

mdi products with catalog numbers as mentioned above, released by QA after the implementation date will have the said changes in Certificate of quality (CoQ). However, the available stock of the same having Certificate of quality (CoQ) without mentioning the manufacturing date and expiry date of product 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
Advanced Microdevices Pvt. Ltd.