

Change Notice No.	Notification date	Implementation date
CN/18/07	April 10, 2018	May 10, 2018

Subject : Addition of dose value of Gamma radiation in Certificate of Quality (CoQ) for mdi Gamma sterilized products

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

- A#####3##
- D#####3##
- F#####3##
- I#####3##
- L#####3##
- Q#####3##
- S#####3##
- V#####3##

Background:

In our efforts to convey to the customer/user more precise information regarding the product they are using, certain additions have been done in Certificate of Quality (CoQ) of **mdi** Gamma sterilized products with catalog numbers as mentioned above. The dose value of Gamma radiations has been added in CoQ. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

The Certificate of Quality (CoQ) of **mdi** Gamma sterilized products with catalog numbers as mentioned above specifies sterilization of products using Gamma Irradiations. Although, the dose value of Gamma radiations is traceable through certificate of Gamma sterilization provided by the service provider, but it is not mentioned in current CoQ. To update the CoQ in terms of more precise information regarding gamma sterilization of products, it has been decided to add Gamma dose value in CoQ of **mdi** Gamma sterilized products with catalog numbers as mentioned above. No changes whatsoever have been made in process, product and sterilization (Gamma Irradiation) specifications.

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How Does It Affect the User:

From the user point of view this is only a paper change in which the CoQ for above mentioned products has been changed in terms of addition of Gamma dose value. 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 Gamma 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** Gamma sterilized products with catalog numbers as mentioned above having CoQ without Gamma dose value 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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