

Change Notice No.	Notification date	Implementation date
CN/D/19/001	Dec 30, 2019	Feb 01, 2020

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

Scope : This change notification will affect the following products

● Nitrocellulose Membrane- All types
● Membrane Laminates- All types
● Plastic Backing

Background:

In order to provide updated information to the customer regarding the products they are using, certain changes have been made in existing COQs for the above mentioned diagnostic products.

Need for Change:

1. Presently, the CoQ of the above mentioned products contains mean/average values of the results for respective test parameters. However, the specifications for the test parameters are not mentioned in existing CoQ and this creates confusion at the customer end regarding acceptance of the product. It has been decided to modify the COQ for the products as mentioned above through addition of specifications for different test parameters for easy reference and convenience.
2. 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, for example from the use of membranes as filters in pharmaceutical industry, and are not relevant for the use of membrane in immunodiagnosics. Accordingly, COQ and product related literature (data sheet etc.) 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 and Blocked Wicking Rate etc.
3. Further, for better correlation between the invoice, packing list and labels, catalogue numbers will be mentioned on CoQ and labels as well.
4. The labels for the products as mentioned above has been restructured for better understanding of the customers.

How Does It Affect the User:

From a practical point of view, it is only a 'paper change' and in no way will affect the product properties, performance or characteristics of the product under actual

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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, Data sheets etc. The old and new CoQ format and label samples are attached for reference.

	Old Label	New Label
Core Id	12µ, CNPC-SS12, 25 mm R-523H E02, 100 Mtr. Lot No. IC 527279I	Cat. No. : MPCB012025XXXXX Type : CNPC-SS12 Pore Size : 12 µm Lot No. : IC527279I Roll No. : R-527A, E02 Size : 25 mm, 100 Mtr.
Outer Box	<p align="center">mdi</p> <p align="center">12µ,CNPC-SS12, 25mm No. of Reels- 8, 800 Mtr. Lot No. IC 527279I</p> <hr/> <p align="center">Advanced Microdevices Pvt. Ltd. 20-21, Industrial Area, Ambala Cantt-133008 INDIA www.mdimembrane.com</p>	<p align="center">mdi</p> <p align="center">Cat. No. : MPCB012025XXXXX Type : CNPC-SS12 Pore Size : 12 µm Lot No. : IC527279I No. of Reels : 8 Quantity : 800 Mtr Size : 25 mm</p> <hr/> <p align="center">ADVANCED MICRODEVICES PVT. LTD. INDIA</p>

Implementation of Change:

mdi Diagnostic products with types as mentioned above, released after **Jan 31, 2020** will have Certificate of Quality 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.



Head - Quality Assurance

Advanced Microdevices Pvt. Ltd.

Certificate of Quality

The Nitrocellulose Membrane Type CNPC has been manufactured in a **mdi** facility in compliance with ISO-9001 regulations using validated production processes.

NITROCELLULOSE MEMBRANE

TYPE : CNPC-SS12
PORE SIZE : 12 μm
LOT NO. : IC527279I

PHYSICAL TESTS

Polyester Thickness (μm) : 100
Membrane Thickness (μm) : 103
Burst Strength with 4mm hole (psi) : 39

FUNCTIONAL TESTS

Ability to be Blocked : Passed Test
Protein Binding with BSA, pH = 7.4 ($\mu\text{g}/\text{cm}^2$) : 39.4
Wicking Rate, 4cm Distance (sec) (Blocked) : 100
Wicking Rate, 4cm Distance (sec) (Normal Saline) : 122
Dot Spreading with 10 μl Solution (sec) : 3-5
Adhesion Test (24 hour in H₂O) : Passed Test
Ability to cut into strips : Passed Test

DIMENSIONAL TESTS

Membrane Width (mm) : 25

SLITTING DATE

: 14-Sep-2019

BEST BEFORE

: One year from date of slitting.

STORAGE CONDITIONS

Temperature : 1-35°C

Note : Membrane should be stored in a cool, dry place in original aluminium foil packing and should be kept away from direct sun light and heat radiators.



Head of Quality Assurance

Issue Date: 07-Dec-19

Advanced Microdevices Pvt. Ltd.
21, Industrial Area, Ambala Cantt, INDIA,
Tel: +91-171-2699290/ 2699274
Website: www.mdimembrane.com
Email: info@mdimembrane.com

An ISO 9001 Company

Certificate of Quality

The Nitrocellulose Membrane Type CNPC has been manufactured in **mdi** facility in compliance with ISO-9001 regulations using validated production processes.

NITROCELLULOSE MEMBRANE

CATALOG NO. : MPCB012025XXXXX
TYPE : CNPC-SS12
PORE SIZE : 12 µm
LOT NO. : IC527279I

PHYSICAL TESTS

	RESULTS	SPECIFICATION
Polyester Thickness (µm)	: 100	102±5
Membrane Thickness (µm)	: 103	105±15

FUNCTIONAL TESTS

Wicking Rate, 4cm Distance (sec) (Normal Saline)	: 122	120±28
Protein Binding with BSA, pH = 7.4 (µg/cm ²)	: Pass	≥33
Dot Spreading with 10µl Solution (sec)	: Pass	≤6
Adhesion Test (24 hour in H ₂ O)	: Pass	
Ability to be Block	: Pass	
Ability to cut into strips	: Pass	

DIMENSIONAL TESTS

Membrane Width (mm)	: 25	25±0.2
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SLITTING/PACKING DATE

: 14-Sep-2019

BEST BEFORE

: 14-Sep-2020

STORAGE CONDITIONS

Temperature	: 1-35°C
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Note : Membrane should be stored in a cool, dry place in original aluminium foil packing and should be kept away from direct sun light and heat radiators.



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