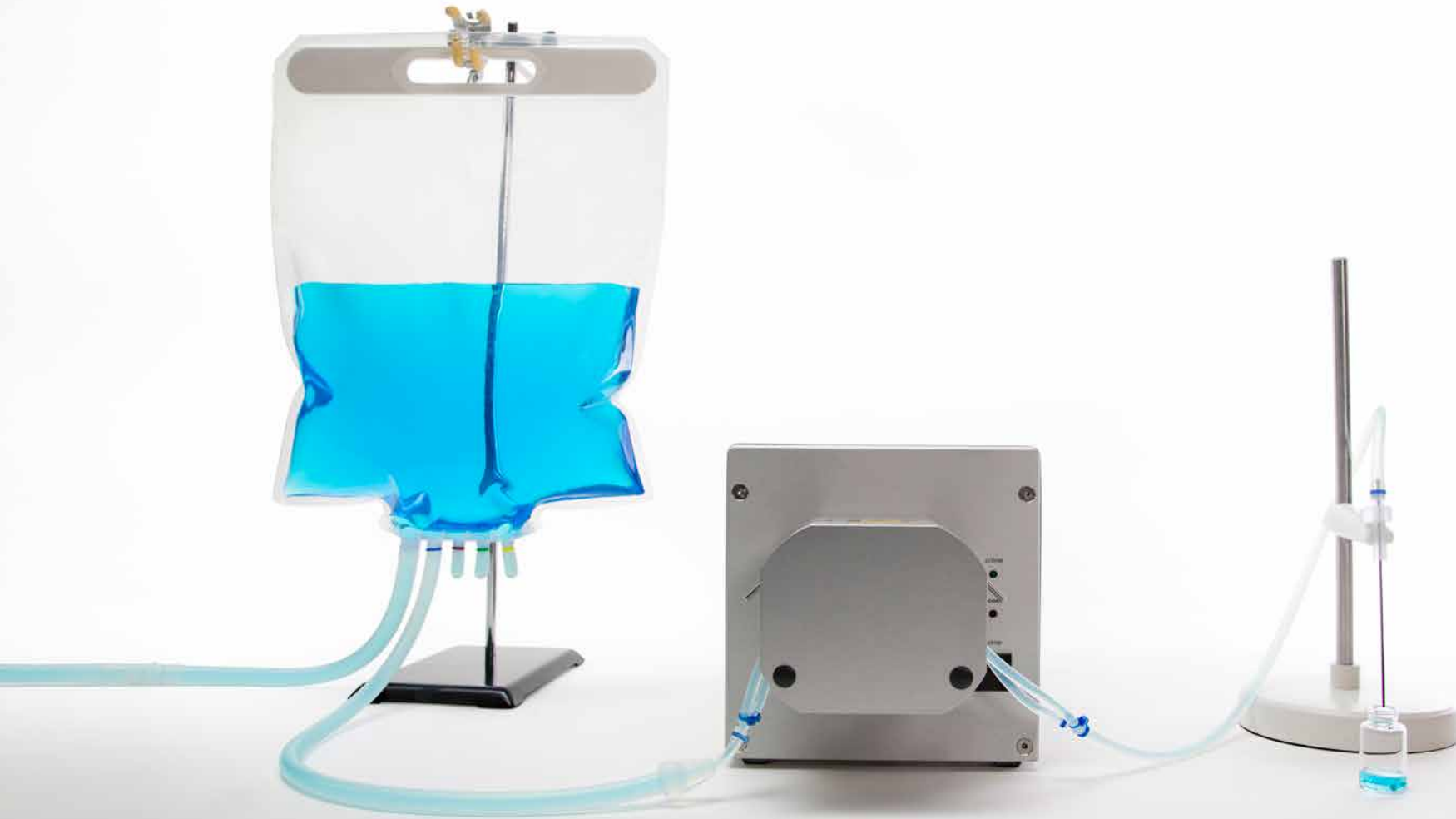


Fill4Sure™

Custom single-use filling assemblies for bioprocessing



Designed by bioprocess engineers, for bioprocess engineers.

Customized products for fabrication and overmolding capabilities

SaniSure® key capability is to offer bespoke, custom plastic assemblies of components available in polypropylene, polyethylene, PVDF, polysulfone, fluoropolymers, polycarbonate and other materials based on individual application needs.

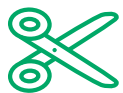
We help to design, develop and optimize your specific process:

Fill4Sure™ – key facts:



Validated library of components

library of validated components to make tailor-made assemblies



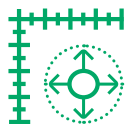
Tailor-made Assemblies

Bespoke, unique assemblies made for the specific drug product.



Customer driven design

we take our customers' needs and convert them to the best designed assembly



Small to full scale

Fill4Sure™ will be applicable for small, bench-top single-needle projects all the way up to full commercial, multi-needle assemblies.

Make Fill-Finish as Easy as ABC

Easily optimize your drug product filling assembly with our seamless solutions. Simplify precision and enhance efficiency effortlessly. Unlock streamlined manufacturing with ease.

A) Design

Consult with our experts to create a bespoke design fit for your product

B) Manufacture

All our assemblies are manufactured in ISO Class 7 cleanrooms with 100% in-line inspection

C) Implementation

Plug and play your new assembly with minimal set-up steps for improved production efficiency and throughput.



Fill4Sure[™]

Bespoke. Optimized. Secure.

Setting the standards for drug product filling:

Fill4Sure[™] offers bespoke final fill assemblies designed around the drug product. With a wide range of sterile-validated components Fill4Sure[™] is fully customizable to ensure your drug product has The Best Home a Drug Can Get[™]. Build security, efficiency and repeatability into your drug product filling.

Fill4Sure™ Features



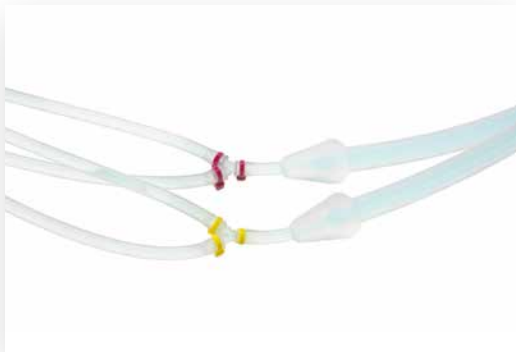
Multi-port 2D Surge Bags



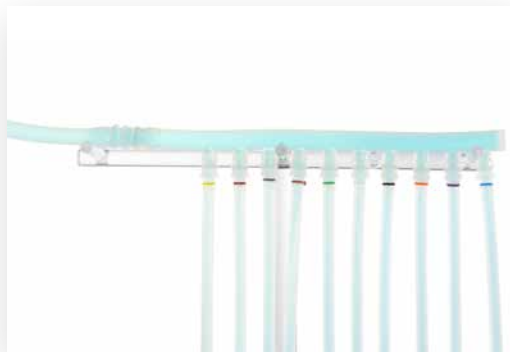
OEM & Custom Single-Use Filling Needles



Custom Ported RTP Bags



Silicone Overmolding



Single-Use Silicone Manifolds



Diversified Tubing Portfolio

Fill4Sure[™]

Multi-port 2D Surge Bags for up to 12 Filling Lines

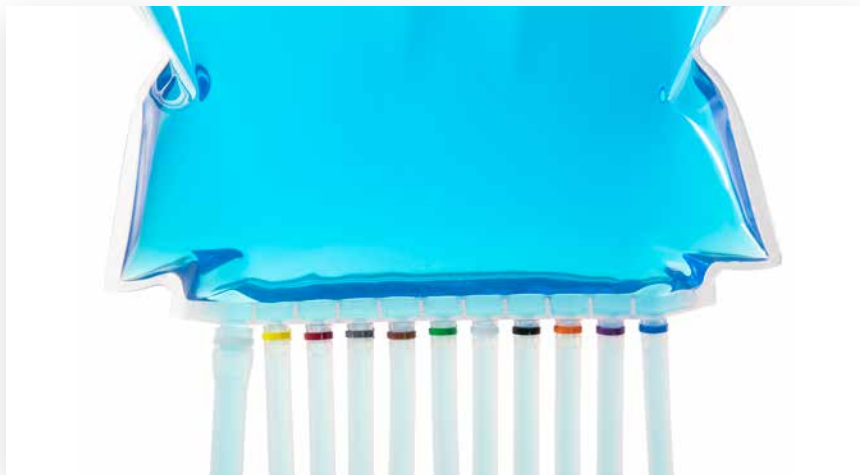
High-throughput, Multi-Needle Filling

Fill4Sure[™] enables multi-line filling without the introduction of downstream line splitting. Each fill line is independent of one another providing superior fluid dynamics to ensure the process pumps can perform optimally for accurate drug product filling. Customize your Fill4Sure[™] surge bags to have between 1 and 12 filling ports dependent on your fill requirements.

Up to 12 Filling Lines

Flexible 2D Bag Systems

- Multi-layer structure with inert PE Fluid contact layer
- Very low extractables and leachables
- Highly transparent film materials for enhanced visual inspection of process fluids
- Good physical strength
- No animal derived components
- 5L 2D bags available with 1 to 12 filling lines



Fill4Sure[™]

OEM & Custom Single-use Filling Needles

A Filling Needle for Every Situation

The Fill4Sure[™] needle range encompassed standard OEM replacement needles and fully customizable needles bespoke to drug product considerations all produced without adhesives or oils for minimal particle generation. Streamline supply-lines with genuine OEM replacements of single-use needles. Fill4Sure[™] needles can also be customized to provide specific nozzle configurations to remediate unfavorable drug product results during filling.

OEM & Custom Single-use Filling Needles

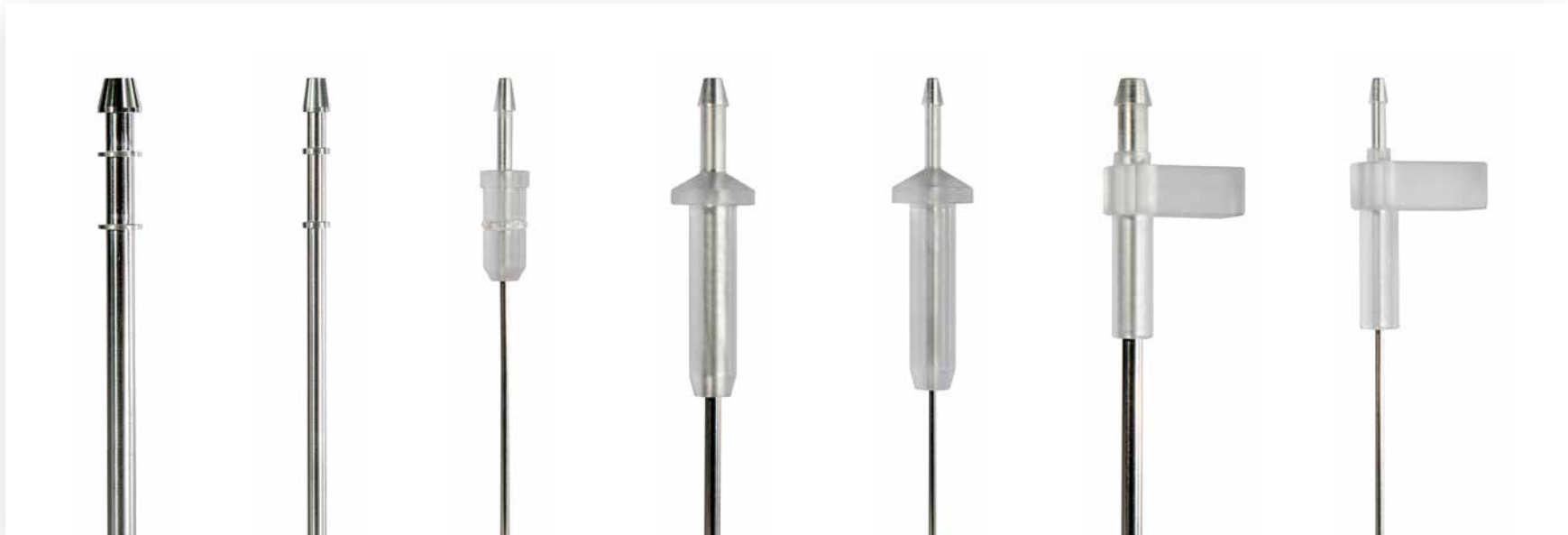
Quality, by Design

Tested to regulatory requirements, Fill4Sure™ meets the requirements of your quality systems to ensure sterility, product integrity and patient safety.

Ensured to meet FDA and EU GMP standards through designed adherence.

Fill4Sure™ Needles are available as:

- Non-irradiated
- Gamma-irradiated to a minimum of 25 kGy
- Sterile (10^{-6} SAL per ANSI/AAMI/ISO11137-2)



Fill4Sure[™]

Custom Ported RTP Bags

Aseptically Port for Efficient Fluid Transfer

Fill4Sure[™] includes the ability to aseptically port standard RTP bags in a customized manner to allow the safe and efficient transfer of drug product into the filling environment. Increase the throughput of filling operations with continued, aseptic delivery of drug product.

Custom Ported RTP Bags



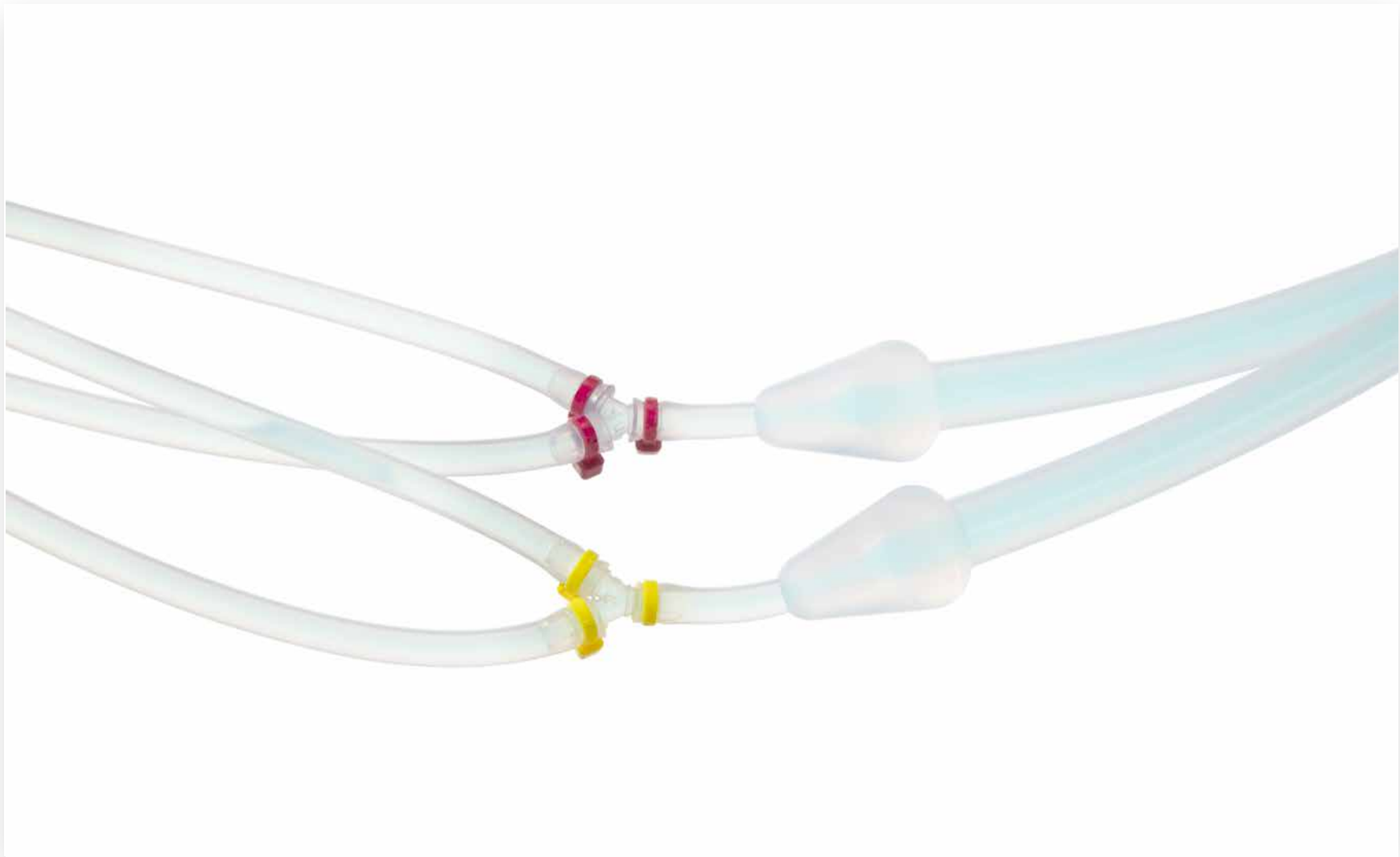
Fill4Sure[™]

Silicone Overmolding

Remove Turbulent Interruptions and Increase Connection Security

Fill4Sure[™] filling assemblies can be made using silicone overmolded tubing connections to provide optimal fluid dynamics with the reduction in component driven bug traps and turbulences. Increasing the connection strength also offers enhanced assembly integrity to ensure the drug products remain secure throughout prolonged filling operations.

Silicone Overmolding



Fill4Sure[™]

Single-use Silicone Manifolds

Single-Use Silicone Manifolds for Robust Drug Product Delivery

Fill4Sure[™] single-use, multi-position manifolds enable aseptic drug product separation into multiple fluid lines without the requirement for a 2D surge bag. For operations where drug product circulation is required for sustained product homogeneity, or the location of process pumps external of the filling environment a truly single-use manifold can enable efficient drug product fluid paths.

Single-use Silicone Manifolds



Fill4Sure[™]

Diversified Tubing Portfolio

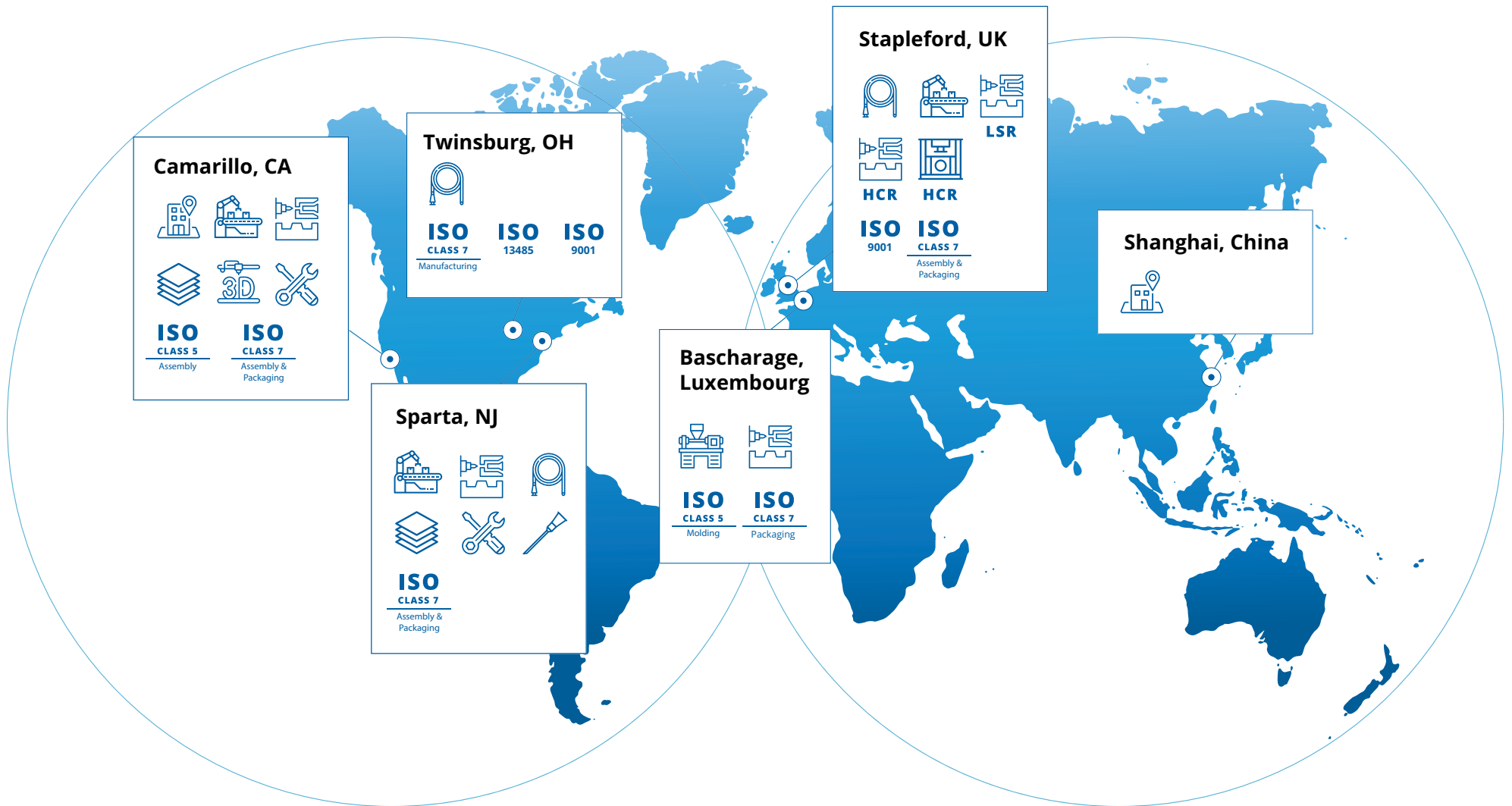
Precision Peristaltic Tubing

With a diverse and precision-focused portfolio of tubing within SaniSure[®], Fill4Sure[™] is perfectly designed to integrate all tubing types to ensure specific drug product considerations are recognized and accuracy of filling is achieved.

Diversified Tubing Portfolio



Our Global Footprint & Certifications



Our global footprint: Headquarter in Camarillo (USA) and five international production sites.

Our quality standards

SaniSure® companies are committed to the highest level of quality in the manufacture, distribution, and support of our products.

Our ISO certificates are a differentiation factor, and we can provide E&L data for our products.

Reach out to our Sales Support Teams to start a conversation with us about our product and for a bespoke Fill4Sure™ filling solution.

Customer Service Americas

SalesSupport-US@SaniSure.com
+1-805-920-7264





















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Legend

| | | | | | | |
|--|---|--|---|-----------------------------|--|--------------------------------------|
|  Headquarter |  3D Printing |  HCR Injection Molding |  ISO CLASS 5 Assembly | ISO Class 5 (Assembly) |  ISO CLASS 7 Packaging | ISO Class 7 (Packaging) |
|  Office |  In-House Tool & Die |  HCR Compression Molding |  ISO CLASS 5 Molding | ISO Class 5 (Molding) |  ISO CLASS 7 Assembly & Packaging | ISO Class 7 (Assembly and Packaging) |
|  Cleanroom Assembly |  Tubing Extrusion |  Injection Stretch-Blow Molding |  ISO CLASS 7 Manufacturing | ISO Class 7 (Manufacturing) |  ISO 13485 | ISO 13485 |
|  Injection Molding |  Sterile Filling Needle Manufacturing and Assembly | | | |  ISO 9001 | ISO 9001 |
|  Fabrication |  LSR Injection Molding | | | | | |

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Please visit our website
to learn more

[sanisure.com](https://www.sanisure.com)