

Change Notice No.	Notification date	Implementation date
CN/A/25/001	January 01, 2025	February 01, 2025

Subject : Categorization of mdi Single Use Systems

Scope : This change will affect all the mdi Single Use Systems with the catalog number mentioned below (# can be any alphabet or numeral):

A#####

Background:

Currently, all single use systems except Aseptiliner are categorized as Single Use Assembly and lot no. for the same starts with alphabet "AS". This does not allow identification of type of products.

Need for Change:

For better identification of single use products, the categorization based on it's application is proposed (as per annexure given on page 2). The lot number of products shall also be categorized. The change will be reflected in product label and Certificate of Quality.

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

How Does It Affect the User:

From the user point of view, change in categories of single use products will provide better identification for different product types. All product specifications including material of construction as well as other performance specifications shall remain unchanged. The said changes will be reflected in the accompanying product labels and Certificate of Quality.

Implementation of Change:

mdi Single Use Products released by QA after the implementation date will have the said changes in product labels and Certificate of Quality.

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



Head - Quality Assurance
Advanced Microdevices Pvt. Ltd.

Change Notice No.	Notification date	Implementation date
CN/A/25/001	January 01, 2025	February 01, 2025

Annexure

In existing System, the lot number of Single Use Assembly is given as **ASXXX5A** in which "AS" stands for Assembly, X can be any numeric digit, 5 is last digit of current year i.e. 2025 and A stands for month in year i.e A is for January, B for February and so on. The change in lot no. For different categorized products are tabulated below:

Sr. No.	Proposed categories of product	Proposed Lot No.
1	Single Use Bag Assembly	ASXXX5A
2	Single Use Bottle Assembly	AOXXX5A
3	Single Use Liner Assembly	ANXXX5A
4	Single Use Tubing Assembly	ATXXX5A
5	Single Use Filter Assembly	AFXXX5A
6	Powder Bag	APXXX5A
7	Aseptic Sampling System	AAXXX5A
8	AseptiMix MI Single Use Mixer Assembly	AMXXX5A
9	AseptiMix MI Single Use Bottle Mixer Assembly	AGXXX5A
10	AseptiMix MI Single Use Mixer Assembly with Filters	AHXXX5A
11	AseptiMix VC Vented Carboy Mixer Assembly	VCXXX5A
12	AseptiMix VB Vented Bottle Mixer Assembly	VBXXX5A
13	AseptiWave Bioreactor Single Use Assembly	AWXXX5A
14	AseptiCel Bioreactor Single Use Assembly	ARXXX5A
15	AcuFil Single Use Filling Line Assembly	AUXXX5A
16	AseptiLiner	ALXXX5A