

◦ Hygienic Components

for the Bio-Pharm Industry



SANI-MATIC®

◦ Cleaning Confidence

A Commitment to Clean

Repeatable results you can count on every time you clean your pharmaceutical parts, lines, process piping and equipment. We call it Cleaning Confidence.

Sani-Matic, Inc. designs and manufactures automated hygienic process cleaning equipment and components for the pharmaceutical, biotech, nutraceutical, personal care, food and beverage industries.

We offer GMP cabinet washers, Immersion Parts Washers and Clean-In-Place (CIP) Systems, including the portable UltraFlow™ 45 and 110 models, directionally drilled spray balls, strainers and more that provide a complete clean – every time. And, we don't stop there. We also provide expert services, including our Preventative Maintenance (PM) programs, Start-up Services and our Tactical Solutions consultative team for system optimization.



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Hygienic Components

Hygienic Spray Deflector	4
Directionally Drilled Spray Ball Assemblies	6
In-Line Strainers	10
Angle-Line Strainers, Straight Line Strainers	
Tee-Line Strainers	12
Documentation / Turnover Packages	14



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◦ Hygienic Spray Deflector



The Solution to Spray Overflow

Sani-Matic's patent-pending Hygienic Spray Deflector features a tri-clamp connected vent housing with an interior reversed dish designed to deflect spray solution from exiting a tank.



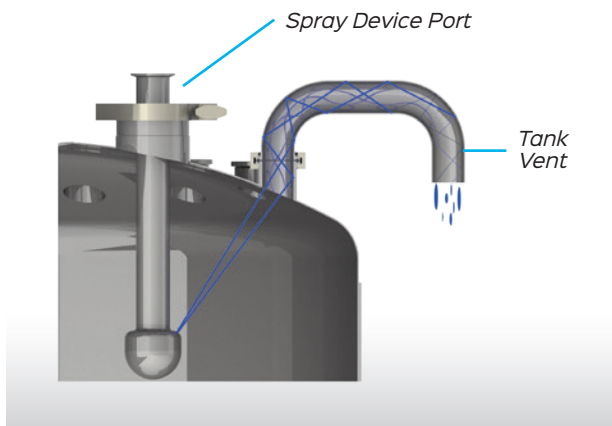
The Hygienic Spray Deflector is designed for tanks where spray devices are used to clean the interior. These vessels include CIP tanks, process tanks, bioreactors and fermenters. It redirects sprayed solution back into the process tank, without inhibiting tank port cleaning. When following the recommended spray device operating requirements, the Hygienic Spray Deflector's design reduces solution from exiting open-to-atmosphere tanks – and reduces vent filter saturation and the potential for a burst rupture disk.



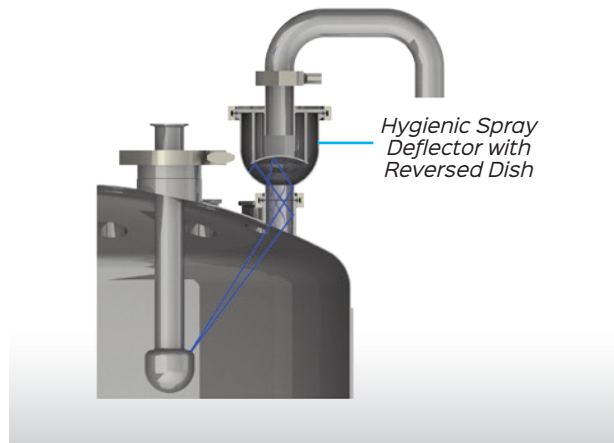
Hygienic Spray Deflectors

Reduce solution from entering your vent filter and minimize filter saturation.

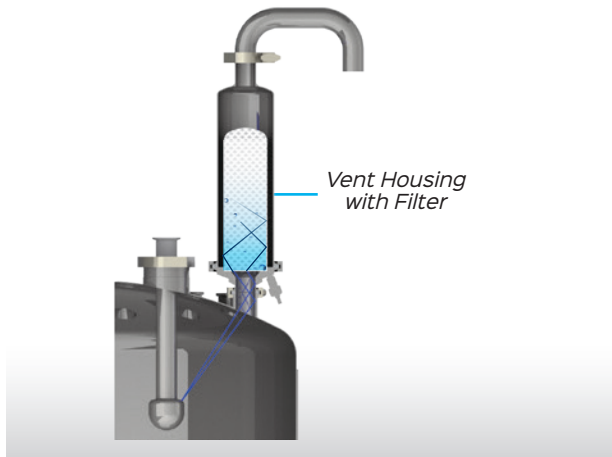
Tank Vent



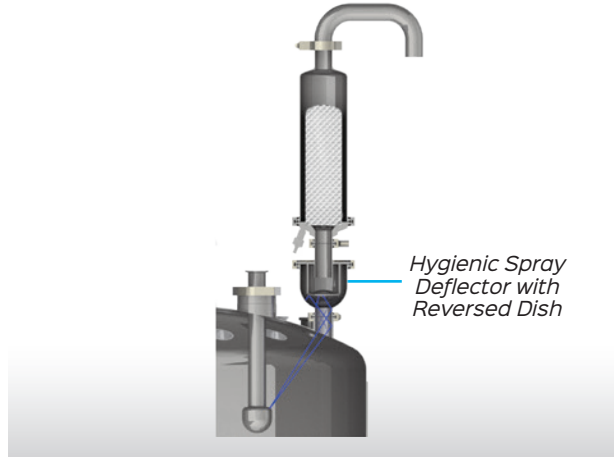
Tank Vent with Deflector



Tank Vent Filter Housing



Tank Vent Filter Housing with Deflector



Applications

- CIP Tanks
- Bioreactors
- Process Tanks
- Fermenters

Features

- 316L stainless steel construction
- Hygienic wetted finish: 15 μ m Ra
- Hygienic non-wetted finish: 32 μ m Ra
- Face-to-face dimensions: 1.5" TC = 6.03"
- Face-to-face dimensions: 2.0" TC = 5.91"

Documentation

- Material Test Report (MTR)
- Component Drawings
- Surface Finish Certification
- EP Certification
- Passivation Certification
- USP Class VI Certification

Note: This documentation package is unique to the Hygienic Spray Deflector.

Achieving Optimum Results

- Follow recommended spray device operating requirements.
- Include vent filter heating jacket where applicable.

Directionally Drilled ◦ Spray Ball Assemblies



Spray Ball Assemblies for Exact, Validatable Spray Coverage

Sani-Matic has decades of experience in spray technology for the bio-pharm industry. Your application needs are closely evaluated to design and manufacture a spray solution with appropriate flows, pressures and exact spray patterns to ensure validatable cleaning for your process vessels.

Sani-Matic's directionally drilled spray ball assemblies meet ASME BPE standards including designs for complete spray coverage, full drainability, proper finish, borescope-inspected orbital welds, and alignment pins for exact, repeatable installation.

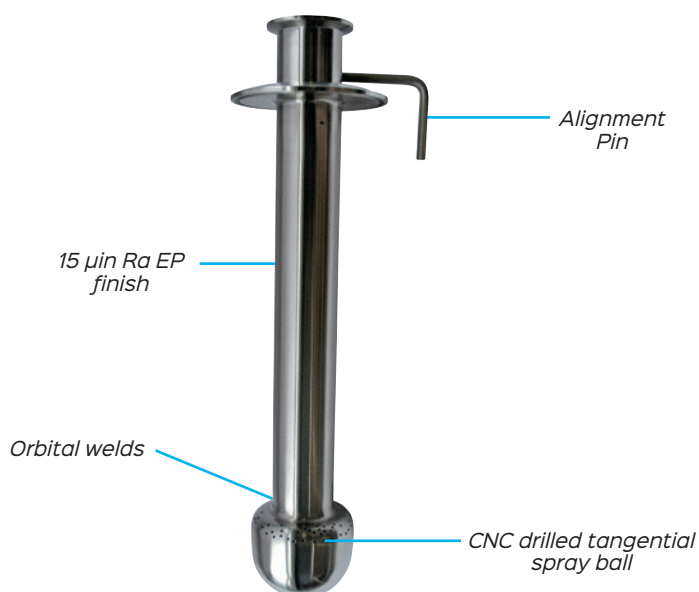
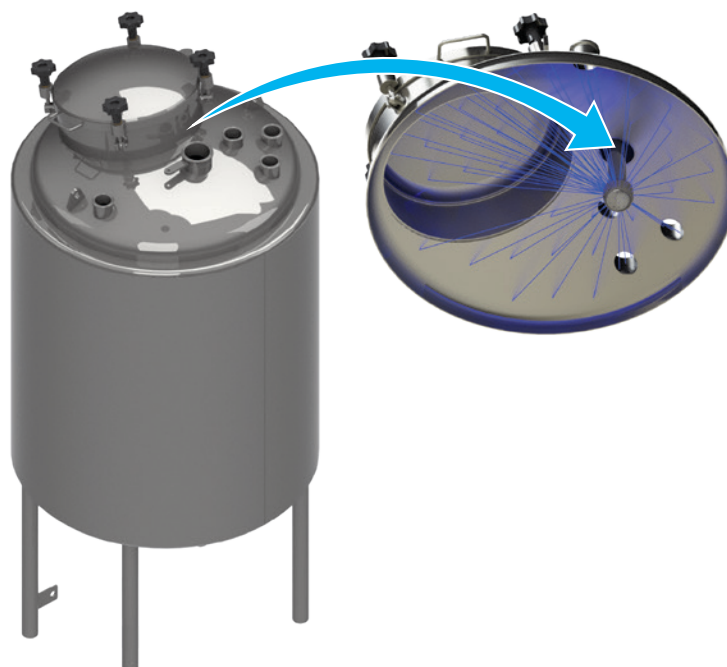


Custom-Engineered Solutions

Sani-Matic creates 3-D models of your process vessels to engineer static spray devices with exact drill patterns for proper coverage of all ports and surfaces. With decades of experience in spray technology and bio-pharm CIP applications, we understand the spray dynamics required to ensure proper flow rates, pressures and coverage.

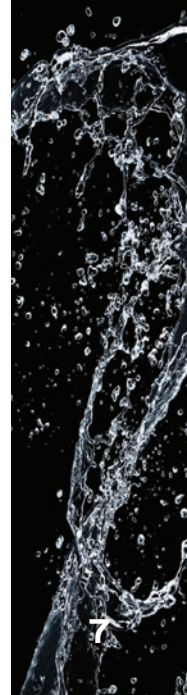
Available Features

- 316L stainless steel construction
- Hygienic wetted finish: 15 μm Ra
- Hygienic non-wetted finish: 32 μm Ra
- Alignment positioning pin
- Orbital welds
- CNC drilled
- Elbowed assemblies
- Electropolish (EP)
- Passivation



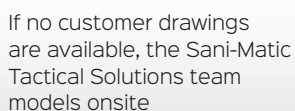
At Sani-Matic we understand the importance of preparing your process to meet validation requirements. That is why we:

- Follow ASME BPE design and testing standards for spray devices such as flow rate recommendations and riboflavin testing procedures.
- Work to understand and identify all potential component process contact surfaces to ensure surface finish specifications are accurate.
- Supply alignment pins for installation orientation and repeatable positioning.
- Design for gravity draining.

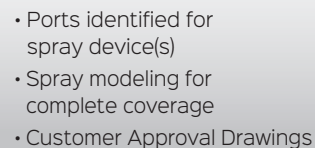


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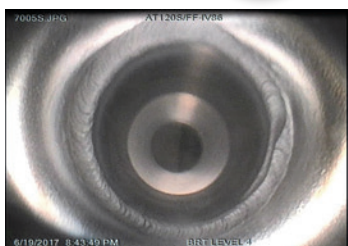
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2



STEP 3

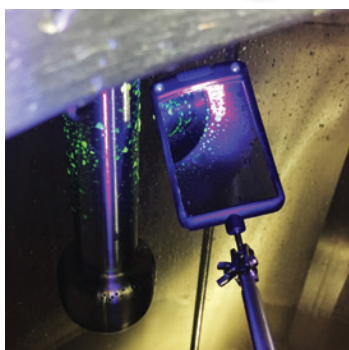


Borescope Weld Inspection

Directionally Drilled Manufacturing

- CNC drilled
- Orbitally welded
- Welds are borescope inspected to meet ASME BPE standards
- Ground, polished to meet required finish

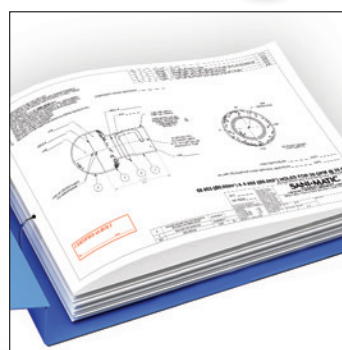
STEP 4



Riboflavin Testing

- Testing performed at your facility by a Sani-Matic field service engineer
- Documented process targeting complete spray coverage

STEP 5



**Ready for
Validation Process**

◦ In-Line Strainers

Hygienic Design for Bio-Pharm Applications

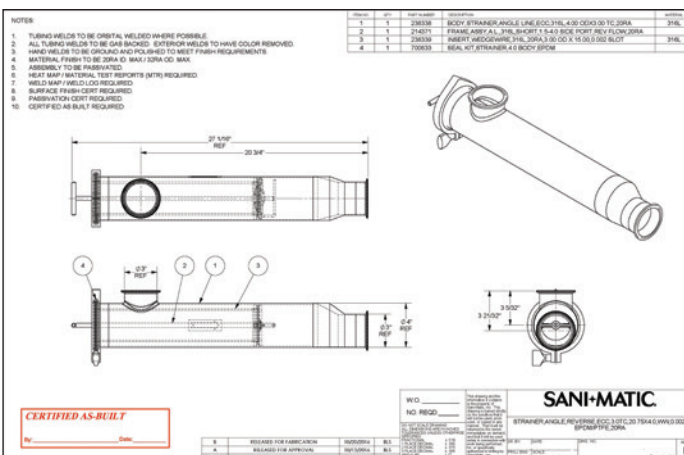
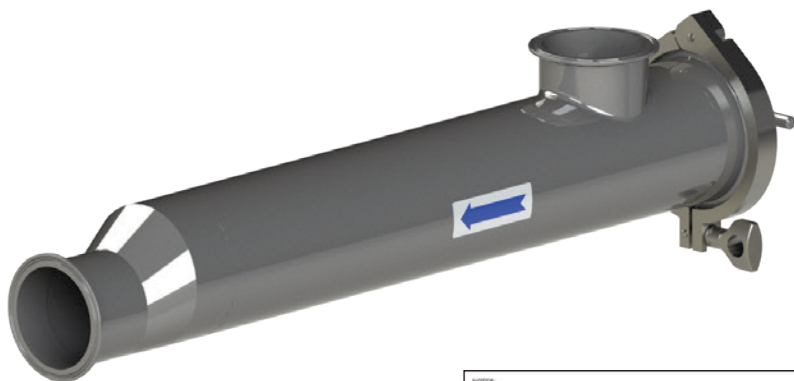
For decades, Sani-Matic has designed and manufactured high-quality, hygienic Angle-Line and Straight-Line strainers serving the pharmaceutical, food and beverage industries.

Angle-Line and Straight-Line Strainer bodies require a straining element to filter particulate from the product stream. Both perforated and wedgewire inserts are available.

Sani-Matic can provide low Ra surface finishes, BPE fittings, orbital welds, eccentric reducers, and more to meet pharmaceutical hygienic design requirements.

Sani-Matic also offers premium bio-pharm documentation packages with hygienic components (see pages 14-15 for more information).

In-Line Strainers for Bio-Pharm Applications



As-Built Drawing: Angle-Line Strainer with eccentric reducer, 20 Ra wetted finish

Available Features

- 316L stainless steel construction
- Tri-clamp or weld connections
- EPDM and other gasket materials
- Orbitally welded tubing
- BPE fittings
- Customer Approval Drawings
- Documentation
- Hygienic wetted finish: 25 μ in Ra
- Hygienic non-wetted finish: 32 μ in Ra
- Eccentric reducers or drain ports for drainability
- Electropolish (EP)
- Passivation

At Sani-Matic we understand the importance of preparing your process to meet validation requirements. That is why we:

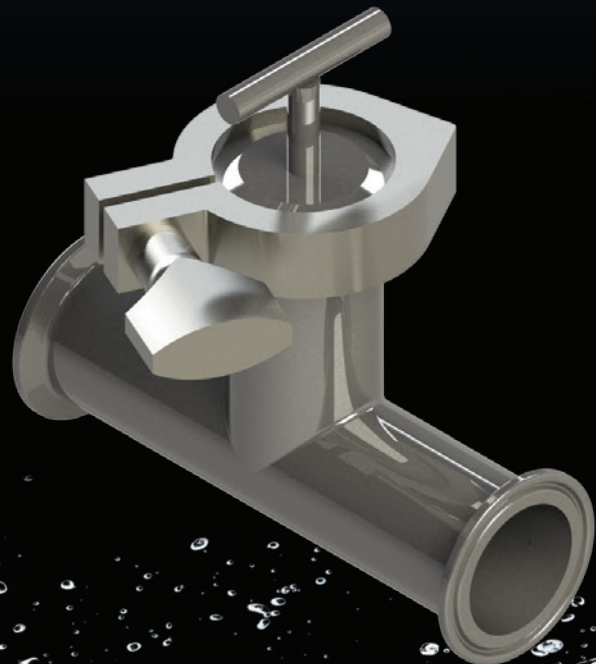
- Can design with BPE fittings, tubing and ferrules.
- Design for drainability by incorporating eccentric reducers or drain ports (based on the application).
- Provide orbitally welded tubing and borescope video documentation as part of the documentation package.
- Provide the turnover packages needed to meet validation requirements.

◦ Tee-Line Strainers

Tee-Line Strainers for Bio-Pharm Applications

Sani-Matic Tee-Line Strainers are designed to keep materials out of your pumps and process equipment. And, when critical cleaning needs for the pharmaceutical industry require hygienic design such as BPE fittings and lower Ra finishes, Sani-Matic has the expertise and craftsmanship to meet those custom needs.

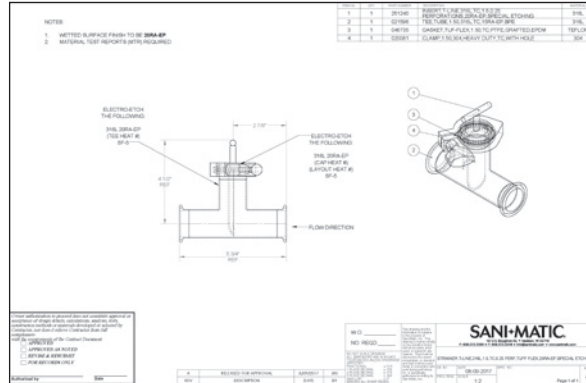
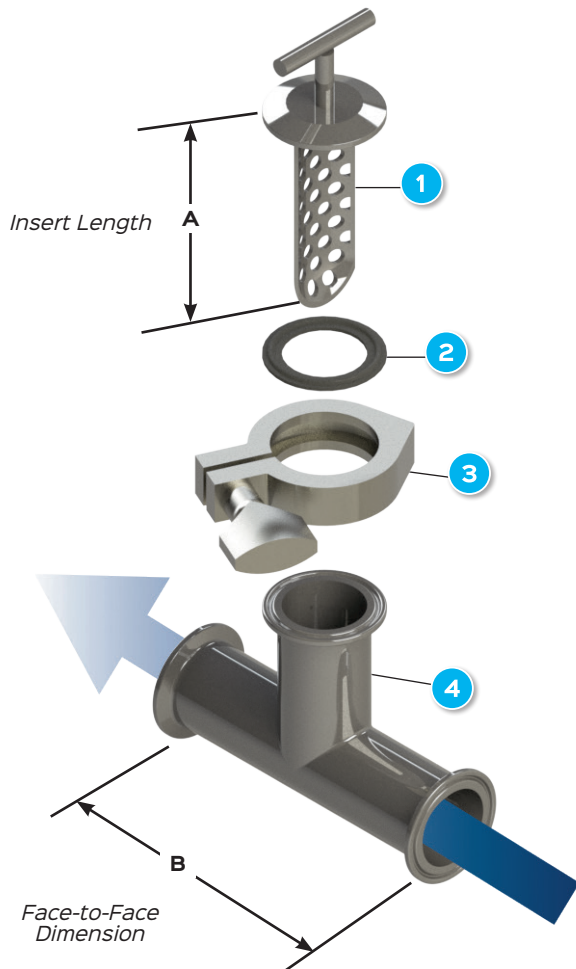
The Tee-Line Strainers are engineered with functionality, simplicity and durability in mind. That is why the insert is designed with an open area of perforation that exceeds line size diameter for a minimal pressure drop to protect the pump from cavitation. The strainer also has a tri-clamp for quick insert removal and easy cleaning.



Tee-Line Strainers: Protect Your Pumps and Process Parts

Available Features

- 316L stainless steel construction
- $\frac{1}{4}$ " or $\frac{1}{8}$ " perforations for inserts
- Tri-clamp or weld connection
- Hygienic wetted finish: 25 μ m Ra
- Hygienic non-wetted finish: 32 μ m Ra
- EPDM and other gasket materials
- BPE fittings
- Alignment positioning pin
- Electropolish (EP)
- Passivation

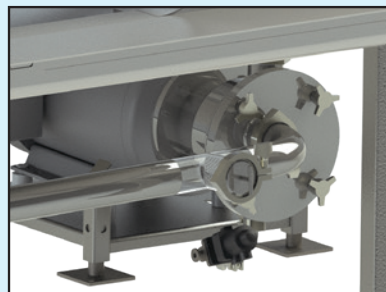


Customer Approval Drawing for Tee-Line Strainer with BPE Fittings

- 1 Insert
- 2 Gasket
- 3 Clamp
- 4 Tee-Line Strainer Body

Want an economical and easy way to prolong the life of your equipment?

Install Tee-Line Strainers at the suction end of the pump to protect the pump, process equipment and valves from foreign materials, such as gasket pieces, bolts and other items.



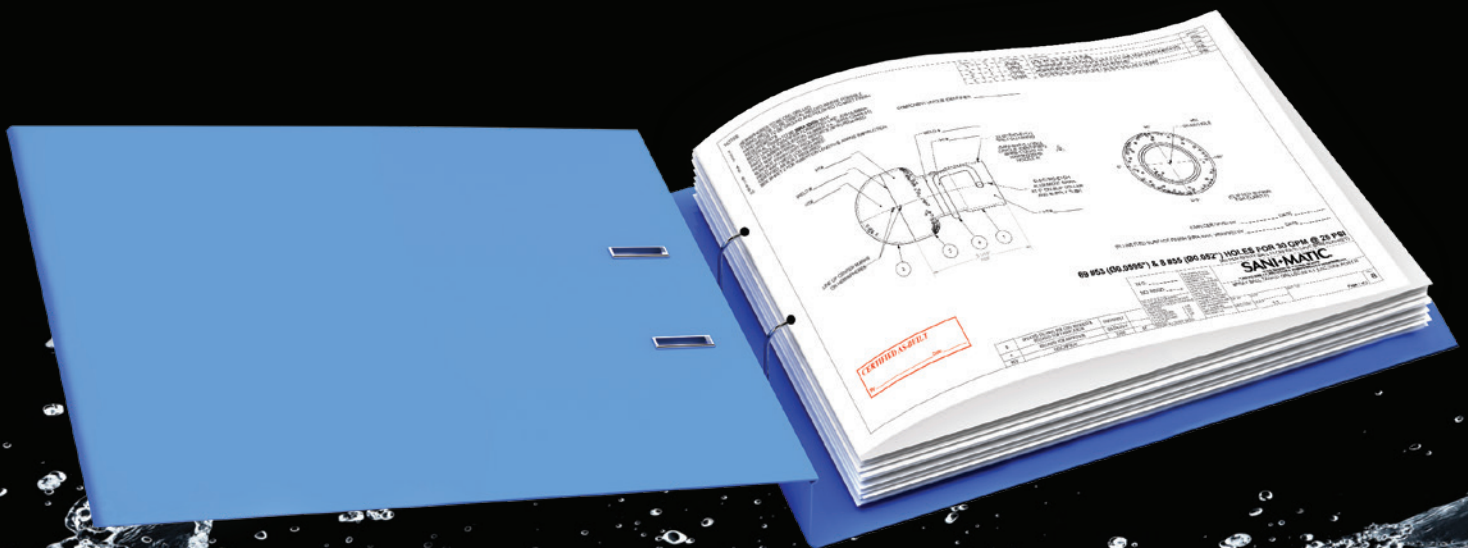
Documentation /

- Turnover Packages

Detailed Turnover Packages to Meet Bio-Pharm Validation Requirements

Documentation is critical to comply with Current Good Manufacturing Practice (cGMP) regulations, which require proof the manufacturing process repeatedly generates pharmaceutical products that meet attributes relating to identity, strength, quality, purity and potency.

Sani-Matic's turnover packages are extremely detailed and designed to minimize your validation costs. A dedicated team of documentation specialists ensures you have the documentation required to validate your cleaning process.



Hygienic Component Documentation / Turnover Packages

Document Name	Document Description	PREMIUM Bio-Pharm*
Material Test Report (MTR)	MTR is a quality assurance document that certifies a material's chemical and physical properties and states the product made is compliant within the specific set of standards. It also states the identification number of the batch/lot of steel which the part/material was made from at the mill.	X
Sani-Matic Certificate of Compliance	A document that states equipment listed conforms fully with Sani-Matic's Internally Accepted Practices.	X
Certified "As-Built"	A certified drawing that documents the As-Built dimensions and surface finish produced in manufacturing.	X
Heat Map	A certified document that contains details of an assembly where each of the material's heat numbers are recorded. A heat map can stand by itself, or be combined with a weld map and slope map.	X
Weld Map	A certified document that contains details of a piping assembly where each weld is identified with a unique number. The identifying number is used on the weld log, which profiles each weld.	X
Weld Log	A certified document that records all welds contained in a weld map. The profile of each weld recorded includes heat numbers of the material, the detail where the weld is located, the welder's I.D., the date of the weld, the machine used to weld, and the Quality Inspector's sign-off for approval.	X
Surface Finish Certification	Part of the As-Built Drawing that states Sani-Matic has verified the assembly or part's surface finish meets the agreed upon requirements in the sales order.	X
Borescope Video Documentation	The AWS certified weld inspector will utilize a borescope to inspect the welds. The inspector will record all weld inspections. The videos are collected and placed on a DVD, which corresponds with the weld map/weld log.	X
Electropolish Certification (EP Cert)	A certified document that states electropolishing was performed to the assembly or parts as agreed upon in the sales order.	X
Passivation Certification	A certified document that states Citric Acid Passivation was performed to assemblies or parts as agreed upon in the sales order.	X
Slope Map	Part of the As-Built Drawing where the actual slope of the piping or sheet is recorded to verify slope for proper drainage.	X

*NOTE: Line items may not apply to all components.

Hygienic Components

Hygienic Spray Deflector • Directionally Drilled Spray Ball Assemblies • Strainers



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