

Change Notice No.	Notification date	Implementation date
CN/18/06	April 10, 2018	May 10, 2018

Subject : Addition of sterilization date in Certificate of Quality (CoQ) for mdi pre-sterilized products (EO sterilized and Gamma sterilized)

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

- A#####3##
- C#####2##
- D#####2##
- D#####3##
- E#####2##
- F#####2##
- F#####3##
- G#####2##
- H#####2##
- I#####2##
- I#####3##
- L#####2##
- L#####3##
- M#####2##
- N#####2##
- P#####2##
- Q#####2##
- Q#####3##
- R#####2##
- S#####2##
- S#####3##
- V#####2##
- V#####3##

Background:

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

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Need for Change:

The Certificate of Quality (CoQ) of **mdi** pre-sterilized products with catalog numbers as mentioned above includes product expiry date along with other product related information such as product catalog number, product type, pore size, product lot number, sterilization cycle number, product serial number, product performance specifications etc. The product expiry date is defined based on the sterilization date which is not mentioned in CoQ of above mentioned products. However, the product sterilization date is traceable through unique sterilization cycle number mentioned in CoQ and product label. In order to communicate the product sterilization date to the customer/user, same has been added in Certificate of Quality (CoQ) of **mdi** pre-sterilized products with catalog numbers as mentioned above. No changes whatsoever have been made in process and product specifications.

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 of addition of product sterilization date. All product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said change will be reflected in the accompanying product Certificate of quality (CoQ).

Implementation of Change:

mdi pre-sterilized products with catalog numbers as mentioned above, released after the implementation date (**May 10, 2018**) will have the said change in the CoQ. However, the available stock of **mdi** pre-sterilized products with catalog numbers as mentioned above having CoQ without product sterilization date will be received by you 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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