

Change Notice No.	Notification date	Implementation date
CN/A/25/002	January 01, 2025	February 01, 2025

Subject : Use of laminated film (AseptiFlex-I) for AseptiMix MI Single Use Mixer Bag and AseptiWave Bioreactor Bag.

Scope : This change will affect the Single Use Assemblies as mentioned below:

- All mixer bags without powder port
- All mixer bags with 4" powder port
- All mixer bags with \geq 1500 L volume capacity
- All AseptiWave Bioreactor bags

Background

AseptiMix MI Mixer Bags and AseptiWave Bioreactor Bags are made up of two films i.e. FBG-1 inner film (fluid contact) and FBG-1 outer film. The inner film of bag can get damage when it presses against the impeller fins.

Need for Change

The two films of bag i.e. inner ULDPE fluid contact film and outer film shall be laminated together to:

1. Reduce possibility of damage to the inner film.
2. Improve the transparency of the film.

The lamination process does not involve any adhesives and the materials of construction of the films shall remain same. The change shall not impact the product performance or it's regulatory compliance.

How Does It Affect the User

From the user point of view, all product specifications including material of construction as well as other performance specifications shall remain unchanged.

Implementation of Change

mdi AseptiMix MI Mixer Bag and AseptiWave Bioreactor Bag mentioned in scope, released by QA after the implementation date shall have the said changes in product.

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



**Head - Quality Assurance Single Use Assembly
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