

Change Notice No.	Notification date	Implementation date
CN/18/012	December 15, 2018	January 15, 2019

Subject : Improved design of liquid transfer needle of mdi Stericheck: Closed Sterility Test System

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

- SHPC#####
- SPCC#####
- SPCM#####
- SPCN#####
- SPCV#####

Background:

In our efforts to provide the user better products with more convenience, certain changes have been made in the liquid transfer needle of **mdi Stericheck: Closed Sterility Test System** with catalog numbers as mentioned above. The change will have no impact on the product's regulatory compliance.

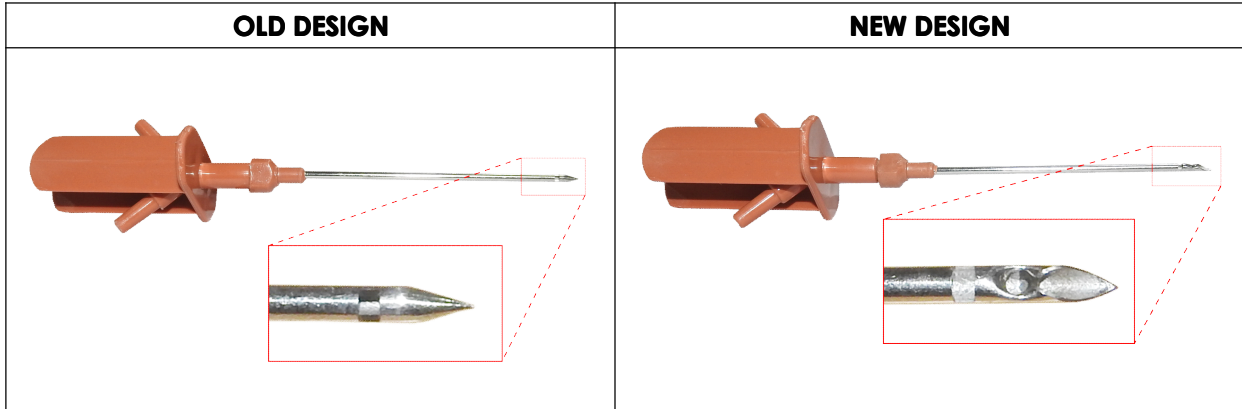
Need for Change:

mdi Stericheck: Closed Sterility Test System with catalog numbers as mentioned above contain two types of needle assemblies/adapters. One is used for transfer of drug substances/liquid and other is used for venting of air. It was observed that when the existing liquid transfer needle assembly is used with plastic containers, it is sometimes difficult to pierce the wall of plastic containers. To address this observation, the design of liquid transfer needle of **mdi Stericheck: Closed Sterility Test System** has been improved for easy piercing of plastic containers. The new design of liquid transfer needle assembly has been verified for critical product performance parameters including piercing of the plastic containers. No change has been done in any other critical dimensions or materials of construction or manufacturing process.

How Does It Affect the User:

From a practical point of view this change only improves the piercing of the plastic containers. All performance specifications and product attributes remain unchanged, except the improved liquid needle.

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Implementation of Change:

mdi Stericheck: Closed Sterility Test System with catalog numbers as mentioned above, manufactured after the implementation date (**January 15, 2019**) will have the said changes. However, the available stock of **mdi** Stericheck: Closed Sterility Test System (with mentioned catalog numbers) having old liquid transfer needle assembly 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'.

Head - Quality Assurance
Advanced Microdevices Pvt. Ltd.