

ADVANCED MICRODEVICES (PVT.) LTD.

21, INDUSTRIAL AREA, AMBALA CANTT -133 001 INDIA

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Reference: CHANGE NOTICE No.: CN/14/05

Subject: Addition/change of specification of sterilization for mdi cartridge and capsule filters

Scope : This change notification will affect all the sizes and pore sizes of the following products:

mdi Polyethersulfone Membrane cartridge filter type CPGK, ClariSure GK

mdi Microglassfiber Cartridge Filter Type CPGP, ClariSure GP

• **mdi** Microglassfiber Cartridge Filter Type CPGS, ClariSure GS

mdi Polypropylene Cartridge Filter Type CPPPA, ClariSure PA

mdi Microglassfiber Capsule Filter Type DGS, ClariCap GS

mdi Microglassfiber Large Capsule Filter Type LGS, ClariCap GS

mdi Polypropylene Capsule Filter Type DOL, ClariCap PP

mdi Polypropylene Large Capsule Filter Type LOL, ClariCap PP

Background:

mdi is manufacturing above mentioned products since long time. Based on the sterilization studies performed, it has been concluded that the above mentioned products can withstand multiple sterilization (autoclave/In-line steam sterilization) cycles at 121 °C for 30 minutes each. Hence, the specification for sterilization (autoclave/In-line steam sterilization), the above mentioned **mdi** products can withstand has been added/changed as mentioned in Table - 1. The Certificate of Quality (CoQ) accompanying the product will reflect the said changes.

Need for Change:

In our efforts to upgrade and provide the user products with better performance, the specification for sterilization (autoclave/In-line steam sterilization) has been added/changed in Certificate of Quality (CoQ) for the above mentioned products.

How Does It Affect the User:

From a practical point of view the changes done will improve the economics of use at user end. All other performance specifications and product attributes remain unchanged.

The accompanying Certificate of Quality (CoQ) for the product types mentioned above will reflect the specification for sterilization (autoclave/In-line steam sterilization) as mentioned in Table-1.



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Table-1

| Product category | Product Type | Trade Name of product | Number of sterilization cycles at 121 °C for 30 minutes each | |
|---------------------|-----------------|--------------------------|---|--|
| | | | Existing | Modified |
| Cartridge Filter | CPGK | ClariSure GK | 5 autoclave/In-line steam sterilization cycles | 25 autoclave/In-line steam sterilization cycles |
| | CPGP | ClariSure GP | | 30 autoclave/In-line steam sterilization cycles |
| | CPGS | ClariSure GS | | |
| | СРРРА | ClariSure PA | | 100 autoclave/In-line steam sterilization cycles |
| Capsule Filter | DGS | · ClariCap G\$ | | 30 autoclave cycles |
| | LGS | | | |
| | DOL | · ClariCap PP | | |
| | LOL | | | |

Effective Date:

mdi cartridge and capsule filters (types mentioned above) shipped after July 26, 2014 will be with said changes.

In case you have any queries, please feel free to contact our Technical Support Team at 'mdi@vsnl.com'.

Quality Assurance

Advanced Microdevices Pvt. Ltd.