

| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/A/23/003       | June 20, 2023     | July 20,2023        |

**Subject: Usage of Laminated EPE (Expanded Polyethylene) foam in the packaging of mdi Single Use Assemblies/Systems instead of Plain EPE (Expanded Polyethylene) foam.**

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

- AXXXXXXXXXXXXXXXXX

**Background:**

To provide a better packaging and to rule out any possibility of visible as well as subvisible particles in Single Use Assemblies and Systems by using Laminated EPE Foam.

**Need for Change:**

Currently, Plain EPE foam is used in packaging to provide cushioning effect and thus protection to the critical components used in Single Use Systems. This Plain EPE Foam is validated for subvisible particles as per USP <788> Particulate Matter in Injection. However, the packaging shall be upgraded to Laminated EPE in order to rule out any incidence of particles from protective packaging.

**How Does It Affect the User:**

From the user point of view, the change shall provide a particle free packaging with the use of Laminated EPE foam. This upgraded EPE foam is validated for sub-visible as per USP <788> Particulate Matter in Injection as well as visible particles as per USP <790> Visible Particulates in Injection.

**Effective Date:**

mdi Single Use Assemblies and Systems, released after the implementation date (July 20, 2023) will have the said changes. However the available stock of the mdi Single Use Assemblies and Systems with Plain EPE foam will be shipped till stocks last.

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



**Head - Quality Assurance (Single Use Systems)  
Advanced Microdevices Pvt. Ltd.**