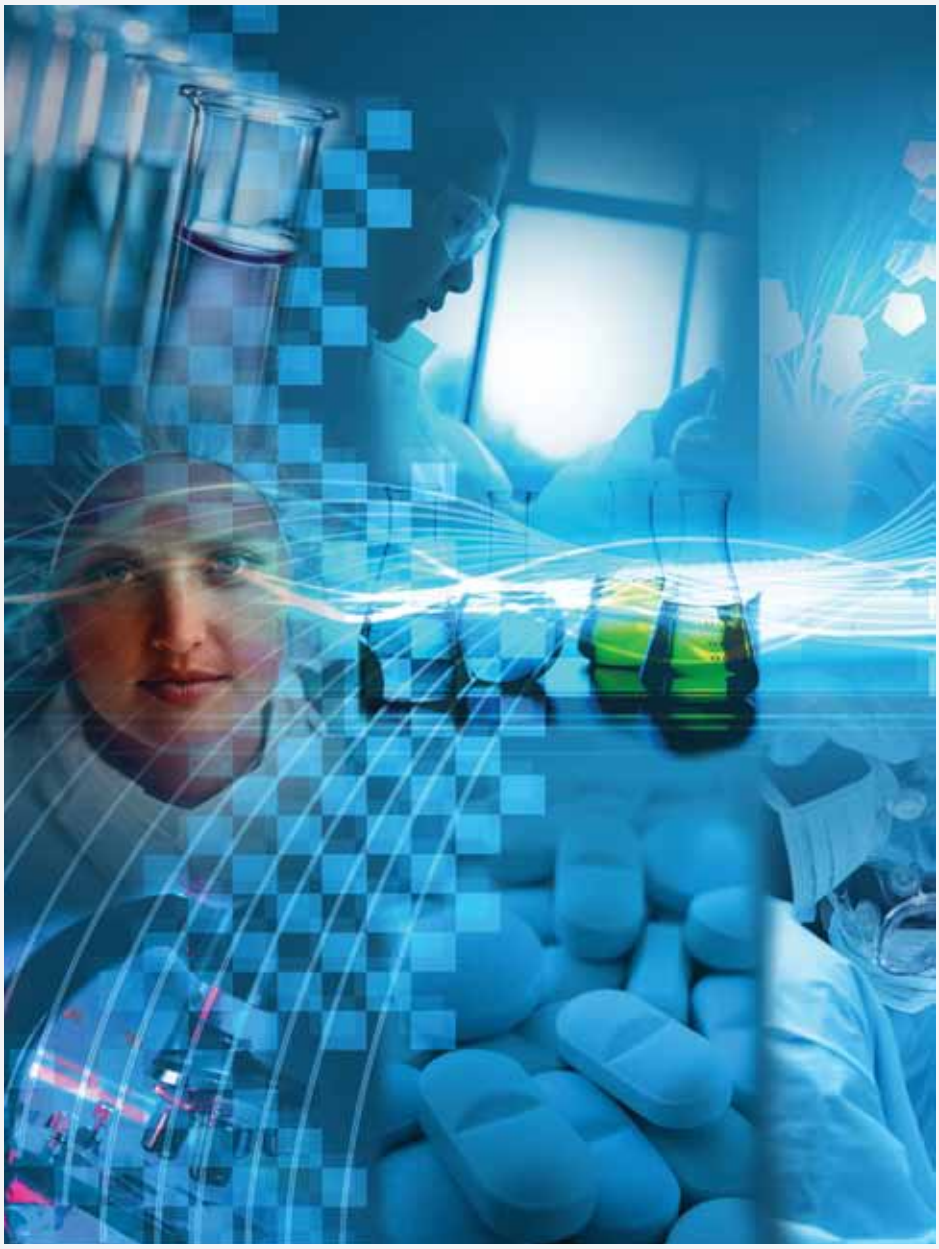
SANITARY VALVES, SAMPLE COOLERS, and SIP ACCESSORIES



Purity
Precision
Reliability

Pressure Regulating Valves
- Pressure Reducing Valves, outlet pressure reduction
- Back Pressure Regulating Valves, inlet pressure regulation

Control Valves
Ball Valves
- 2-way
- 3-way

Check Valves
Clean (Pure) Steam SIP Specialties
- Steam Traps
- SIP Specialties

Sample Cooler - Heat exchangers
Sight Glass
Gas Distribution Manifolds

STERIFLOW
a division of Jordan Valve

Steriflow is the single source for high performance, high quality, sanitary valves. Steriflow has earned its reputation for quality through twenty-five years of success in bio-pharmaceutical, pharmaceutical, food, cosmetics, and clean process industries. We have the most experience in designing and manufacturing valves and steam traps in the industry.

Bioprocess batch quality starts here

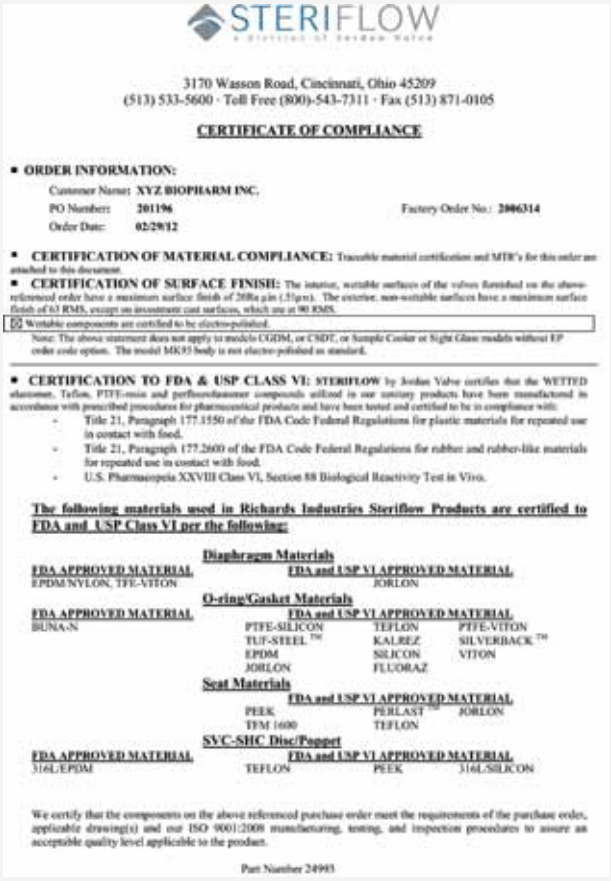
From the certified and documented raw materials we incorporate into our products, to the process components that go into our mechanical and electropolish process, Steriflow represents quality you can count on.

Certification and Documentation

The following documentation is shipped with each order at no charge:

- Steriflow Unicert: The unicert is Steriflow's master quality control document. It ties our individually serialized valves and their component heat numbers to the following certificates of compliance and attached MTR's.
  - Certificate of Material Compliance with Traceable Material Heat Number for all wetted parts (body, stem, ferrules)
  - Certificate of Compliance to FDA and USP Class VI
  - Certificate of Surface Finish Compliance

- 100% traceability: each valve has a unique serial number traceable to component heat numbers and their MTR's
- Final Test Reports, Certificate of Origin, and any other required documentation available upon request at time of order



STERIFLOW

3170 Wasson Road, Cincinnati, Ohio 45209
(513) 533-5600 · Toll Free (800)-543-7311 · Fax (513) 871-0105

CERTIFICATE OF COMPLIANCE

- **ORDER INFORMATION:**

Customer Name: **XYZ BIOPHARM INC.**
PO Number: **201196** Factory Order No.: **2006314**
Order Date: **02/29/12**

- **CERTIFICATION OF MATERIAL COMPLIANCE:** Traceable material certifications 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 µin (.51µm). The exterior, non-wettable surfaces have a maximum surface finish of 63 RMS, except on investment cast surfaces, which are at 90 RMS.

☑ Wettable components are certified to be electro-polished.

Note: The above statement does not apply to models CGDM, or CSDT, or Sample Cooler or Sight Glass models without EP order code option. The model MK95 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 perfluoroelastomer components 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. Pharmacopeia XXVIII Class VI, Section 88 Biological Reactivity Test in Vivo.

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

Diaphragm Materials

FDA APPROVED MATERIAL	FDA and USP VI APPROVED MATERIAL
EPDM/NYLON, TFE-VITON	JORLON

O-ring/Gasket Materials

FDA APPROVED MATERIAL	FDA and USP VI APPROVED MATERIAL		
BUNA-N	PTFE-SILICON	TEFLON	PTFE-VITON
	TUF-STEEL ™	KALREZ	SILVERBACK ™
	EPDM	SILICON	VITON
	JORLON	FLUORAZ	

Seat Materials

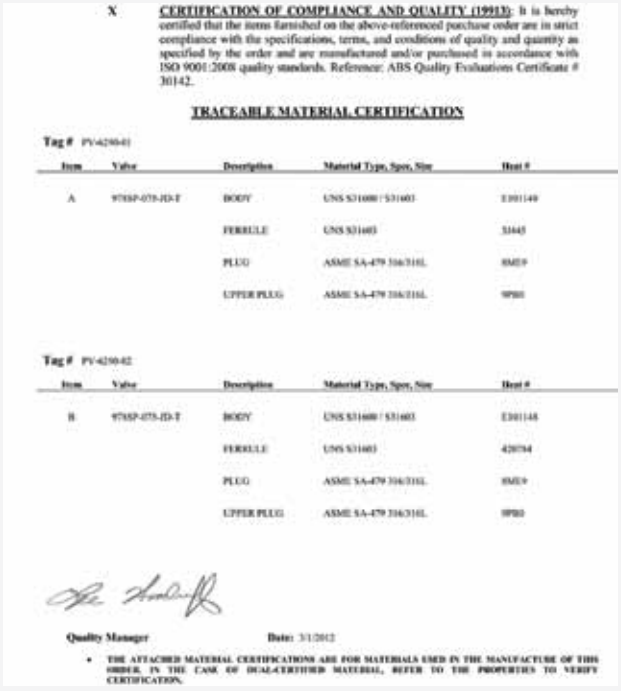
FDA and USP VI APPROVED MATERIAL		
PEEK	PERLAST ™	JORLON
TFM 1600	TEFLON	

SVC-SHC Disc/Poppet

FDA APPROVED MATERIAL	FDA and USP VI APPROVED MATERIAL		
316L/EPDM	TEFLON	PEEK	316L/SILICON

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.

Part Number 24993



X **CERTIFICATION OF COMPLIANCE AND QUALITY (19913):** It is hereby certified that the items furnished on the above-referenced purchase order are in strict compliance with the specifications, terms, and conditions of quality and quantity as specified by the order and are manufactured and/or purchased in accordance with ISO 9001:2008 quality standards. Reference: ABS Quality Evaluations Certificate # 30142.

TRACEABLE MATERIAL CERTIFICATION

Tag # PV-6250-01

Item	Valve	Description	Material Type, Spec, Size	Heat #
A	97HSP-075-HD-T	BODY	UNS S31600 / S31603	E301149
		FERRULE	UNS S31603	31445
		PLUG	ASME SA-479 316/316L	8MU9
		UPPER PLUG	ASME SA-479 316/316L	9PB0

Tag # PV-6250-02

Item	Valve	Description	Material Type, Spec, Size	Heat #
B	97HSP-075-HD-T	BODY	UNS S31600 / S31603	E301148
		FERRULE	UNS S31603	420784
		PLUG	ASME SA-479 316/316L	8MU9
		UPPER PLUG	ASME SA-479 316/316L	9PB0

Quality Manager **Date:** 3/1/2012

- **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.**

Quality

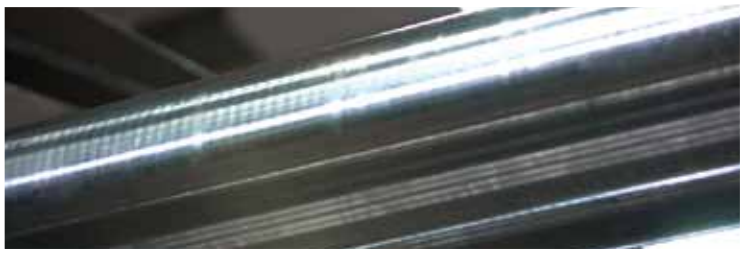
Steriflow's quality begins with pride at our manufacturing plant in Cincinnati Ohio. We meet our customer's quality needs with a wide range of new and proven lean manufacturing technologies. Complete in-house CNC machining, surface coating, assembly and testing, along with material traceability and extensive quality procedures assures that Steriflow products will exceed the most demanding customer's expectations. Over 100,000 square feet are devoted to CNC turning centers, vertical machining centers, milling machines and drill presses. Custom and innovative engineering, and an exceptional veteran work force are the foundation to our superior manufacturing capabilities.

Inventory

A large inventory of finished product and subcomponents is one of the hallmarks of the Steriflow and Jordan valve product lines. This enables us to assemble, test and ship what you need, when you need it to meet capital project deadlines. Steriflow Valve Express was created to facilitate next day shipment of small quantities of quite a few of our products. Consult the website for more information on Steriflow Valve Express.

Lean Practices

Lean manufacturing at Steriflow is more than just applying lean tools and techniques to the shop floor. Since 2000, the application of Lean has helped create an environment where we are continuously identifying and acting on opportunities to eliminate waste, reduce lead times, improve quality, and enhance innovation. All employees participate regularly in lean improvement teams that look for opportunities and eliminate waste to reduce costs.



Steriflow is your single source for high performance, high quality, sanitary valves. We have earned our reputation for quality through twenty-five years of success in bio-pharmaceutical, pharmaceutical, food, cosmetics, and clean process industries. We have the most experience in designing and manufacturing valves and steam traps in the industry.

Purity

- **SCV/SHC Check Valve:** Our WFI, Bio and Parenteral process check valve is in a cGMP class of it's own. It's the first and only check valve specifically designed for these systems. It has no spring, stem, wetted guide, guiding mechanisms, or spring forced plugs that our endemic to spring loaded designs. As a result, there are no crevices, it is fully drainable, and particle shedding is greatly reduced.

- **JSR Clean Gas Regulator:** Our JSR is the first gas regulator designed specifically for Bioprocess gas systems. All other designs on the market started life regulating industrial gas, and were adapted for use in biopharm gas applications. JSR minimizes the number of cracks and crevices where particulate can accumulate, and the stem design is less likely to generate particulate.

- **Mark 96, Mark 95 Pure Steam PRV, WFI BPRV:** The Mark 96 and Mark 95 are the most accurate regulators in their industry class, and the only regulators in the industry with stem guiding completely above the diaphragm. This design aspect of the ASME BPE Guideline minimizes the creation of particulate, and is another reason why these regulators are specified by major pharmaceutical companies more often than any other brand.

- **Fault free SIP solutions:** Steriflow knows SIP. From precise regulation and control of pure steam to the industry best subcooling performance (lowest condensate backup) of our clean steam traps, to our innovative newer products the SSC, and the Mark 934, we can help you get to temperature, and consistently stay at temperature so that your process equipment is available on time, every time.

- **SSC Series:** Our unique, compact sanitary subcooled condenser is the only device in the industry that can end troublesome steam trap condensate back up that is the source of most validation temperature sensor alarms, while drastically reducing the space envelope required for these SIP assemblies.

Precision

Over the years, Steriflow has sold thousands of sanitary control valves and pressure regulators into the most demanding applications. From precise nutrient and WFI flow control into bioreactors, to flow control of buffer into delicate chromatography columns, the world's premier pharmaceutical and biotech firms call on Steriflow to help them research, develop and manufacturer their cutting-edge products.

Steriflow control valves and regulators are tested and sized following ISA75.01, .02 and IEC standard 60534.2.1. Unlike most other sanitary control valve manufacturers, we refrain from making blanket turndown statements and rely on our proven testing and sizing program to select the right trim for the process application under evaluation.

- Mark 978 Series: Our Mark 978 control valve's inherent flow characteristics are determined by innovative plug geometry. Unlike other manufacturers, our Linear, Equal % and Custom Modified Characteristics (trim) can be changed in the field in most cases. And, this unique plug geometry also insures precise flow control, especially under low flow conditions, compared to a competitors formed, soft laminated diaphragm closure.
- Mark 95, Mark 96 Series: Our pure steam and WFI regulators were the first valves of their kind. Designed at the advent of the Biopharm revolution, we have more experience in continuous pressure regulation than any of our competitors. It shows. Our wide Jorlon™ diaphragm area and low stroke characteristics, offer the industries best droop (set point offset) accuracy characteristics bar none.

  If automation is desired, our air augmented Mark 95AA back pressure regulator (for WFI - end of loop or bypass control; buffer or elution over pressure control) and Mark 96AA pressure regulator (pure steam SIP delivery, CGA-gas pressure control) offer an accurate, lower cost alternative to a control valve for pressure control.
- SVC/SHC Check Valves: Besides being designed with the purity required for use in Bioprocess and WFI, these valves also have industry best performance characteristics. The stem and springless design, insure precise, low cracking pressure (<3 mBar), low DP and high repeatability.

Reliability

When it comes to reliability, at Steriflow Valve we put our reputation, and profitability, behind our words with the best warranties in the industry.

- Control Valves and Regulators: Our control valve and regulator diaphragms have an industry first and best, lifetime warranty. We have so thoroughly vetted our diaphragm that if it ever fails while operating within the valve design parameters, we will ship the replacement diaphragm to you at our expense.
- Mark 93 Series Steam Traps: Our low subcooling Mark 93 steam trap has two warranties backing up our years of experience and test data on subcooling and reliability. If our trap causes condensate to back up more than 8 inches between the validation temperature sensor and trap (major cause of temp sensor wetting/cooling alarms) under normal loads and operating conditions, we will replace the element or the trap at no charge.

Applications	
Product Class & Model Prefix	**Typical GMP Application**
Regulators	
Pressure Reducing Valves	
MK96, MK96C: Spring Loaded, Manual Set Point	For manual or automated (AA) pressure regulation of: Clean Steam for SIP point of use, CDG, buffer, CIP or purified water
MK96A, MK96AA: Air Loaded, Hybrid Regulator	
JSR, JSRLF, JSRHF: Spring Loaded Manual Set Point	To regulate CDA/CDG pressure for end point use on Sparge Gas, Filter FIT and drying, and blanket/motive gas. Can be used for Clean Condensate seal pressure maintenance
MK968: Spring Loaded Manual Set Point	To regulate large volume CDG end point of use applications like Sparge Gas, Filter FIT and drying, blanket gas and motive force gas
Back Pressure Regulators	
MK95, MK95FT: Spring Loaded Manual Set Point	For manual or automated (AA) back (inlet) pressure regulation of WFI, USP PW, CIP, Buffer, for end of loop or head pressure maintenance, or pump bypass. For CDA/CDG, vessel vent pressure maintenance
MK95AA, MK95FTAA: Air Loaded Hybrid Regulator	
JSB: Spring Loaded Manual Set Point	
MK958: Spring Loaded Manual Set Point	For regulating low pressure, large volume CDA/CDG outflow on large vessels
Control Valves	
MK978JD (Jorlon Diaphragm): Diaphragm Seal Control Valve	For precise, automated control of Bioreactor/Fermentor/Chromatography vessel inputs (WFI, Buffer, Nutrient, Sparge and blanket gas, elution media) and sanitization utility flows (CIP, USP PW, Clean Steam
MK978OR (O-Ring): O-Ring Seal Control Valve	
MK978LF (Low Flow): O-Ring Seal Control Valve	
Ball Valves	
MK9020: 2-way ASME BPE Connections	For discrete manual and air/electric actuated isolation and flow direction control of clean (pure) steam and condensate, CDG, gas, waste, acid, caustic and solvent applications
MK9020D or S: 2-way DIN or ISO 11866 Connections	
MK9030: 3-way, Connections	
Check Valves	
SVC	Vertical up and down flow, GMP back flow prevention
SHC	Horizontal flow GMP back flow prevention
Clean (Pure) Steam SIP Specialities	
Steam Trap	
MK93:	For validated tubing drain trap, and small vessel and filter drain trap applications, or on larger vessels for temperature hold bypass traps. With inverted U-tube, for filter/vessel SIP air vent.
MK93__P:	For distribution line drain trap applications. Also for high temperature short duration SIP tubing drain trap and small vessel and filter drain trap applications or temperature hold bypass
MK94:	For medium to large vessel and filter drain trap and air vent applications
MK934:	For very large vessel drain trap with, or without, bypass circuit.
CSDT	For plant steam applications in a clean room environment
SIP Accessories	
SSC (Subcooled Condenser):	A compact temperature sensor and condensate chamber with steam trap assembly. Designed to eliminate validation temperature sensor alarms and minimize space for compact installations. Ideal for mobile and fixed SIP installations.
Sample Coooler - Heat Exchangers	
SC30:	Portable or fixed station heat exchanger for safe extraction of hot WFI or condensate from Clean (Pure) steam for testing purposes
SC60:	
SC50:	
Sight Glass	
SG:	For inline viewing of liquid, gas or powder process flows
Miscellaneous	
CGDM:	Clean Gas Distribution Manifold. For distribution of CDG or CDA for Point of Use Installation, or instrument air in a clean room environment

Process & Clean Utility Media											
WFI	Buffer	Nutrient	Bio or Parenteral Process	Clean (Pure) Steam	Clean Condensate	USP PW	CIP	Clean Dry Gas or Air	Solvent*	Acid*	Caustic*
X	X			X	X	X	X	X	X	X	X
X	X			X	X	X	X	X	X	X	X
				X	X	X		X			
								X			
X	X				X	X	X	X	X	X	X
X	X				X	X	X	X	X	X	X
X	X				X	X	X	X			
								X			
X	X	X	X	X	X	X	X	X	X	X	X
				X		X	X	X	X	X	X
				X		X	X	X	X	X	X
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X	X	X	X	X	X	X	X	X	X	X	X
								X			

* Steriflow makes no warranty for use in any specific application. It is the customers final responsibility to determine applicability of valve, and valve materials, particularly for solvent, acid and caustic service.

Mark 978 Series Sanitary Control Valve

Designed to meet the rigid specifications for all sterile process control applications. Strict adherence to ASME BPE guidelines makes the MK978 suitable for a wide variety of applications in the bio-pharmaceutical, pharmaceutical, cosmetic, dairy and food & beverage industries.

True characterized trim, a variety of Cv offerings, superior temperature and pressure ratings along with a lifetime diaphragm warranty make the Mark 978 the sanitary control valve for all of your sanitary liquid, gas and clean steam services.

Common Application Experience:

Control of WFI, Pure Steam, CDA/CDG, Buffer, Elution Media, CIP and Bioprocess

Key Features

- Lifetime warranty on Jorlon diaphragm
- All stem guiding above the diaphragm (wet process) to eliminate particulate generation
- Self-draining geometry in most vertical or horizontal orientation allows installation flexibility
- INLINE horizontal connections are offered as an option on most of our models
- Corrosion resistant actuator coating with SST fasteners
- Extended PEEK guide bushing ensures smooth, stable movement throughout entire stroke length regardless of valve orientation (on it's side or upright)
- Contoured plug design for true equal percentage or linear flow characteristics throughout entire stroke length
- Bolted bonnet provides enhanced strength and durability over clamped bonnet designs especially when units are mounted horizontally
- Corrosion resistant SST Namur yoke assembly suitable for washdown, permitting easy mounting of positioners
- Solid ASME A479 316L barstock construction offers excellent chemical resistance, ensures consistent material integrity and surface finish
- FDA/USP Class VI Jorlon diaphragm resistant to aggressive chemicals, suitable for indefinite steam service, offers unsurpassed service life

Quick Specs

- Sizes: 1/2" – 3" (DN15 – DN80) with Jorlon diaphragm; 1/2" – 2" (DN15 – DN50) with O-Ring seal
- End Connections: Tri-Clamp® fitting, tube weld to ASME BPE, DIN or ISO
- Body and all wetted material: ASTM A479 316L SST barstock
- Seat materials: ASTM A479 316L SST; Teflon or PEEK optional to FDA & USP Class VI
- Diaphragm materials: Jorlon (FDA, USP <87>, USP <88> Class VI @ 121°C); TFE/Viton to FDA
- O-ring materials: EPDM, Viton, Buna-N, Silicone, Kalrez, TFE (all FDA) and FDA and USP <88> Class VI)
- Shutoff: to ANSI Class VI
- SF5 (20 Ra µin (0,5 Ra µm) electropolish) standard internal finish (8 Ra µin electropolish optional)

Mark 978LF Sanitary Low Flow Control Valves

Designed to meet the stringent specifications for low flow sterile processes. Steriflow's strict adherence to ASME BPE make these low flow control valves suitable for a wide variety of sterile liquid media.

Common Application Experience

The Mark 978LF is ideal for use with sparge gas, WFI, buffers, elution flows or ingredient addition to sanitary and aseptic processes in the pharmaceutical, biotechnology, cosmetic, dairy, and food & beverage industries.

Whether the need is to control pressure, temperature, flow, pH, level or other variables, the Mark 978LF's true characterized trims and excellent repeatability make it the right choice for your sanitary process applications.

Key Features

- All stem guiding above the wetted process – to eliminate particulate generation
- No internal crevices below the process seal – prevents accumulation of contaminants
- Self-draining – when mounted in vertical or horizontal orientations
- Wetted parts made of 100% ASTM A479 316L Stainless Steel barstock
- Maintenance friendly – easy to perform maintenance with simple disassembly, reassembly and steam-in-place/ clean-in-place capabilities
- Epoxy coated multi-spring actuators provide excellent corrosion resistance during washdown
- SF5 (20 Ra µin (0,5 Ra µm) electropolish) standard; 8 Ra optional
- FDA and USP Class VI conformity on all process seal materials

Quick Specs

- Sizes: 1/2" & 3/4" (DN15 & DN20)
- Cv's: 0.05 – 0.1
- End Connections: Tri-Clamp®, tube weld to ASME, BPE, DIN/ISO optional
- Body and all wetted material: ASTM A479 316L SST barstock
- SF5 (20 Ra µin (0,5 Ra µm) electropolish) standard internal finish, (8 Ra µin electropolish optional)
- Body/Bolt Seal: Teflon® gasket (FDA/USP Class VI)
- O-ring materials: EPDM, Viton, Silicone, Flouraz, Kalrez (all FDA/USP Class VI)
- Jorlon diaphragm seal designs available
- Shutoff: ANSI Class III

Mark 96 & Mark 96C Series Sanitary Pressure Regulators

The Mark 96 Series are designed to meet the design guidelines of ASME BPE pressure reducing valves. The Mark 96 is a bolted bonnet design and offered in sizes from 3/4" – 3". The Mark 96C is a 1/2" – 1" clamped body design. Both valves regulate downstream pressure of process and clean utility applications in sanitary and aseptic systems.

How it works:
The MK96 regulators are force balance mechanisms. The downstream pressure acts on the bottom of the diaphragm, opposing the adjustable spring force. If the downstream process pressure increases and approaches the set point pressure (adjustable spring force), that pressure overcomes the force exerted by the spring, moving the diaphragm and plug towards the seat, closing the valve. This reduces the downstream pressure putting the forces in equilibrium at the set point pressure.

Common Application Experience:

Self-contained pressure control of Pure (Clean) Steam, CDA, CDG, Buffers, Elution flows, USP PW, WFI

Key Features

- Lifetime warranty on Jorlon diaphragm
- Steriflow is the only manufacturer offering 100% guiding above the diaphragm area and not the seat/orifice area which eliminates metal-to-metal particulate generation
- Accuracy: droop (set point offset) performance is best in the industry
- Soft seat for ANSI Class VI shutoff available
- Corrosion resistant ASTM A479 316L body, housing and T-handle
- Spring cylinder contains spring when disassembled, improving safety and retaining setpoint (clamped version only)
- Diaphragm restraint standard – supports diaphragm during vacuum service
- Body/ferrule heat numbers on bottom surface for material traceability

Quick Specs

- Mark 96 Series in sizes 3/4" – 3"; Mark 96C Series in sizes 1/2" – 1"
- End Connections: Tri-Clamp® fitting, tube weld to ASME BPE, DIN/ISO optional
- Body and all wetted material: ASTM A479 316L SST barstock
- SF5 (20 Ra µin (0,5 Ra µm) electropolished) standard internal finish; 8 Ra µin electropolished (internal or external) optional for critical process or clean room installations
- Seat material: Standard hard seat – integral 316L SST; Optional soft seat – FDA & USP Class VI compliant Teflon, PEEK
- Diaphragm material: Jorlon (FDA, USP <87>, USP <88> Class VI @ 121°C) & USP Class VI compliant, EPDM/Nylon, SS
- O-ring material: FDA & USP Class VI compliant EPDM, Buna-N, Viton, Silicone, Teflon-Encapsulated Viton, Teflon-Encapsulated Silicone
- Shutoff: ANSI Class III hard seat or Class VI soft seat
- Setpoint spring ranges: 2 – 135 psi (0,14 – 9,3 bar) across 5 ranges

Mark 96A Series Air Loaded Pressure Regulators

The Mark 96A is a compact air loaded sanitary pressure reducing valve designed to permit the user to change setpoints remotely via a cabinet/panel mounted air regulator or through a distributed control system and an I-P transducer.

The Mark 96A is an ideal choice for automating the SIP/CIP process in tight locations where a Mark 96AA does not fit. For example, by adjusting (increasing) the air pressure loaded to the dome, the valve will fully open during CIP to ensure full velocity and turbulence for sanitization. At the end of the CIP cycle, the dome pressure can be reduced so that the valve returns to its previous position.

Key Features

- Compact design for space-constrained installations
- Air loaded for remote setpoint adjustment
- 316L Stainless Steel, or light weight anodized aluminum spring housing
- All stem guiding above the diaphragm (wet process) to eliminate particulate generation
- Remote operation and finish options make MK96A ideal for clean room installations
- Optimized diaphragm area for minimal offset and extended life
- Light bias spring for stable operation at low flows
- Jorlon diaphragm delivers extreme longevity
- Soft sealing for ANSI Class VI shutoff

Quick Specs

- Sizes: 1" (DN25), 1-1/2" (DN40), 2" (DN50)
- End Connections: Tri-Clamp®, tube weld end
- Body and all wetted material: ASTM A479 316L SST barstock
- Seat material: Teflon®, PEEK (FDA and USP Class VI approved)
- Diaphragm material: Jorlon (FDA, USP <87>, USP <88> Class VI @ 121°C) & USP Class VI compliant)
- O-ring material: FDA and USP Class VI approved Teflon-Encapsulated Viton
- Shutoff: to ANSI Class VI
- Maximum setpoint: 100 psi (6,9 bar) / minimum setpoint: 20 psi
- SF5 (20 Ra µin (0,5 Ra µm) electropolished) standard internal finish; 8 Ra µin electropolished (internal or external) optional for clean room installations

Mark 96AA Series Air Augmented Pressure Regulators

The Mark 96 with air augmentation (AA) option offers the same line sizes, Cv choices and seats as the standard MK96. By connecting an air pressure signal to the 1/4" FNPT dome fitting via an air regulator or I/P, the set point can be changed remotely by "sending an air signal instead of a technician".

The hybrid MK96AA gives users the ability to change pressure set points to any point in excess of the springs minimum set point (2 psi with a 2-8 psi spring range, for example). Users adjust the regulator's spring to the lowest set point, or to the lowest set pressure that the regulator will operate at (sterilization steam pressure for example). To achieve a higher pressure set point (CIP or WFI flush), air pressure is added to the MK96AA spring housing via an I/P connected to the DCS or PLC, or by tubing to a manual air regulator installed in a more convenient location (outside a cleanroom for example). The spring inside the housing also gives users operational security in the event of a compressor failure.

Key Features

- Lifetime diaphragm warranty
- All stem guiding above the diaphragm (wet process) to eliminate particulate generation
- Automate existing manual installations. MK 96AA upgrade kits available for Mark 96 regulators
- Maximizes the functional operating range by minimizing droop. This is especially useful on high turndown SIP steam delivery applications
- Reduce project CapEx. Used with an I/P, the MK96AA reduces the time required for steam pressure balancing, commissioning and validation of SIP loops by putting the regulator's set point adjustment in the hands of the Control Room Technician
- Remote operation and finish options make MK96AA ideal for clean room installations
- Complete range of products for any size or Cv requirement. The available sizes and Cv's are the same as the current Mark 96 product range
- With preset spring, users maintain control in the event of power (air failure).

Quick Specs

- Sizes: 3/4" – 3" (DN20 – DN80)
- End Connections: Tri-Clamp® fitting, tube weld to ASME BPE, DIN/ISO optional
- Body and all wetted material: ASTM A479 316L SST barstock
- Seat material: Standard hard seat – integral 316L SST; Optional soft seat – Teflon, PEEK (FDA & USP Class VI compliant
- Diaphragm material: Jorlon, (FDA, USP <87>, USP <88> Class VI @ 121°C) and USP Class VI specification
- O-ring material: EPDM, Buna-N, Viton, Silicone, Teflon-Encapsulated Viton, Teflon-Encapsulated Silicone FDA and USP Class VI
- SF5 (20 Ra µin (0,5 Ra µm) electropolished) standard internal finish; 8 Ra µin electropolished (internal or external) optional for clean room installations
- Shutoff: ANSI Class III hard seat or Class VI soft seat

Mark 95 & Mark 95FT Series Back Pressure Regulators

The Mark 95 is designed to regulate or relieve the upstream pressure in continuous circulation loops. It is most commonly used to maintain validated pressure at the end of WFI loops upstream of the spray ball. Two other common installations are used as a pump dead head and use to insure head pressure at the outlet of a pump.

The Mark **95FT** has all the features and benefits of the Mark 95, but offers an additional connection to allow straight through flow. The MK95FT is intended for pump by-pass applications, or any other installation where you need an inline, drainable valve to maintain pressure at the valve inlet by releasing excess flow to a bypass loop. The FT option reduces the space required, and installed cost of a traditional angled body back pressure regulator in a bypass application.

Key Features

- Lifetime warranty on Jorlon diaphragm
- Steriflow is the only manufacturer offering 100% guiding above the diaphragm area and not the seat/orifice area which eliminates metal-to-metal particulate generation
- 316L Stainless Steel spring housing
- 100% ASTM A479 316L body and trim
- T-handle screw for easy handling and setpoint adjustments
- Thumblock for securing and retaining setpoint
- Bolted bonnet for increased safety and pressure/temperature rating
- SF5 (20 Ra µin (0,5 Ra µm) electropolished) standard internal finish; 8 Ra µin electropolished (internal or external) optional for clean room installations

Quick Specs

- Sizes: 3/4" – 3" (DN20 – DN80)
- End Connections: Tri-Clamp®, tube weld end, DIN/ISO sanitary connections
- Body and trim material: 316L Stainless Steel (ASTM A479)
- Seat Materials: Integral 316L SST – standard; Jorlon, PEEK or TFE – optional
- Diaphragm materials: Jorlon (FDA, USP <87>, USP <88> Class VI @ 121C), 316L SST, EPDM/Nylon
- O-ring materials: EPDM, Buna-N, Viton, Silicone, Teflon-Encapsulated Viton, Teflon-Encapsulated Silicon – (FDA, USP <87>, USP <88> Class VI @ 121°C) & USP Class VI
- Shutoff: ANSI Class III hard seat or Class VI soft seat

Mark 95AA Series Air Augmented Pressure Regulators

The Mark 95 with air augmentation (AA) option offers the same line sizes, Cv choices and seats as the standard MK95. By connecting an air pressure signal to the 1/4" FNPT dome fitting via an air regulator or I/P, the set point can be changed remotely by "sending an air signal instead of a technician".

The Mark 95AA gives users the ability to change back pressure set points to any point in excess of the springs minimum set point (2 psi with a 2-8 psi spring range, for example). The valve can be run in a hybrid mode using the spring set point and air pressure, or it can be operated in full automatic mode by adjusting the regulator's spring to the lowest set point, or to the lowest set pressure at which the regulator will operate. To change the set point, air pressure is added or subtracted from the MK95AA spring housing via an I/P connected to the DCS or PLC, or by tubing to a manual air regulator installed in a more convenient location (outside a clean production suite for example)

Key Features

- Lifetime diaphragm warranty
- All stem guiding above the diaphragm (wet process) to eliminate particulate generation
- Automate existing manual installations. MK 95AA upgrade kits available for Mark 95 regulators
- Maximizes the functional operating range by minimizing droop This is especially useful on high turndown SIP steam delivery applications
- Reduce project CapEx. Used with an I/P, the MK95AA reduces the time required for pressure balancing, commissioning and validation of WFI loops by putting the regulator's set point adjustment in the hands of the Control Room Technician
- Remote operation makes the MK95AA ideal for hard to reach hot WFI, and USP PW applications in clean utility rooms.
- Complete range of products for any size or Cv requirement. The available sizes and Cv's are the same as the current Mark 95 product range
- With preset spring, users maintain control in the event of power (air failure)

Quick Specs

- Sizes: 3/4" – 3" (DN20 – DN80)
- End Connections: Tri-Clamp® fitting, tube weld to ASME BPE, DIN/ISO optional
- Body and all wetted material: ASTM A479 316L SST barstock
- Seat material: Standard hard seat – integral 316L SST; Optional soft seat – Teflon, PEEK (FDA & USP Class VI compliant)
- Diaphragm material: Jorlon, (FDA, USP <87>, USP <88> Class VI @ 121°C) and USP Class VI specification
- O-ring material: EPDM, Buna-N, Viton, Silicone, Teflon-Encapsulated Viton, Teflon-Encapsulated Silicone FDA and USP Class VI
- SF5 (20 Ra µin (0,5 Ra µm) electropolished) standard internal finish; 8 Ra µin electropolished (internal or external) optional for clean room installations
- Shutoff: ANSI Class III hard seat or Class VI soft seat

J-Pure Series High Purity Pressure Regulators: JSR, JSRLF, JSRHF & JSB

The J-Pure regulator is ideally suited for pressure and back pressure regulation of high purity gases, clean dry air, or gas (CGA, CDG) commonly found in biotech and pharmaceutical applications.

This compact pressure reducing and back pressure valves are the first in their class to be designed and built specifically for biopharm gas applications and with ASME BPE in mind. Unlike all other manufacturer's, this isn't an industrial regulator converted for biopharm service.

Common Application Experience:

Upstream and point of use pressure, and back pressure regulation of CDA and CDG used for vessel sparge, blanket or motive force applications, and for testing or drying of sterile filters.

Key Features

- Designed specifically for Bio and Parenteral process gas services: minimized internal volume and crevices
- Body, stem, and bonnet materials ASTM A479 316L suitable for any environment and washdown
- SF5 (20 Ra µin (0,5 Ra µm) electropolish) – standard internal and external finish suitable for clean room installation
- FDA/USP Class VI seat material for ANSI Class VI shutoff
- Fine thread pitch for precision setpoint adjustments
- Jorlon diaphragm (FDA, USP <87>, USP <88> Class VI @ 121°C); unsurpassed life
- Panel mounting optional
- Five minute trim change via standard inline maintainability

Quick Specs

- Sizes: 1/4" (NPT only), 3/8", 1/2", 3/4", 1". Availability depends on model
- End Connections: Tri-Clamp® or tube weld ends to ASME BEPE are standard; DIN/ISO, NPT, or VCR connections are optional
- Cv 0.012, 0.08, 0.20, (JSRLF); 0.50, 0.80 (JSR and JSB); 1.25, 2.0 (JSRHF)
- Body, stem, seal and bonnet material: ASTM A479 316L
- Diaphragm material: Jorlon, (FDA, USP <87>, USP <88> Class VI @ 121°C) and USP Class VI specification
- Maximum Inlet Pressure: JSR & JSB: 150 psig (10,5 bar); JSRLF: 450 psig (31 bar) for sanitary connections; 4000 psig (276 bar) for NPT; JSRHF: 150 psig (10.5 bar)
- Adjustable range: 4 – 125 psi (0,28 – 8,6 bar) across multiple ranges
- SF5 (20 Ra µin (0,5 Ra µm) electropolish), 8 Ra µin electropolished (internal or external) optional for clean room installations
- Options: panel mounting, captured vent, self relieving

Mark 9020 Sanitary Ball Valves

The Mark 9020 Series ball valves take ASME BPE guidelines to heart. This valve was designed from the beginning to meet every aspect of ASME BPE.

The Mark 9020 Series was designed by Steriflow to meet the rigors of clean steam, but can be used in a variety of applications including CDA, CDG, acids, solvents and drain applications where inline valve cleaning is desired. From the materials chosen for seats and seals to the final marking and documentation, you can trust the Steriflow name.

Key Features

- New DIN 11866-A, and B (ISO) tube weld end models available
- Designed to meet ASME BPE 2009
- Traceable industry grade high density 316L body, ball, steam and end caps with <3% ferrite standard, 1% optional
- Certified TFM 1600 body seal, seat, thrust washer, and packing material meet: FDA 21 CFR 177 and final form materials certified to meet USP <88> Class VI (in-vivo), and USP <87> (in-vitro) testing requirements
- Documented surface finish on all wettable components is SF1 (20 Ra mechanical polish), SF4 (15 Ra µin mechanical/electropolish optional)
- Ball port has identical ID as inlet/outlet tubing to prevent holdup
- Pressure ratings up to 1000 psig @ 100°F
- Anti-blowout stem design
- ISO 5211 actuator mounting pads
- Integral lockout/tagout facility
- Live loaded packing to insure against leaks or contaminant ingress

Quick Specs

- Sizes: 1/2" – 4" (DN15 – DN100)
- End Connections: ASME BPE, Tri-clamp® or extended tube weld ends; and DIN 11866-A, or B (ISO) ext. tube weld ends standard and in stock
- Body material: ASTM A351 CF3M 316L 3% Ferrite (standard), CF3M 1% Ferrite (optional)
- SF1 (20 Ra µin (0,5 Ra µm) Mechanical Polish) standard internal finish, SF4 (15 Ra mechanical/electropolish) optional
- 4" (100mm) stem extensions standard and in stock
- Manual or automation packages available

Mark 9030 Sanitary Ball Valves

The Mark 9030 Series ball valves take ASME BPE guidelines to heart. These 3-way sanitary ball valves were designed from the beginning to meet every aspect of ASME BPE. From the materials chosen for seats and seals to the final marking and documentation, you can trust the Steriflow name.

Use the MK9030 for discrete manual, and air/electric actuated isolation and flow direction control of clean (pure) steam and condensate, CDG, CDA, gas, waste, acid, caustic, and solvent applications.

Key Features

- ASME BPE 2009 guidance compliance
- Traceable industry grade high density 316L body, ball, steam and end caps with <3% ferrite standard, 1% optional
- Certified TFM 1600 body seal, seat, thrust washer, and packing material meet: FDA 21 CFR 177 and final form materials certified to meet USP <88> Class VI (in-vivo), and USP <87> (in-vitro) testing requirements
- Documented surface finish on all wettable components is SF1 (20 Ra µin (0,5 Ra µm) mechanical polish), SF4 (15 Ra µin) mechanical/electropolish optional)
- Ball port has identical ID as inlet/outlet tubing to prevent holdup
- Pressure ratings up to 1000 psig @ 100°F
- Anti-blowout stem design
- ISO 5211 actuator mounting pads
- Integral lockout/tagout facility
- Live loaded packing to insure against leaks or contaminant ingress

Quick Specs

- Sizes: 1/2" – 4" (DN15 – DN100)
- End Connections: ASME BPE, extended tube weld ends – standard, Tri-clamp® ends available
- Body material: ASTM A351 CF3M 316L 3% Ferrite (standard), 1% Ferrite (optional)
- SF1 (20 Ra µin (0,5 Ra µm) Mechanical Polish) standard internal finish, SF4 (15 Ra µin mechanical/electropolish) optional
- 4" (100mm) stem extensions available
- Manual or automation packages available

Mark 93 Series Sanitary Steam Traps

The Mark 93 is a balanced port, thermostatic steam trap designed specifically for use in validated clean steam systems. The sanitary design follows ASME BPE guidelines including a 20Ra µin internal finish, self draining design, and all relevant materials, marking and documentation guidelines.

The MK93 has been specifically designed to provide higher flow rates at low pressures and low subcooling levels. In lab testing, the MK93 consistently exhibited excellent flow rates at subcooling levels of less than 3°F or less (<1,7°C). Note: Low subcooling operation insures that condensate won't back up and wet (cool) the upstream validated temperature sensor.

Key Features

- Industry Best Warranty:
  - 2 year warranty certifying that condensate will not back up more than 8" upstream of trap under normal operating conditions
  - 5 year warranty against material and workmanship defects
- All ASTM A479 316L housing and barstock internal compounds
- ASME BPE Tri-Clamp® and ext, tube weld ends, and DIN 11866-A and B (ISO) ext tube weld ends are standard. Other connections are available upon request
- Self draining
- Impossible to put element in backwards; one element standard for all traps
- Interchangeable orientations using the same bellows minimizes inventory

Quick Specs

- Sizes: 1/2" (DN15), 3/4" (DN20), 1" (DN25)
- Design Pressure/Temperature Rating: Maximum Allowable Pressure (PMA): 145 psig (10,0 bar); Maximum Allowable Temperature (TMA): 350°F (177°C)
- Maximum Operating Conditions: MK93: 10 – 50 psi (0,7 – 3,4 bar); MK93 Option P: 45 – 90 psi (3,1 – 6,2 bar)
- Available installation orientations: vertical, horizontal or mixed connections
- End Connections: ASME BPE Tri-Clamp and ext. tube weld ends, and DIN and ISO ext tube weld ends
- Body inlet/outlet material: ASTM A479 316L Stainless Steel
- O-ring materials: Viton, Teflon, Encapsulated and others, all FDA and USP Class VI approved
- Surface Finish: SF1 (20 Ra µin (0,5 Ra µm) Mechanical Polish) standard internal finish, SF5 (20 Ra µ in (0,5 Ra µm) mechanical/electropolish) optional

Mark 94 Series Sanitary Steam Traps

The Mark 94 is a thermostatic steam trap designed specifically for use in higher capacity SIP applications like large filter, and medium to large vessel applications. It features a 20 Ra internal finish, and a self-draining design, to minimize the possibility of medium entrapment and bacterial growth. The Mark 94 has been designed to provide high condensate flow rates during SIP heat up, allowing vessels and other process equipment to reach validation temperature in minimum time.

The proprietary fill, bellows and orifice design minimize the subcooling (3°F/ -1.7°C) required to open the trap during heat up, and SIP temperature hold, insuring fast drainage under lower load conditions to minimize condensate back up and help insure against validation temperature faults.

Key Features

- Body and solid internal components constructed of ASTM A479 316L
- Sanitary clamp ends standard, other ends (tube weld, threaded, ISO/DIN) available upon request
- Self draining when installed vertically (outlet side down)
- New design provides excellent flow rates with low subcooling 3°F (<1,7°C) or less) during heat up and temperature hold period, minimizing the probability of validation temp alarms caused by condensate back up
- FDA, USP Class VI gasket standard

Quick Specs

- Sizes: 3/4", 1", 1-1/2"
- End Connections: ASME BPE, Tri-clamp® and ext tube weld ends, and DIN and ISO ext tube weld ends are standard. Others available as options upon request
- Body Material: ASTM A479 316L housing and barstock internal compounds
- Surface Finish: SF1 (20 Ra µin (0,5 Ra µm) Mechanical Polish) standard internal finish, SF5 (20 Ra µ in (0,5 Ra µm) mechanical/electropolish) optional
- Maximum Operating Pressure (PMO): 50 psig (3,5 bar)
- Maximum Allowable Temperature (TMA): 350°F (177°C)
- O-ring materials: Viton, Teflon, Encapsulated and others, all FDA and USP Class VI approved

Mark 934 Series Sanitary Steam Traps

The Mark 934 sanitary steam trap system is specifically designed to facilitate the sterilization of very large vessels including fermentors, bioreactors and formulation vessels without the addition of a SIP Heat up bypass loop. The system consists of a high flow sanitary steam trap and a standard capacity sanitary trap in the same body. The combined capacity of the two traps handles the highest condensate and air flows during initial heat up, replacing the need for a bypass loop. This trap also manages the lower rate of condensate production during the SIP temperature maintenance period.

The Mark 934 is designed to operate up to a maximum differential pressure of 50 psig (3,4 bar) and will control condensate subcooling to less than 5°F, over a range from 10 to 50 psig.

Key Features

- Capital Expense (CAPex) Reduction: Piping simplification: Elimination of bypass tubing, tubing components, 3-way valve, and I/O capacity. And, minimization of associated labor: welding, polishing, wiring and commissioning
- Utility Cost Reduction: Efficient air and condensate drainage without live steam or pressure loss. All available heat is transferred to the vessel, not the drain.
- Vessel Availability Increase: More efficient heat transfer increases vessel availability by reducing heat-up time and SIP total cycle time
- Polished components-body interior and exterior mechanically polished to SF1, 20 Ra µin (0,51 Ra µm)
- Self-draining, no hold up
- Ease of disassembly and maintenance
- Highest condensate flow rates in the industry
- FDA, USP Class VI gaskets standard

Quick Specs

- Size: 1", 1-1/2" & 2"
- End Connections: ASME BPE Tri-Clamp and ext. tube, and DIN and ISO ext tube weld ends are standard. Others available as options upon request
- Body inlet/outlet material: ASTM A479 316L Stainless Steel
- Maximum Operating Pressure (PMO): 50 psig (3,4 bar)
- Maximum Allowable Temperature (TMA): 350°F (177°C)

SIP Specialties

SSC Series

The SSC Sanitary Subcooled Condenser is a patent pending sanitary condensate chamber and steam trap assembly that was designed to replace the 12 - 18" downcomer (drip leg) traditionally installed between SIP temperature sensors and sanitary steam traps.

The finned-chamber geometry of the SSC offers the best available technology for insuring rapid SIP heat-up and uninterrupted hold cycles, while offering a more economical alternative (re: space utilization costs) to conventional SIP downcomer designs.

Project CAPex Savings

- Significant TIC Cost (Total Installed Cost) reduction for SIP sensor/drip leg/trap assemblies
- Significant installation envelope space reduction: reduces installation space by 75%.

Increased Process Availability

- Reduces average annual SIP time by reducing heat up time, and minimizing the probability of wetted temperature sensor faults during temperature maintenance
  - The SSC has more than 4 times the condensate capacity and 5 times the surface area as a 3/4" SIP downcomber. This ensures rapid condensate cooling which improves trap drainage and eliminates condensate backup.
- Optional preassembly with steam trap, valves, SIP sensor, t-well and/or temperature transmitter
- Twelve installation configurations
- Constructed from certified ASTM A479 316L barstock
- Fully drainable in full size, or compact versions
- Certified SF1 (20 Ra µin) internal surface finish standard. SF 5 (8 Ra µin) electropolish optional

Quick Specs

- 3/4" Tri-Clamp® end connections standard
- ASTM A479 316L barstock construction
- All gaskets certified to FDA 21 CFR 177, and USP <88> Class VI
- SF1 (20 Ra µin (0,51 Ra µm) internal finish standard/ SF 5 electropolish optional
- Maximum water flow capacity: 24773 #/hr @ 15 psid

Sanitary Check Valves

SVC/SHC Series Check Valves

The patented SVC/SHC Series vertical and horizontal check valves **designed specifically for use in biopharmaceutical and parenteral drug manufacturing applications**. The SVC and SHC have no spring, hinge, mechanical return mechanism or wet guided stem. They are crevice free, have no areas for particle entrapment, minimize particulate shedding, and are fully drainable. These check valves, and the first check valves to really follow the valve design guidelines within ASME BPE 2009.

The SVC/SHC Series check valves are applicable for gas or liquids, and suitable for CIP, SIP, and are autoclavable.

Sanitary Steam Traps and SIP Specialties

CSDT Series Compact Sanitary Disc Traps

The CSDT Series is a 316L polished, stainless steel, thermodynamic disc trap, that is compact with a lightweight design and Tri-Clamp® end connections.

Though non-sanitary in the traditional sense, the exterior is polished to 20 Ra and can be used in clean room environments. The thermodynamic action meets the requirements of quick response and higher capacity applications for plant steam in a sanitary environment. Condensate entry below and concentric to the disc ensures a clean parallel lift off the seat, minimizing wear.

The CSDT is ideal for fluctuating loads and pressures and higher capacity plant steam applications in a clean room environment. It is virtually maintenance free with a one year replacement warrant

Sample Coolers

Sample Coolers

Steriflow sample coolers are used to safely extract WFI and Pure steam condensate for Biological purity and chemical analysis. We know that the highest quality construction is needed for this process. As such, our sample coolers are designed and manufactured following the ASME BPE guidelines.

Steriflow's range of sample coolers allow clean steam and high purity water samples to be taken quickly and easily while maintaining a sterile testing environment. The SC50 and SC60 units are designed to be mounted at the sampling point, while the SC30 is a free-standing portable unit. All models can be operated with potable or chilled water as the cooling medium.

Where the quality of the cooling water may cause fouling of the coil, the SC50 can be easily disassembled to allow tube bundle cleaning. A wide range of ancillary products (sample valves, sanitary hose assemblies and carrying cases) are available for use with all models of sample cooler.

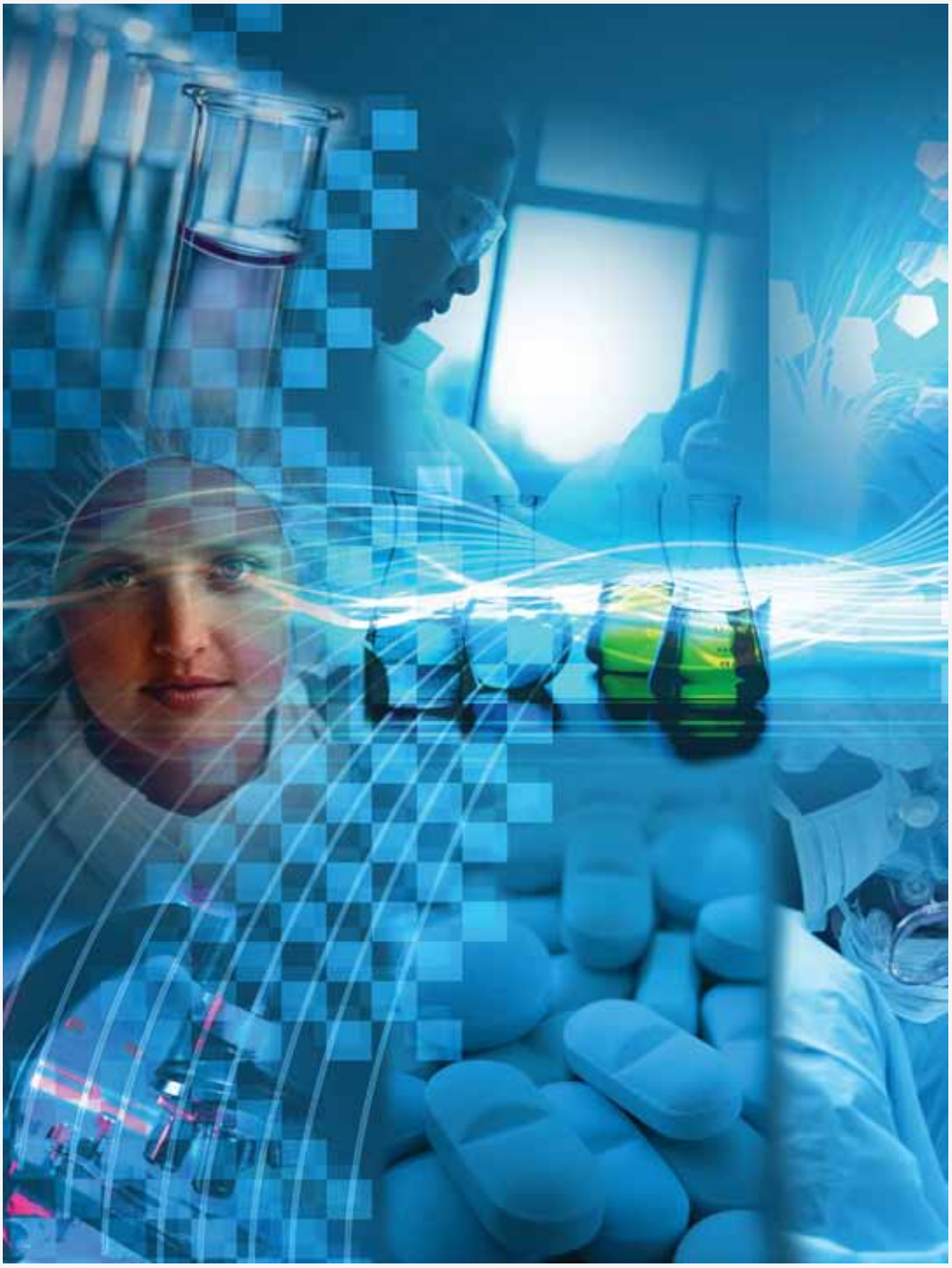
In-Line Sight Glasses

Sight Glasses

The in-line sight glasses offered by Steriflow are suitable for a wide range of applications in high purity tubing systems typically found in the biopharmaceutical and pharmaceutical industry.

The extra large double window design provides a 240° process viewing area and eliminates the need for a back light. The rigid, two piece body construction has a metal-to-metal stop, which controls o-ring compression and ID protrusion to within ASME BPE limits. This feature also provides metal to metal conduction of piping torque and expansion without affecting o-ring or the condition of the borasilicate glass.

Size range is 1/2"-4" Tri-Clamp® (some DIN and ISO ranges are available)



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