

Change Notice No.	Notification date	Implementation date
CN/F/24/008	July 05, 2024	August 05, 2024

Subject : Improvement primary blister packaging of mdi Stericheck: Closed sterility test system

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

- SH#####
- SL#####
- SML#####
- SMP#####
- SP#####
- SV1#####
- SV2#####
- SV3#####
- SV4#####
- SVC#####

Background:

In our efforts to continuously improve the products, certain changes have been initiated for the primary blister packaging of mdi Stericheck with catalog numbers as mentioned in the scope. A punch hole shall be made in a corner (peel off area) of the primary blister packaging of mdi Stericheck.

This advance change notification is initiated to provide the advance notification regarding the said change to the user.

The changes will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

mdi Stericheck canisters are packed in a primary blister packaging.

Based on the customer feedback It was found that some application require hanging of Stericheck device along with primary blister packaging and the existing packaging does not have provisions to cater to this requirement. Hence, it has been decided to implement a punch hole in a corner (peel off area) in blister packaging of Stericheck without compromising the package integrity.

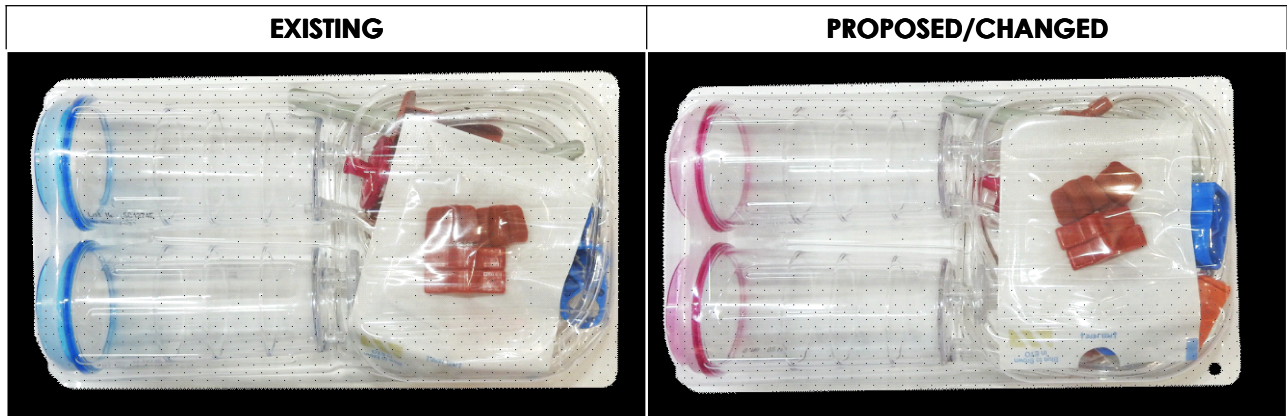
No changes have been made to the materials of construction or performance parameters or manufacturing process or critical dimensions or identification/traceability.

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How Does It Affect the User:

From a user's point of view the changes done will improve the use of mdi Stericheck in specific applications where the Stericheck device needs to be hung along with the primary blister packaging. All product specifications including materials of construction and performance specifications shall remain unchanged. Representative pictures depicting the existing and proposed Stericheck blister packaging are shown in figure-1.

Figure - 1



Implementation of Change:

mdi Stericheck with catalog numbers as mentioned in the scope, manufactured after the implementation date, will have changed packaging.

However, the available stock of mdi Stericheck with catalog numbers as mentioned in the scope and having primary blister packaging without punch holes will be supplied until 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
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