

| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/F/24/012       | October 30, 2024  | November 30, 2024   |

**Subject : Use of mdi gamma irradiation facility for sterilization of mdi products**

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

- A#####3##
- D#####3##
- F#####3##
- H#####3##
- I#####3##
- L#####3##
- M#####3##
- Q#####3##
- S#####3##
- V#####3##

**Background:**

This change notification is initiated to notify our customers regarding the new mdi gamma irradiation facility which shall be used for sterilization of mdi products with catalog numbers as mentioned above. This facility shall be used in addition to existing service providers qualified and used by mdi for gamma irradiation of different products.

The change will have no impact whatsoever on the product performance or the regulatory compliance.

**Need for Change:**

Currently, mdi products with catalog numbers as mentioned in the scope are irradiated from outsourced gamma irradiation service providers. These service providers are qualified through audit.

The demand for gamma sterile products is continuously increasing and it is sometimes not possible to get the irradiation done timely from existing service providers. This results in delays in product delivery and increases the product lead time.

In order to serve customer better and to reduce lead times, a new mdi gamma irradiation facility has been setup. This facility will serve in addition to the existing service providers.

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**mdi** facility has been setup in close proximity to the manufacturing site (within 10 KM) and validation for the same has been completed as per guidelines provided by Atomic Energy Regulatory Board, India and ISO 11137, Sterilization of health care products - Radiation.

The address of **mdi** facility is as mentioned below:

Advanced Microdevices Pvt. Ltd.

Unit No. 7, Near Bazeedpur bus stop

Saha - Sahabad highway,

VPO - Kesari

District: Ambala, PIN - 133102 (India)

No change has been done in any materials of construction or performance parameters or any critical dimensions or manufacturing process or packaging of the products.

**How Does It Affect the User:**

The products as mentioned in the scope, irradiated at **mdi** facility as well as irradiated at existing service providers shall be received by the user/customer.

All product specifications including materials of construction as well as other performance specifications shall remain unchanged.

**Implementation of Change:**

**mdi** products with catalog numbers as mentioned in the scope, irradiated at **mdi** facility shall be supplied after the implementation date.

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.**