

Reference : CHANGE NOTICE No.: CN/15/07

Subject : Redefining of product expiry date/shelf life of Gamma Irradiated Products

Scope : This change notification is applicable to the following products supplied Gamma Irradiated:

- **mdi** Gamma Irradiated Capsule Filters (All types and all sizes)
- **mdi** Gamma Irradiated Inline Filters (All types and all sizes)
- **mdi** Gamma Irradiated Inline Vent Filters (All types and all sizes)
- **mdi** Stericheck: Closed Sterility Test System (All types)

Background:

In our efforts to rationalize the product expiry date/shelf life based on validation studies performed on different products, the expiry date/shelf life of Gamma Irradiated products (as mentioned above) has been redefined from 3 years to 2 years after date of Gamma Irradiation.

Need for Change:

As above.

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 Gamma Irradiated products. All performance specifications, product attributes and traceability remain unchanged.

- The product expiry date/shelf life is now **2 years** after date of Gamma Irradiation instead of 3 years earlier. The accompanying product labeling and certificate of Quality will reflect the same.

Effective Date:

mdi Gamma Irradiated products (as mentioned above) manufactured after September 10, 2015 will have said changes.

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



Quality Assurance
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