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Reference : **CHANGE NOTICE No. CP/13/06**

Subject : **Addition of Cytotoxicity Test to Certificate of Quality for mdi Polyethersulfone membrane Filters**

Scope : **This change notification will affect the following products:**

- **mdi** Polyethersulfone membrane capsule filters types DKL, DKS, DK2S, LKL, LKS, LK2S (All sizes and pore sizes).
- **mdi** Polyethersulfone membrane cartridge filters types CPPKS, CPHS (All sizes and pore sizes).
- **mdi** Polyethersulfone membrane filters types IKL, VKS, VKXS, VKXL, VKLX, VK2S (All sizes and pore sizes).

Background:

As described in USP <87>, the membrane filters should pass Biological Reactivity Test, *In vitro* for Cytotoxicity. So the same test has been conducted for above mentioned filters.

Need for Change:

As above.

How Does It Affect the User:

From a practical point of view, the above mentioned change will improve reliability of the product under actual conditions of use. All other performance specification and product attributes remains unchanged.

Certificate of quality (CoQ) for above mentioned product types will now include information on Biological Reactivity Test, *In vitro* for Cytotoxicity as described in USP <87>.

Effective Date:

mdi Polyethersulfone membrane filters (types mentioned above) shipped after November 1, 2013 will be with said changes.

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

Quality Assurance
Advanced Microdevices Pvt. Ltd.