

Change Notice No.	Notification date	Implementation date
CN/A/20/004	10 th November 2020	25 th November 2020

Subject: Change in Certificate of Quality regarding the Endotoxin level of Bags and Liners used in MDI Single Use Assemblies and AseptiBag Gold Assemblies.

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

- ABXXXXXXXXXXXXX
- ALXXXXXXXXXXXXX

Background: In our efforts to provide the user more robust products, it has been decided to make change in the certificate of quality regarding endotoxin level of bags and liners used in **mdi** Single Use Systems and AseptiBag Gold Assemblies with catalog numbers as mentioned above.

Need for Change: Existing endotoxin level mentioned in CoQ of AseptiLiners and AseptiBag Gold under heading "Validated for" is < 0.25 EU/ml. In order to meet the market requirements, the endotoxin levels for AseptiLiners and AseptiBag Gold have been validated to be less than <0.125 EU/ml. The same shall be changed in the certificate of quality.

How Does It Affect the User: This change certifies the tightening of the specifications for Endotoxin level <0.125 EU/ml of AseptiLiners and AseptiBag Gold. All performance specifications, product attributes, traceability and lot release criteria will remain unchanged and there is no detrimental impact on the product quality. The accompanying product literature like Certificate of Quality, Validation Guide, Product datasheet etc. will reflect the said change.

Effective Date: **mdi** AseptiBag Gold assemblies and AseptiLiners as mentioned above, manufactured after the implementation date **(25th November 2020)** will have the said changes. However, the available stock of MDI AseptiBag Gold Assemblies and AseptiLiners will be received by you till the stock's last.

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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