

Change Notice No.	Notification date	Implementation date
CN/A/20/002	September 16, 2020	September 23, 2020

Subject: Change in Certificate of Quality for the recommended storage temperature of *AseptiBag Gold* (Bags) storage and transfer systems and bag assemblies used in **mdi** Single Use Systems.

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

- ABXXXXXXXXXXXXX
- AXXXXXXXXXXXXX

Background: In our efforts to provide the user more robust products, it has been decided to make certain changes in the recommended storage temperature of *AseptiBag Gold* (Bags) used in **mdi** Single Use Systems with catalog numbers as mentioned above.

Need for Change: The *AseptiBag Gold* bags used in the **mdi** single use systems with catalog numbers as mentioned above have recommended storage temperature range from -80°C to 45°C. The *AseptiBag Gold* bags have been validated at -80°C for freeze thaw study. However, during the study on prolonged storage of *AseptiBag Gold* at -80°C, slight brittleness was observed near the sealing area under the stress conditions. This could lead to failure of integrity of the bag. To rule out any possibility of integrity failure during prolonged storage at -80°C, it has been decided to change the recommended storage temperature from -80°C to 45°C to -20°C to 45°C.

How Does It Affect the User: From the practical point of view, the recommended change in the storage temperature will avoid damage to the bag during storage for prolonged time at -80°C. All other performance specifications, product attributes remain unchanged and possess no impact on the product quality.

Effective Date: **mdi** *AseptiBag Gold* and bag assemblies as mentioned above, manufactured after the implementation date (**September 23, 2020**) will have the said changes.

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



Quality Assurance
Advanced Microdevices Pvt. Ltd.