

<b>Change Notice No.</b>	<b>Notification date</b>	<b>Implementation date</b>
<b>CN/17/23</b>	<b>November 01, 2017</b>	<b>December 01, 2017</b>

**Subject : Change in number of sterilization cycles of mdi Pre-filters type ClariPro GK and ClariSure GK**

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

- CGKX##01####1##
- DGKX#####1##
- IGKX#####1##
- LGKX#####1##
- VGKX#####1##

**Background:**

In our efforts to update the user/customer regarding product performance related information, the specification for number of sterilization cycles for **mdi** pre-filter filters type ClariPro GK and ClariSure GK with catalog numbers as mentioned above has been changed based on our recent testings and validations. The specification for number of sterilization cycles (autoclave cycles for ClariPro GK and Steam-in-place cycles for ClariSure GK) has been upgraded from 05 to 25.

**Need for Change:**

**mdi** is manufacturing above mentioned products since long time. Based on the validation studies performed, it has been concluded that the number of 30 minutes sterilization cycles at specified temperature that **mdi** pre-filters type ClariPro GK and ClariSure GK can withstand has always been more than 25. Hence, the specification for number of sterilization cycles for **mdi** pre-filters with catalog numbers as mentioned above has been changed from 05 to 25. No change has been done in any critical dimensions or materials of construction or manufacturing process.

The related product literature such as certificate of quality, validation guide, product data sheet, product insert etc will reflect the said changes

**How Does It Affect the User:**

From a practical point of view this change allows the use of product for more numbers of sterilization cycles. All other product specifications including materials of construction as well as other performance specifications remain unchanged. The accompanying product literature e.g. Certificate of quality, validation guide, product insert etc. will reflect the said change.

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**Implementation of Change:**

**mdi** pre-filters type ClariPro GK and ClariSure GK with catalog number as mentioned above, manufactured after the implementation date (**December 01, 2017**) will have the said changes. However, the available stock of **mdi** pre-filters type ClariPro GK and ClariSure GK with catalog numbers as mentioned below having old specifications for number of sterilization cycles (05 cycles) will be received by you till the stocks last.

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



**Head - Quality Assurance**  
**Advanced Microdevices Pvt. Ltd.**