

Change Notice No.	Notification date	Implementation date
CN/F/19/014	October 03, 2019	November 03, 2019

**Subject : Addition of maximum dose specification of Gamma radiations 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):**

- A0#####3##
- A1#####3##
- A2#####3##
- A3#####3##
- A4#####3##
- A5#####3##
- AB#####3##
- AL#####3##
- D#####3##
- L#####3##

**Background:**

In our efforts to convey to the customer/user more precise and relevant 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 maximum dose specification 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 current Certificate of Quality (CoQ) of mdi Gamma sterilized products with catalog numbers as mentioned above incorporates minimum dose specification of Gamma radiations. But, the maximum dose specification of Gamma radiations is not captured in current Certificate of Quality (CoQ). To update the CoQ in terms of updated information regarding gamma sterilization of products, it has been decided to add maximum dose specification of Gamma radiations in CoQ of mdi Gamma sterilized products with catalog numbers as mentioned above. No changes whatsoever have been made in materials of construction, manufacturing process, product attributes and sterilization process (Gamma Irradiation).

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**How Does It Affect the User:**

From the user point of view this change only improves the CoQ for above mentioned products in terms of maximum dose specification of Gamma radiations in addition to the minimum dose specification of gamma radiations. 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's Certificate of quality (CoQ).

**Implementation of Change:**

**mdi** Gamma sterilized products with catalog numbers as mentioned above, released after the implementation date 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 maximum dose specification of Gamma radiations 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'.



**Head - Quality Assurance**  
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