

Change Notice No.	Notification date	Implementation date
CN/F/22/005	March 21, 2022	March 23, 2022

**Subject : Redefining of product expiry date/shelf life of EO sterile Syringe Filters**

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

- SYNNO307MNXX2##
- SYPP0611MNXX2##

**Background:**

This change notice has been initiated to notify our customers/users about the updated information regarding the products they are using. The shelf life in terms of expiry date of **mdi** EO sterile Syringe filters with catalog numbers as mentioned above has been re-defined from existing 3 years to 5 years from the date of sterilization. The change will have no impact on the product performance or it's regulatory compliance.

**Need for Change:**

The shelf life of **mdi** EO sterile Syringe filters with catalog numbers as mentioned above is defined as 3 years from the date of sterilization and same is reflecting in respective Certificate of Quality (CoQ). Results of the real time shelf life studies conducted on **mdi** EO sterile Syringe filters revealed that the performance of Syringe filters with catalog numbers as mentioned above was well within the acceptance criteria for a period of more than 5.5 years from the date of sterilization. Hence, shelf life of **mdi** products with catalog numbers as mentioned above has been re-defined as 5 years from the date of sterilization after keeping safety margin. No change has been made in manufacturing/sterilization process and other product specifications.

**How Does It Affect the User:**

From a practical point of view, the changes are done in the product expiry, based on studies performed on EO sterile Syringe filters. All product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said change will be reflected in the accompanying product Certificate of Quality (CoQ).

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**Implementation of Change:**

**mdi** products with catalog numbers as mentioned above, released by QA after the implementation date will have the said changes in Certificate of quality (CoQ).

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



**Head - Quality Assurance  
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