

Certificate of Quality

The **Stericheck-C SVP1** has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

STERICHECK: CLOSED STERILITY TEST SYSTEM

Catalog No. : SV1C0902XXXX302
Type : **Stericheck-C SVP1**
Pore Size : 0.45 µm
Lot No. : SC9984I
Ster. No. : R6964
Date of Sterilization : 2024 - 09
Expiry Date : 2026 - 09

MATERIALS

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

DIMENSIONS

Canisters : 51mm (D) x 120mm (H)
Tubing Length : 850mm
Sterilization : Pre-sterilized with Gamma Irradiations at ≥ 25 kGy.

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: ≥ 29 psi (2.04 Kg/cm²).
- Package Integrity : Integrity of final packaging has been tested as per ASTM F1929.
- Retention Efficiency : Retains microbial challenge of *Serratia marcescens* (ATCC 14756) as per ASTM D3863 .
- Burst Pressure : Meets minimum burst pressure requirements of 65 psi (4.58 Kg/cm²).
- Water Flow Rate : Typical water flow rates were 0.3 lpm at 0.70 Kg/cm² (10 psi) at 25 °C.

VALIDATED FOR

Sterility : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10⁻⁶ in accordance with ISO 11137.
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.
Maximum Operating Temperature : 35°C Continuous
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.

T. No.: COQ/STK/004-01



Head of Quality Assurance

Issue Date: 14-Sep-24

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