

- Reference** : Change Notice No. CP/09/03
- Subject** : Change in Minimum Bubble Point test specification for **mdi**
Polyethersulfone membrane products
- Scope** : This change notification will affect the following products:
- **mdi** Polyethersulfone Membrane Filters – All Type
 - **mdi** Polyethersulfone Membrane Capsule Filters – All Types
(DPL/DPS/DKL/DKS/LPS/LKS)
 - **mdi** Polyethersulfone Membrane Cartridge Filters – All Types
(CPPPMS/CPPPKS)

Background:

mdi is manufacturing Polyethersulfone membrane products for more than 7 years. Based on statistical trend analysis for these many years, the minimum water wetted bubble point values of **mdi** Polyethersulfone membrane products were always more than 50 psi, hence the minimum water wetted bubble point specification for mdi sterilizing grade 0.2 µm Polyethersulfone membrane products has been changed from 45 psi to 50 psi. The accompanying Certificates of Quality (CoQ) will reflect the new minimum water wetted bubble point specification of 50 psi.

Need for Change:

PDA Technical report 26, suggests that one of the membrane filter used for bacterial challenge test should have water bubble point value close to minimum water bubble point specification of test filter.

How Does It Affect Filter User:

From a practical point of view it is only a 'paper change' and in no way will it affect the filter properties and performance characteristics of the product under actual conditions of use. All performance specifications and product attributes (materials of construction, extractables and endotoxin specifications) remain unchanged.

Effective Date:

All filters shipped after October 7, 2009 will have 50psi minimum water wetted bubble point specification.

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

Yours Sincerely



Quality Assurance

Advanced Microdevices Pvt. Ltd.