

# Certificate of Quality

The **Stericheck-C PFS** has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

## STERICHECK: CLOSED STERILITY TEST SYSTEM

Catalog No. : SPFC0902XXXX202  
Type : **Stericheck-C PFS**  
Pore Size : 0.45 µm  
Lot No. : SC8897G  
Ster. No. : 045  
Date of Sterilization : 2017 - 07  
Expiry Date : 2020 - 07

### MATERIALS

Canisters : SAN  
Membrane : 0.45µm, Cellulose Nitrate  
Tubings : PVC

### DIMENSIONS

Canisters : 51mm (D) x 120mm (H)  
Tubing Length : 850mm

Sterilization : Pre-sterilized with EO gas using validated sterilization process with well controlled Relative Humidity, Temperature, Pressure and Exposure Time.

### INPROCESS TEST

Sealing and housing Integrity : Each unit is tested for sealing and housing integrity during manufacture to assure integrity of welds at all places in the device.

### LOT RELEASE TESTS

Each lot has been sampled, tested and released for the following characteristics:

- Membrane Integrity : The Stericheck canisters have been tested for membrane integrity by Bubble Point test using DI water. Membrane Bubble point was:  $\geq 29$  psi (2.04 Kg/cm<sup>2</sup>).
- Package Integrity : Integrity of final packaging has been tested as per ASTM F1929-98.
- Retention Efficiency : Retains  $\geq 10^7$  organisms/cm<sup>2</sup> of *Serratia marcescens* ATCC 14756 challenge.
- Sterility : Pre-sterilized canisters were tested for sterility as per USP and found sterile.
- Burst Pressure : Meets minimum burst pressure requirements of 45 psi (3.15 Kg/cm<sup>2</sup>).
- Water Flow Rate : Meets minimum water flow requirements of 0.3 lpm at 0.70 Kg/cm<sup>2</sup> (10 psi) at 25 °C.
- Microbial Recovery : Exhibits microbial recovery for *Pseudomonas aeruginosa* MTCC 1688 (ATCC 9027), *Clostridium sporogenes* MTCC 1349 (ATCC 11437), *Bacillus subtilis* MTCC 441 (ATCC 6633), *Staphylococcus aureus* MTCC 737 (ATCC 6538), *Candida albicans* MTCC 227 (ATCC 10231) and *Aspergillus brasiliensis* MTCC 1344 (ATCC 16404) as per USP.

### VALIDATED FOR

Maximum Operating Temperature : 35°C Continuous  
Residual EO : < 6 ppm  
Safety (Vent plug blown off pressure) : Rubber Plug on canister vent is designed to blow off much below the rated burst pressure of the canister assuring total operator safety.

### PRECAUTIONS

1. **mdi** Stericheck Closed Sterility Test System is a pre-sterilized device and its sterility will be compromised in case the pack is damaged or tampered with. Do not use the device in such cases.
2. During handling, avoid contamination of inlet.

### CUSTOMER SUPPORT

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.



Head of Quality Assurance

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