ADVANCED MICRODEVICES (PVT.) LTD.
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Change Notice No.	Notification date	Implementation date
CN/D/21/002	July 8, 2021	August 8, 2021

Subject : **Change in Certificate of Quality (CoQ), Labels and Datasheet for mdi Diagnostic Products**

Scope : **This change notification will affect all types of the following products:**

- Absorbent Pad - AP
- Blood Separation Membrane - FR and WFR
- Conjugate Release Matrix - PT
- Cover Tape and Masking Tape
- Immunofiltration Membrane - CLW and CNJ
- Immunodiffusion Products- Dipsticks and Combs
- Plastic Cassettes - Device 1, 2, 3, 4, 5, 6, 9, 10
- Immunofiltration Products - FT-12, F-5, PF-12, FTR-12
- Sample Pad - GFB and FGM
- Glass Fiber Pad - GFN
- Silica Gel
- Aluminium Pouches - RAP1170, RAP1265
- B-Stick Device
- Filter Cups

Background:

In our efforts to convey to the customer precise and updated information regarding the products they are using, certain changes have been made to the contents of product related literature for **mdi** products as mentioned above.

Need for Change:

1. For better correlation between the invoice, packing list and labels, catalogue numbers will be mentioned on CoQ and labels as well.
2. The labels for the products as mentioned above have been restructured for better understanding.
3. It was observed that existing CoQ for some products contains only the test parameters but information like slitting/packing date, product expiry, storage conditions are not reflected on CoQ of all products. In order to have uniformity in the system, CoQ has

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CN/D/21/002	July 8, 2021	August 8, 2021

been restructured by adding slitting/packing date, best before and storage conditions for products.

4. In addition, during product review it was observed that there are some parameters mentioned in existing CoQ which are non-critical and not relevant. These parameters were historically incorporated in CoQ and are not relevant for intended use. Accordingly, CoQ for the products as mentioned above is restructured by including only the test parameters actually required and relevant. This includes removal of some test parameters such as Burst Strength, Bubble Point and Void Volume etc. which have origin from the use of membranes as filters and have no relevance in diagnostics applications.
5. It was observed that mdi products were being tested for some parameters but same was not reflected in the datasheet. To rationalize the datasheets as per the CoQ certain additions have been made to the contents of Datasheet for applicable products. The details are as mentioned below:

A. Blood Separator (FR):

- Specification for migration time of FR-2 (0.7 & 0.8) has been added.

B. Conjugate Release Matrix (PT-R):

- Specification for product type PT-R0 has been added.

C. Paper cast Nitrocellulose membrane (CLW-040-SH34):

- Specification for protein binding has been added.

D. Plastic Devices:

- Specifications for Device-3, Device-5, Device-6, Device-9 and Device-10 have been added/updated.

6. Shelf life for all above mentioned products, except for Immunofiltration Membranes (CLW and CNJ), has been increased from one year to two years under defined storage conditions mentioned on the CoQ.

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How Does It Affect the User:

From a practical point of view, these all are 'paper changes' and in no way will affect the product properties, performance or characteristics of the product under actual conditions of use. In addition, all product specifications and attributes including materials of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product related literature e.g. Certificate of Quality (CoQ), Data sheets, Labels etc.

Implementation of Change:

mdi Diagnostic products with types as mentioned above, released after **August 8, 2021** will have Certificate of Quality (CoQ) and labels with above said changes.

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

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