

Change Notice No.	Notification date	Implementation date
CN/F/21/003	March 15, 2021	April 15, 2021

Subject: Re-defining of lot release criteria for PES membrane Syringe Filters

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

- SYKG#####
- SYPG#####
- SYPL#####
- SYPN#####

Background:

This change notice has been initiated to notify our customers/users, correct information regarding the products they are using. The Certificate of Quality (CoQ) for PES membrane syringe filters with catalog numbers as mentioned above has been updated with regards to re-defined lot release criteria. The change will have no impact whatsoever on the product performance or its regulatory compliance.

Need for Change:

MDI PES membrane syringe filters with catalog numbers as mentioned above are validated for Bacterial Endotoxin levels by Limulus Amebocyte Lysate (LAL) test as per the USP <85>. But, the Certificate of Quality is wrongly reflecting it as the lot release criteria. To correct this error, the Certificate of Quality (CoQ) for MDI PES membrane syringe filters with catalog numbers as mentioned above has been corrected. The compliance to Bacterial Endotoxin levels will be reflected as 'validated for' in the Certificate of Quality. No change has been done in any product performance parameter or materials of construction or manufacturing process or test methodology or frequency of testing of MDI PES membrane syringe filters with catalog numbers as mentioned above.

How Does It Affect the User:

This change corrects the lot release criteria mentioned in respective CoQ, as per actual practice. All product specifications including materials of construction as well as performance specifications will remain unchanged. The said change will be reflected in the accompanying product Certificate of Quality (CoQ).

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Implementation of Change:

MDI PES membrane syringe filters with catalog numbers as mentioned above, released after the implementation date will have the said changes in Certificate of quality (CoQ). However, the available stock of the same having Certificate of quality (CoQ), with Bacterial Endotoxin levels reflected as lot release criteria will be supplied till the stocks last.

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



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