

Change Notice No.	Notification date	Implementation date
CN/F/21/002	February 20, 2021	March 20, 2021

**Subject : Redefining product expiry date/shelf life of Non sterile Disc Filters**

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

- GF1Z#####1##
- GF2X#####1##
- GFHX#####1##
- GFN4#####1##
- GFN6#####1##
- GFN7#####1##
- GFNF#####1##
- GFSX#####1##
- GFSZ#####1##
- HNNX#####1##
- HVFX#####1##
- NNXX#####1##
- NNZX#####1##
- PLXX#####1##
- PNNX#####1##
- PPXX#####1##
- PSXX#####1##
- PVFX#####1##
- TF2X#####1##
- TF3X#####1##

**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 non sterile disc filters with catalog numbers as mentioned above has been re-defined from existing 3 years to 5 years from the date of manufacturing. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

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**Need for Change:**

The shelf life of MDI non sterile disc filters is defined as 3 years from the date of manufacturing and same is reflecting in respective Certificate of Quality (CoQ). Results of the real time shelf life studies conducted on MDI non sterile disc filters revealed that the performance of disc filters was well within the acceptance criteria for up to a period of 6 years from the date of manufacturing. Hence, shelf life of MDI products with catalog numbers as mentioned above has been re-defined as 5 years from the date of manufacturing after keeping safety margin. No change whatsoever has been made in 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 physical studies performed on non sterile disc 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).

**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). However, the available stock of the same having Certificate of quality (CoQ) with product shelf life/expiry of 3 years will be supplied 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**  
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