



AseptiVent VF- γ

Gamma Irradiatable PVDF Capsule Filters

for Sterile Filtration of Air/Gases in Biopharmaceuticals

Data Sheet

Biopharmaceutical manufacturing involves sterile filtration of air and gases for a multitude of critical processes such as air sparging, bioreactor venting, fermentor exhaust etc. The critical nature of biopharmaceutical processes and associated high costs require the highest degree of reliability for the filter device with regard to its retention efficiency, flow rates, service life and mechanical and thermal stability.

In order to do away with validation, energy and cleaning costs associated with reusable process assemblies and bioreactors, biopharma industry is moving towards single use disposable systems. Gamma sterilizable hydrophobic membrane filter devices offering high quality and reliability have become a necessity.

mdi gamma sterilizable *AseptiVent VF- γ* hydrophobic PVDF membrane capsule filters with a wide range of end connections and different sizes for linear scalability are specially designed for use with disposable single use assemblies for biopharmaceutical processes.

These filters are validated for microbial retention with liquid bacterial challenge test to ensure reliable performance under worst case conditions.

Applications

- Sterile air sparging
- Sterile venting
- Fermentor exhaust

Key Features

- Absolute retention
- 100% integrity tested
- High hydrophobicity
- High air flow rates
- Low Bioburden, <1000 cfu/device
- Endotoxin level certified to be <0.5 EU/ml
- Widest range of end connections
- Products available for total scalability from seed reactors to process scale bioreactors/fermentors
- Total traceability (unique serial number for each filter)
- Individual certificate of quality for each device
- Sterilizable by Gamma irradiation or autoclaving

Quality Assurance

mdi's quality management system emphasizes on quality by design rather than by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each *AseptiVent VF-γ* is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Even though *AseptiVent VF-γ* is used for air/gas filtration, it is validated by liquid bacterial challenge test to subject the filter to most stringent conditions for higher degree of assurance.

Integrity test data have been correlated to actual microbial retention with *Brevundimonas diminuta* ATCC 19146 as per ASTM F838-05 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiVent VF-γ* capsule filter is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

AseptiVent VF-γ capsule filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated to meet pre-determined burst pressure specifications to ensure user safety in case of inadvertent pressure build-up.

Bioburden Testing

Device bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit <0.25 EU/ml as established by *Lumulus Amebocyte Lysate* (LAL) test.

Gamma Sterilizability

AseptiVent VF-γ are gamma sterilizable with up to 50 kGy of gamma irradiation.

Total Traceability

AseptiVent VF-γ capsule filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

AseptiVent VF-γ capsule filters are fitted with vent caps and are packed in double polyethylene bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In vivo, USP <88> for class VI Plastics

Easy Connect

Widest Range of End Connections

Critical nature of biopharmaceutical processes involving steps such as sterile venting, air sparging, fermentor exhaust etc requires high quality, reliable, flexible and functionally convenient connectivity with filters.

mdi filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including gamma irradiation and autoclaving.



3/4" Sanitary Flange



1 1/2" Sanitary Flange



1/2" HB



1/2" Single Stepped HB



1/4" SHB



Quick Connector



**Male Luer Slip Outlet
for 25 mm**



**Female Luer Lock Inlet
for 25 mm**

Some end connections
available with *AseptiVent VF-γ*

Customized Connectivity

mdi filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



**1 1/2" Sanitary Flange
to 1/2" Barb Hose**

**1 1/2" Sanitary Flange
to 3/4" Sanitary Flange**



**HighSecurity
1/2" hose barb connection**

Linear Upscaling from R&D to Production Process

Datasheet

Scientists in process development labs working with cell factories or small bioreactors require small area hydrophobic filters for air/gas filtration or sterile venting.

A scale up of these processes for larger productions requires larger area devices.

mdj offers a wide range of *AseptiVent VF-γ* Hydrophobic PVDF capsule filters to provide linear scale up from lab scale to pilot scale to full scale biopharmaceutical manufacturing processes. The appropriate size filter can be selected on the basis of the bioreactor size and required flow rates.



AseptiVent VF-γ
25 mm, 5 cm²



AseptiVent VF-γ
50 mm, 20 cm²



AseptiVent VF-γ
1", 250 cm²



AseptiVent VF-γ
2", 500 cm²



AseptiVent VF-γ
5", 1000 cm²



AseptiVent VF-γ
8", 2000 cm²

Bioreactor Size	Filter Devices	EFA* (Nominal)
200 ml Cell Factories	<i>AseptiVent VF-γ</i> 25 mm	5 cm ²
Up to 1 liter Cell Factories	<i>AseptiVent VF-γ</i> 37 mm	10 cm ²
Up to 5 liter	<i>AseptiVent VF-γ</i> 50 mm	20 cm ²
Up to 50 liter	<i>AseptiVent VF-γ</i> 1"	250 cm ²
Upto 100 liter	<i>AseptiVent VF-γ</i> 2"	500 cm ²
Upto 300 liter	<i>AseptiVent VF-γ</i> 5"	1000 cm ²
Upto 1000 liter	<i>AseptiVent VF-γ</i> 8"	2000 cm ²
Upto 5000 liter	<i>AseptiVent VF-γ</i> 10"	6000 cm ²



AseptiVent VF-γ
10", 6000 cm²

Specifications

Datasheet

0.2µm AseptiVent VF-γ

Construction

Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm ²	10 cm ²	20 cm ²
Membrane	0.2 µm Hydrophobic PVDF		
Support Layers	Polyester		
Plastic Parts	Gamma Stable Polypropylene		
Dimension (End to End)	¼" SHB I/O	-	64 mm
	¾" Sanitary Flange I/O	-	51 mm
	Female Luer Lock Inlet/ Male Luer Slip Outlet	23 mm	-
Operational Radius	15 mm	23 mm	28 mm

Operational

Max. Operating Temperature	80° C @ ≤ 0.5 Kg/cm ² (7psi)	
Max. Differential Pressure	1.5 Kg/cm ² (22 psi) @ 30° C	
Minimum Acceptable Bubble Point with 50% IPA/Water	≥ 1.27 Kg/cm ² (18 psi)	
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy
	By Autoclave	Autoclavable at 125 °C for 30minutes, 1 Cycle after gamma irradiation. Can not be in line steam sterilized

Assurance

Toxicity	Passes biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> per cm ² of filter area as per ASTM F 838-05 against liquid bacterial challenge
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Fractional Dissolution	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Datasheet

0.2µm AseptiVent VF-γ (1", 2", 5", 8")

Construction

Size	1"	2"	5"	8"	
Effective Filtration Area (Nominal)	250cm ²	500cm ²	1000cm ²	2000 cm ²	
Membrane	0.2 µm Hydrophobic PVDF				
Support Layers	Polyester				
Body and Core	Gamma Stable Polypropylene				
Dimension (End to End)	1½" Sanitary Flange I/O	91 mm	110 mm	161 mm	211 mm
	½" HB I/O	90 mm	112 mm	164 mm	215 mm
	Quick Connector	100 mm	111 mm	163 mm	212 mm
	¼" SHB I/O	94 mm	122 mm	172 mm	223 mm
	¾" Sanitary Flange	91 mm	103 mm	155 mm	205 mm
Operational Radius (with Vent/ Drain)	30 mm	65 mm	65 mm	65 mm	
Vent and Drain	¼" Hose Barb with Silicone "O" ring				

Operational

Max. Operating Temperature	80° C @ 2 Kg/cm ² (30psi)	
Max. Differential Pressure	4Kg/cm ² (60psi) @ 30° C	
Minimum Acceptable Bubble Point with 50% IPA	≥ 1.27 Kg/cm ² (18 psi)	
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy
	By Autoclave	Autoclavable at 125 °C for 30minute, 1 Cycle after gamma irradiation. Can not be in line steam sterilized

Assurance

Toxicity	Passes biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> per cm ² of filter area as per ASTM F 838-05 (liquid bacterial challenge)
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Specifications

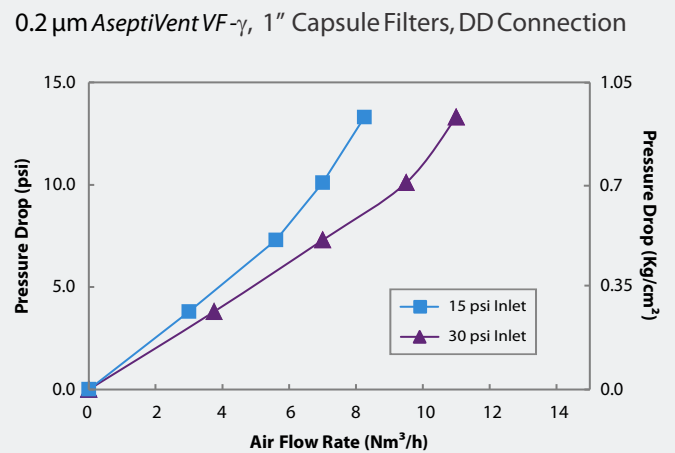
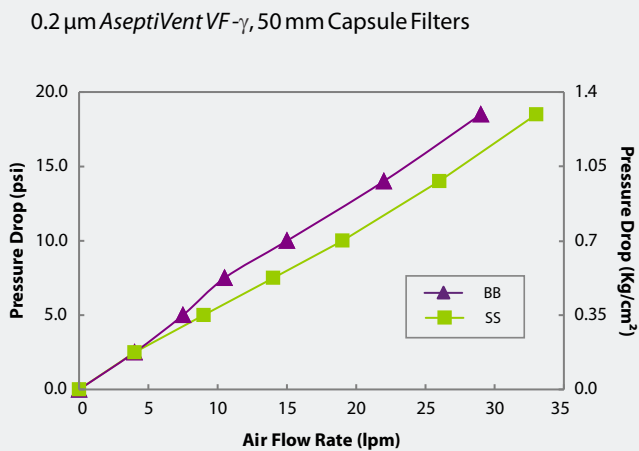
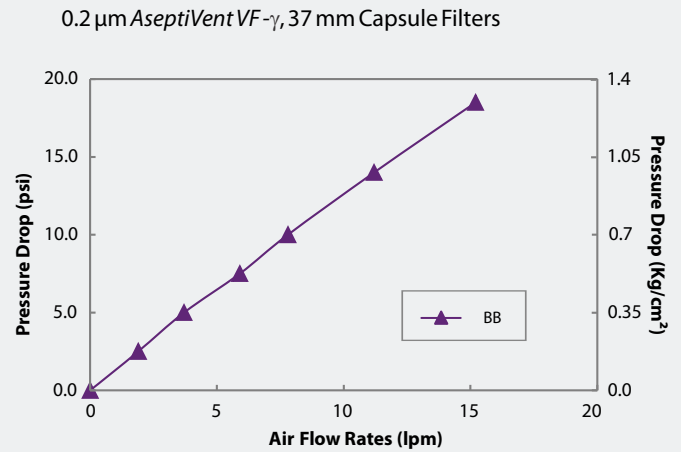
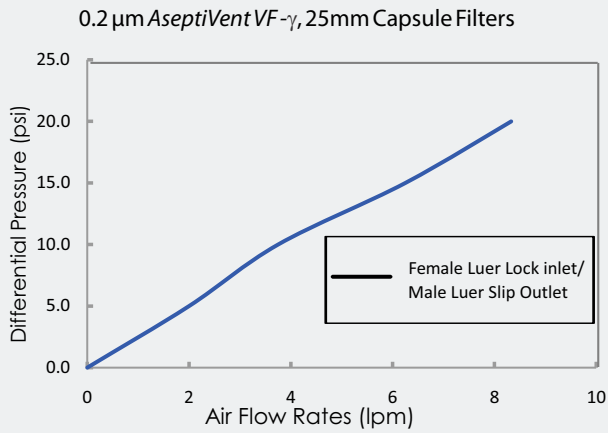
Datasheet

0.2µm AseptiVent VF-γ 5", 10", 20", 30"

Construction					
Size		5"	10"	20"	30"
Effective Filtration Area (Nominal)		3000cm ²	6000cm ²	12000cm ²	18000 cm ²
Membrane	0.2 µm Hydrophobic PVDF				
Support Layers	Polyester				
Body and Core	Gamma Stable Polypropylene				
Dimension (End to End)	1½" Sanitary Flange	207 mm	326 mm	601 mm	876 mm
	½" Single Step Hose Barb	217 mm	332 mm	607 mm	882 mm
Operational Radius (with Vent/ Drain)		78 mm	78 mm	78 mm	78 mm
Vent and Drain	1/4" Hose Barb with Silicone "O" ring				
Operational					
Max. Operating Temperature	80° C @ 2Kg/cm ² (30psi)				
Max. Differential Pressure	4Kg/cm ² (60psi) @ 30° C				
Minimum Acceptable Bubble Point with 50% IPA	≥ 1.27 Kg/cm ² (18 psi)				
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy			
	By Autoclave	Autoclavable at 125 °C for 30minute, 1 Cycle after gamma irradiation. Can not be in line steam sterilized			
Assurance					
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics				
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1				
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> per cm ² of filter area as per ASTM F 838-05 (liquid bacterial challenge)				
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>				
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release				
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections				
Fractional Dissolution	Comply with USFDA 21 CFR Part 177.1520				
Oxidizable Substances	Passes test as per USP <1231>				
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520				
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices				
Quality Management System	ISO-9001 Certified				
USFDA	DMF No. 015554				

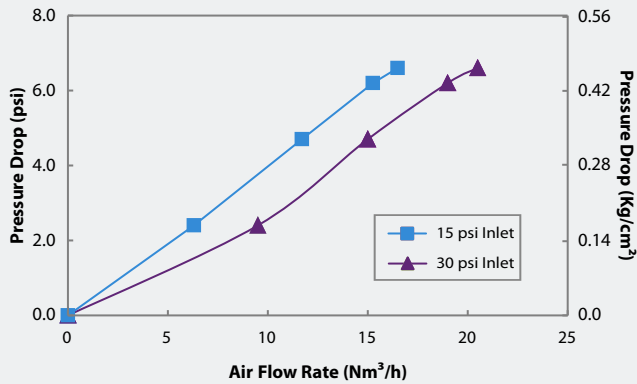
AseptiVent VF-γ is produced using a high hydrophobicity PVDF membrane. This ensures good flow rates even with high moisture content in the inlet air.

AseptiVent VF-γ capsule filters are designed to offer high air/gas flow rates at low differential pressures.

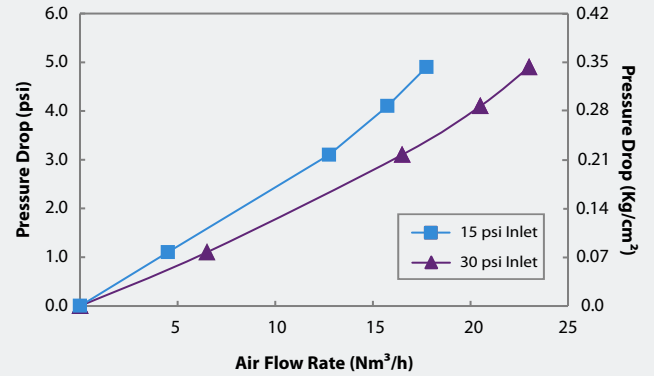


End Connection Type: **B:** ¼" Stepped Hose Barb **S:** ¾" Sanitary Flange **D:** ½" Hose Barb

0.2 μm AseptiVent VF- γ , 2" Capsule Filters, DD Connection



0.2 μm AseptiVent VF- γ , 5" Capsule Filters, DD Connection



End Connection Type: D: 1/2" Hose Barb

Ordering Information

Datasheet

0.2 µm AseptiVent VF-γ 25mm PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code	Yes	Code			Code		Code
AseptiVent VF-γ	IVFX	25 mm	06	0.2µm	01	1/8" Hose Barb	H	Yes	R		Non Sterile	1	100	04
						Female Luer Lock	M	No*	X		Gamma Sterile	3		
						Male Luer Slip	N							
						Male Luer Lock	L							
						1/4" Hose Barb	B							

Example:

IVFX	06	01	MN	R	X	1	04
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* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: IVFX0601MNRX104

Example for gamma Sterile: IVFX0601MNXX304

0.2 µm AseptiVent VF-γ 37mm, 50mm PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code	Yes	Code			Code		Code
AseptiVent VF-γ	IVFX	37 mm	08	0.2µm	01	¼" SHB	B	Yes	R		Non Sterile	1	10	02
		50 mm	10			¾" Sanitary Flange	S	No*	X		Gamma Sterile	3		

Example:

IVFX	10	01	BB	R	X	1	02
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* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: IVFX0801BBRX102

Example for gamma Sterile: IVFX0801BBXX302

Note: Inlet/Outlet Connections and Pack Sizes available with different diameter filters as follows:

Connections Available			
Inlet/Outlet	25mm	37mm	50mm
1/4" - 3/4" Stepped Hose Barb	X	√	√
3/4" Sanitary Flange	X	X	√
Female Luer Lock	Inlet Only	X	X
Male Luer Slip	Outlet Only	X	X
1/8" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
1/4" Hose Barb	√	X	X

Pack Size Available			
Pack Size	25mm	37mm	50mm
10/Pack	X	√	√
100/Pack	√	X	X

Ordering Information

Datasheet

0.2 µm AseptiVent VF-γ PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF-γ	DVLX	1"	51	0.2µm	01	¼" SHB	A	Yes	R		Non Sterile	1	1	01
		2"	52			½" Hose Barb	D	No*	X		Gamma Sterile	3		
		5"	53			Single Step ½" Hose Barb	Q							
		8"	57			1½" Sanitary Flange	E							
						¾" Sanitary Flange	S							
						Quick Connector	J							
						½" Single Step Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						3/16" Hose Barb	N							
						3/8" Hose Barb	I							

Example:

DVLX	57	01	EE	R	X	1	01
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* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: DVLX5301QQRX101

Example for gamma Sterile: DVLX5301QQXX301

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
1/4" Stepped Hose Barb	√	√	√	√
½" Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3/16" Hose Barb	√	√	Outlet Only	X
3/8" Hose Barb	X	√	√	√

0.2 µm AseptiVent VF-γ PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/T-Line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
Aseptivent VF-γ	LVLX	5"	53	0.2µm	01	½" Single Step Hose Barb	Q	Yes	R	Inline	X	Non Sterile	1	1	01
		10"	54			1½" Sanitary Flange	E	No*	X	T-line**	T	Gamma Sterile	3		
		20"	55			3/8" Hose Barb	I								
		30"	56			1" Hose Barb	Z								

Example:

LVLX	54	01	EE	R	X	1	01
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* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: LVLX5401QQRX101 Example for gamma Sterile: LVLX5401QQXX301

** T-line is not available in 5" Capsule filter

** T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Inline				T-Line		
	5"	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	√	X	X	X
1½" Sanitary Flange	√	√	√	√	√	√	√
3/8" Hose Barb	√	√	√	√	X	X	X
1" Hose Barb	X	√	√	√	X	X	X

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA

Tel : +91-171-2699290, 2699471

E-mail : info@mdimembrane.com

Website : www.mdimembrane.com