ADVANCED MICRODEVICES PVT. LTD.
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Phone : + 91 - 171 - 2699290, 2699471, 2699274
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Change Notice No.	Notification date	Implementation date
CN/19/008	**June 10, 2019**	**July 10, 2019**

Subject : **Change in lot release criteria for mdi 0.45µm rated Products**

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

- AK####02#######
- AN####02#######
- CHR###02#######
- CKR###02#######
- CPH###02#######
- CPK###02#######
- CPM###02#######
- CPN###02#######
- CPT###02#######
- CWH###02#######
- DGP###02#######
- DK####02#######
- DN####02#######
- DP####02#######
- DT####02#######
- DW####02#######
- IK####02#######
- IN####02#######
- IPG###02#######
- IPT###02#######
- IT####02#######
- IW####02#######
- LK####02#######
- LT####02#######
- LW####02#######
- MD####02#######
- NN####02#######
- VFP###02#######
- VK####02#######

Background:

In our efforts to keep our customers updated about the improvements done time to time, certain changes have been made in lot release criteria of **mdi** 0.45µm rated products with catalog numbers as mentioned above. These products are currently being released based on lot basis Microbial Retention testing and shall now be released on the basis of compliance to the physical Integrity test results against the pre-defined acceptance criteria. The Microbial Retention testing still be carried out at the time of validation only. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

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Need for Change:

mdi has been manufacturing 0.45µm rated products for more than 20 years. Every lot of **mdi** 0.45µm rated product is sampled and tested for Microbial Retention Test with *S. Marcescens* (ATCC 14756) with Log Reduction Value, LRV > 7.

Based on the verification of Microbial Retention test results of **mdi** 0.45µm rated products for the past as many years, it has been decided that the Microbial Retention Test shall be removed from lot release criteria and release of **mdi** 0.45µm rated products with catalog numbers as mentioned above shall be done on the basis of compliance to the physical Integrity test results against the pre-defined acceptance criteria.

However, the Microbial Retention test shall be carried out at the time of validation and will be reflected as validation activity in respective documents. No change has been done in any critical dimensions or materials of construction or manufacturing process or other performance parameters of **mdi** 0.45µm rated products.

How Does It Affect the User:

From a practical point of view this change only re-defines the lot release criteria in terms of Microbial retention Testing with *S. Marcescens* (ATCC 14756). All other product specifications including materials of construction as well as other performance specifications remain unchanged. The said changes will be reflected in the accompanying product literature e.g. Certificate of quality, product data sheets etc.

Implementation of Change:

mdi Products with catalog numbers as mentioned above, manufactured after the implementation date (**July 10, 2019)** will have the said changes. However, the available stock of **mdi** Products with Certificate of Quality (CoQ) having Microbial retention Test as lot release criteria 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.