

Reference : CHANGE NOTICE No. MB/11/05

Subject : Change in Certificate of Quality for mdi Closed Sterility Test Device type Stericheck (All types)

Scope : This change notification will affect the following Clauses of the Certificate of Quality:

- Package Integrity : Added
- Biosafety/Toxicity : Removed
- Inprocess Tests (Sealing and housing Integrity) : Re-structured
- Membrane Integrity : Re-structured
- Burst Pressure : Re-structured
- Water Flow Rate : Re-structured
- Maximum Operating Temperature : Re-structured
- Residual EO : Re-structured
- Safety : Re-structured and updated
- Sterility : Re-structured and updated
- Microbial Recovery : Re-structured and updated

Background:

In our efforts to inform the user about more relevant and properly structured information regarding the products they use, it has been decided to make certain changes in the contents of the Certificate of Quality for mdi Closed Sterility Test Device type Stericheck (All types).

Need for Change:

As above.

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 and performance characteristics of the product under actual conditions of use. All performance specifications and product attributes remain unchanged.

- **Package Integrity:** This test has been added in Certificate of Quality.
- **Biosafety/Toxicity:** This test has been removed for Certificate of Quality.
- **Inprocess Tests (Sealing and Housing Integrity), Membrane Integrity Test, Burst Pressure Test, Water Flow Rate Test, Maximum Operating Temperature and Residual EO:** These tests have been re-structured.
- **Safety, Sterility and Microbial Recovery:** These tests have been re-structured and updated in Certificate of Quality.

Effective Date:

mdi Closed Sterility Test Device type Stericheck (All types) manufactured after 20th June, 2011 will have Certificate of Quality with said changes.

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



Quality Assurance

Advanced Microdevices Pvt. Ltd.