

Change Notice No.	Notification date	Implementation date
CN/18/10	September 10, 2018	October 10, 2018

Subject : Change in minimum Burst Pressure specification for mdi Stericheck Canisters (Stericheck: Closed Sterility Test System)

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

- SH#####
- SL#####
- SM#####
- SP#####
- SV1#####
- SV2#####
- SV3#####
- SV4#####
- SVC#####

Background:

In our efforts to provide the user/customer updated information with regards to the burst pressure of Stericheck canisters, certain changes have been made to the contents of product related literature for **mdi** Stericheck: Closed Sterility Test System with catalog numbers as mentioned above. The specification for minimum burst pressure has been upgraded from 45 psi to 65 psi. The change will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

mdi is manufacturing above mentioned product types since long time (more than 10 years). Based on trends analysis of data of these product types for the past years, the minimum burst pressure of **mdi** Stericheck canisters has always been more than 65 psi, hence the minimum burst pressure specification of **mdi** Stericheck: Closed Sterility Test System with catalog numbers as mentioned above has been changed from existing 45 psi to 65 psi. No change has been done in any critical dimensions or materials of construction or manufacturing process.

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

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How Does It Affect the User:

From a practical point of view this change has upgraded the specifications and only affect the product related literature e.g. certificate of quality, validation guide, product data sheet etc. of above mentioned products by providing upgraded minimum burst pressure specification. All product attributes and other performance specifications remain unchanged.

Implementation of Change:

mdi Stericheck: Closed Sterility Test System with catalog numbers as mentioned above, manufactured after the implementation date **(October 10, 2018)** will have the said change in minimum burst pressure specification. However, the available stock of **mdi** Stericheck: Closed Sterility Test System with catalog numbers as mentioned above having minimum burst pressure specification as 45 psi 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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