

Change Notice No.	Notification date	Implementation date
CN/16/12	16 th August 2016	16 th September 2016

Subject : Redefining product expiry date/shelf life of EO Sterilized Capsule Filters

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

- DG*****2**
- DK*****2**
- DN*****2**
- DO*****2**
- DP*****2**
- DT*****2**
- DW*****2**
- DX*****2**
- LK*****2**
- LN*****2**
- LO*****2**
- MD*****2**

Background:

In our efforts to rationalize our systems and to provide the user updated information regarding the product they use, the expiry date/shelf life of **mdi** EO (Ethylene Oxide) Sterilized Capsule Filters with catalog numbers as mentioned above has been re-defined.

Need for Change:

Real time shelf life studies on **mdi** EO sterilized capsule filters were performed for up to 5 years. The capsule filters were found passing the acceptance criteria for Sterility as well as other parameters. However, during review it was observed that shelf life with safety margin specified for all other EO sterilized product is 3 years. Hence, shelf life of **mdi** EO sterilized capsule filters has been re-defined as 3 years from the date of EO sterilization.

How Does It Affect the User:

From a practical point of view the changes done will only re-define the product expiry date/shelf life of EO (Ethylene Oxide) Sterilized Capsule Filters. All performance specifications, product attributes, traceability, packaging method and sterilization method remain unchanged.

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The product expiry date/shelf life is now 3 years after date of EO sterilization instead of 5 years earlier. The accompanying product labeling and certificate of Quality will reflect the same. **mdi** EO sterilized Capsule Filters manufactured after the implementation date as mentioned above will have the said changes.

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.