

Change Notice No.	Notification date	Implementation date
CN/19/005	04 th June, 2019	05 th June, 2019

Subject : Addition of drawing revision number in product package label and Certificate of Quality (COQ) for mdi Single Use Assemblies

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

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Background:



In our efforts to provide robustness to the product traceability, a change has been done in product package label and Certificate of Quality of **mdi** Single use Assemblies with catalog numbers as mentioned above.

Need for Change:

Existing product package label and Certificate of Quality of **mdi** Single Use Assemblies includes the product details such as Catalog number, Lot number, Serial number, Sterilization cycle number etc. Single Use Assemblies are manufactured according to the approved customized drawing. Sometimes a change is required in the customer approved drawing and same is implemented through an approved revision in the drawing. But, presently the drawing revision number is not reflecting in product package label and COQ. Hence, to incorporate the same, product package label and certificate of quality of **mdi** Single use Assemblies with catalog numbers as mentioned above has been changed and a 'drawing Revision Number' has been included for better traceability.

How Does It Affect the User:

From a practical point of view, this change only affects the product package label and certificate of quality of **mdi** Single Use Assemblies. All performance specifications, product attributes, traceability and lot release criteria will remain unchanged. All packaging and labeling attributes such as packaging box, pack size and content of the product package label remain same as before, only additional information in the form of 'Drawing Revision number' has been incorporated .

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EXISTING PRODUCT PACKAGE LABEL		MODIFIED PRODUCT PACKAGE LABEL
		

Implementation of Change:

mdi Single use Assemblies with catalog numbers as mentioned above, manufactured after the implementation date (**June 5th 2019**) will have the said changes. However, the available stock of **mdi** Single use Assemblies having product package label and certificate of quality without drawing revision number will be received by you till the stock's last.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



Quality Assurance
Advanced Microdevices Pvt. Ltd.