ADVANCED MICRODEVICES PVT. LTD.
20 - 21, INDUSTRIAL AREA, AMBALA CANTT – 133 001, INDIA
Phone : + 91 - 171 - 2699290, 2699471, 2699274
Website: www.mdimembrane.com

Change Notice No.	Notification date	Implementation date
CN/19/006	**June 10, 2019**	**July 10, 2019**

Subject : **Addition of Bacterial Endotoxin test (BET) in Certificate of Quality for mdi Products**

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

- CB##########
- CH2##########
- CHR##########
- CK##########
- CNZ##########
- CPH##########
- CPK##########
- CPM##########
- CPN##########
- CPT##########
- DB##########
- DK##########
- DN##########
- DP##########
- DT##########
- DV##########
- IKL##########
- IKS##########
- IKT##########
- IKX##########
- IN##########
- IPN##########
- ITF##########
- IV##########
- LB##########
- LK##########
- LN##########
- LT##########
- LV##########
- MD##########
- VB##########
- VK##########
- VN##########
- VT##########

Background:

In our efforts to provide the user updated information regarding the products they are using, it has been decided to make certain addition in the contents of the Certificate of Quality (CoQ) for **mdi** Products with catalog numbers as mentioned above.

Need for Change:

mdi Products with catalog numbers as mentioned above are tested/validated for Bacterial Endotoxin levels by Limulus Amebocyte Lysate (LAL) test as per the USP <85> requirements for Sterile Water for Injection (WFI). But, the compliance to this test is not reflecting in current Certificate of Quality (CoQ). Hence, the Certificate of Quality (CoQ) for **mdi** Products with catalog numbers as mentioned above has been updated. No change has been done in any other critical dimensions or materials of construction or manufacturing process of **mdi** Products with catalog numbers as mentioned above.

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How Does It Affect the User:

From a practical point of view this change specifically states the compliance to Bacterial Endotoxin levels. Test was already carried out but the compliance was not stated/reflected in the Certificate of Quality (CoQ). All product specifications including materials of construction as well as performance specifications remain unchanged. The accompanying product literature e.g. Certificate of quality, validation guide, product data sheet etc. will reflect the said change.

Implementation of Change:

mdi Products with catalog numbers as mentioned above, manufactured/released after the implementation date (**July 10, 2019)** will have the said changes. However, the available stock of **mdi** Products having Certificate of Quality (CoQ) without Bacterial Endotoxin levels 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.