WAY 15

Closed System Isolators Validated to Meet FDA Guidance by Containment Technologies Group, Inc.

The MIC Family of Isolators have been validated to meet FDA guidance. This allows your facility the peace of mind in knowing that a closed system isolator from CTG provides the utmost in patient safety.

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Containment Technologies Group, Inc.

Founded: 1994
Employees: Private
Stock Symbol: Private
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Company Background

Containment Technologies Group, Inc. provides isolation technology to a broad range of the healthcare industry including pharmaceutical, medical devices, compounding and hospital pharmacies. Our President and CEO is an active hospital pharmacist and is fully committed to providing innovative isolation systems focused on both patient safety and containment of hazardous materials. The MIC family of isolators have been validated to meet FDA expectations for sterility assurance while protecting the provider and the environment. Our engineering staff designed the MIC family of isolators based on extensive experience gained in developing advanced aseptic processing and containment solutions in FDA regulated industries. The MIC family of isolators is widely accepted in a variety of settings in the United States as well as a number of facilities internationally. Containment Technologies Group, Inc. remains committed to our goal of protecting the patient, the health care provider and the environment.

Product Overview

Did You Know?

That using current manual decontamination techniques such as wipe or spray will still leave significant micro-contamination on the component surfaces being placed into an ISO class 5 environment. The manual decontamination also creates variability in the sterility assurance levels of the preparations leading to unknown levels of sterility.

Good News! Containment Technologies Group, Inc. has validated the MIC Family of Isolators to meet FDA guidance for closed system isolators. The validation not only includes confirmation of an ISO class 5 environment but also incorporates procedures that when followed confirm FDA acceptable sterility assurance levels for components being placed into the direct compounding zone of the isolator.

The Sterility Assurance Levels That are Validated Include:

- The standard MIC Isolator configuration incorporates procedural spray down of components in the static airlock. Providing a defined area, decontamination solution, plus entry and exit protocols results in exceeding published data contamination rates expected in a USP <797> compliant clean room with open primary engineering controls.
- The standard MIC configuration can be modified to incorporate an automated decontamination airlock. The vapor phase hydrogen peroxide is an effective decontaminate with a broad range of capabilities that leaves no residue. The validation of this onsite modification demonstrates a sterility assurance level that meets the FDA expectation for sterility assurance (10^{-4}) of product produced by aseptic processing in approximately two minutes.
- The MIC-EDU System is our most advanced closed system isolator. It uses batch decontamination technology that allows for continuous compounding with no downtime. The vapor phase hydrogen peroxide provides a repeatable method of reaching all interior surfaces contained within the closed system isolator. This unit has been validated to show sterility assurance levels at 10^{-5}.

Features & Options

- Fully validated to meet the FDA's guidance for closed system aseptic processing isolators.
- Provides for superior airflow in a continuous ISO Class 5 or better compounding zone.
- Produces decontamination levels that far exceed standard procedures.
- Validated 4 log reduction with the MIC Family of Isolators and a 5 log reduction with the MIC EDU Systems.
- Testing, procedures, protocols that exceed USP standards and state board regulations.

Additional Product Lines

MIC Family of Isolators (hazardous and non-hazardous solutions): MIC Single, MIC Dual, MIC TPN, MIC 797P, MIC Nuclear and MIC EDU Systems