

Change Notice No.	Notification date	Implementation date
CN/17/17	August 05, 2017	September 05, 2017

Subject : Addition of Cytotoxicity in Certificate of Quality for mdi Hydrophobic PTFE Membrane Filters

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

- CPTF*****
- CPTH*****
- DTLX*****
- ITFX*****
- LTLX*****
- VTFX*****

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 Hydrophobic PTFE Membrane Filters with catalog numbers as mentioned above.

Need for Change:

mdi Hydrophobic PTFE Membrane Filters are tested and certified for Biological Reactivity Tests, *In Vitro* (Cytotoxicity) as described in USP <87>. The compliance to this test is not reflecting in current Certificate of Quality (CoQ). Hence, the Certificate of Quality (CoQ) for mdi Hydrophobic PTFE 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 Biological Reactivity Tests, *In Vitro* (Cytotoxicity). Test was 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 Hydrophobic PTFE Membrane Filters with catalog numbers as mentioned above, manufactured after the implementation date (**September 05, 2017**) will have the said changes. However, the available stock of **mdi** Hydrophobic PTFE Membrane Filters having Certificate of Quality (CoQ) without Cytotoxicity test 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
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