

ADVANCED MICRODEVICES (PVT.) LTD.

21, INDUSTRIAL AREA, AMBALA CANTT -133 001, INDIA

Phone: +91 - 171 - 2699290, 269947, 2699274

Fax : + 91 - 171 - 2699221, 2699008

Change Notice No.	Notification date	Implementation date
CN/16/11	05 ^h August 2016	05 th September 2016

Subject : Change in Lot numbering system of mdi pre-sterilized Syringe Filters (All types)

Scope

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

- SMKG******2**
- SYCA**********
- SYKG*******2**
- SYNN********
- SYNU********
- SYPG*******
- SYPL********
- SYPI *******3**
- SYPN******2**
- SYPP******2**
- SYTF********2**
- SYTG******2**
- SYVF**********
- SYVF******3**
- SYVG******2**

Background:

In keeping with our continuous efforts to provide the user products with easy and clear identification, certain changes have been made in the lot number system of **mdi** pre-sterilized Syringe Filters with catalog numbers as mentioned above.

Need for Change:

Lot number identification on packaging label of **mdi** pre-sterilized Syringe Filters includes product code, membrane code, last 3 digits of production batch number, last digit of manufacturing year, manufacturing month code, pouch sealing sheet number and sterilization cycle number. Pouch sealing sheet number and sterilization cycle number are three digits each. The possibility of interchange in these two values could not be ruled out resulting in wrong traceability. The pouch sealing sheet number is a production step which can be traced back through production batch number. Hence, it is not necessary to include it in the Lot Number. Thus the lot number identification on packaging label of **mdi** pre-sterilized Syringe Filters has been changed.



ADVANCED MICRODEVICES (PVT.) LTD.

21, INDUSTRIAL AREA, AMBALA CANTT -133 001, INDIA

Phone: + 91 - 171 - 2699290, 269947, 2699274

Fax : + 91 - 171 - 2699221, 2699008

Change Notice No.	Notification date	Implementation date
CN/16/11	05 ^h August 2016	05 th September 2016

How Does It Affect the User:

From a practical point of view, this change only affects the lot numbering system printed on packaging label. All performance specifications, product attributes, materials of construction, product packaging and traceability remain unchanged.

Lot number identification on packaging label has been changed to lot number and sterilization cycle number (Ster. No.) only. Pouch sealing sheet number has been removed. Product packaging label will change accordingly (table-1). **mdi** pre-sterilized Syringe Filters manufactured after the implementation date as mentioned above will have the said changes.

Table - 1

	EXISTING	PROPOSED
Lot No.	Lot No.: SN5736E-123-001	Lot No.: \$N5736E
ion	'S' is the product code	'S' is the product code
	'N 'is the membrane code	'N 'is the membrane code
Cript	'573' are last 3 digits of production batch	'573' are last 3 digits of production batch
desc	number	number
Lot number description	'6' is the last digit of respective year	'6' is the last digit of respective year
E S	'E' is the code for month of manufacture	'E' is the code for month of manufacture
ot o	'123' is the pouch sealing sheet No.	
	'001' is sterilization cycle No.	'001' is sterilization cycle No.
Product packaging Label	mdi SYRINGE FILTER Cat. No. : SYNN0601MNXX204 Type : SY25NN -S (Nylon) Pore Size : 0.2 µm STERILE EO Diameter : 25 mm Quantity : 100 Nos. Lot No. : SN5736E-123-001	mcli SYRINGE FILTER Cat. No. : SYNN0601MNXX204 Type : SY25NN -S (Nylon) Pore Size : 0.2 µm
Proc	ADVANCED MICRODEVICES PVT. LTD. 21, IND. AREA, AMBALA CANTT 133 006 INDIA www.mdimembrane.com	ADVANCED MICRODEVICES PVT. LTD. 21, IND. AREA, AMBALA CANTT 133 006 INDIA www.mdimembrane.com

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.