

### ADVANCED MICRODEVICES (PVT.) LTD.

21. INDUSTRIAL AREA. AMBALA CANTT -133 001. INDIA Phone: +91 - 171 - 2699290, 2699274

Change Notice No.	Notification date	Implementation date
CN/D/22/001	November 12, 2022	December 12, 2022

Subject

: Change in lot numbering system of all types of NC membrane rolls and laminates

of mdi diagnostic products.

: This change notification will affect the products with following catalog numbers:

MPCXXXXXXXXXXXXXX

MPFXXXXXXXXXXXXXX

MPHXXXXXXXXXXXXX

LCXXXXXXXXXXXXXXX

LBXXXXXXXXXXXXXXX

LKXXXXXXXXXXXXXXX

LNXXXXXXXXXXXXXX

LOXXXXXXXXXXXXXX

• LIXXXXXXXXXXXXX

#### Background:

Scope

In keeping with our continuous efforts to provide the user products with improved identification and traceability, certain changes have been made in the lot numbering system of mdi diagnostic products with catalog numbers as mentioned above in scope.

The change will have no impact whatsoever on product performance or regulatory performance.

#### **Need for Change:**

Existing lot numbering system of mdi diagnostics with catalog number mentioned above include last three digits of production batch number, last two digits of ending production batch number, year of slitting of membrane, month of slitting. In case of 4 digit lot number traceability of material is difficult as there would be repetition of last three digits after every 1000 lot number. For e.g. For NC membrane type CNPC-15µm Batch no-1000 and 2000 will have the same lot no. -NIC000002L, that leads to confusion in future.

To make the material more traceable, new lot numbering system is introduced which include 4 digit of batch number, then X (W in case of white polyester), year of slitting of membrane, month of slitting.

No change has been done in any materials of production, performance parameters or any critical dimensions.



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#### How Does It Affect the User:

From practical point of view, this change will only affect the lot numbering of all types of NC membrane rolls and laminates of mdi diagnostic products with catalog numbers mentioned above in scope. All performance specifications, product attributes, materials of production, product packaging remain unchanged.

#### In case of NC membrane rolls:

	EXISTING	PROPOSED	
Lot No.	NJH821212L	NJH0821X2L	
Lot Number description	N : Nitrocellulose diagnostic membrane J : membrane pore size H : NC membrane type 821 : last three digits of starting production batch number 21 : last two digits of ending production batch number 2 : the year of slitting of membrane (2022 in this case) L : month of slitting (December in this case)	N: Nitrocellulose diagnostic membrane J: membrane pore size H: NC membrane type 0821: four digits of production batch number X: blank (or W in case of white polyester) 2: the year of slitting of membrane (2022 in this case) L: month of slitting (December in this case)	

#### In case of NC membrane Laminates:

	EXISTING	PROPOSED
Lot No.	NJH821212L-001	NJH0821X2L-001
Lot Number description	N : Nitrocellulose diagnostic membrane J : membrane pore size H : NC membrane type 821 : last three digits of starting production batch number 21 : last two digits of ending production batch number 2 : the year of slitting of membrane (2022 in this case) L : month of slitting (December in this case) 001 : production sheet number	N : Nitrocellulose diagnostic membrane J : membrane pore size H : NC membrane type 0821 : four digits of production batch number X : blank 2 : the year of slitting of membrane (2022 in this case) L : month of slitting (December in this case) 001 : production sheet number



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### Implementation of Change:

mdi Diagnostic products with catalog number as mentioned in scope, packed after implementation date will have the said changes. However, the available slitted stock of NC membranes with catalog number mentioned above having old type of lot number will be received by you till the stock lasts.

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

Quality Assurance - Diagnostics

**Advanced Microdevices Pvt. Ltd.**