

Change Notice No.	Notification date	Implementation date
CN/A/23/002	April 06, 2023	May 06, 2023

Subject : Addition of individual Assembly Serial Number in Certificate of Quality (CoQ) of mdi Single Use Assembly/System in which sterilizing grade filter are used.

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

- AXXXXXXXXXXXXXXXXX (single use assemblies/system in which sterilizing grade filters are used)

Background:

This change notice has been initiated to improve the traceability of Single Use Assemblies with sterilizing grade filters. In order to do so, the serial number of individual assembly (already being mentioned on the labels of primary packaging) shall be incorporated in the Certificate of Quality of mdi Single Use Assemblies/Systems in which sterilizing grade capsule filters are used as a component.

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

Need for Change:

Currently, labels on primary packaging of mdi Single Use Assembly/System with sterilizing grade filters specify the serial number of the assembly. However, the serial number is not mentioned on the COQ. Sometimes, this results in issues with traceability at customer's end. To improve the traceability, following changes are proposed:

- CoQ for each Single Use Assembly/System in a lot shall be provided.
- The envelope containing all the CoQs for the lot along with the envelope containing all the CoQs of sterilizing grade filter used in that lot shall be provided in one of the packaging boxes with label "**Certificate of Quality Inside**" pasted on two sides of the box.
- No change has been done in any performance specification, product attribute, material of construction and manufacturing process of mdi Single Use Assemblies/Systems.

How Does It Affect the User:

From the user point of view, the changes done will have no impact on the quality of the product (as the change is done only for the better traceability of sterilizing grade filter through CoQ).

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Effective Date: mdi Single use assemblies/systems with catalog numbers as mentioned above, manufactured after the implementation date **(May 06, 2023)** will have the said changes. However, the available stock 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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