



# AseptiSure HSR 0.1µm Polyethersulfone Membrane Cartridge Filters

mdi Polyethersulfone (PES) membrane cartridge filters type AseptiSure HSR are high temperature resistant filtration devices. These are designed to withstand high pressure differential at high steam sterilization temperature upto 135°C. These filters exhibit high mechanical stability, and wide chemical compatibility even with alkaline process fluids.

These filters come with Polyethersulfone membrane serial layers and Polypropylene support layers to offer 1-14 pH compatibility.

mdi AseptiSure HSR cartridge filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates

#### **Special Features**

- Low protein binding
- · Non-toxic material of construction
- Multiple Autoclave
- · Long service life
- Heat sealed, no glues or adhesives
- Each filter comes with an individual certificate of quality
- Total Traceability:
   Unique identification number is laser etched on each filter

#### **Application**

 Sterile filtration of culture media for mammalian cell culture

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



#### **Material of Construction**

Core and Sleeve: Polypropylene
Filter Membrane: Hydrophilic PES
Support Layers: Polypropylene

#### **Integrity Test Data**

Bubble Point (50% IPA/Water Wetted)	≥ 31 psi (2.18 Kg/cm²)
Air Diffusion Flow	≤ 15 ml/min
5" Cartridge	@ 50 psi (3.51
(Water Wetted)	kg/cm²)
Air Diffusion Flow	≤ 29 ml/min
10" Cartridge	@ 50 psi (3.51
(Water Wetted)	kg/cm²)

# Water Flow Rate (Typical) for 10" Cartrdige Filters

Pore Size	Flow Rate
0.1µm	15 lpm @ 0.70 kg/cm² @ 27°C

## **Specification**

# Pore Size Rating

0.1 µm

#### **Microbial Retention**

LRV>7 for *Acholeplasma laidlawii* (ATCC 23206) per cm<sup>2</sup>

#### Sterilization

 25 Autoclave/In-line steam sterilization cycles at 135°C for 30 min., Δp=5 psi (0.3kg/cm²)

#### **Maximum Differential Pressure**

50 psi (3.5Kg/cm<sup>2</sup>) @ 25°C

## **Maximum Operating Temperature**

80°C @ ≤ 30psi (2Kg/cm<sup>2</sup>)

#### **Reverse Pressure**

≤ 10 psi (0.7Kg/cm<sup>2</sup>) @ 25°C

#### **Biosafety**

- Passes the Biological Reactivity tests for Class VI plastics as per USP <88>
- Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP <87>

#### Oxidizable Matter

Passes test as per USP <1231>

# Fiber Release

Complies with USFDA CFR Title 21, 210.3(b)(6).

# Particle Release

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

# **TOC (Total Organic Carbon)**

Meets the WFI requirements of USP <643> for Total Organic Carbon after a 3 liter WFI flush.

# Conductivity

Meets the WFI requirements of USP <645> for Conductivity after a 3 liter WFI flush.

# **Ordering Information**

Туре		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size		
	Code		Code		Code		Code		Code		Code		Code	
AseptiSure HSR		CHP1	5"*	53	0.1 µm	36	7P	A0	Silicone	SS	Non	1	1	01
(0.2µm Upstream)		10"	54			,0,	D0	Viton	SV	Sterile				
AseptiSure HSR	CHRX	20"	55			7P without Fin	A1	EPDM	SE					
(0.45µm Upstream)	CHKA	30"	56			28 with Fin	C0	FEP						
								Encapsulated	FV**					
								Viton						
								Adaptor Code otor Code A0 (7					nly	
EXAMPLE	CHRX		55		36	A0		SS		1			01	