

Change Notice No.	Notification date	Implementation date
CN/17/04	February 12, 2017	March 12, 2017

Subject : Changes related to product catalog number, product lot number and certificate of quality of mdi Aseptic Sampling System

Scope : This change notification will affect the products with following catalog numbers:

- SSBX12XXXXXX302
- SSBXB106XXXX302

Background:

mdi currently offers "Single Use Assemblies" under two product categories:

1. Product type Single Use Assembly
2. Product type Aseptic Sampling System

In our efforts to maintain the uniformity among different Single Use Assemblies, certain changes have been done to product catalog number, product lot number and certificate of quality of mdi Aseptic Sampling System with catalog numbers as mentioned above.

Need for Change:

mdi product type 'Single Use Assembly' have well defined catalog numbers which include reference to approved drawing number. The inclusion of approved drawing number in product catalog number provides more reliability during manufacturing and testing through verification of several aspects such as components used, component specification, number of each component type, orientation of components, placement of components etc. as per approved drawing. The product catalog number of Aseptic Sampling Systems currently lacks reference to approved drawing number.

To maintain the uniformity among different Single Use Assemblies and for more reliability during manufacturing and testing, the product catalog number and product lot number of mdi Aseptic Sampling Systems with catalog numbers as mentioned above have been rationalized. In addition to this, a unique trade name has been assigned to Aseptic Sampling Systems.

The certificate of quality of mdi Aseptic Sampling Systems with catalog numbers as mentioned above has also been re-structured including verification of components used, component specification, number of each component type, orientation of components, placement of components etc. as per approved drawing.

Change Notice No.	Notification date	Implementation date
CN/17/04	February 12, 2017	March 12, 2017

How Does It Affect the User:

From a practical point of view, this change only affects the product catalog number, product lot number and certificate of quality of **mdi** Aseptic Sampling Systems with catalog numbers as mentioned above. All performance specifications, product attributes, traceability and materials of construction will remain unchanged. All packaging attributes such as packaging box, number of assemblies in a box and labeling will remain same as before, only with changes to product catalog number and product lot number.

The existing as well as changed details of **mdi** Aseptic Sampling Systems are described as below:

- **Product Catalog Number** – The existing and changed catalog number are as mentioned below:

Existing catalog number	Changed catalog number	
	Catalog number	Description of changed catalog number
SSBX12XXXXXX302	BTSXXVA001XX302	1 st letter B is for Bags 2 nd letter T is for tubings 3 rd letter X is for Sampler and denoted by S 4 th letter X is for Sterile Connector and denoted by C 5 th letter X is for Filter and will be denoted by F 6 th letter X is for Valves and will be denoted by V
SSBxB106XXXX302	BTSXXVA002XX302	A001 is the reference to unique approved drawing number 11 th letter X remains as such 12 th letter X remains as such 13 th digit 3 stands for Gamma irradiation 14 th and 15 th letters 02 stands for pack size (pack of 10)

- **Product Lot Number** - The existing and changed catalog number are as mentioned below:

Existing Lot Numbering system	Changed Lot Numbering system
0026F-R001	AS0026F Ster. No. R001
'002' are last 3 digits of production batch number '6' is the last digit of respective year 'F' is the code for month of manufacture 'R001' is the sterilization cycle No.	'AS' is for Aseptic Sampling System '002' are last 3 digits of production batch number '6' is the last digit of respective year 'F' is the code for month of manufacture 'R001' is the sterilization cycle No. (separately written)

Change Notice No.	Notification date	Implementation date
CN/17/04	February 12, 2017	March 12, 2017

- **Product trade name** – a unique trade name 'ASESS' has been assigned to Aseptic Sampling Systems.
- **Certificate of quality** – The information in existing certificate of quality has been re-structured and updated including verification of components used, component specification, number of each component type, orientation of components, placement of components etc. as per approved drawing.

Implementation of Change:

mdi Aseptic Sampling Systems with catalog numbers as mentioned above, manufactured after the implementation date (**March 12, 2017**) will have the said changes. However, the available stock of **mdi** Aseptic Sampling Systems without above changes will be received by you till the stocks last.

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.