

Change Notice No.	Notification date	Implementation date
CN/18/08	April 10, 2018	May 10, 2018

**Subject : Addition of used filter details in Certificate of Quality (CoQ) for mdi Single Use Assembly**

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

- A010#####C3##
- A012#####C3##
- A019#####C3##
- A033#####C3##
- A034#####C3##
- A035#####C3##
- A040#####C3##
- A043#####C3##
- A047#####C3##
- A052#####C3##
- A053#####C3##
- A054#####C3##
- A058#####C3##
- A065#####C3##

**Background:**

In our efforts to keep our customers updated about the changes effected from time to time, certain additions have been made in Certificate of Quality (CoQ) of **mdi** Single Use Assemblies with catalog numbers as mentioned above. The CoQ has been updated with details (Catalog number and Lot number) of used filters. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

**Need for Change:**

**mdi** Single Use Assemblies with catalog numbers as mentioned above are being manufactured using filters of different types. Although, the used filters details are traceable through Batch Manufacturing Records (BMR) of respective lot of Single Use Assembly, but it is not captured in current Certificate of Quality (CoQ). In order to update the information regarding the used filter, it has been decided to incorporate the same in Certificate of Quality (CoQ) of **mdi** Single Use Assemblies with catalog numbers as mentioned above. No changes whatsoever have been made in process and product specifications.

<b>Change Notice No.</b>	<b>Notification date</b>	<b>Implementation date</b>
<b>CN/18/08</b>	<b>April 10, 2018</b>	<b>May 10, 2018</b>

The CoQ for above mentioned Single Use Assemblies will now have product catalog number and lot number along with other product related information of the filters used.

**How Does It Affect the User:**

From the user point of view this is only a paper change in which CoQ for above mentioned products has been changed in terms of addition of used filter details. 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** Single Use Assemblies 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** Single Use Assemblies with catalog numbers as mentioned above having CoQ without used filter details 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**  
**Advanced Microdevices Pvt. Ltd.**