

**mdi** AseptiSure WS are low protein binding hydrophilic PVDF membrane mini cartridge filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

These cartridge filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

### Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables

### Applications

- Antibodies
- Protein Solutions
- Buffers
- Vaccine concentrates
- Small Volume Parenterals



Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 210.3(b)(6)

Meets and Exceeds USFDA 21 CFR 177.1520

### Specifications

**Pore Size**  
0.2 µm

#### Materials of Construction

|                    |                  |
|--------------------|------------------|
| Membrane           | Hydrophilic PVDF |
| Support Layer      | Polyester        |
| Plastic Components | Polypropylene    |

#### Microbial Retention

LRV >7 for *B. diminuta* (ATCC 19146) per cm<sup>2</sup>

#### Sterilization

Autoclavable/ Inline steam sterilizable at 135°C for 3 cycles of 30 minutes each.

#### Maximum Operating Temperature

80 °C @ ≤30 psi (2 Kg/cm<sup>2</sup>)

#### Maximum Differential Pressure

50 psi (3.5 Kg/cm<sup>2</sup>) @ 25 °C

#### Bubble Point

≥50psi (3.51Kg/cm<sup>2</sup>) with Water

#### Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

#### Cytotoxicity

Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity

#### Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

#### Fiber Release

Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release

#### Particle Release:

The filtrate complies with USP <788> test for particulate matter in injections

#### TOC and Conductivity

Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after flushing with a specified volume of WFI

#### Extractables with WFI

Passes test as per USP <661>

#### Oxidizable Substances

Passes test as per USP <1231>

### Ordering Information

| Type                                |      | Size                         |      | Pore Size |      | Adaptor |      | Elastomer |      | Sterility   |      | Pack Size |      |
|-------------------------------------|------|------------------------------|------|-----------|------|---------|------|-----------|------|-------------|------|-----------|------|
|                                     | Code | Length and EFA               | Code |           | Code |         | Code |           | Code |             | Code |           | Code |
| AseptiSure WS<br>(0.45 µm upstream) | CWHX | 2.5" (1000 cm <sup>2</sup> ) | 50   | 0.2 µm    | 01   | 4463    | E0   | Silicone  | SS   | Non-Sterile | 1    | 1         | 01   |
|                                     |      | 5" (2000 cm <sup>2</sup> )   | 53   |           |      | 4463B   | H0   |           |      |             |      |           |      |
|                                     |      |                              |      |           |      | 4440    | U0   |           |      |             |      |           |      |
|                                     |      |                              |      |           |      | Seal-K  | G0*  |           |      |             |      |           |      |
|                                     |      |                              |      |           |      | Seal-O  | F0** |           |      |             |      |           |      |
|                                     |      |                              |      |           |      | Seal-M  | J0   |           |      |             |      |           |      |

\*G0 adaptor code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

\*\*Adaptor code F0 is available only in 5" cartridge filters

EFA: Effective Filtration Area

Example

|      |    |    |    |    |   |    |
|------|----|----|----|----|---|----|
| CWHX | 53 | 01 | E0 | SS | 1 | 01 |
|------|----|----|----|----|---|----|