

| Change Notice No. | Notification date | Implementation date |
|-------------------|--------------------|---------------------|
| CN/A/21/005 | September 08, 2021 | September 15, 2021 |

Subject: Change in the Certificate of Quality and Serial Numbering System used in mdi Single Use Assemblies/Systems.

This change notice does not apply to the Single Use Assemblies/Systems in which sterilizing grade filters are used.

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

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

Background: The current practice includes labeling of **mdi** Single Use Assemblies/Systems with individual serial numbers. A certificate of quality for each assembly/system is also provided. However, only one Certificate of Quality per lot is provided for the Aseptiliner family and AseptiBag Gold assemblies.

The serial numbering is not required for all single use assembly/system. It is only required for single use assembly/system in which sterilizing grade filters are used.

Need for Change: Serial numbering is necessary in assemblies with serial numbered sterilizing grade filters to ensure traceability. Due to oversight, same practice is followed in assemblies in which sterilizing filters are not used. This results in printing of certificate of quality for each and every type of assembly/system. This is an overdoing/excessive activity that adds no value to quality of the product and requires lot of paper which is not environment friendly. To rectify the problem, the following changes are proposed:

- Serial numbering shall only be allotted to Single Use Assemblies/Systems with sterilizing grade filter. No serial numbering will be allotted to other single use assembly/system in which filters are not used.
- Only one Certificate of Quality (CoQ) for the respective lot of single use assemblies/ systems shall be provided with the shipment. However, CoQ will be available on the website for ready reference.
- Individual CoQ's of all sterilizing grade filters in the lot of single use assembly/system shall be provided separately as a bunch with the shipment.
- All CoQ's shall be put 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.

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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.

Effective Date: mdi Single use assemblies/systems with catalog numbers as mentioned above, manufactured after the implementation date (**September 15, 2021**) 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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