

| Change Notice No. | Notification date | Implementation date |
|--------------------------|--------------------------|----------------------------|
| CN/A/24/002 | June 05, 2024 | June 20, 2024 |

Subject : Harmonization of Certificate of Quality for AseptiLiner w.r.t

- Revision of Endotoxin level specifications
- Addition of Revision Number

Scope : This change will affect the product having following catalog no.(X can be any alphabet or numeral)

- ALXXXXXXXXXXC301

Background:

This change notice has been initiated to notify for the changes made in the Certificate of Quality (CoQ) of AspetiLiner. The following changes shall be made in product related literature.

1. Revision of endotoxin level specification
2. Addition of Revision No.

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

Need for Change:

mdj Single Use Assemblies and AseptiLiner are validated for Endotoxin level as per USP <85> Bacterial Endotoxin and the specification for the same is 0.25 EU/ml. However, the specification for AseptiLiner mentioned in product literature (Certificate of Quality, validation guide and data sheet etc.) is 0.125 EU/ml. Therefore, to harmonize the Endotoxin level specification for AseptiLiner, the same shall be revised from 0.125 EU/mL to 0.25 EU/mL in product literature.

Also, the customers/users require information regarding revision number of the drawing for better traceability. In order to communicate the revision no. to the customer/user in a better way the same shall be added in the certificate of quality.

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

How Does It Affect the User:

From the user point of view, this is only a document change in terms addition of revision no. and change in specification. All product specifications including materials of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product literature.

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Effective Date:

The Certificate of Quality of AseptiLiner, released by QA after the implementation date will have the said changes. However, the available stock of the same having Certificate of Quality (CoQ) without mentioning the revision number and previous endotoxin level specification of product will be supplied till the stocks last.

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



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