

Reference : CHANGE NOTICE No.: CN/15/08

Subject : Change in Certificate of Quality for **mdi** Closed Sterility Test Device type Stericheck

Scope : This change notification will affect all types of **mdi** Closed Sterility Test Device type Stericheck.

Background:

In our efforts to inform the user more relevant information regarding traceability of test method as per the regulatory requirement, it has been decided to make certain addition in the contents of the Certificate of Quality for **mdi** Closed Sterility Test Device type Stericheck (All types).

Need for Change:

Microbial Recovery Test (as defined in the USP) is performed for **mdi** Closed Sterility Test Device type Stericheck. USP specifically recommends the use of ATCC (American Type Culture Collection) microorganism for Microbial Recovery Test. Presently, we are using the MTCC (Microbial Type Culture Collection) microorganism which are traceable to ATCC microorganism. The traceability of MTCC microorganism to ATCC microorganism has been added in the Certificate of Quality for **mdi** Closed Sterility Test Device type Stericheck (All types).

How Does It Affect the User:

From a practical point of view it is only a 'paper change' and in no way will affect the properties, performance characteristics and traceability of the product under actual conditions of use. All performance specifications and product attributes remain unchanged.

- The ATCC traceability of microorganism has been added in brackets against each MTCC microorganism.

Effective Date:

mdi Closed Sterility Test Device type Stericheck (as mentioned above) manufactured after September 01, 2015 will have the certificate of Quality accompanying the said changes.

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

