ADVANCED MICRODEVICES PVT. LTD.
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Change Notice No.	Notification date	Implementation date
CN/F/23/002	April 25, 2023	May 25, 2023

Subject : **Addition of Cytotoxicity (USP <87>) in documentation related to mdi PES Membrane Filters**

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

- DBKO##########
- DKLO##########
- DKO###########
- DPLO##########
- LBKO##########
- LKLO##########
- LKO###########
- CHR###########
- CKR###########
- CPKR##########
- CPMR##########
- IKO###########

Background:

This advance change notification is initiated to provide the user updated information regarding the products they are using. It has been decided to incorporate the details of Biological Reactivity Tests, *In Vitro* (Cytotoxicity), as described in USP <87>, in documentation (e.g. Certificate of Quality, product data sheet, validation guide etc.) related to **mdi** Polyethersulfone (PES) Membrane Filters with catalog numbers as mentioned in the scope.

Need for Change:

The materials of construction of **mdi** PES Membrane Filters having catalog numbers as mentioned in the scope are tested and certified for Biological Reactivity Tests, *In Vitro* (Cytotoxicity) as described in USP <87>. But, the details of this test is not reflecting in current product related documentation (e.g. Certificate of Quality, product data sheet, validation guide etc.). Hence, the documentation related to **mdi** PES Membrane Filters with catalog numbers as mentioned in the scope shall be updated to incorporate the details (along with compliance status) of Biological Reactivity Tests, *In Vitro* (Cytotoxicity), as described in USP <87>.

No change has been done in materials of construction or performance parameters or manufacturing process or critical dimensions or traceability.

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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), as described in USP <87>. The test was already carried out and the results are complied with the acceptance criteria. However, the details/compliance was not stated/reflected in documentation related to **mdi** PES Membrane Filters with catalog numbers as mentioned in the scope. All product specifications including materials of construction as well as performance specifications remain unchanged. The accompanying product related documentation (e.g. Certificate of Quality, product data sheet, validation guide etc.) will reflect the said change.

Implementation of Change:

mdi PES Membrane Filters with catalog numbers as mentioned in the scope, released after the implementation date will have the said changes. However, the available stock of **mdi** PES Membrane Filters with catalog numbers as mentioned in the scope and without details/compliance of Biological Reactivity Tests, *In Vitro* (Cytotoxicity), as described in USP <87>, mentioned in product related documentation 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.