charles river

MICROBIAL SOLUTIONS

# Sterisart® NF System for Celsis® Sterility Applications

### Benefits of the Sterisart® NF System for Celsis®

- Achieve sterility results in about half the time of the compendial test
- Lot verification with Celsis® instruments, ensuring controlled ATP background and process consistency
- No change to sample preparation processes when compared to the compendial test method
- Septum port feature ensures safe, sterile sample extraction for rapid detection
- Multiple tubing and needle assemblies span a range of sample container formats

When implementing a rapid microbial method, many scientists focus solely on the specifications, software features, and performance of the instrument used without evaluating the potential changes that may be required to their sample preparation protocols and validated test methods. A lab must also factor in these additional considerations, along with changes to their validated preparation methods, adding further complexity to the implementation process.

When conducting sterility tests, it's important to eliminate as many variables as possible. Experienced labs know that new, unforeseen changes can adversely impact a validation project timeline, as well as long-term test consistency and instrument performance. With Celsis® rapid detection, sample preparation methods are left nearly untouched. Charles River has partnered with Sartorius Stedim, a leading international supplier of single-use solutions for the biopharmaceutical industry, to provide the Sterisart® NF closed filtration system qualified specifically for use with Celsis® instruments.

Labs can now take advantage of a complete RMM platform that combines state-of-the-art canisters used for years in sterility testing prescribed through harmonized pharmacopeia chapters, with the process control that comes with ATP qualification, ensuring reproducible results, test-to-test and lot-to-lot.

### Pre-Verified for Use with Celsis® Instruments

Celsis®-qualified Sterisart® disposables are specifically tested for use with Celsis® instruments. The Sterisart® systems are also subjected to rigorous in-process and final quality control tests by Sartorius, according to ISO 9001 standards.

### System Overview

The Sterisart® NF systems are double packaged in ready-to-use assemblies, and ergonomically designed specifically for sterility testing performed inside isolators as described in multiple pharmacopeia. Each assembly consists of two clear plastic canisters connected by flexible tubing to a single sampling probe via a Y-distributor. Provided in two options, these

### Technical Specifications

**Protective cap:** Polyethylene

**Septum material:** Latex and acrylonitrile butadiene styrene (ABS)

**Membrane type:** Regenerated cellulose (RC) membrane

**Nominal pore size:**
0.45 $\mu$m; specified according to harmonized pharmacopeia, e.g., USP <71>; Ph. Eur. 2.6.1

Gamma-sterilized at 25 kGy in compliance with DIN EN 552 and ISO 11137

**Shelf life:**
Sterile for up to three years from date of manufacture

canisters enable the testing of pharmaceutical solutions held in containers that are either closed with an extraction port or septum (option 16466CR-GSD), or in containers, ampoules, or plastic bags with an opening (option 16467CR-GSD).

When used in conjunction with a dedicated peristaltic pump, they support the standard membrane filtration sterility test method by delivering equivalent sample volumes of each into of the two test canisters.

Each canister has a validated 50 mm diameter, 0.45 $\mu$m pore size membrane filter. Graduated marks on each canister indicate approximately 50, 75, and 100 mL levels. A validated sterile vent filter and a septum for sterile sample extraction are fixed to the top of the canister.

The sampling probe is either a 4 cm long vented dual-needle metal spike for closed sample containers, or a 5.2 cm long straight needle for openable sample containers. Color-coded clamps (two white, two yellow) are pre-mounted to the tubing for convenient closing of the tubing as required during the sterility sample preparation procedure.

All necessary accessories (two rubber caps for the vent filters, two plastic wing nut plugs for the canister outlets, and, for version 16467 only, a short needle with air sterilizing filter) are included with each system.

### Sterisart® Septum for Simple, Aseptic Sub-Sampling for Rapid Detection

The Sterisart® septum feature simplifies a critical step in the sterility testing process, extracting samples for rapid detection on Celsis® instruments. The port eliminates the need to pierce tubing or compromise the internal integrity of the test canister, reducing the risks of operator error and introducing false positives through external contamination.

To prepare the sample for rapid detection, 50 $\mu$L test aliquots can be withdrawn from each Sterisart® NF test canister after incubation using the sampling port and a sterile syringe. The aliquots can then be transferred to Celsis® cuvettes and read on Celsis® luminometers. The septum-port design ensures the remaining sample in the canister is safely protected for additional incubation or further confirmatory testing, such as identification, if a positive sample is detected.

### Sterile, Gas-Impermeable Packaging

Each set of Celsis® qualified canister test kits is sealed in a gas-impermeable plastic bag to eliminate the possibility of contaminating the Sterisart® NF system with disinfectants used in standard isolator entry sterilization procedures, such as vapor-phase hydrogen peroxide (VHP). The Sterisart® NF canister test kits are double-wrapped in a controlled production area and packaged in an outer box that is gamma-sterilized at 25 kGy, in compliance with DIN EN 552 and ISO 11137, and marked with color-change sterilization indicators.

## Sterisart® NF System for Celsis® Sterility Applications

| Product | Quantity | Code |
|---|---|---|
| **Celsis® Qualified Sterisart® NF Septum with 4 cm dual-needle** (for closed, septum-topped sample containers) | **10 packages per case, 2 disposables per package** | 16466CR—GSD |
| **Celsis® Qualified Sterisart® NF Septum with 5.2 cm needle** (for openable top sample containers such as ampoules, bottles, or bags) | **10 packages per case, 2 disposables per package** | 16467CR—GSD |

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