

Change Notice No.	Notification date	Implementation date
CN/F/22/001	January 15, 2022	February 15, 2022

Subject : Change in number of SIP cycles for AseptiSure WS

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

- CWH#####

Background:

This change notice has been initiated to notify our customers/users about the updated information regarding the products they are using. The number of sterilization (SIP) cycles for MDI Cartridge filters type AseptiSure WS with catalog numbers as mentioned above has been re-defined from existing 01 to 03. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

MDI Cartridge filters type AseptiSure WS are recommended for one steam sterilization cycle at 135°C for 30 minutes and same is reflecting in existing product related literature such as certificate of quality, validation guide, product data sheet, product insert etc.

Based on the recent validation studies performed on MDI Cartridge filters type AseptiSure WS, it has been concluded that the number of steam sterilization cycles at 135 °C for 30 minutes each that MDI Cartridge filter type AseptiSure WS can withstand is more than thee (03). Hence, the specification for number of steam sterilization cycles for MDI filters with catalog numbers as mentioned above has been re-defined from 01 to 03. No change has been done in other performance parameters or any critical dimensions or materials of construction or manufacturing process.

The related product literature such as certificate of quality, validation guide, product data sheet, product insert etc. will reflect the said changes.

How Does It Affect the User:

From a practical point of view, this change will improve the process economy by allowing the use of product for more numbers of steam sterilization cycles. All other product specifications including materials of construction as well as other performance specifications shall remain unchanged. The accompanying product literature e.g. certificate of quality, validation guide, product data sheet, product insert etc. will reflect the said change.

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Implementation of Change:

MDI Cartridge filters type AseptiSure WS with catalog number as mentioned above, released after the implementation date will have the said changes. However, the available stock of MDI Cartridge filters type AseptiSure WS with catalog numbers as mentioned above having one number of steam sterilization cycle 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'.

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