

| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/17/07          | February 28, 2017 | March 28, 2017      |

**Subject : Addition of Bacterial Endotoxin and Cytotoxicity in Certificate of Quality for mdi Hydrophilic PVDF Membrane Filters**

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

- DKW\*\*\*\*\*
- DWL\*\*\*\*\*
- DWS\*\*\*\*\*
- IWS\*\*\*\*\*
- LWL\*\*\*\*\*
- LWS\*\*\*\*\*

**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 Hydrophilic PVDF Membrane Filters with catalog numbers as mentioned above.

**Need for Change:**

mdi Hydrophilic PVDF Membrane Filters are tested and certified for Bacterial Endotoxin levels by Limulus Amebocyte Lysate (LAL) test as per the USP <85> requirements for Sterile Water for Injection (WFI). They also comply to Biological Reactivity Tests, *In Vitro* (Cytotoxicity) as described in USP <87>. The compliance to these tests are not reflecting in current Certificate of Quality (CoQ). Hence, the Certificate of Quality (CoQ) for mdi Hydrophilic PVDF Membrane Filters with catalog numbers as mentioned above has been updated.

**How Does It Affect the User:**

From a practical point of view this change specifically states the compliance to Bacterial Endotoxin levels and Biological Reactivity Tests, *In Vitro* (Cytotoxicity). Tests were already being 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.

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**Implementation of Change:**

**mdi** Hydrophilic PVDF Membrane Filters with catalog numbers as mentioned above, manufactured after the implementation date (**March 28, 2017**) will have the said changes. However, the available stock of **mdi** Hydrophilic PVDF Membrane Filters having Certificate of Quality (CoQ) without Bacterial Endotoxin and Cytotoxicity 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'.



**Quality Assurance**

**Advanced Microdevices Pvt. Ltd.**