

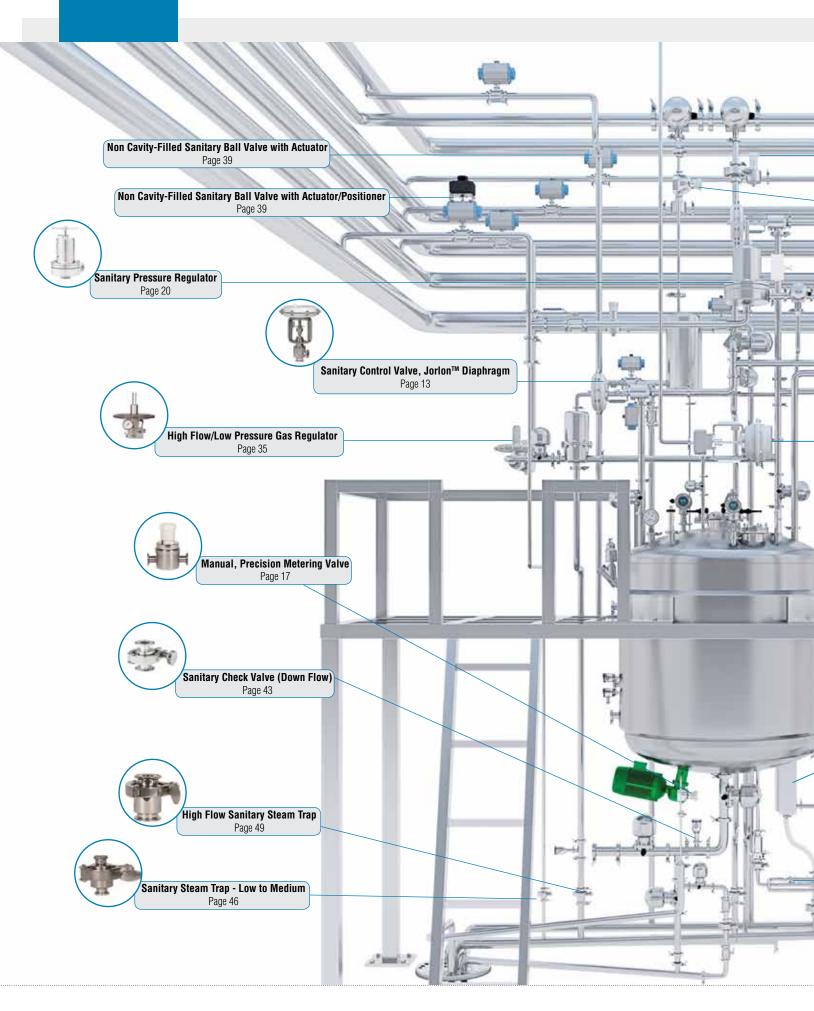
High performance, high quality sanitary valves and accessories....

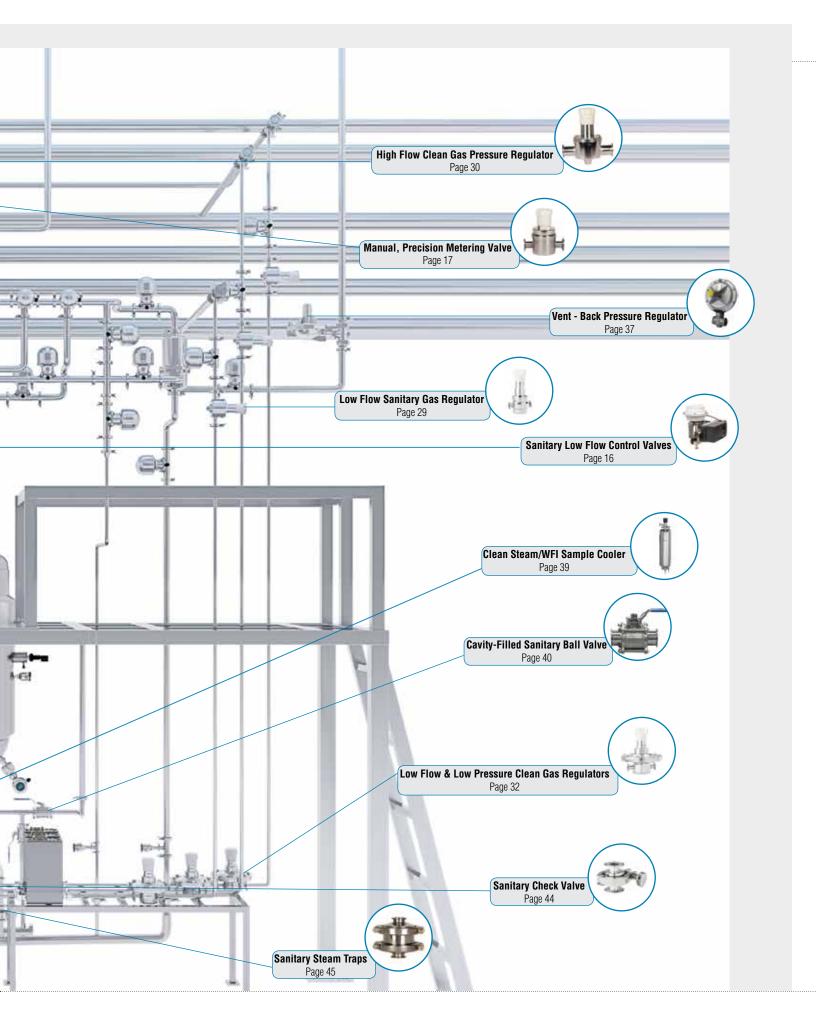
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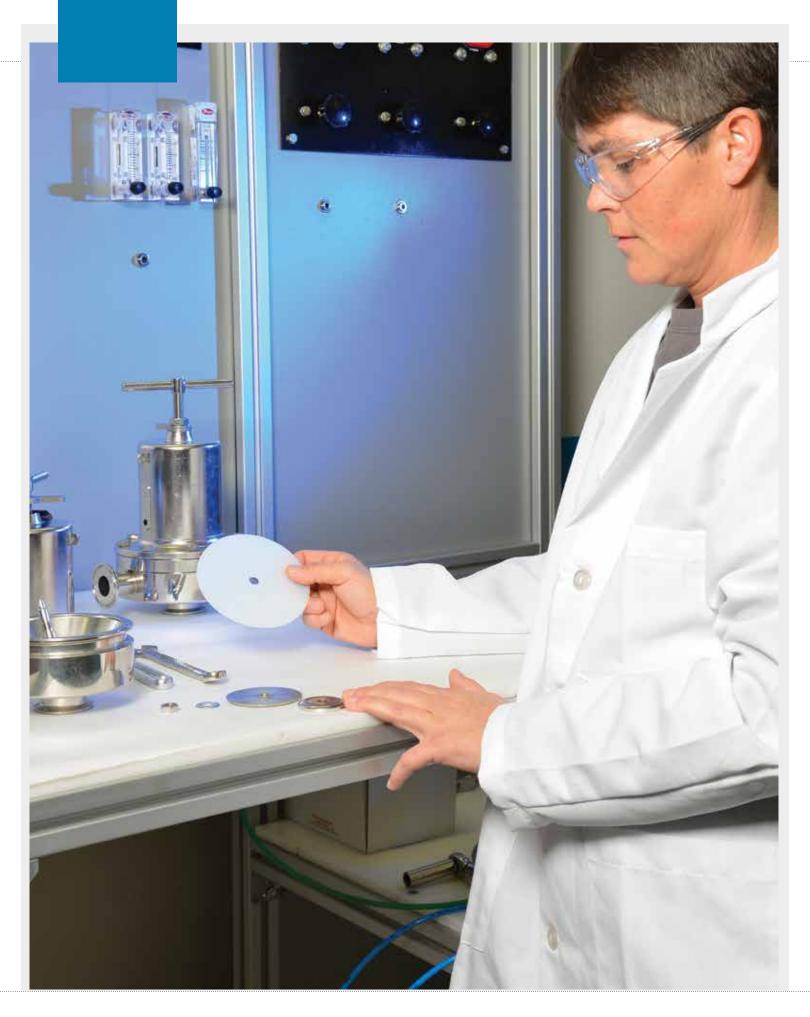


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# Industry leader for sanitary regulators & control valves for over twenty-five years

# **Our History**

Steriflow Valve introduced the Mark 96 and Mark 95 pressure regulators in the late 1980's and has been an industry leader ever since.

The new bio-pharmaceutical industry presented opportunities for innovative valve manufacturers to create technology for pressure control of validated steam and purified water. Jordan Valve's Steriflow "Regulator" was first to market with a very reliable pressure reducing valve and back pressure regulator that met the industry's strict standards for drainability, particulate minimization, surface finish and minimal offset. Within ten years, Steriflow regulators became the most frequently specified valves for clean steam pressure control, buffer pressure control and purified water back pressure control in the world.

By 2007, Steriflow Valve had successfully introduced several control valves, regulators and clean steam specialty products. The Steriflow Valve division was created to nurture continued innovation and to broaden its product scope.

Today, Steriflow Valve has a complete line of pressure regulators, control valves, gas pressure regulators, check valves, steam traps, ball valves and SIP accessories.

# Steriflow has introduced a broad range of industry firsts for the bio-pharmaceutical Industry:

- The industry's first and only Lifetime Diaphragm Warranty
- The first true spring-less and crevice-free check valve for horizontal and vertical line WFI and Bioprocess applications
  - The world's only down-flow check valve for Bioprocess drain applications
- The world's first precision aseptic metering valve
- The world's largest pure steam trap and accessory product range including:
  - Products that shorten SIP heat-up time and eliminate validation temperature alarm
  - \_ Reduce dripleg length
- The first clean gas regulator product line developed specifically for Bio-pharmaceutical applications.
  - The first clean gas regulators designed specifically for reliable control of low flows and low pressures

How may we help you today? Call us at 513.533.5600, Email us at steriflow@richardsind.com, Follow Us on LinkedIn, Facebook and Twitter.

# Certifications, Credentials, & Affiliations

# **Certifications**

- All Material Test Reports comply with the requirements of BSEN 10204, Type 3.1
- Plastic and elastomer Certifications of Compliance included with every order:
  - FDA CFR Title 21, Paragraph 177.1550 for plastic materials FDA
  - FDA CFR Title 21, Paragraph 177.2600 for elastomer materials
  - U.S. Pharmacopeia XXVIII Class VI, Chapter 88 Biological Reactivity Test in Vivo
  - U.S. Pharmacopeia XXVIII, Chapter 87 Biological Reactivity Test in Vitro
  - ADI/TSF Free Certificate
  - Batch lot traceability for elastomer and plastic components
- Steam trap fill fluids meet FDA/ICH Q3C/FDA Class 3 criteria designation

# **Documentation & Traceability**

- All Steriflow Valves have serial numbers that are directly traceable to our Unicert, and to the heat numbers on the type 3.1 material test reports attached.
- · Refer to Unicert Sample on opposite page

#### **Affiliations**

- ASME
- ASME BPE (membership & committee member)
- ISPE
- FCI (membership and Chairman)
- P.E. Registered Profession Engineer State of Ohio, USA

#### **Credentials**

- ISO 9001:2008
- Pressure Equipment Directive (PED) 97/23/EC-PED Category 1
- . (6
- $\cdot$   $(\epsilon_{x})$  available on designated products
- CRN Canadian Registration available for all products



#### CERTIFICATE OF COMPLIANCE

#### ORDER INFORMATION

Customer Name: XYZ Company

P.O. Number: XXXX Order Date: XX/XX/XXXX

Factory Order No: Serial # PrefixXXXX

- CERTIFICATION OF MATERIAL COMPLIANCE: Traceable material certification and MTR's for this order are attached to this document.
- CERTIFICATION OF SURFACE FINISH: The interior, wettable surfaces of the valves furnished on the above-referenced order have a maximum surface finish of 20Ra (0.50µm). The exterior, non-wettable surfaces have a maximum surface finish of 40Ra µin (1.00 µm), except the spring housing will have a casting finish.

☐ Wettable components are certified to be electro-polished.

Note: The above statement does not apply to models CGDM CSDT, Sample Cooler or Sight Glass models without EP order code option. The model MK93 body is not electro-polished as standard.

- CERTIFICATION TO FDA & USP CLASS VI: Steriflow by Jordan Valve certifies that the WETTED elastomer, Teflon, PTFE-resin and perflourolastomer compounds utilized in our sanitary products have been manufactured in accordance with prescribed procedures for pharmaceutical products and have been tested and certified to be in compliance with:
  - Title 21, Paragraph 177.1550 of the FDA Code Federal Regulations for plastic materials for repeated use in contact with food.
  - Title 21, Paragraph 177.2600 of the FDA Code Federal Regulations for rubber and rubber-like materials for repeated use in contact with food.
  - U.S. Parmacopeia XXVIII Class VI, Section 88 Biological Reactivity Test in Vivo.

**Diaphragm Materials** 

#### The following materials used in Richards Industries' Steriflow Products are certified to FDA and USP Class VI per the following:

#### FDA APPROVED MATERIAL

EPDM/NYLON. TFE-VITON

FDA AND USP VI APPROVED MATERIAL

Jorlon

#### **FDA APPROVED MATERIAL**

**BUNA-N** 

# **O-Ring/Gasket Materials**

FDA AND USP VI APPROVED MATERIAL

TFE-SILICON **TEFLON** TFE-VITON TUF-STEEL™ KALRE7  $\mathsf{SILVERBACK}^{\mathsf{TM}}$ **EPDM** SILICON VITON **JORLON FLUORAZ** TUF-FI FX® TFE-EPDM

#### **Seat Materials**

#### FDA AND USP VI APPROVED MATERIAL

PERLAST™ **JORLON** 

TFM 1600 **TEFLON** 

#### SVC-SHC Disc Poppet

# FDA APPROVED MATERIAL

316L/EPDM

#### FDA AND USP VI APPROVED MATERIAL

316L/SILICON TEFLON PEEK

We certify that the components on the above referenced purchase order meet the requirements of the purchase order applicable drawing(s) and our ISO 9001:2008 manufacturing, testing, and inspection procedures to assure an acceptable quality level applicable to the product.

#### TRACEABLE CERTIFICATE OF CERTIFICATION

Serial # Suffix	Valve	Description	Material Type, Spec, Size	Heat #
А	96-100-6L	BODY	ASME SA-479 316/316L	8SF0165-90
		FERRULE	UNS S31603	E130287///F
		LWR DIAPH PLT	ASTM A479, S31603	E151151
		STEM	ASTM A479, S31603	V4L6
		SEAL RETAINER	ASTM A479, S31603	W0Y0

#### **Quality Manager** Date

The attached material certifications are for materials used in the manufacture of this order. In the case of dual-certified material, refer to the properties to verify certification

# The Jorlon™ Diaphragm: Unparalleled Reliability

#### What is Jorlon™?

Jorlon™ is structurally modified pure PTFE. It is manufactured by a proprietary technique where PTFE layers are combined and formed in a unique process to reduce the creep and cold flow associated with conventionally formed solid, or laminated PTFE or Teflon.

A table of physical properties and compliance facts is available below.

Jorlon™ is featured in all of Steriflow's valve product lines:

- Mark 978 Control Valves
- JSHM Manual Metering Valve
- Mark 96 Pressure Regulating Valves
- Mark 95 Back Pressure Regulating Valves
- Mark 96A, 96AA, 95A, 95AA Air Loaded Regulators
- J Series Clean Gas Pressure and Back Pressure Regulating Valves

# Physical Properties of Jorlon™

Color		Clear, translucent
Composition		PTFE
Temperature	Maximum	500°F
Creep relaxation (ASTM F38)	%	35
Specific Gravity (D792)		2.19
Compressibility (ASTM F36)	% Range	20 - 25
Recovery (ASTM F36)	Min. %	50
Tensile Strength (ASTM D1708)		
X Direction	psi (N/mm²)	5000 (35)
Y Direction	psi (N/mm²)	5100 (36)
Ultimate Elongation (ASTM D1708)		
X Direction	%	500
Y Direction	%	520
Gas Permeability (ASTM D1434V)	Cc/M <sup>2</sup> /24 hrs	10,000
Flammability		Will not burn

Industry Approvals/Certifications: FDA CFR 21 177.1550,

USP<88> Class VI

USP<87> ADI Free

## **Lifetime Warranty**

Jorlon™ is warranted for a lifetime of use on our Mark 95, Mark 96, Mark 96AA, Mark 95AA regulators, MK978 Series control valves, J-series regulators, and JSHM metering valve.

## **Product Applications**

Jorlon<sup>™</sup> has been specified in biopharm applications including WFI, clean steam (up to 100 psig), buffers, acids, cryogenic liquids, clean utility gas, biological intermediates and final process fluids

#### **Customer Use**

Since its inception, thousands of Steriflow valves with Jorlon™ diaphragms have been installed in systems which have been validated by the FDA

# **Cycle Testing**

Jorlon™ has been tested on a variety of Steriflow control valves on 45 psig (3 bar) continuous steam service to over 1 million full stroke cycles. One of those valves was further tested with an additional 100 Steam and vacuum cycles without failure.

### Lab Testing

Lab tests comparing Jorlon™ to 316L diaphragms have shown continued life after exceeding the SST failure cycle count by more than 100 times

#### Jorlon™ Material

Jorlon<sup>™</sup> has been used by Steriflow for over 15 years. To date, not one valve has been returned due to diaphragm failure when operating within it's use parameters. Jorlon<sup>™</sup> has been nitrogen pressure tested to over 1200 psi without failure.

# Sanitary Control Valves



Biopharmaceutical companies from around the world have appreciated the reliability of Steriflow's MK978 control valves for many years. We've grown our business by replacing competitors valves on difficult applications. **The MK978 has replaced competitive valves on:** 

- Elution and WFI rinse flow control on chromatography skids because of better low flow control
- Clean steam SIP pressure control because of repeated laminate diaphragm failures and, in other cases, because of difficulty fine tuning a competitor's valve stem drive mechanism
- End of loop WFI back pressure control because of better control
- · Bioreactor low flow input control of additives because of better control
- Lyophilizer, clean steam, and purified water distribution flow control after catastrophic failures of other laminated diaphragms
- A West Coast Biopharma Reliability Engineer informed us recently that they bumped their PM date on their population of MK978 Control valves (replaced competitor starting 8 years ago) to 4 years. His desire going forward, is to bump it to 8 years.

# Mark 978 Series - Control Valve

# Medium to High Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Angle style or inline control valve, for continuous precision control of media, process, purified water and clean utilities in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Bioreactor/Fermenter process input control: Growth Media, Buffer, WFI, Sparge and Blanket Gas
- Separation input and out control: WFI, Process, Product & Waste Streams
- Purification input and output control: Elution media, Solvents, Buffer, WFI
- Formulation/Fill Control: WFI and other vessel inputs, blanket gas, dosing pressure
- Clean Utilities: WFI, Pure Steam, CIP, Clean compressed air & gas
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities



# **Quick Specifications**

Size	Angle and Inline body: 1/2" (DN15) through 3" (DN80)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	0.2 - 125 Cv (0,17 - 108 Kv), Linear, Equal Percentage or Quick Opening Trim Characteristics
Max. Pressure/ Temperature	150 psi (10,3 bar) at 100°F (38°C) dependent upon construction 100 psi (6,9 bar) at 340°F (171°C) dependent upon construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional
Stem Seal - Diaphragm	Jorlon™ (1/2" - 3") all materials certified to FDA/USP Class VI
Soft Seat Option (CV≥3.5 only)	PTFE FDA/USP Class VI PEEK FDA/USP Class VI

- Jorlon<sup>™</sup> diaphragm with lifetime warranty
- Mechanically polished internal components - 20Ra (0,5µm) finish, electropolish - standard; 8Ra (0,2 µm) optional
- Gravity draining/no holdup and a variety of installation orientations possible
- A variety of true flow characteristics available

# Mark 978 Series - Control Valve

# Medium to High Flow, O-Ring Stem Seal

# **Description & Application:**

Angle style control valve, for continuous precision control of gas, air, USP PW (purified water), CIP fluids in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Bioreactor/Fermenter process input control: Clean compressed air and gas
- Separation/Purification: Clean compressed air and gas
- Clean Utilities: USP PW, CIP, Clean compressed air and gas
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities





# **Quick Specifications**

Quiok openioutions		
Size	1/2" (DN15) through 2" (DN50)	
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld	
Cv & Flow Characteristic	0.2 - 60 Cv (0,17 - 51,6 Kv), Linear, Equal Percentage or Quick Opening Trim Characteristics	
Max. Pressure/ Temperature	450 psi (31 bar) at 100°F (38°C), dependent upon construction 450 psi (31 bar) at 450°F (232°C) body and o-ring dependent upon construction	
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional	
Stem Seal - O-Ring	Various - all certified to FDA/USP Class VI	
Soft Seat Option (CV≥3.5 only)	PTFE FDA/USP Class VI PEEK FDA/USP Class VI	

- A variety of FDA/USP Class VI, o-ring materials to choose from
- Mechanically and electropolished internal components - 20Ra (0,5µm) finish, standard; 8Ra (0,2 µm) optional
- Gravity draining/no holdup and a variety of installation orientations possible
- A wide variety of true flow characteristics available

# Mark 978LF-JD Series - Control Valve

# Low Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Angle style control valve for continuous precision low flow control of media, process, purified water and clean utilities in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Small Bioreactor/Fermenter process input control: Growth Media, WFI, Process Sparge and Blanket Gas
- Separation input and output control: WFI, Process, Product & Waste Streams
- Small vessel formulation/fill control: WFI and other vessel inputs, blanket gas, dosing pressure
- Purification input and output control: Elution media, Solvents, Buffer, WFI
- Clean Utilities: USP PW (purified water), WFI, Pure Steam, CIP, Clean compressed air and gas
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Waster and Clean Utilities



Size	1/2" (DN15) and 3/4" (DN20)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	0.005 - 0.1 Cv (0,0043 - 0,086 Kv) Linear or Equal Percentage trim
Max. Pressure	200 psi (13,8 bar) temperature dependent on o-ring construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional
Stem Seal - o-ring	Various - all certified to FDA/USP Class VI



- The smallest nominal flow offering in the industry. Six Cv's between 0.005 and 0.1 enables you to control flow for any application
- Maintenance friendly quick change trim simplifies disassembly, reassembly, and steam-in-place/clean-in-place capabilities
- Mechanically and electropolished internal components - 20Ra (0,5µm) finish, others upon request
- FDA and USP Class VI conformity on all process seal materials
- Gravity draining/no holdup and a variety of installation orientations

# Mark 978LF-OR Series - Control Valve

# Low Flow, O-Ring Stem Seal

#### **Description & Application:**

Angle style control valve, for continuous precision control of gas, air, USP PW (purified water), CIP fluids in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Small vessel process input control: Clean compressed air and gas
- Clean Utilities: USP PW, CIP, Clean compressed air and gas
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities



# **Quick Specifications**

Size	1/2" (DN15) and 3/4" (DN20)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	0.005 - 0.1 Cv (0,0043 - 0,086 Kv)
Pressure at Maximum Temperature	200 psi (13,8 bar) at 300°F (149°C) dependent on o-ring construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra optional
Stem Seal -	Various - all certified to FDA/USP Class VI

- The smallest nominal flow offering in the industry. Six Cv's between 0.005 and 0.1 enables you to control flow for any application
- Maintenance friendly easy to perform maintenance with simple disassembly, reassembly, and steam-in-place/clean-in-place capabilities
- Mechanically and electropolished internal components - 20Ra (0,5µm) finish, others upon request
- FDA and USP Class VI conformity on all process seal materials
- Self-draining (no hold-up) when mounted in either vertical (as shown) or horizontal orientations

# **JSHM** Series

# Manual Control, Low to Medium Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Angle style or inline manual control valve, for precision control of media, process, purified water and clean utilities in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Bioreactor/Fermenter process input control: Growth Media, Buffer, WFI, Sparge and Blanket Gas
- Separation input and output control: WFI, Process, Product and Waste Streams
- Purification input and output control: Elution media, Solvents, Buffer, WFI
- Clean Utilities: USP PW (purified water), WFI, Pure Steam, CIP, Clean compressed air and gas
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities



# **Quick Specifications**

Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	0,4 - 3.5 Cv (0,35 - 3,0 Kv)
Max. Pressure/ Temperature Tube End & Tri-Clamp	150 psi (10,3 bar) at 350°F (177°C) with PEEK seats 150 psi (10,3 bar) at 150°F (66°C) with PTFE seats
Wetted Material & Surface Finish	ASTM A479 316L, or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra optional
Stem Seal - Diaphragm	Jorlon™ 1/2" - 1-1/2", certified to USP Class VI
Soft Seats	PTFE, FDA, USP Class VI, PEEK

- Available in both inline and angled body variants
- Top entry design facilities inline, five minute maintenance
- Minimal internal volume
- Zero holdup and gravity draining through the outlet with valve open in vertical down flow installation.
   Separately drainable inlet and outlet with valve open in horizontal installation

# Sanitary Pressure Regulators



#### **Customer References**

- A Biopharmaceutical company in New England reported that only one regulator in a facility population of 207 required maintenance over a nine year period.
- A biopharmaceutical manufacturer utilizes parallel MK96s to minimize droop on WFI pressure control thereby eliminating the need for costly control loops. This resulted in a CAPEX savings of over \$200,000, by using mechanical valves over control valves.
- A multinational vaccine manufacturer uses air-loaded MK96s for SIP pressure control at their HQ plant and reports stable SIP pressure (no offset) from heat-up through temperature hold.
- Many purification skid manufacturers use our pressure regulators to hold constant pressure in buffer dilution installations for instant buffer delivery for chromatography.
- An official with a parental CMO in Germany recently commented that they use our pressure regulators because they are "fit and forget".

# Mark 96C Series - PRV

# Manual, Low Flow, Jorlon™ Diaphragm

# **Description & Application:**

Angle style, pressure reducing valves with Tri-Clamp® body for low flow purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Media Prep: AWFI (ambient WFI) or buffer dilution
- Bioreactor/Fermenter process input control: AWFI
- Separation input and out control: AWFI
- Purification input and output control: AWFI, Buffer
- Clean Utilities: USP PW, WFI, CIP, CCA, CCG
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities



# **Quick Specifications**

Size	1/2" (DN15), 3/4" (DN20), 1" (DN25)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	0.3 - 5.5 Cv (0,26 - 4,7 Kv)
Max. Pressure/ Temperature	Dependent upon construction
Setpoint Range	3 psi (0,2 bar) to 135 psi (9,3) bar: dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional
Diaphragm Materials	Jorlon™ FDA, USP Class VI EPDM/Nylon - FDA only
Soft Seat Option	(Selection is size and Cv dependent) Jorlon™ (All materials to FDA & USP Class VI), PEEK, Teflon

- Jorlon<sup>™</sup> diaphragm: USP Class VI, FDA approved PTFE based material which provides excellent chemical resistance and an extremely long life
- Smallest Cv (kv) of any process regulators
- No guiding surfaces in the fluid minimizes particulate generation
- Self draining design
- Manual CIP pin allows user to lock the regulator in full open position during Rinse/CIP/Rinse cycle.
- Low offset (droop)

# Mark 96 Series - PRV

# Manual, Medium to High Flow, Jorlon™ Diaphragm

# **Description & Application:**

Angle style or inline, pressure reducing valves with bolted body for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Media Prep: AWFI (ambient WFI) and buffer dilution
- Bioreactor/Fermenter process input control: AWFI, buffer, other additives
- Separation input and out control: AWFI
- · Purification input and output control: AWFI, Buffer
- Clean Utilities: USP PW, WFI, CIP, CCA, CCG
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities



# **Quick Specifications**

•	
Size	3/4" (DN20) through 3" (DN80)
End Connections	ASME, DIN and ISO Tri-Clamp, Extended Tube Weld
Cv & Flow Characteristic	1.5 - 23 Cv (1,3 - 19,8 Kv)
Max. Pressure/ Temperature	Dependent upon construction
Setpoint Range	3 psi (0,2 bar) to 135 psi (9,3 bar); dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional
Diaphragm Material	Jorlon™ FDA, USP Class VI EPDM/Nylon - FDA only 316L (Selection is size & Cv dependent)
Soft Seat Option	Jorlon™, PEEK, Teflon (All FDA and USP Class VI)

- No guiding surfaces in the fluid minimizes particulate generation
- 100% 316L barstock body no wetted parts made from castings
- Best accuracy (least droop set point offset) in the industry
- Jorlon™ diaphragm lifetime warranty
- Tri-clamp gauge port
- Manual CIP pin allows user to lock the regulator in full open position during Rinse/CIP/Rinse cycle.

# Mark 96A and Mark 96AA Series - PRV

# Hybrid or Automated, Jorlon™ Diaphragm

#### **Description & Application:**

Angle style or inline, automated or hybrid pressure reducing valves for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Media Prep: AWFI (ambient WFI)
- Bioreactor/Fermenter process input control: AWFI
- Separation input and out control: AWFI
- Purification input and output control: AWFI, Buffer
- Clean Utilities: Clean Steam, USP PW, WFI, CIP, large volume CCA, CCG
- F & B and Consumer H & B Process: Inputs, Outputs, Purified Water and Clean Utilities





# **Quick Specifications**

Size	3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 3" (DN80)
End Connections	ASME, Tri-Clamp, , ASME Butt Weld, ASME Tube Weld, DIN/ISO Tri-Clamp and Tube Weld
Cv & Flow Characteristic	1.5 - 23 Cv (1,3 - 19,8 Kv), model dependent
Max. Pressure/ Temperature	Model dependent
Setpoint Range	3 psi (0,2 bar) to 135 psi (9,3 bar); dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2 µm) optional
Stem Seal - Diaphragm	Jorlon™ FDA, USP Class VI
Soft Seat Option	(Selection is size and Cv dependent) Jorlon™, PEEK, Teflon (All materials to FDA & USP Class VI)

- Available with extended range I-P transducer or a SST gas regulator
- Fully automated operation when used with I/P. Outlet set point pressure, and operation at full open during Rinse/CIP/Rinse cycle is controlled by PLC, or DCS menu
- Automated operation drastically reduces offset (droop) compared with spring loaded regulators.
- MK95A, Air-loaded design significantly reduces size and weight
- Optimized diaphragm material, surface area and support system for unsurpassed performance and life

# Sanitary Back Pressure Regulators



#### **Customer References**

- A European biopharmaceutical customer reports excellent MK 95 performance on chromatography applications for maintaining constant differential pressure across the column.
- In Ireland, a Biopharmaceutical company uses our MK95FT (Flow-Through) to relieve volume pressure upsets in process lines to prevent recurring rupture disc failures. The MK95's modulating relief function relieves the excess line pressure through the bottom port to a sterile containment vessel.
- A unique buffer application in the United States demonstrates the versatility of the air-loaded Mark 95AA. The valves are installed in a typical back pressure application; however, the customer successfully uses reverse flow when performing CIP on this system.
- A beverage skid manufacturer utilizes the Mark 95s on the outlet of their system to regulate temperature by controlling the steam pressure in the vessels.

# Mark 95 Series - BPRV

# Manual, Low to High Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Angle style, back pressure reducing valve for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- WFI Distribution Loop: return loop pressure maintenance upstream of spray ball
- Media/Buffer prep., upstream process:
  - input back pressure control for mixing buffer, media
  - pressure maintenance and relief to sterile containment
- Separation input and output control: for perfusion TFF, for Trans-Membrane Pressure (TMP) control.
- Purification input and output control: for Chromatography column, TFF, or depth filtration differential pressure control
- Pump head pressure maintenance or pressure bypass
- Agitator or pump seal water pressure maintenance
- F & B Consumer H & B process inputs: outputs, purified water and clean utilities

#### **Quick Specifications**

•	
Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 3" (DN80)
End Connections	ASME, Tri-Clamp, ASME Tube Weld Ends, DIN/ISO Tri-Clamp Connections, DIN/ISO Tube Weld Ends
Cv & Flow Characteristic	0.5 - 28 Cv (0,4 - 24,1 Kv)
Max. Pressure/ Temperature	Dependent upon construction
Setpoint Range	3 psi (0,2 bar) to 90 psi (6,2 bar) dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra (0,2µm) optional
Diaphragm Material	Jorlon™ FDA, USP Class VI, 316L, EPDM/Nylon (FDA only)
Soft Seat Option	Jorlon™, PEEK, Teflon (all materials FDA, USP Class VI)



- No guiding surfaces in the fluid minimizes particulate generation
- Soft seat option for ANSI Class VI shutoff
- 100% 316L barstock body and trim
- Low offset (creep)
- Lifetime warranty of Jorlon™ diaphragm
- New integral Gauge Ports optional
- Removing spring force during Rinse/ CIP/Rinse cycle allows valve to fully open with minimal line pressure

# Mark 95FT Series - BPRV

# Manual, Flow-Through Body, Low to High Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Inline, bottom outlet, back (inlet) pressure reducing valve for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Media/Buffer prep., upstream process:
  - input back pressure control for mixing buffer media
  - pressure maintenance with drainable relief to sterile containment
- Separation input and output control: perfusion TFF for Trans-Membrane Pressure (TMP) control
- Purification input and output control: chromatography and depth filtration back pressure control
- For process pressure control, with overpressure bottom bypass to sterile containment
- F & B and Consumer H & B Process Inputs: Outputs, Purified Waster and Clean Utilities



# **Quick Specifications**

Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 3" (DN80)
End Connections	ASME, Tri-Clamp, ASME Tube Weld Ends, DIN/ISO Tri-Clamp Connections, DIN/ISO Tube Weld Ends
Cv & Flow Characteristic	0.5 - 28 Cv (0,4 - 24,1 Kv)
Max. Pressure/ Temperature	Dependent upon construction
Setpoint Range	3 psi (0,2 bar) to 90 psi (6,2 bar) dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST; ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra optional
Diaphragm Material	Jorlon™ FDA, USP Class VI, 316L, EPDM/Nylon (FDA only)
Soft Seat Option	Jorlon™, PEEK, Teflon (all materials FDA, USP Class VI)

- Lifetime warranty of Jorlon™ diaphragm
- Low offset (creep)
- Modulates open during over pressure events allowing volume excess to be drained to sterile containment
- New integral Gauge Ports optional
- Removing spring force during Rinse/CIP/Rinse cycle allows valve to fully open with minimal line pressure
- No guiding surfaces in the fluid minimizes particulate generation
- 100% 316L barstock body and trim

# Mark 95A and Mark 95AA Series - BPRV

# Hybrid or Automated, Low to High Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Fully automated or hybrid back (inlet) pressure reducing valve for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- WFI Distribution Loop: return loop pressure maintenance upstream of spray ball
- Media/Buffer prep., upstream process:
  - input back pressure control for mixing buffer, media
  - pressure maintenance and relief to sterile containment
- Separation input and output control: For menu driven perfusion; TFF Trans-Membrane Pressure (TMP) control.
- Purification input and output control: For menu driven chromatography,
   TFF, or depth filtration differential pressure control
- Pump head pressure maintenance or pressure bypass
- · Agitator or pump seal water pressure maintenance
- F & B Consumer H & B process: inputs, outputs, purified water and clean utilities

# **Quick Specifications**

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Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 3" (DN80)
End Connections	ASME, Tri-Clamp, ASME Tube Weld Ends, DIN/ISO Tri-Clamp Connections, DIN/ISO Tube Weld Ends
Cv & Flow Characteristic	0.5 - 28 Cv (0,4 - 24,2 Kv)
Max. Pressure/ Temperature	Dependent upon construction
Setpoint Range	3 psi (0,2 bar) to 90 psi (6,2 bar) dependent on size and construction
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435 SST: ASME BPE SF5, 20Ra (0,5µm) electropolish is standard, 8ra optional
Stem Seal - Diaphragm	Jorlon™ USP Class VI
Soft Seat Option	(All materials FDA, USP Class VI) Teflon, PEEK, Jorlon™



- Available with extended range I-P transducer or a SST gas regulator
- Allows fully automated operation of set points from PLC/DCS menu when used with I/P
- Change set point to 0 from PLC/ DCS menu during Rinse/CIP/ Rinse Cycle
- Automated operation drastically reduces offset compared with spring loaded regulators
- Lifetime warranty on Jorlon diaphragm
- 100% 316L barstock body and trim
- No guiding surfaces in the fluid minimizes particulate generation

# JSB Series - BPRV

# Manual, Compact Body, Low to Medium Flow, Jorlon™ Diaphragm

# **Description & Application:**

Miniature inline or angle style, back pressure reducing valve for purified water, clean utilities and media in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Pilot or Clinical scale Media/Buffer prep., upstream process:
  - input back pressure control for mixing buffer, media
  - pressure maintenance and relief to sterile containment
- Pilot or Clinical scale Separation input and output control: for perfusion TFF and for Trans-Membrane Pressure (TMP) control.
- Pilot or Clinical Scale Purification input and output control: chromatography, TFF, or depth filtration differential pressure control
- Pump head pressure maintenance or pressure bypass
- Agitator or pump seal water pressure maintenance
- F & B Consumer H & B process: inputs, outputs, purified water and clean utilities



# **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN, & ISO Tri-Clamp, Tube weld end or NPT
Cv & Flow Characteristic	Cv 0.8 (Kv 0,7); Cv for relief valve sizing is 1.9 (Kv 1,64) Cv 0.5 (Kv 0,43); Cv for relief valve sizing is 0,6 (Kv 0,5)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	8 - 125 psi (0,06 - 8,6 bar)
Wetted Material & Surface Finish	ASTM A479 316L OR 1.4435; ASME BPE SF5, 20Ra µin (0,5µm) electropolish is standard, 8ra (0,2µm) optional
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	All materials to FDA & USP Class VI Jorlon™, PEEK, Teflon

- In-line removable trim significantly reduces maintenance time
- Fully drainable (no hold up) when oriented for downflow with spring pressure removed and positive pressure at inlet
- No threaded connections below the diaphragm
- · Minimized internal volume
- High flow rate coupled with high rangeability reduces need for reduced trim sizes
- Proprietary Jorlon<sup>™</sup> diaphragm material provides exceptionally long life and CIP/SIP capability

# **JSBLF Series - BPRV**

# Manual, Low Flow, Jorlon™ Diaphragm

## **Description & Application:**

Minature inline or angle style, back pressure reducing valve for purified water, clean utilities and media in the Biopharmaceutical, Food & Beverage and Consumer Health and Beauty industires.

- Pilot or Clinical scale Media/Buffer prep., upstream process:
  - input back pressure control for mixing buffer, media
  - pressure maintenance and relief to sterile containment
- Pilot or Clinical scale Separation input and output control: for perfusion TFF and for Trans-Membrane Pressure (TMP) control.
- Pilot or Clinical Scale Purification input and output control: chromatography, TFF, or depth filtration differential pressure control
- Pump head pressure maintenance or pressure bypass
- Agitator or pump seal water pressure maintenance
- F & B Consumer H & B process: inputs, outputs, purified water and clean utilities



# **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN, & ISO Tri-Clamp or Weld-end, NPT, VCR® connections optional - CF
Cv (Kv)	0.05, 0.15, 0.25, 0.35 (0,04; 0,13; 0,21; 0,30)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	8 - 125 psi (0,06 - 8,6 bar)
Wetted Material & Surface Finish	ASTM A479 316L OR 1.4435; ASME BPE SF5, 20Ra µin (0,5µm) electropolish is standard, 8ra (0,2µm) optional
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	All materials to FDA & USP Class VI TFM, PEEK

- In-line removable trim significantly reduces maintenance time
- Fully drainablewith minimized internal volume
- No threaded connections or contaminant traps below the diaphragm
- Proprietary Jorlon™ diaphragm material provides exceptionally long life and CIP/SIP capability
- Lifetime diaphragm warranty

# Compressed Air & Gas Pressure Regulators



#### **Customer References**

- A vaccine manufacturer in Canada was having trouble holding precise, low pressures on their nitrogen blanketing of small formulation hold vessels. They installed our JSRLP Series valves and are now able to fine tune and reliably hold their low pressure N2 overlay.
- A multinational manufacturer in Singapore uses our MK968 series for their large scale Single Use Bioreactor stations, for bag inflation and integrity testing.
- Several processing facilities in the U.S. utilize our J series valves for low pressure, gas motive force fluid movement, and for drying permanent process filters after SIP.

# **JSRLF Series - PRV**

# Manual, Low Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Inline style, pressure reducing valves for low flow clean compressed air and gas point of use applications in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- **Bioreactor/Fermenter**: sparge gas, purge/blanket/motive force gas regulation
- **Separation**: purge/blanket/motive force gas regulation for process vessels
- Purification: purge/blanket/motive force gas regulation for process vessels
- Formulation: purge/blanket/motive force gas regulation for process vessels
- Lyophilization: purge/blanket/motive force gas regulation for process vessels
- Clean Utility: CGG (clean compressed gas) pressure control for post SIP drying of small vessels, tubing, filters, etc.
- F & B Consumer H & B process: purge/blanket/motive force gas regulation



# **Quick Specifications**

Size	1/4" (DN8), 3/8" (DN10), 1/2" (DN15), 3/4" (DN20)
End Connections	ASME BPE, DIN and ISO Tri-Clamp, Tube Weld End and NPT (VCR® connections optional - contact factory)
Cv (Kv)	Cv 1.012 (Kv 0,01) - Cv 0.20 (Kv 0,17)
Max. Pressure/ Temperature	Tube End & Tri-Clamp: 450 psi @ 350°F (31,0 bar @ 177°C) with PEEK seats; 450 psi @ 150°F (30,1 bar @ 66°C) with PTFE seats  NPT: 2165 psi @ 350°F (149 bar @ 177°C) with PEEK seats; 3600 psi @ 150°F (248 bar @ 66°C) with PTFE seats
Setpoint Range	5 psi (0,3 bar) to 750 psi (52 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish . Non-EP is optional, as are other finishes
Diaphragm	Jorlon™ FDA & USP Class VI
Soft Seat Option	PTFE, PEEK, EPDM (all materials to FDA and USP Class VI)

## **Key Features**

- Proprietary Jorlon<sup>™</sup> diaphragm provides exceptionally long life
- Top entry design facilitates in-line cleaning and maintenance
- Low lock-up with EPDM seat
- Four Cv's between 0.01 and 0.20 and six spring ranges guarantee a Cv fit for your application
- Barstock construction guarantees material integrity and quality surface finish

# JSR Series - PRV

# Manual, Low to Medium Flow, Jorlon™ Diaphragm

#### **Description & Application:**

Inline style, pressure reducing valves for low to medium flow clean compressed air and gas point of use applications in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- **Bioreactor/Fermenter**: sparge gas, purge/blanket/motive force gas regulation
- Separation: purge/blanket/motive force gas regulation for process vessels
- Purification: purge/blanket/motive force gas regulation for process vessels
- Formulation: purge/blanket/motive force gas regulation for process vessels
- Lyophilization: Purge gas regulation
- Clean Utility: CGG (clean compressed gas) pressure control for post SIP drying of small vessels, tubing, filters, etc.
- F & B Consumer H & B process purge/blanket/motive force gas regulation



# **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN and ISO Tri-Clamp, Weld-stud, or NPT ends (VCR® connections optional - contact factory)
Cv (Kv)	Cv 0.8 (Kv 0,7) Cv 0.5 (Kv 0,43)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	5 - 125 psi (0,03 - 8,6 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish non-EP is optional, as are other finishes
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	PTFE, PEEK, EPDM (all materials to FDA USP Class VI)

#### **Key Features**

- Proprietary Jorlon™ diaphragm provides exceptionally long life and FDA and USP Class VI compliance
- · Low lock-up with EPDM seat
- In-line removable seat and trim facilitate cleaning and maintenance
- No exposed threaded connections below diaphragm
- Barstock construction guarantees material integrity and surface finish

# **JSRH Series - PRV**

# Manual, Medium to High Flow, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, pressure reducing valves for medium to high flow clean compressed air and gas point of use and distribution applications in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- **Bioreactor/Fermenter**: regulation of sparge gas, purge/blanket/motive force gas for mid to large size vessels
- Separation: regulation of purge/blanket/motive force gas for mid to large size vessels
- Purification: regulation of purge/blanket/motive force gas for mid to large size vessels
- Formulation: regulation of purge/blanket/motive force gas for mid to large size vessels
- Lyophilization: Medium to high flow purge gas regulation
- Clean Utility: CGG (clean compressed gas) pressure control for post SIP drying of large vessels, tubing, filters, etc.
- F & B Consumer H & B process purge/blanket/motive force gas regulation

# **Quick Specifications**

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Size	1/2" (DN15), 3/4" (DN20), 1" (DN25)
End Connections	ASME BPE, DIN and ISO Tri-clamp, Tube Weld End and NPT
Cv (Kv)	Cv 1.5 (Kv 1,3), Cv 1.9 (Kv 1,64), line size dependent
Max. Pressure/ Temperature	150 psi (10,3 bar) at 275°F (135°C)
Setpoint Range	5 psi (0,34 bar) to 150 psi (10,3 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish, non-EP is optional, as are other finishes
Diaphragm	Jorlon™, PTFE, FDA & USP Class Vi
Soft Seat Option	PTFE, FDA/USP Class VI



# **Key Features**

- Proprietary Jorlon<sup>™</sup> diaphragm material provides exceptionally long life and FDA and USP Class VI compliance
- In-line removable seat and trim facilitate cleaning and maintenance
- No exposed threaded connections below diaphragm
- Barstock construction guarantees material integrity and quality surface finish

# JSRHF Series - PRV Manual, High Flow, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, pressure reducing valves for high flow clean compressed air and gas point of use and distribution applications in the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Primary pressure reduction in large line CCG (clean compressed gas) distribution systems
- Separation: Pressure regulation of high flow purge/blanket/motive force gas
- Purification: Pressure regulation of high flow purge/blanket/motive force gas
- Formulation: Pressure regulation of high flow purge/blanket/motive force gas
- Clean Utility: CCA pressure control for post SIP drying of large vessels, tubing, filters, etc.
- F & B Consumer H & B process purge/blanket/motive force gas regulation



# **Quick Specifications**

Size	3/4" - 2" (DN20 - DN50)
End Connections	ASME BPE, DIN and ISO Tri-clamp, Tube weld-end, NPT
Cv (Kv)	Cv 2.5 (Kv 2,16), Cv 10 (Kv 8,65) line size dependent
Max. Operating Temperature	250 psig @ 275°F (10,5 bar @ 135°C)
Setpoint Range	5 - 250 psi (0,3 - 17,2 bar)
Max Operation Pressure	300 psi @ 100°F (20,7 bar @ 37,8°C)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish, non-EP is optional, as are other finishes
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	PTFE, FDA/USP Class VI Teflon

#### **Key Features**

- Proprietary Jorlon™ diaphragm material provides exceptionally long life and FDA and USP Class VI compliance
- In-line removable seat and trim facilitate cleaning and maintenance
- High flow rate coupled with high rangeability reduces need for reduced trim sizes
- Soft seat material for ANSI Class VI shutoff
- Barstock construction guarantees material integrity and surface finish

# **JSRLFLP Series - PRV**

# Manual, Low Flow, Low Pressure, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, pressure reducing valves for low flow, low pressure clean compressed air and gas point of use applications in stainless steel and *single use disposable* vessels for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Small stainless steel or single use disposable bioreactor/fermenter, sparge gas, purge/blanket/motive force gas regulation and bag integrity testing
- Separation: purge/blanket/motive force gas regulation and bag integrity testing
- Purification: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Formulation: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Lyophilization: purge gas regulation
- F & B Consumer H & B process purge/blanket/motive force gas regulation

# **Quick Specifications**

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Size	1/4" (DN8), 3/8" (DN10), 1/2" (DN15), 3/4" (DN20)
End Connections	ASME BPE, DIN and ISO Tri-Clamp, Tube Weld End and NPT , VCR® connections optional - CF
Cv (Kv)	Cv 0.012 (Kv 0,01) - Cv 0.20 (Kv 0,17)
Max. Pressure/ Temperature	Tube End & Tri-Clamp: 150 psi @ 350°F (10,3 bar @ 177°C) with PEEK seats; 150 psi @ 150°F (10,3 bar @ 66°C) with PTFE seats  NPT: 2165 psi @ 350°F (149 bar @ 177°C) with PEEK seats; 3600 psi @ 150°F (248 bar @ 66°C) with PTFE seats
Setpoint Range	1 psi (0,07 bar) to 75 psi (5,2 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish, non-EP is optional, as are other finishes
Diaphragm	Jorlon™, FDA & USP Class Vi
Soft Seat Option	PTFE, PEEK, EPDM, all materials to FDA and USP Class VI



# **Key Features**

- Stable outlet pressure setpoint regulation as low as 1 psig (69 mB)
- Top entry design facilitates in-line cleaning and maintenance
- Barstock construction guarantees material integrity and quality surface finish
- Four Cv's from 0.01 to 0.2 guarantee an application fit
- Large, proprietary Jorlon™ diaphragm provides exceptionally long life and sensitivity to minimal pressure changes.
- Low lock-up with EPDM seat

# **JSRLP Series - PRV**

# Manual, Low to Medium Flow, Low Pressure, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, pressure reducing valves for low to medium flow, low pressure clean compressed air and gas point of use applications in stainless steel and *single use disposable* vessels for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Small to medium small stainless steel or single use disposable bioreactor/fermenter, sparge gas, purge/blanket/motive force gas regulation and bag integrity testing
- Separation: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- **Purification**: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Formulation: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Lyophilization: Purge gas regulation
- F & B Consumer H & B process purge/blanket/motive force gas regulation

# **Quick Specifications**

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Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN and ISO Tri-Clamp, Weld-stud, or NPT ends , VCR® connections optional - CF
Cv (Kv)	Cv 0.8 (Kv 0,7) Cv 0.5 (Kv 0,43)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	1 - 50 psi (0,07 - 3,4 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF1, 20Ra µin (0,5 µm) electropolish, non-EP is optional, as are other finishes
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	PTFE, PEEK, EPDM (All materials to FDA USP Class VI)



## **Key Features**

- Stable outlet pressure setpoints to as low as 1 Psi (69 mB)
- Top entry design facilitates in-line cleaning and maintenance
- Barstock construction guarantees material integrity and quality surface finish
- Proprietary Jorlon<sup>™</sup> diaphragm material provides exceptionally long life
- Low lock-up with EPDM seat

# JSB Series-BPRV

# Manual, Low to Medium Flow, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, back pressure regulating valves for low to medium flow, clean compressed air and gas applications in the biopharmaceutical, pharmaceutical, food & beverage and consumer health & beauty industries:

- Bioreactor/Fermenter: regulated venting of small to mid size vessels
- Separation: regulated venting of purge/blanket/motive force gas
- Purification: regulated venting of purge/blanket/motive force gas
- Formulation: regulated venting of purge/blanket/motive force gas
- For regulated venting of F & B and consumer H & B process purge/ blanket/motive



# **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN, & ISO Tri-Clamp, Weld-stud, or NPT ends , VCR® connections optional - CF
Cv (Kv)	Cv 0.8 (Kv 0,7) Cv 0.5 (Kv 0,43)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	8 - 125 psi (0,06 - 8,6 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF5, 20Ra µin (0,5µm) electropolish is standard, 8ra (0,2µm) optional
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	PEEK, Teflon (All materials to FDA & USP Class VI)

- No threaded connections below the diaphragm
- Proprietary Jorlon<sup>™</sup> diaphragm material provides exceptionally long life and CIP/SIP capability
- · Minimized internal volume
- In-line removable trim significantly reduce maintenance time
- High flow rate coupled with high rangeability reduces need for reduced trim sizes

# JSBLF Series - BPRV Manual, Low Flow, Jorlon™ Diaphragm

# **Description & Application:**

Inline style, back pressure regulating valves for low flow, clean compressed air and gas applications in the biopharmaceutical, pharmaceutical, food & beverage and consumer health & beauty industries

- For regulated venting of purge/blanket/motive force gas from smaller sized vessels in the following application areas:
  - Bioreactors/Fermenters
  - Separation
  - Purification
  - Formulation
- For regulated venting of F & B and consumer H & B process purge/ blanket/motive for gas from small vessels



## **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
End Connections	ASME BPE, DIN, & ISO Tri-Clamp or Weld-end, NPT, VCR® connections optional - CF
Cv (Kv)	0.05, 0.15, 0.25, 0.35 (0,04; 0,13; 0,21; 0,30)
Max. Inlet Pressure	150 psig (10,5 bar)
Setpoint Range	8 - 125 psi (0,06 - 8,6 bar)
Wetted Material & Surface Finish	ASTM A479 316L or 1.4435; ASME BPE SF5, 20Ra µin (0,5µm) electropolish is standard, 8ra (0,2µm) optional
Diaphragm	Jorlon™ FDA/USP Class VI
Soft Seat Option	All materials to FDA & USP Class VI TFM, PEEK

- In-line removable trim significantly reduces maintenance time
- Fully drainable with no threaded connections, or contaminant traps below the diaphragm
- Minimized internal volume
- Proprietary Jorlon<sup>™</sup> diaphragm material provides exceptionally long life and CIP/SIP capability
- Lifetime diaphragm warranty

### Mark 908X Series - PRV

# Barstock Construction, Low Flow, Very Low Pressure

#### **Description & Application:**

Angle style, barstock, pressure reducing valves for regulating low flow, very low pressure clean compressed air and gas point of use applications in stainless steel and *single use disposable* vessels for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Small stainless steel bioreactor/fermenter: very low pressure sparge and purge/blanket/motive force gas regulation
- Small single use disposable bioreactor/fermenter. very low pressure sparge and purge/blanket/motive force or integrity testing gas regulation
- Small separation: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Small purification: purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Small formulation: pruge/blanket/motive force gas regulation and bag integrity testing for process vessels
- F & B consumer H & B process purge/blanket/motive force gas regulation

#### **Quick Specifications**

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Size	1/2" (DN15) & 3/4" (DN20)
End Conn.	ASME BPE, ISO or DIN Tri-Clamp, Flanged or NPT
Cv (Kv)	CV 0.15, 0.2, 0.4 (0,13; 0,17; 0,35)
Spring Ranges	4 spring ranges from 0.5" wc - 1.5 psi (1,24 - 103,4 mbar)
Body/Wetted Trim Materials	ASTM A479 316L (1.4404), 1.4435; other materials upon request
Diaphragm	Ultra lightweight Teflon FDA/USP Class VI
Seats, O-rings & Balanced Diaphragm	EPDM (FDA USP Class VI compliant), Viton (FDA compliant)
Max Operating Inlet Pressures	200 psig (13,79 barg)
Max Operating Temp	250°F (121°C)
Max Downstream Pressure	20 psig (1,38 barg) (Safety Rating)



- Accurate regulation down to 1/2" wc (1,25 mbarb)
- Accurate regulation at very low flows - down to 0.15 Cv (0,13 Kv)
- Three flow coefficients to meet any of your flow requirements
- ASTM A479 316L barstock construction with ASME BPE SF5 finish standard
- All FDA and USP Class VI materials ANSI Class VI
- Optional purge feature
- ANSI Class VI shutoff

## Mark 908 Series - PRV

# Barstock Construction, Mid to High Flow, Very Low Pressure

#### **Description & Application:**

Inline style, barstock, pressure reducing valves for regulating very low flow to high flow, low pressure clean compressed air and gas point of use applications in stainless steel and *single use disposable* vessels for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Stainless steel bioreactor/fermenter: very low pressure sparge and purge/ blanket/motive force gas regulation
- Single use disposable bioreactor/fermenter: very low pressure sparge and purge/blanket/motive force or integrity testing gas regulation
- Separation: Purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- **Purification**: Purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- Formulation: Purge/blanket/motive force gas regulation and bag integrity testing for process vessels
- F & B Consumer H & B process purge/blanket/motive force gas regulation

#### **Quick Specifications**

	•	
	Size	3/4" (DN20), 1" (DN25)
	End Connections	ASME BPE, ISO or DIN Tri-Clamp, Flanged or NPT connections.
	Cv (Kv)	1.0 - 10 (0,86 - 8,65)
	Max Pressure Temperature	Maximum Inlet: 200 psi (13,79)@ 250°F (121°C)
	Set Point Range	1/2" wc (1,25 mbarg) - 1.5 psi (103.4 mbarg)
	Wetted Material Surface Finish	ASTM A479 316L ASME BPE SF 5, 20Ra µin (0,5 µm) electropolish
	Diaphragm	Ultra lightweight Teflon FDA/USP Class VI
	Main Valve Seal Material	EPDM and 316/Viton (All material is FDA/USP Class VI)



- Accurate regulation down to 1/2" wc (1,25 mbarb)
- Five flow coefficients to meet any of your flow requirements
- ASTM A479 316L barstock construction with ASME BPE SF5 finish standard
- All FDA and USP Class VI materials ANSI Class VI
- · ANSI Class VI shutoff

### Mark 968 Series - PRV

# Manual, Cast, Medium to High Flow, Very Low Pressure

#### **Description & Application:**

Inline style, cast pressure reducing valves for medium - high flow, very low pressure, clean compressed air and gas for point of use applications in stainless steel and *single use disposable vessels* for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Medium to large stainless steel or single use disposable bioreactor/ fermenter, sparge gas, purge/blanket/motive force gas regulation and bag integrity testing
- Separation: purge/blanket/motive force gas regulation and integrity testing for process vessels
- **Purification**: purge/blanket/motive force gas regulation and integrity testing for process vessels
- Formulation: purge/blanket/motive force gas regulation and integrity testing for process vessels
- F & B Consumer H & B process purge/blanket/motive force gas regulation



4	
Size	3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50)
End Connections	Tri-clamp - ASME BPE or ISO/DIN Flanged - 150#, 300#, PN25/40
Flow Range	201 SCFH to 19,258 SCFH (5,7NM³/H to 545 NM³/H) size dependent
Max. Pressure/ Temperature	Size dependent
Setpoint Range	2,0 inch w.c. to 5 psi (5,0 mbar - 344,7 mbar)
Maximum Inlet Pressure	Size dependent
Wetted Material & Surface Finish	ASTM A351 CF8M (316SS) or CF3M (316L SS) Internal and external cast body components are 130 Ra µin (3,30 Ra µm) minimum after electropolishing
Shutoff	ANSI Class VI



- 360° body orientation on 3/4" and 1" sizes
- Robust design emergency outlet pressure may reach 100
- Easy maintenance seat and plug can be inspected without removing body from the line
- Electropolishing standard
- FDA-approved seals and diaphragms
- Tight shutoff-soft elastomer plug provides ANSI Class VI shutoff
- Completely self-operated no external power source required

### Mark 958 Series - BPRV

### Cast, Medium to High Flow, Very Low Pressure

#### **Description & Application:**

Inline style, cast back pressure regulating valves for medium - high flow, very low vent pressure gas regulation in stainless steel and *single use disposable vessels* for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- For regulated venting of medium to large stainless steel or single use disposable bioreactor/fermenter, sparge gas, purge/blanket/motive force gas
- Separation: For regulated venting of purge/blanket/motive force gas
- Purification: For regulated venting of purge/blanket/motive force gas
- Formulation: For regulated venting of purge/blanket/motive force gas
- For regulated venting of F & B Consumer H & B process purge/blanket/ motive force gas



#### **Quick Specifications**

Size	3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50)
End Connections	Tri-Clamp - ASME BPE or ISO/DIN Flanged - 150#, 300#, PN25/40
Flow Range	368 SCFH to 22,953 SCFH (10 NM³/H to 650 NM³/H)
Max. Pressure/ Temperature	Size dependent
Set Point Range	2.0 inch w.c. to 5 psi (5 mbar to 344,7 mbar)
Diaphragm	FDA approved Viton
Maximum Inlet Pressure	Size dependent
Wetted Material & Surface Finish	Internal and external cast body components are 130 Ra µin (3,30 Ra µm) minimum after electropolishing
Body & Housing	SA 351 Gr. CF8M 316SS or CF3M 316L
Seat & Plug	ASTM A479 316L (Plug with FDA approved Viton)
Shutoff	ANSI Class VI

- 360° body orientation on 3/4" and 1" sizes
- Robust design emergency outlet pressure may reach 100% of inlet pressure without damaging valve
- Electropolishing standard
- Easy maintenance seat and plug can be inspected without removing body from the line
- FDA-approved seals and diaphragms
- Tight shutoff-soft elastomer plug provides ANSI Class VI shutoff
- Completely self-operated no external power source required

# Sanitary Ball Valves



#### **Customer References**

- A biopharm company on the US west coast uses the MK9020 ball valve on clean compressed air and gas applications.
- A German multinational biopharm company uses the MK9020D (with DIN bore) on a variety of pure steam and clean compressed gas applications.
- A new biopharm manufacturer in South East Asia uses the MK9020 with integral condensate bypass, on their product development plant.

### Mark 9020 Series-Ball Valve

Tri-Clamp, Tube Weld End, ASME BPE, DIN & ISO

Bore ID = Connection ID

#### **Description & Application:**

Three piece, full bore sanitary ball valve with controlled ferrite 316L construction, designed following ASME BPE guidelines for Biopharmaceutical and Pharmaceutical applications:

- Clean utilities: clean steam, USP PW, CIP, acids, and solvents
- Clean compressed air and gas
- Pneumatic powder conveyance
- Process and clean utility waste lines



#### **Quick Specifications**

Size	1/2" - 4" (DN15 - DN100)
End Connections	ASME BPE, Tri-clamp or extended tube weld ends DIN 11866-A or B (ISO) extended tube weld ends standard and in stock
Max Pressure/ Temperature	To 1000 psig (68,9 barg) @ 100°F (38°C); 500 psig (34,5 barg) @ 295°F (146°C)
Seat & Seal Material	TFM 1600 non-cavity filler seats and all seals. FDA, USP <88> Class VI and USP <87>
Wetted Material & Surface Finish	ASTM A351 CF3M with <3% or 1% ferrite SF1, 20 Ra µin (0,5 Ra µm) mechanical polish standard SF4, 15Ra µin (0,4 Ra µm) electropolish optional

- Ball port has same ID as inlet/ outlet for all end sizes and connections to prevent hold up
- Live loaded stem seal
- Optional integral condensate drain and purge ports, stem extensions
- Stem grounding standard
- ISO 5211 actuator mounting flange
- Tongue & groove body seal to insure gasket containment and precise alignment regardless of vibration
- · Anti-blowout stem seal
- Optional Cavity filler seats available for non-BPE applications

### Mark 901 Series - Ball Valve

### Tri-Clamp & Cavity-Filled, Bore ID = Connection ID

#### **Description & Application:**

Three piece, full bore sanitary ball valve, 316L construction designed for Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- Process inputs: potable water, USP PW (purified water)
- Clean utilities: CIP, rinse water, clean steam, acids, solvents
- Clean compressed air and gas
- Pneumatic powder conveyance
- · Process drain lines
- Food & beverage and consumer health & beauty input, process and output applications



Size	1/2" - 4" (DN15 - DN100)
End Connections	ASME BPE, Tri-clamp
Max Pressure/ Temperature	To 1000 psig (68,9 barg) @ 100°F (38°C); 200 psig (13,8 barg) @ 300°F (150°C)
Seat & Seal Material	Cavity-filled PTFE TF1641 seat and seals (FDA/USP Class VI approved resins)
Wetted Material & Surface Finish	ASTM A351 CF3M 316L ASME BPE SF1 (20 Ra µin (0,5 Ra µm) mechanical polish) External finish as cast



- Lockable handle prevents accidental opening or closing of valve
- Ball port has same ID as inlet/ outlet for all end sizes and connections to prevent hold up
- Designed for simple maintenance with in-line repairable feature
- Anti-blowout stem
- Live-loaded stem seal, no threads in packing chamber
- No sharp internal fillet radius for smooth finish

# Sanitary Check Valves



Biopharmaceutical process design engineers have rarely felt comfortable specifying "sanitary" spring check valves in WFI, buffer or direct process applications. The crevices, exposed springs, high particulate and cracking pressure with increasing differential pressure at increased flow, are just some of the reasons that spring and stem guided check valves are not used. Those are the specific reasons the SVC and SHC check valves were developed.

#### **Customer References**

- A biopharmaceutical company in Ireland identified particulate caused by sanitary spring loaded check valves
  with Teflon seats. After a month-long cycle test on Nitrogen, our SVC check valve performed so well, the process
  engineer specified our valves on a greenfield project the following year.
- A European multinational Biopharm Company used our check valves to prevent nitrogen blanket gas from leaking out of mobile process holding and formulation vessels during vessel movement.
- Our down-flow check valve is the first of it's kind in the industry. A buffer dilution system manufacturer uses our SVC downflow valve in buffer waste lines to prevent drain back flow.

### SHC Series - Check Valve

# Horizontal line, Low to High Flow, Springless, Crevice-Free

#### **Description & Application:**

Two piece, spring-less horizontal line sanitary check valve for BioProcess Media and purified water applications for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- WFI loop: non-return at pump out
- Media/buffer prep: back flow prevention during dilution
- Upstream process: sparge line back flow prevention
- Separation: centrifuge waste line back flow prevention
- Purification, chromatography: waste line back flow prevention
- Pump head pressure maintenance or pressure bypass
- F & B and consumer H & B process inputs, outputs, purified water and clean utility back flow prevention



#### **Quick Specifications**

Size	1/2" (DN15) - 2" (DN50)
End Connections	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Cv (Kv)	3.4 - 23.1 Cv (2,94 - 20 Kv)
Max. Pressure/ Temperature	230 psi @ 100°F (16 bar @ 38°C) (Max temperature dependent on seal and disc selection)
Wetted SS Material	ASTM A479 316L or optional DIN 1.4435
Disc Material	316/EPDM, Teflon, Peek (All materials are FDA and USP Class VI)
O-ring Material	Various, all materials are FDA and USP Class VI Various
Cracking (opening) Pressure:	Polymer Discs: 0.04 psid (2,76 millibar) 316/EPDM: 0.13 psid (8,76 millibar)
Metallic Surface Finish	Wetted parts: ASME BPE SF5 (20 Ra μin (0,5 Ra μin) electropolished) standard: 8 Ra μin (0,2 Ra μin) electropolished optional

- Removal of traditional spring and stem guide:
  - eliminates areas where bioburden and bacteria can accumulate
  - potential for particulate generation
- No hold up
- High flow rates with minimal pressure loss at increased flow compared with mechanical return check valves Very low cracking (opening) pressure
- Very low cracking (opening) pressure

### SVC Series - Check Valve

# Vertical Line Down-Flow - For Drain Lines, Low to High Flow, Springless, Crevice-Free

#### **Description & Application:**

Two piece, spring-less sanitary check valve for vertical up-flow for BioProcess media and purified water applications for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- WFI point of use: back flow prevention, below point of use valve
- Media/buffer prep: back flow prevention during dilution
- Separation: Centrifuge waste line to drain, back flow prevention
- Purification, Chromatography: waste line to drain back flow prevention
- Agitator or pump seal water outlet to drain back flow prevention
- F & B and consumer H & B process inputs, outputs, purified water and clean utility down line back flow prevention



#### **Quick Specifications**

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Size	1/2" (DN15) - 3" (DN80)	
End Connections	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends	
Cv (Kv)	3.5 - 58.6 Cv (3,03 - 50,7 Kv)	
Wetted SS Material	ASTM A479 316L or optional DIN 1.4435	
Disc Material	Polypropylene (All materials FDA and USP Class VI)	
Gasket Material	Various (All materials FDA and USP Class VI)	
Max Pressure Temperature	230 psi @ 100°F (16 bar @ 38°C) Max temperature dependent on disc and gasket material	
Cracking (opening) Pressure	Valve is always open, will only close if water based liquid rises in outlet drain line	
Metallic Surface Finish	Wetted parts: ASME BPE SF5 20 Ra μin (0,5 Ra μin) electropolished) standard: 8 Ra μin (0,2 Ra μin) electropolished optional	

- The first and only vertical down flow sanitary check valve that is normally open and continuously self-draining
- Removal of traditional spring and stem guide:
  - eliminates areas where bioburden and bacteria can accumulate
  - potential for particulate generation
- Very low cracking (opening) pressure
- High flow rates with minimal pressure loss at increased flow compared with mechanical return check valves

### SVC Series - Check Valve

# Vertical Line Up-Flow, Low to High Flow, Springless, Crevice-Free

#### **Description & Application:**

Two piece, spring-less sanitary disc check valve for vertical up-flow for BioProcess media and purified water applications for the Biopharmaceutical, Pharmaceutical, Food & Beverage and Consumer Health & Beauty industries:

- WFI loop, pump out: vertical line up-flow, downstream of pump
- WFI loop, standby pump validation: vertical line up-flow, downstream of standby pump with precision bleed for back flow of hot WFI bleed
- Media/Buffer Prep: back flow prevention during dilution or pump out
- Bioreactor: Vessel bottom inlet sparge line back flow prevention
- Process Vessel: over pressure and vacuum protection upstream of vent filter
- F & B and consumer H & B process inputs, outputs, purified water and clean utility back flow prevention



#### **Quick Specifications**

Size	1/2" (DN15) - 3" (DN80)
End Connections	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Cv (Kv)	3.5 - 58.6 Cv (3,03 - 50,7 Kv)
Wetted SS Material	ASTM A479 316L or optional DIN 1.4435
Disc Material	316/EPDM, Teflon, PEEK (all materials FDA and USP Class VI)
Gasket Material	Various, (all materials FDA and USP Class VI)
Max Pressure Temperature	230 psi @ 100°F (16 bar @ 38°C) Max temperature dependent on disc and gasket material
Cracking (opening) Pressure	Polymer Discs: 0.04 psid (2,76 millibar) 316/EPDM: 0.13 psid (8,76 millibar)
Metallic Surface Finish	Wetted parts: ASME BPE SF5 (20 Ra μin (0,5 Ra μin) electropolished) standard: 8 Ra μin (0,2 Ra μin) electropolished optional

- Removal of traditional spring and stem guide:
  - eliminates areas where bioburden and bacteria can accumulate
  - potential for particulate generation
- Very low cracking (opening) pressure
- High flow rates with minimal pressure loss at increased flow compared with mechanical return check valves

# Clean Steam, SIP Accessories



Biopharmaceutical process design and maintenance engineers know that the two most important criteria for choosing a clean steam trap for draining SIP condensate are low subcooling operating and maintenance reliability. Without either, you will have unexpected downtime caused by slow SIP heat-up or validation temperature sensor alarms.

- A formulation/fill/finish facility in Puerto Rico improved SIP heat-up time on their formulation vessels by an average of 10 minutes by using our SSC (sanitary subcooled condensor) and MK93 steam trap assembly.
- A mid-western Biopharm facility found our MK934 trap handled their CIP, Rinse and SIP large vessel loads without the expense of installing a bypass under the vessel. Another user in New England enjoys faster drain time on process vessels.
- A European multinational user first discovered the low subcooling and best in class design features of our MK93 Series during testing at their clinical and pilot facility. The customer has since standardized on the MK93 worldwide and purchased thousands on capital projects.
- A German CMO has standardized on the MK934 dual element trap because it drains condensate well and has lower total installation costs than the traditional multi-component valve and trap assembly.

# Mark 93 Series - Clean Steam Trap

# Medium to high flow, <3°F (1,7°C) subcool operation



Two piece-tri-clamp body, balanced port, medium high flow thermostatic sanitary steam trap with vertical or horizontal inlet and outlet connections for pure steam SIP and loop drainage applications in biopharmaceutical and aseptic food & beverage and certain consumer health and beauty industry applications.

- Up and downstream process vessel: small to medium sized vessel, or large vessel bypass loop trap, validated SIP drainage applications
- Up and downstream process: validated SIP tubing drain applications
- Sterile filter: validated SIP condensate drain from filters
- Clean steam distribution: loop drainage and point of use PCV drainage applications
- Clean steam humidification drainage in air handlers



Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40)
Installation Connection Orientation	Vertical, Horizontal
Connection Type	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Maximum Pressure Temperature	145 psig (10 barg) @ 350°F (177°C)
Max. Recommended Differential Pressure	MK93: 10 - 50 psi (0,7 - 3,4 bar) MK93 Option P. 45 - 90 psi (3,1 - 6,2 bar)
Materials of Construction	Wetted body/plug material: ASTM A479 316L or optional DIN 1.4435 Body gaskets: Various, all FDA and USP Class VI
Nominal Cv (Kv)	3.8 Cv (3,29 Kv)
Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 Ra µm) electropolish or better optional
Subcooling	Less than 3°F (1,7°C)



- Low subcooling operation reduces probability of SIP delays caused by temperature validation faults
- Lay-in dimension allows drop in replacement of higher subcool, competitive traps
- Easy thermal element (bellows assembly replacement only installs in one direction) errorproof
- New design provides excellent flow rates with low subcooling improves heat-up drainage
- Self draining when installed vertically (body outlet side down)
   either vertical or horizontal connections
- Solid barstock body with fewer cracks and crevices than competitive designs

# Mark 93JR Series - Clean Steam Trap

## Compact, Low to Medium Flow, <3°F (1,7°C) Subcool Operation

#### **Description & Application:**

Compact, two piece-tri-clamp body, balanced port, low - medium flow thermostatic sanitary steam trap with vertical or horizontal inlet and outlet connections for pure steam SIP and loop drainage applications in biopharmaceutical and aseptic food & beverage and certain consumer health and beauty industry applications.

- Up and downstream process vessel: small vessel or medium vessel bypass loop, validated SIP drainage applications
- Up and downstream process: validated SIP tubing drain applications
- Sterile filter: validated SIP condensate drain from filters
- Clean steam distribution: loop drainage and point of use PCV drainage applications
- Clean steam humidification drainage in air handlers



#### **Quick Specifications**

Size	1/4" (DN8), 1/2" (DN15), 3/4" (DN20), 1" (DN25)
Installation Connection Orientation	Vertical
Connection Type	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Max. Pressure Temperature	145 psig (10 barg) @ 350°F (177°C)
Max. Recommended Differential Pressure	10 - 100 psi (0,7 - 6,9 bar)
Materials of Construction	Wetted body/plug material: ASTM A479 316L or optional DIN 1.4435 Body gaskets: Various, all FDA and USP Class VI
Nominal Cv (Kv)	Cold water: 1.31 Cv (1,13 Kv)
Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 Ra µm) electropolish or better optional
Subcooling	Less than 3°F (1,7°C)

- Low subcooling operation reduces probability of SIP delays caused by temperature validation fault
- Compact dimension allows drop in replacement of lesser quality, higher subcool, competitive traps
- Easy thermal element (bellows assembly replacement, only installs in one direction) errorproof
- New design provides excellent flow rates with low subcooling improves heat-up drainage
- Self draining when installed vertically (body outlet side down) either vertical or horizontal connections

# Mark 93TH Series - Clean Steam Trap

# Threaded, Compact, Low to Medium Flow <3°F (1,7°C) Subcool Operation

#### **Description & Application:**

Two piece threaded body, balanced port, low to medium flow thermostatic sanitary steam trap with 3°F subcool operation, vertical inlet and outlet threaded connections (for tube fitting applications). Designed specifically for biopharmaceutical and food & beverage pilot and trail scale skid equipment manufacturers for pure steam SIP and loop drainage applications.

- Up and downstream process vessel: small to medium sized vessels with validated SIP drain lines
- Up and downstream process tubing: validated SIP drainage
- Filters: small filter validated SIP drainage
- · Clean steam distribution drainage





#### **Quick Specifications**

	Size	1/4" (DN8), 3/8" (DN10), 1/2" (DN15), 3/4" (DN20), 1" (DN25)
	Connection Type	Standard: NPT Optional: BSP, EN ISO 228-1
	Maximum Operating Conditions	Maximum Operating Pressure: 90 psig (6,2 barg) Maximum Allowable Pressure: 145 psig (10,0 barg) Maximum Allowable Temperature: 350°F (177°C)
	Max. Recommended Differential Pressure	MK93TH: 10 - 50 psi (0,7 - 3,4 bar) MK93TH Option P. 45 - 90 psi (3,1 - 6,2 bar)
	Materials of Construction	Wetted body/plug material: ASTM A479 316L Body gaskets: Various, all FDA and USP Class VI
	Nominal Cv	Cold water. 1.63 (1,41 Kv)
	Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 Ra µm) electropolish or better optional External: 40 Ra µin (1,0 Ra µm) standard, 40 Ra µin (1,0 Ra µm) electropolish or better optional
	Subcooling	Less than 3°F (1,7°C)

- Low subcooling operation reduces probability of temperature validation faults and resultant SIP delays
- Lay-in dimension allows drop in replacement of higher subcool competitive traps
- Compact construction of solid 316L barstock
- Simple, three piece design with fewer components, cracks and crevices than competitive designs
- Self draining when installed vertically (body outlet side down) either vertical or horizontal connections

# Mark 94 Series - Clean Steam Trap High Flow, <3°F (1,7°C) Subcool Operation

#### **Description & Application:**

Two piece-tri-clamp body, balanced port, high flow thermostatic sanitary steam trap with vertical or horizontal inlet and/or outlet connections for pure steam SIP and loop drainage applications in biopharmaceutical and aseptic food & beverage and consumer health and beauty industry applications.

- Up and downstream process vessel: medium sized vessel, validated SIP drainage applications
- Up and downstream process tubing: high flow validated SIP tubing drain applications
- Sterile filter. large vent and product filters validated SIP condensate drain applications



#### **Quick Specifications**

Size	3/4" (DN20), 1" (DN25), 1-1/2" (DN40)
Installation Connection Orientation	Vertical, Horizontal
Connection Type	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Max. Allowable Pressure/ Temperature	145 psig (10 barg) 350°F (177°C)
Maximum Operating Pressure	50 psi (3,4 bar)
Materials of Construction	Wetted body/plug material: ASTM A479 316L or optional DIN 1.4435  Various, all FDA and USP Class VI
Nominal Cv (Kv)	4.0 Cv (3,46 Kv)
Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 Ra µm) electropolish or better optional
Subcooling	Less than 3°F (1,7°C)

- Low subcooling operation reduces probability of SIP delays caused by temperature validation faults
- Easy thermal element (bellows assembly replacement only installs in one direction) errorproof
- New design provides excellent flow rates with low subcooling improves heat-up drainage
- Self draining when installed vertically (body outlet side down)
   either vertical or horizontal connections
- Solid barstock body with fewer cracks and crevices than competitive designs

# Mark 934 Series - Clean Steam Trap

# High - Ultra Flow, <3°F (1,7°C) Subcool Operation



Three piece, bolted tri-clamp body, very high capacity, dual balanced port, thermostatic sanitary steam trap with integral bypass, and vertical or horizontal inlet and/or outlet connections for pure steam SIP and clean utility drain applications in biopharmaceutical and aseptic food & beverage and consumer health and beauty industry applications

- Up and downstream process vessel: large vessel, validated SIP drainage applications
- Up and downstream process vessels:
  - Use instead of SIP bypass loop on large vessels
  - Validated SIP drainage from very large vessels
- · Large filter validated SIP drainage
- Filling machine or other larger volume validated SIP drainage
- Large autoclaves

#### **Quick Specifications**

Size	1" (DN25), 1-1/2" (DN40), 2" (DN50)
Installation Connection Orientation	Vertical, Horizontal
Connection Type	ASME, DIN, ISO Tri-Clamp and Tube Weld Ends
Max. Allowable Pressure/ Temperature	145 psig (10 barg) 350°F (177°C)
Maximum Operating Pressure	50 psi (3,4 bar)
Materials of Construction	Wetted body/plug material: ASTM A479 316L or optional DIN 1.4435 Body gaskets: Various, all FDA and USP Class VI
Nominal Cv (Kv)	5.7 Cv (4,93 Kv)
Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 Ra µm) electropolish or better optional
Subcooling	Less than 3°F (1,7°C)



- Significant CAPex savings: the MK934 with it's integral bypass, is designed to eliminate the need for an automated 3-way clean utility bypass valve at bottom of vessel
- Plant availability increase:
  elimination of the bypass valve
  expedites heat-up and/or reduces
  pure steam waste as it disallows
  escape of pure steam before heat up
  to 85°C. All of the steam heats the
  vessel.
- Low subcool operation reduces probability of temperature validation faults and resultant SIP delays
- For very large process vessels and equipment
- Self draining when installed with body vertical, regardless of whether inlet/outlet connections are vertical or horizontal

# SSC Series - Clean Steam Subcooled Condenser

# For compact, validated SIP sensor/steam trap drain installations

#### **Description & Application:**

Compact, drainable, sanitary condensate chamber and steam trap assembly designed to replace or reduce the 12 - 18" (300 - 450mm) c-c dimension between traditional steam trap and validation sensors. Designed to reduce the time required for heat-up (improves drainage), and prevent condensate back-up during temperature maintenance (validation alarms).

- Upstream and downstream process vessels:
  - To accelerate heat-up and eliminate validation temperature alarms
  - To allow installation of validated SIP drain line/traps where space is limited
- Mobile or stationary formulation vessel: To expedite SIP heat-up by installation on fixed, validated drain lines



#### **Quick Specifications**

Connection Size/Type	3/4" ASME BPE Tri-clamp end connections standard
Maximum Operating Pressure	145 psig (10 barg) Note: Drain system maximum operating pressure is determined by attached steam trap
Materials of Construction	Wetted material: ASTM A479 316L or Din 1.4435
Capacity	Capacity dependent on trap attached to outlet. Unit cools condensate before steam trap enabling the bellows to contract, opening orifice further
Surface Finish	Internal: SF1, 20 Ra µin (0,5 µm) standard; SF5, 20 Ra µin (0,5 µm) electropolish optional
Radiant and Convective Heat Loss	Cools entering condensate by an average 30°F at ambient temperatures

- Increases process availability by:
  - decreasing SIP heat-up time
  - Lowering the probability of SIP validation temperature alarms
- Increases drainage by cooling condensate before entering trap enabling the bellows to contract, opening orifice
- Can reduce CAPEX if assembly is purchased per-assembled compared with site fabricated installations
- Reduces the lineal space required for a validated SIP steam trap downcomber assembly by 80%

# CSDT Series - Compact Sanitary Disc Trap

# For Plant Steam Drainage in a Clean Environment

#### **Description & Application:**

Polished, tri-clamp end, low to high flow thermodynamic sanitary steam trap for horizontal or vertical installation in plant steam or non-validated clean steam applications in Biopharmaceutical clean room environments. Can also be used in Food & Beverage and Consumer Health & Beauty applications.

- Plant steam or non-validated clean steam condensate drainage in a clean room environment:
  - heat exchangers
  - vessel jackets
  - WFI still
  - clean steam generator



#### **Quick Specifications**

Size	1/2" (DN15) & 3/4" (DN20)
Installation Connection Orientation	Vertical (preferred) Horizontal
Connection Type	ASME BPE tri-clamp
Max. Allowable Pressure/ Temperature	227 psig (15,6 barg) 842° (450°C)
Materials of Construction	Body: Casting, AISI 316L Disc: AISI 316L
Surface Finish	Internal: as machined and cast External: 20 Ra µin (0,5 Ra µm) mechanical polish standard, except at junction of threaded cap and body

- 316L body construction
- Operates in any position
- Solid cast 316L body with 20 Ra µin (0,5 Ra µm) external finish standard

# Inline Sight Glasses, Sight Glass Windows



Steriflow Inline Sight Glasses are a simple construction. Two precision machined body sections, one tight tolerance, fabricated borosilicate glass tube, and two o-rings. However, the features are what really set it apart from the competition.

- Two large windows capture the optimum view angle into your process while still maintaining pressure ratings.
- Exacting metal to metal threaded stops prevent pipe torque from affecting the ideal o-ring compression (minimizing ID protrusion) or the glass.

### SG Series

### Inline Sight Glasses, Tri-Clamp

#### **Description & Application:**

Inline tri-clamp, double window sight glass for bioprocess, media and purified water applications for the biopharmaceutical, and pharmaceutical, food & beverage and consumer health and beauty industries.

- Media/buffer prep lines: viewing mix and clarity
- Upstream process: input line and process outflow viewing
- Perfusion: retentate or permeate clarity
- Separation: Centrifuge or filtration process clarity
- · Purification:
  - Chromatography: process stream clarity, bubble detection
  - Ultrafiltration: process clarity
- F & B and consumer H & B process mix viewing



#### **Quick Specifications**

	Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 2-1/2" (DN65), 3" (DN80), 4" (DN100)
	End Connections	ASME BPE Tri-Clamp compatible DIN and ISO Tri-Clamp upon request
	Max Pressure/ Temperature	145 psig (10 bar) Max temperature varies with o-ring selection
	Materials of Construction	ASMT A479 316L standard. DIN 1.4435 and other materials upon request. Borosilicate glass O-rings: EPDM, Viton, Silicone, FEP-silicone or Perlast (FFKM), all FDA and USP VI compliant
	Wetted Surface Finish	Wetted parts: ASME BPE SF1 20 Ra µin (0,5 µm) mechanical finish, standard; Electropolish (SF5) optional External: 32 Ra µin (0,8 Ra µm) mechanical finish, electropolish optional

- Full bore flow path
- Large viewing area two large windows
- Metal stop provides ideal o-ring compression and prevents pipe torque from affecting glass
- Compact design
- Suitable for CIP and SIP
- Better than SF1, 20 Ra µin mechanical polish (0,5 Ra µm), electropolish optional

### **SGW Series**

## Sight Glass Windows, Tri-Clamp

#### **Description & Application:**

Tri-clamp sight glass windows for bioprocess and media vessel and large line viewing applications in the bio-pharmaceutical and pharmaceutical, food & beverage and consumer health & beauty industries.

- Media/buffer prep vessel: viewing mix and clarity
- Upstream process: vessel process viewing window
- · Perfusion: retentate or permeate clarity
- Separation: centrifuge or filtration process clarity
- · Purification:
  - Chromatography: process stream clarity, bubble detection
  - Ultrafiltration: process stream clarity
- F & B and consumer H & B process mix viewing





#### **Quick Specifications**

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Size	1/2" (DN15), 3/4" (DN20), 1" (DN25), 1-1/2" (DN40), 2" (DN50), 2-1/2" (DN65), 3" (DN80), 4" (DN100), 6" (DN150)
End Connections	ASME BPE Tri-clamp compatible Contact factory for other availability
Max. Pressure/ Temperature	Varies by size, see data sheet
Materials of Construction	Duplex stainless steel (UNS 31803/32205) Borosilicate glass Gasket and clamp supplied by user
Wetted Surface Finish	Wetted parts: ASME BPE SF5 20 Ra µin (0,5 µm) electropolished, standard; other finishes upon request External: 20 Ra µin (0,5 Ra µm) electropolished standard

- · Large viewing area
- Compact design
- Exceptional strength: one continuous fusion of glass and Duplex stainless steel
- Hygienic design: no interface line between glass and steel means no cracks or crevices
- Suitable for CIP and SIP
- SF5 surface finish standard

# Sample Coolers



Steriflow's sample coolers are constructed to higher quality standards than others we have tried.... You can see the care taken with the exterior construction. But it's more than that. The single piece of uncut, unblemished sample tubing from sample inlet to outlet means less probability of sample contamination. It's that simple.

Quality Control Engineer

## SC Series

#### Permanent and Portable Installation

#### **Description & Application:**

Our 316L Sample Coolers are shell and spiral tube heat exchangers designed specifically to condense and cool pure steam, WFI, or USP PW via mains or chilled water. The sample is precision metered by an upstream sample metering valve, and flows down through the spiral sample tube for safe, sterile extraction of room temp samples at the bottom of coolers. The cooling media flows through the shell in the opposite direction, efficiently removing the warmest water first. Sample coolers are designed and manufactured following applicable ASME BPE guidelines.

- Model SC60 and SC50 are designed to be permanently mounted at the sampling point
- Model SC50 has a Tri-clamp body that can be easily disassembled to allow extraction and cleaning of the tube bundle
- Model SC30 is a free-standing portable unit meant to be carried and connected to each sample point via flexible Tri-clamp tubing



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Connection Size/Type	Sample connections: (inlet/outlet) 1/2" ASME BPE Tri-clamp Cooling water connections: - SC30: 3/4" ASME BPE Tri-clamp - SC50: 3/4" ASME BPE Tri-clamp - SC60: 1/2" NPT, BSPT or 1/2" or 3/4" ASME BPE Tri-clamp compatible
Design Pressure	Coil: 145 psig @ 347°F (10 barg @ 175°C) Shell: 145 psig @ 212°F (10 barg @ 100°C)
Materials of Construction	Shell: 316L SS Tube: 316L SS, one continuous length from inlet to outlet (no tube welds)
Capacity	Pure Steam - 10 l/h of condensate at 86°F (30°C) from steam at 3 barg Purified Water - 30 l/h of water from 185°F to 86°F (85°C to 30°C)



- 316L stainless steel construction

   designed specifically for clean
   steam and WFI, USP PW systems
- One continuous piece of tubing from inlet to outlet - no tubing welds
- Self-draining design eliminates possibility of sample retention
- Autoclavable or SIP satisfies validation criteria
- Simple to install wall mounting kits included for SC50 and SC60.
   Use of Tri-clamp compatible fittings on sample connections

# Sample Valves



The SV sample valve is specifically designed to precisely control the flow of fresh clean steam or hot WFI into a sample cooler. Opening at the inlet, the valve precisely meters any fluid into the drainable body and outlet.

Quality Technician

### **SV** Series

## Angle style O-Ring Sample Valves

#### **Description & Application:**

The SV was designed for use in high purity steam systems and water systems. The SV Series utilizes a steam resilient Perlast® seat seal to ensure optimum service life and bubble tight shut-off. Because of these design characteristics, the SV is also used for any general pharma sampling application where a manual valve is required.

- WFI, USP PW (purified water), or Clean Steam sample cooler metering valve
- Upstream process: sample valve, or metering for bioreactor additives
- Downstream process: sample valve for process analysis
- Media prep: sample valve or manual additive metering valve
- F & B Consumer H & B sample valve for additive or final process fluid analysis



#### **Quick Specifications**

Size	1/2" (DN15) & 1" (DN25)
End Connections	ASME BPE Tri-clamp compatible
Max Pressure	116 psig (8,0 barg)
Max Temperature	347°F (176°C)
Materials of Construction	Body and wetted stem: 316L Seat Seal: Perlast® (FFKM), FDA and USP Class VI compliant Stem Seal: Viton, FDA and USP Class VI compliant Handle: Plyethermide (Autoclavable)
Wetted Surface Finish	ASME BPE SF1 20 Ra µin (0,5µm) is standard, SF5 optional
External Surface Finish	Satin 32 Ra µin (0,8 Ra µm) mechanical finish is standard. Electropolish optional

See our data sheet for Sample Hoses and other accessories

- Fully drainable when installed with handle facing up or on it's side
- Compact design
- Autoclavable
- Suitable for CIP and SIP
- Fine stem threads for precision metering
- SF1 surface finish

Notes

