Millipore®
Preparation, Separation, Filtration & Monitoring Products

Data Sheet

Viresolve® Pro Solution

Proven viral safety solution designed to provide the highest levels of retention assurance and productivity

Robust. Productive. Proven.

The Viresolve® Pro Solution provides a comprehensive, flexible template solution for virus filtration in biologics manufacturing. This proven viral clearance solution delivers the highest levels of retention assurance and processing efficiency across a broad range of feed streams.

The Viresolve® Pro Solution is comprised of the innovative, high-performing Viresolve® Pro Device in conjunction with the Viresolve® Pro Shield or the Viresolve® Pro Shield H prefilters. These products are designed to work together to meet your needs providing high parvovirus retention, capacity and flux. Our industry-leading products and services, coupled with our viral clearance expertise, will help you successfully develop, implement, and validate the Viresolve® Pro Solution.

Benefits

Viresolve® Pro Solution: High-productivity Virus Filtration

- Improved process economics with high mass capacity
- High flux for faster processing
- Consistent batch-to-batch performance
- Easy to install, use and integrity test
- Caustic sanitizable

Viresolve® Pro Device: Robust Parvovirus Clearance

- ≥ 4.0 log removal of parvovirus
- Devices are 100% integrity tested with air/water diffusion and Binary Gas
- Robust retention maintained during process interruption/depressurization

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Prefilters: Viresolve® Pro Shield & Viresolve® Pro Shield H

Provides robust adsorptive (cation/mixed-mode) prefiltration to remove fouling protein aggregates

- Enhance throughput and process robustness of Viresolve® Pro Devices
- Effective across a broad range of pH and conductivity conditions

Enhanced Process Robustness

For feed streams with high levels of fouling protein aggregates, the Viresolve® Pro Shield or Viresolve® Pro Shield H can be used to improve the capacity of the Viresolve® Pro Device.

These membrane prefilters adsorb protein aggregates that foul or plug the pores in the Viresolve® Pro membrane. Viresolve® Pro Shield and Viresolve® Pro Shield H have different membrane surface modifications to maximize adsorption of protein aggregates under a broad range pH and conductivity conditions (Figure 1).

The Viresolve® Pro Prefilter Selector Guide (TB1140EN00) provides guidance and information on prefilter selection.

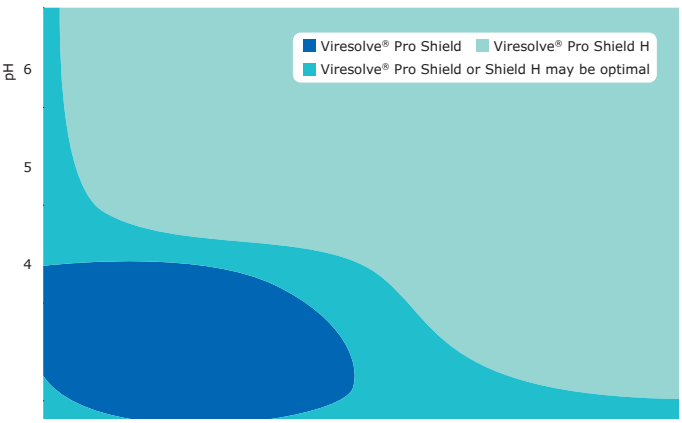
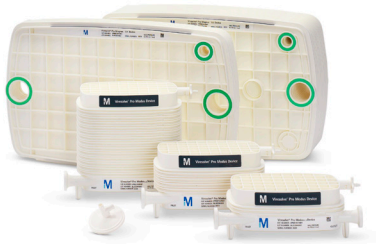


Figure 1.
Contour plot showing the optimal pH and conductivity conditions for Viresolve® Pro Shield and Viresolve® Pro Shield H.

Virus Filter: Viresolve® Pro Device



Provides robust viral clearance

- ≥ 4.0 logs of Minute Virus of Mice clearance
- ≥ 5.0 logs of Murine Leukemia Virus clearance
- Delivers high capacity

High Virus Retention

Retention performance of the Viresolve® Pro Micro 40 Devices, containing two lots of membrane, was evaluated under aggressive processing conditions. Testing was performed with a monoclonal antibody feed stream at 60 psi to a filtration endpoint of 90% flow decay, followed by a 20 L/m^2 buffer flush. Samples were collected from final filtrate pools and a summary of calculated log reduction values (LRV) is shown in Figure 2. As can be seen from the results, the Viresolve® Pro Solution achieved at least 5.8 logs of MVM retention. These results demonstrate robust virus clearance, even out to 90% flow decay, at high pressure.

Virus retention performance of the Viresolve® Pro Solution under a range of processing conditions is summarized in the application note *Virus Retention Performance of Viresolve® Pro Devices under a Range of Processing Conditions* (WP3374EN).

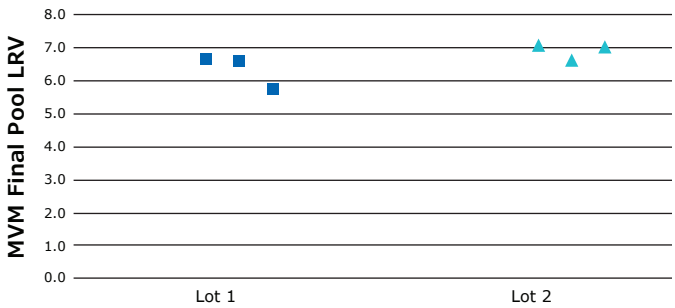


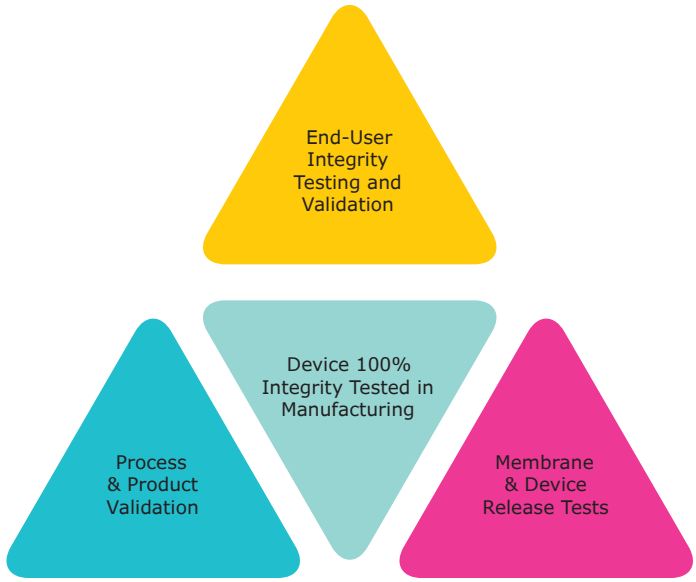
Figure 2.
Summary of MVM results for two membrane lots of Viresolve Pro® Micro 40 Devices.

Building Quality

The virus retention performance and integrity of Viresolve® Pro Devices is assured with our comprehensive approach to quality.

Assuring Retention

Retention performance is assured with our proprietary Binary Gas test which detects defects as small as 3-5 microns, that cannot be detected using a traditional air/water diffusion test, Figure 3. This high sensitivity test is especially valuable for Viresolve® Pro Devices, where small defects could impact virus retention performance. Every Viresolve® Pro Device must pass Binary Gas testing before release, assuring the highest levels of virus retention for your filtration operations.



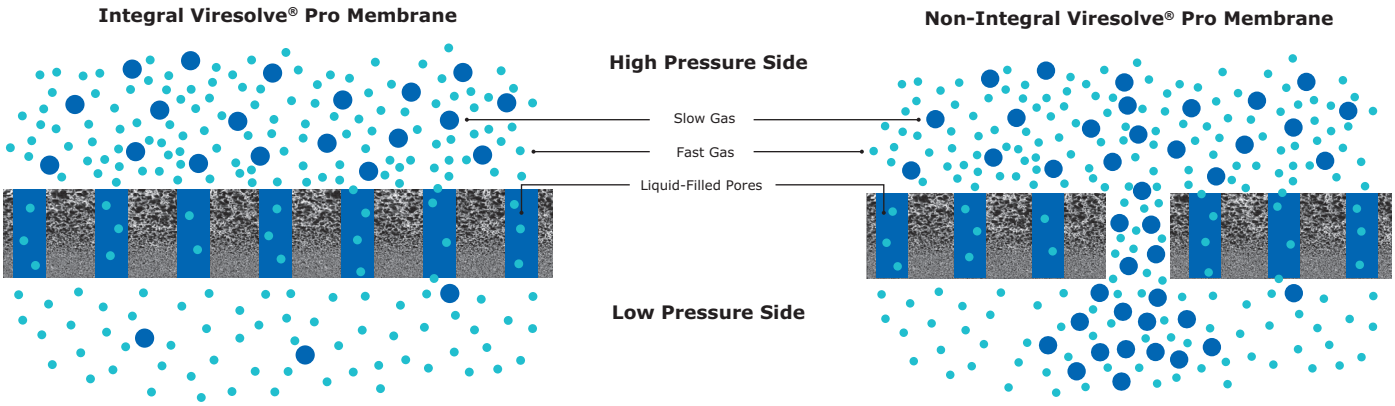


Figure 3.
Principles of Binary Gas Test. This proprietary test measures the composition of a mixture of two gases on the upstream and downstream sides of the Viresolve® Pro membrane to detect defects as small as 3-5 microns in size.

High Capacity and Flux

The Viresolve® Pro Solution efficiently processes feed streams of different pH, conductivities and protein concentrations. When used upstream of Viresolve® Pro Devices, Viresolve® Pro Shield and Shield H enhance the throughput and processing robustness of filtration operations.

Figure 4 shows the results of throughput testing with Viresolve® Pro Devices alone (A) or in conjunction with Viresolve® Pro Shield and Shield H (B). In most cases, implementing the prefilter increased the capacity of the Viresolve® Pro Device by an average of two-fold. The Viresolve® Pro Solution enables rapid processing delivering mass flux in the 1.25-2.5 kg/m²/hr range.

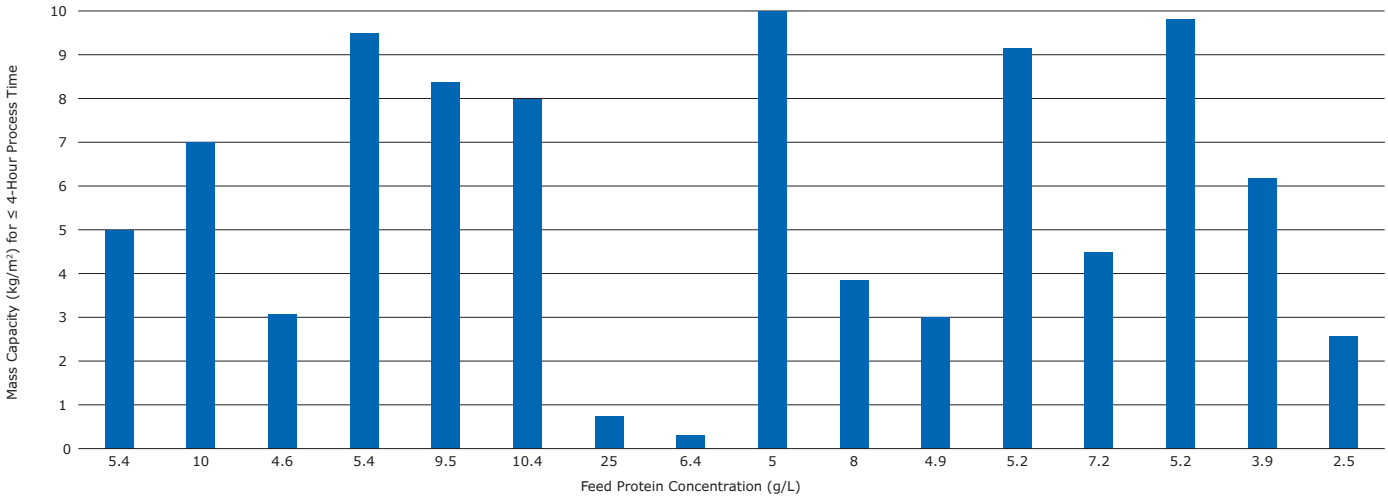


Figure 4A.
Mass capacity on Viresolve® Pro Devices with mAbs of different protein concentrations. In all cases, processing time was less than four hours.

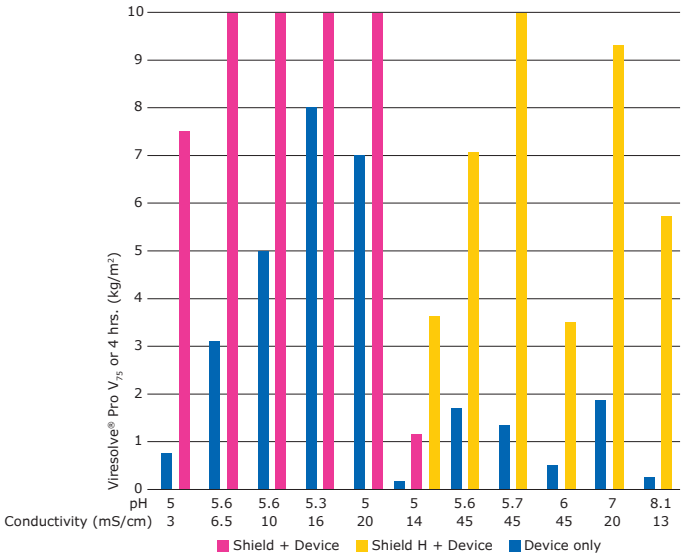


Figure 4B.
Mass capacity of the Viresolve® Pro Solution across a range of pH and conductivities. In all cases, processing was stopped at 75% flow decay or four hours.

Flexible Manufacturing

The Viresolve® Pro Shield, Viresolve® Pro Shield H and Viresolve® Pro Devices are easily integrated into flexible, easy-to-use systems for pilot to full-scale manufacturing.

Viresolve® Pro/Pro+ Magnus Holders for Viresolve® Pro Solution

Viresolve® Magnus Holders are designed for large volume processing. The Viresolve® Pro Magnus Holder is designed to run the Viresolve® Pro Device alone, while the Viresolve® Pro+ Magnus Holder is designed to run the Viresolve® Pro Device coupled with either the Viresolve® Pro Shield or Shield H.

- Quick and easy loading and unloading
- No product contact
- Minimized holder footprint with vertical orientation
- Rods in multiple lengths for various sized installations
- Simple manual hydraulics

Mobius® FlexReady Solution for Virus Filtration

The Mobius® FlexReady Solution for large-scale virus filtration is an easy-to-use system featuring an optimized single-use flow path designed to fully support your virus filtration needs.

For more information on the Mobius® FlexReady Solution for large scale virus filtration, refer to datasheet DS1259EN00.

Viresolve® Pro+ Magnus Holder

Viresolve® Pro Magnus Holder

Mobius® FlexReady Solution

Partner with a leader in viral safety

Virus Filtration Process Development Service

Optimizing a virus filtration process involves evaluating the effects of multiple process parameters to identify conditions that will ensure a robust, consistent, and economical operation. We work side-by-side with development engineers and manufacturers, helping them develop efficient, cost-effective filtration operations.

We can help you:

- Maximize filtration efficiency
- Maximize process robustness
- Meet your economic targets

The Viresolve® Pro Solution is supported by the Emprove® Program - your fast track through regulatory challenges.

Complementing our product portfolio, the Emprove® Program provides three types of dossiers to support different stages of development and manufacturing operations such as qualification, risk assessment and process optimization. The dossiers consolidate comprehensive product-specific testing data, quality statements and regulatory information in a readily-available format to simplify your compliance needs.

Viral Clearance Services

Viral clearance studies are critical to the validation of downstream processes, ensuring sufficient reduction of potential viral contaminants during downstream processing.

BioReliance® viral clearance studies are designed and executed by experts in regulatory, downstream processing, and virology at our facilities in Singapore, the U.S., and the UK. Our global experts can support you with your IND and BLA studies in accordance to regulatory guidelines for monoclonal antibodies, recombinant proteins, and plasma derivatives. Our dedicated project management support and local teams of experienced technical experts accelerate your time to results and minimize risk as you bring your product to market.

Virus Filter Implementation Service

Our engineers can leverage the results of bench-scale studies to help implement your pilot or production scale virus filtration operation. This streamlines implementation and avoids the pitfalls that can impact production timelines and process economics.

Nominal Dimensions and Weights

Viresolve® Pro Shield, Viresolve® Pro Shield H, Viresolve® Pro Devices, and Holders

Size	Nominal Dimensions	Nominal Effective Filtration Area	Nominal Weight
Micro 40 Device	Height: 4.03 cm (1.59 in.) Diameter: 4.37 cm (1.72 in.)	3.4 cm^2	Empty: 14.73 grams
Micro Shield and Shield H	Height: 3.83 cm (1.51 in.) Diameter: 3.07 cm (1.21 in.)	3.1 cm^2	Empty: 4 grams
Modus 1.1	Length: 18.62 cm (7.33 in.) Width: 9.22 cm (3.63 in.) Height: 5.92 cm (2.33 in.)	0.017 m^2	Empty: 0.37 Kg (0.8 lbs)
Modus 1.2	Length: 18.62 cm (7.33 in.) Width: 9.22 cm (3.63 in.) Height: 7.85 cm (3.09 in.)	0.07 m^2	Empty: 0.63 Kg (1.4 lbs)
Modus 1.3	Length: 18.62 cm (7.33 in.) Width: 9.22 cm (3.63 in.) Height: 13.56 cm (5.34 in.)	0.22 m^2	Empty: 1.39 Kg (3.1 lbs)
Magnus 2.1	Length: 34.30 cm (13.50 in.) Width: 20.96 cm (8.25 in.) Height: 4.42 cm (1.74 in.)	0.51 m^2	Empty: 2.6 Kg (5.7 lbs) Full of water: 3.4 Kg (7.5 lbs)
Magnus 2.2	Length: 34.30 cm (13.50 in.) Width: 20.96 cm (8.25 in.) Height: 9.50 cm (3.74 in.)	1.53 m^2	Empty: 5.8 Kg (12.8 lbs) Full of water: 8.3 Kg (18.3 lbs)
Viresolve® Pro Magnus Holder (VPMH103000 / VPMH105000 / VPMH107000)	Length: 78 cm (30.9 in.) Width: 76 cm (30 in.) Height: 127 cm (50 in.)	Not Applicable	141.5 Kg (312 lbs)
Viresolve® Pro+ Magnus Holder (VPMH203000 / VPMH205000 / VPMH207000)	Length: 104 cm (40.9 in.) Width: 76 cm (30 in.) Height: 127 cm (50 in.)	Not Applicable	186 Kg (410 lbs)

Materials of Construction

Viresolve® Pro Shield, Viresolve® Pro Shield H, and Viresolve® Pro Devices, and Holders

Device	Membrane	Components	O-Rings/Gaskets
Micro 40	Polyethersulfone (PES)	Bottom Endcap/Top Endcap: Polyvinylidene fluoride (PVDF)	Not Applicable
Modus 1.1, Modus 1.2, Modus 1.3, Magnus 2.1, Magnus 2.2	Polyethersulfone (PES)	Bottom Endcap/Top Endcap: Polyvinylidene fluoride (PVDF)	Silicone

Shield and Shield H	Membrane	Components	O-Rings/ Gaskets	Connections*
Micro	Polyethersulfone (PES)	Inlet Cap/Outlet Cap: Polypropylene/Polyethylene (copolymer)	Not Applicable	Inlet and Vent: Female Luer-Lok™ Fitting Outlet: Male Luer Slip
Modus 1.1, Modus 1.2, Modus 1.3	Polyethersulfone (PES)	Bottom Endcap/Top Endcap: Polyvinylidene fluoride (PVDF)	Silicone	Inlet and Outlet: 1.91 cm (.75 in.) sanitary fittings Integrated Vent: 0.32 cm (0.125 in.) with hose barb with double O-ring seal
Magnus 2.1, Magnus 2.2	Polyethersulfone (PES)	Bottom Endcap/Top Endcap: Polyvinylidene fluoride (PVDF)	Silicone	Inlet and Outlet: 3.81 cm (1.5 in.) sanitary fittings Vent: 1.90 cm (0.75 in.) sanitary fitting for the port

* Fittings sold seperately

Materials of Construction (continued)

Viresolve® Pro Shield, Viresolve® Pro Shield H and Viresolve® Pro Devices, and Holders

Holders	Membrane	Components	O-Rings/ Gaskets	Connections
Viresolve® Pro Magnus Holder	Not Applicable	Plates & Frames: 316 L stainless steel	Not Applicable	Not Applicable
		Clamp Rods: 300 series stainless steel		
		Fasteners, other components: 300 series stainless steel		
Viresolve® Pro + Magnus Holder	Not Applicable	Plates & Frames: 316 L stainless steel	Not Applicable	Not Applicable
		Clamp Rods: 300 series stainless steel		
		Fasteners, other components: 300 series stainless steel		
Fittings Kit	Not Applicable	Polyvinylidene fluoride (PVDF)	Silicone	Not Applicable

Specifications

Viresolve® Pro Shield, Viresolve® Pro Shield H and Viresolve® Pro Devices

ISO 9001 Quality Standard	These products are manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.
Particulate and Bioburden	These products are manufactured in an ISO Class 8 (Per ISO 14644-1) controlled environment for particulate classification only.
Animal Origin	All components used in the manufacturing of these products are either animal-free or in compliance with EMEA/410/01.
USP <87> Biological Reactivity Tests	Component materials for these products were tested and meet the criteria for non-cytotoxicity for the USP <87> Cytotoxicity L929 MEM Elution Tests.
USP <88> Biological Reactivity Tests	Component materials for these products were tested and meet the criteria for USP <88> Biological Reactivity Tests for Class VI Plastics.
Bacterial Endotoxin	An aqueous extract from these products contains less than 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test.
Membrane Bacteriophage Retention	Membrane samples exhibited ≥ 4.0 LRV of φX 174 bacteriophage at a minimum challenge level of 107 pfu/cm^2 in the presence of a model protein at V_{75}.
Bacteriophage Retention	Viresolve® Pro Device samples exhibited ≥ 4.0 LRV of φX 174 bacteriophage at a minimum challenge level of 10^7 pfu/cm^2 in the presence of a model protein at V75.
Non-Fiber Releasing	These products are non-fiber releasing filters as defined in 21 CFR 210.3(b)*.
Hydraulic Stress Test	Samples were integral based on an Air/ Water Diffusion Test, before and after a forward stress to 4.1 bar (60 psid) at 25 °C.
Manufacturing Integrity Test	All Viresolve® Pro Micro 40 Devices included in the Viresolve® Pro Micro 40 Device Kit must pass the Binary Gas Test. All Viresolve® Pro Modus and Magnus Devices must pass the Pressure Hold, Water Flow Rate, Air/Water Diffusion Test and Binary Gas Test. All Viresolve® Pro Shield and Viresolve® Pro Shield H must pass an aerosol particle challenge and housing pressure hold. All Viresolve® Pro Devices exhibited an air diffusion flow rate at 3.4 bar (50 psig) in water at 25 °C of less than or equal to: • 0.7 cc/min per Viresolve® Pro Modus 1.1 Device • 2.7 cc/min per Viresolve® Pro Modus 1.2 Device • 8.8 cc/min per Viresolve® Pro Modus 1.3 Device • 20 cc/min per Viresolve® Pro Magnus 2.1 Device • 60 cc/min per Viresolve® Pro Magnus 2.2 Device
Caustic Sanitization	These products may be sanitized by one 60-minute flush at 1.8 bar (25 psig) in 0.5 Normal Sodium Hydroxide at 25 °C followed by a maximum 16-hour static soak.

*Filters with the non-fiber releasing claim, as defined in 21 CFR 210.3(b)(6), will also support filter use for liquid filtration in the manufacture, processing or packing of injectable drug products, based on 21 CFR 211.72 cGMP for finished pharmaceuticals.

Ordering Information

Description	Primary Use	Qty/Pk	Cat. No.
Viresolve® Pro Device			
Viresolve® Pro Micro 40 Device Kit	Process Development or Viral Clearance Evaluations	9	**VPMKVALNB9**
Viresolve® Pro Modus 1.1 Device	Small-scale studies/pilot	1	**VPMD101NB1**
Viresolve® Pro Modus 1.2 Device	Pilot/small-volume	1	**VPMD102NB1**
Viresolve® Pro Modus 1.3 Device	Pilot/small-volume	1	**VPMD103NB1**
Viresolve® Pro Magnus 2.1 Device	Large-volume processing	1	**VPMG201NB1**
Viresolve® Pro Magnus 2.2 Device	Large-volume processing	1	**VPMG202NB1**
Viresolve® Pro Shield			
Viresolve® Pro Micro Shield Kit	Process Development or Viral Clearance Evaluations	9	**VPMSKITNB9**
Viresolve® Pro Modus 1.1 Shield	Small-scale studies/pilot	1	**VPPS101NB1**
Viresolve® Pro Modus 1.2 Shield	Pilot/small-volume	1	**VPPS102NB1**
Viresolve® Pro Modus 1.3 Shield	Pilot/small-volume	1	**VPPS103NB1**
Viresolve® Pro Magnus 2.1 Shield	Large-volume processing	1	**VPPS201NB1**
Viresolve® Pro Magnus 2.2 Shield	Large-volume processing	1	**VPPS202NB1**
Viresolve® Pro Shield H			
Viresolve® Pro Micro Shield H Kit	Process Development or Virus Validation Studies	9	**VPMHKITNB9**
Viresolve® Pro Modus 1.1 Shield H	Small-scale studies/pilot	1	**VPPH101NB1**
Viresolve® Pro Modus 1.2 Shield H	Pilot/small-volume	1	**VPPH102NB1**
Viresolve® Pro Modus 1.3 Shield H	Pilot/small-volume	1	**VPPH103NB1**
Viresolve® Pro Magnus 2.1 Shield H	Large-volume processing	1	**VPPH201NB1**
Viresolve® Pro Magnus 2.2 Shield H	Large-volume processing	1	**VPPH202NB1**
Holders, Accessories, Services and Spare Parts			
Viresolve® Pro Magnus Holder	For 1 to 3 Viresolve® Pro Devices	1	**VPMH103000**
	For 1 to 5 Viresolve® Pro Devices	1	**VPMH105000**
	For 1 to 7 Viresolve® Pro Devices	1	**VPMH107000**
Viresolve® Pro+ Magnus Holder	For 1 to 3 Viresolve® Pro Devices and 1 to 3 Viresolve® Pro Shields or Viresolve® Pro Shield H	1	**VPMH203000**
	For 1 to 5 Viresolve® Pro Devices and 1 to 5 Viresolve® Pro Shields or Viresolve® Pro Shield H	1	**VPMH205000**
	For 1 to 7 Viresolve® Pro Devices and 1 to 7 Viresolve® Pro Shields or Viresolve® Pro Shield H	1	**VPMH207000**
Split clamp insert		1	**VPMHINSERT**
Rod handle		1	**VPMHRDKN0B**
Rods	For 1 to 3 Viresolve® Pro Devices	2	**VPMHRD0103**
	For 1 to 5 Viresolve® Pro Devices	2	**VPMHRD0105**
	For 1 to 7 Viresolve® Pro Devices	2	**VPMHRD0107**
Fittings Kit (three 3.81 cm (1.5 in.) sanitary fittings, two 3.81 cm (1.5 in.) blanks, one 1.27 cm (.5 in.) vent fitting and one 1.27 cm (.5 in.) blank)	Viresolve® Pro and Pro+ Magnus Holder	1	**VPMHADAPSK**
3.81 cm (1.5 in.) Sanitary fittings	For feed/permeate port	6	**VPMHADAPSF**

Ordering Information (Continued)

Description	Primary Use	Qty/Pk	Cat. No.
Holders, Accessories, Services and Spare Parts Coutinued			
3.81 cm (1.5 in.) Blanks	For feed/permeate port	6	**VPMHADAPSB**
1.27 cm (.5 in.) Vent fittings	For vent port	6	**VPMHADAPVF**
1.27 cm (.5 in.) Vent blanks	For vent	6	**VPMHADAPVB**
Hydraulic pump		1	**MP0DHYPUMP**
Pressure gauge	For design without quick connector	1	**MP0DHYGAGE**
Hydraulic fluid (1 liter)		1	**MP0DHFLUID**
1/4 inch ball valve	For design with quick connector	1	**VPMHSOVALVE**
1/4 inch ball valve	For design without quick connector	1	**VPMHFNPTVAL**
Hydraulic pressure system gauge	For design with quick connector	1	**VPMHHYGAGE**
Hydraulic cylinder		1	**VPMHHYCYL**
Viresolve® Pro and Pro+ Magnus Holder Services			
IQ/OQ Protocol	Commissioning, installation and operational qualification (IQ/OQ) protocol	1	**DOCVMHIQOQ**
IQ/OQ Protocol and Service	Commissioning, installation and operational qualification (IQ/OQ) protocol and service	1	**SSVIOQMGN**
On-Site Preventive Maintenance (PM) Service	Equipment checks, testing for proper functionality, adjustments and parts replacement (sold separately).	1	**CSVOPMMGN**
Mobius® FlexReady Solutions for Virus Filtration			
Refer to data sheets (DS2562EN00 and DS1259EN00) for specific ordering information.			

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To place an order or receive technical assistance

Please visit **MerckMillipore.com/contactPS**

For additional information, please visit **MerckMillipore.com**

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