

Change Notice No.	Notification date	Implementation date
CN/A/19/001	5 th December 2019	5 th January 2020

Subject: Change in the capacity of Bags used in MDI Single Use Assemblies and AseptiBag Gold Assemblies

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

ABDXE*****, ABDXF*****, A0*****301, A1*****301,
A2*****301, A3*****301, A4*****301, A5*****301,
A6*****301

Background:

In our efforts to provide a better product to the customer, a change has been done in capacity of 5 liters and 10 liters bags of MDI Single use Assemblies and AseptiBag Gold Assemblies with catalog numbers as mentioned above.

Need for Change:

Existing 5 liters and 10 liters bag used in MDI Single Use Assemblies and AseptiBag Gold Assemblies are having liquid holding capacity of 5.8 and 11.2 liters respectively. In order to meet the market specifications and to provide the safety margin in the bags the liquid holding capacity of 5 and 10 Liters bags has been increased to 6.5 and 12.5 liters, respectively. Hence, to incorporate the same, the length of the 5 and 10 liters bags has been increased from 39 cm to 41cm and from 59 cm to 62 cm, respectively in MDI Single use Assemblies and AseptiBag Assemblies with catalog numbers as mentioned above.

How Does It Affect the User:

From a practical point of view, this change only increases the length and thus volume holding capacity of the 5 liter and 10 liter Bags to be used in MDI Single Use Assemblies and AseptiBag Gold Assemblies. All performance specifications, product attributes, traceability and lot release criteria will remain unchanged. All packaging and labeling attributes such as packaging box, pack size and content of the product package label remain same as before, only length of the 5 liter and 10 liter bags has been increased.

Implementation of Change:

MDI Single use Assemblies and AseptiBag Gold assemblies with catalog numbers as mentioned above, manufactured after the implementation date (**5th January, 2020**) will have the said

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changes. However, the available stock of MDI Single use Assemblies and AseptiBag Gold assemblies having Bags with less liquid holding capacity 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
Advanced Microdevices Pvt. Ltd.