



# Mixed4Sure™

Bottom Mount

The Best Home a Drug Can Get™

Single-use, small-volume, comprehensive, and out-of-the-box mixing platform for biopharmaceutical mixing steps

**FIRST BOTTLE  
MIXING SYSTEM FOR  
COMMERCIAL  
BIOMANUFACTURING**

Mixed4Sure™



# FIRST BOTTLE MIXING SYSTEM

## for commercial biomanufacturing

### **Changing the standards of small-volume mixing:**

- Reducing the risks of undesirable effects in mixing
- Less financial investment
- Reduced set-up time
- Enhanced flexibility in mixing processes between 500ml-20L



**Heating/Cooling Finger**



**pH Sensor**



**Conductivity Sensor**



**1.5" Powder Addition Port**

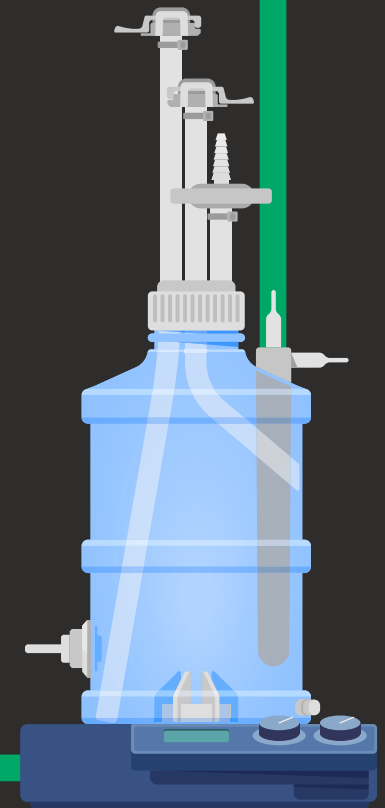
Mixed4Sure™



# 2X

**lower shear forces** than in  
comparable mixing system

In downstream mixing steps shear forces can have undesirable effects on your sensitive protein, such as degradation and aggregate formation. Mixed4Sure™ has been demonstrated to create shear forces that are ½ that of a comparable mixing system, and a magnitude of 4 lower than the forces leading to protein degradation.



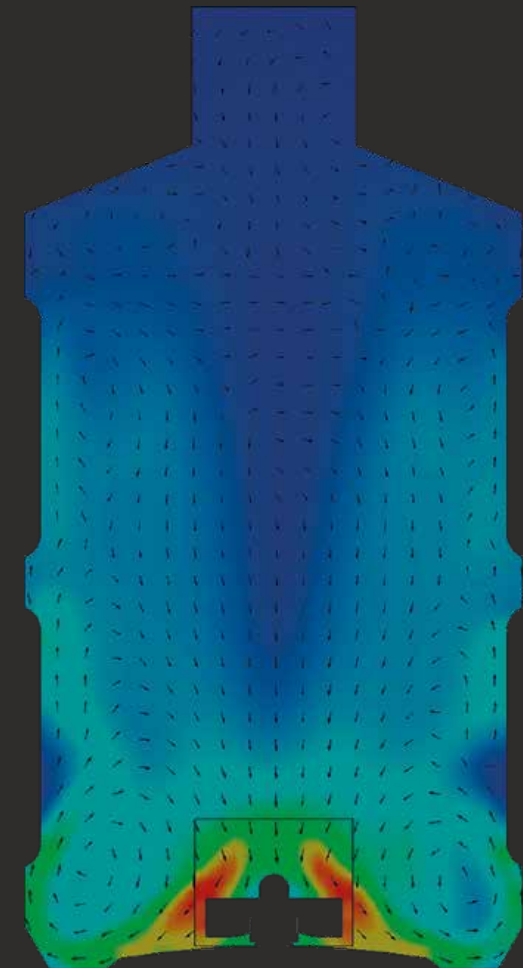
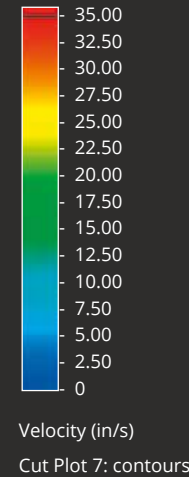
# Shear Forces

## Computational Fluid Dynamics

- Provides a mathematical simulation of fluid flows in a system.
- CFD demonstrated enhanced turnover in the corners of the vessel.
- All volumes and speeds resulted in shear forces  $\sim 10^3 \text{ s}^{-1}$  (significantly lower than the  $10^7\text{-}10^8$  where protein degradation occurs).\*

\* Thomas, C. R., and D. Geer. 2011. "Effects of shear on proteins in solution." *Biotechnology Letters*, 443-456.

Mixer SHEAR RATE S <sup>-1</sup>			
RPM	200	450	600
5L	$1.710 \times 10^3$	$6.335 \times 10^3$	$9.536 \times 10^3$
10L	$1.419 \times 10^3$	$5.103 \times 10^3$	$7.687 \times 10^3$
20L	$1.385 \times 10^3$	$5.126 \times 10^3$	$8.631 \times 10^3$



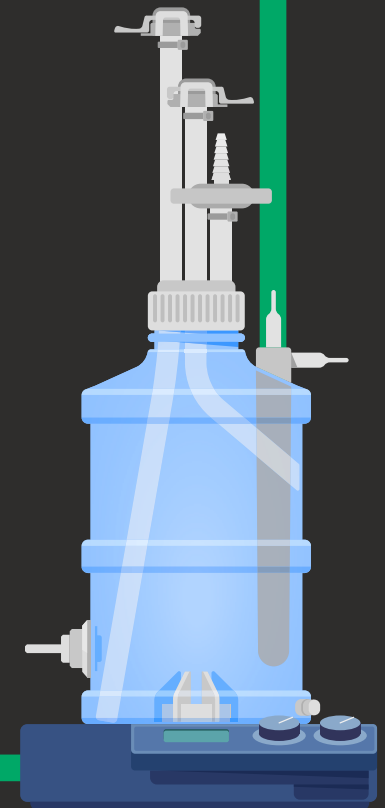
Mixed4Sure™



# 10x

**lower CapEx** compared to an equivalent jacketed bag system

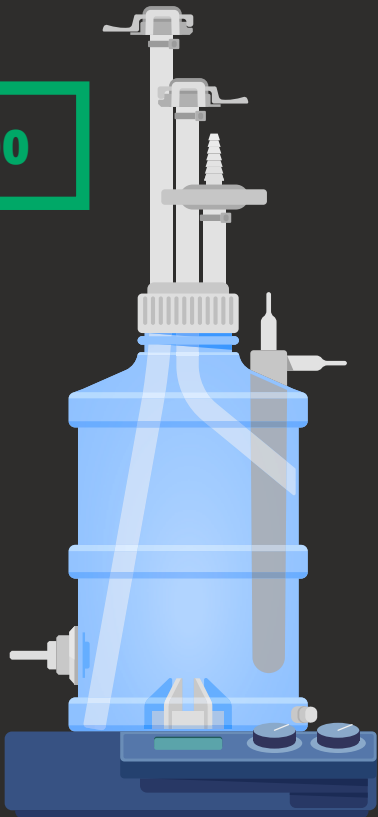
Double-walled or jacketed stainless-steel containers can cost many tens of thousands of dollars, and the corresponding mixing drive can further increase the capital expenditure associated with a mixing step. Mixed4Sure™ dramatically reduces the hardware cost by integrating with common, standard mixing plates and is the only hardware required for the system.



# CapEx Saving

~\$40,000

\$4,000



Mixing Plate \$4,000



Drive unit ~\$13,000  
Jacketed tank ~\$29,000

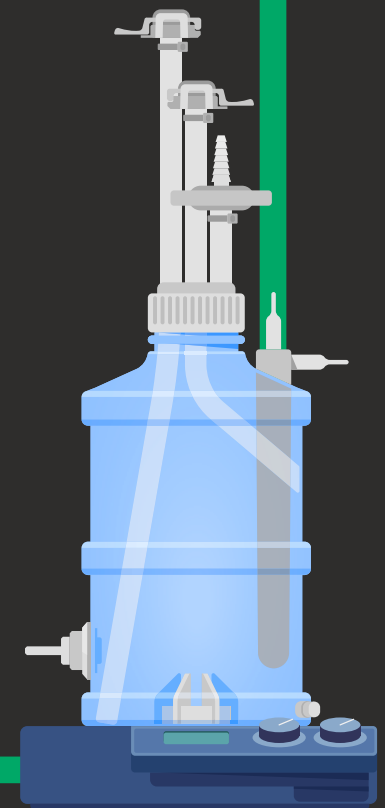
Mixed4Sure™



# 10x

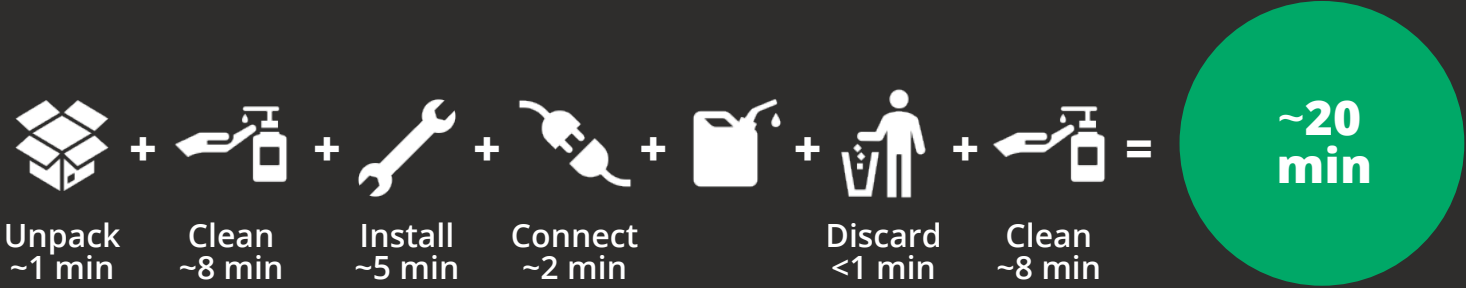
**quicker set-up** than bags  
(~20 min vs. 2 min)

Cycle-time optimization is a key requirement in all biomanufacturing unit operations. Mixed4Sure™ represents the next step in single-use implementation by offering true out-of-the-box operation. The Mixed4Sure™ is unpacked, placed on the mixing plate, connected to the fluid inlet, and optionally connected to the heating/cooling finger. It is ready for filling in under 2 minutes.





# Time Saving



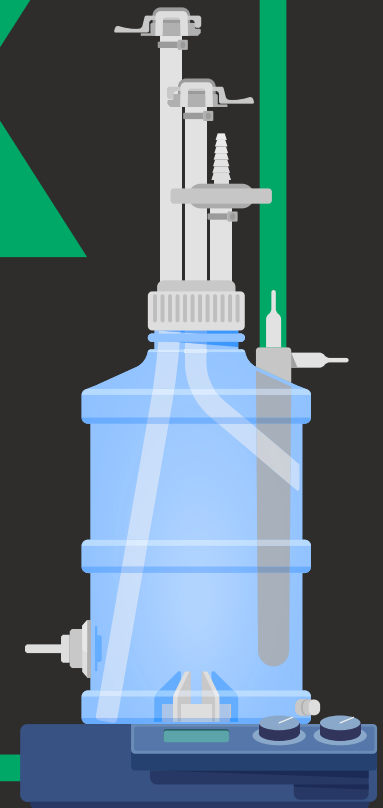
Mixed4Sure™



# 200x

**lower minimum mixing volume**  
than in bags (50ml vs. 10L)

No matter what volume your mixing step requires Mixed4Sure™ offers the ability to continuously mix at all process volumes from 50ml – 20L. Furthermore, you can maintain mixing and fluid homogeneity during offload down to 50ml, which ensures the consistency of your drug is maintained to the last drop.

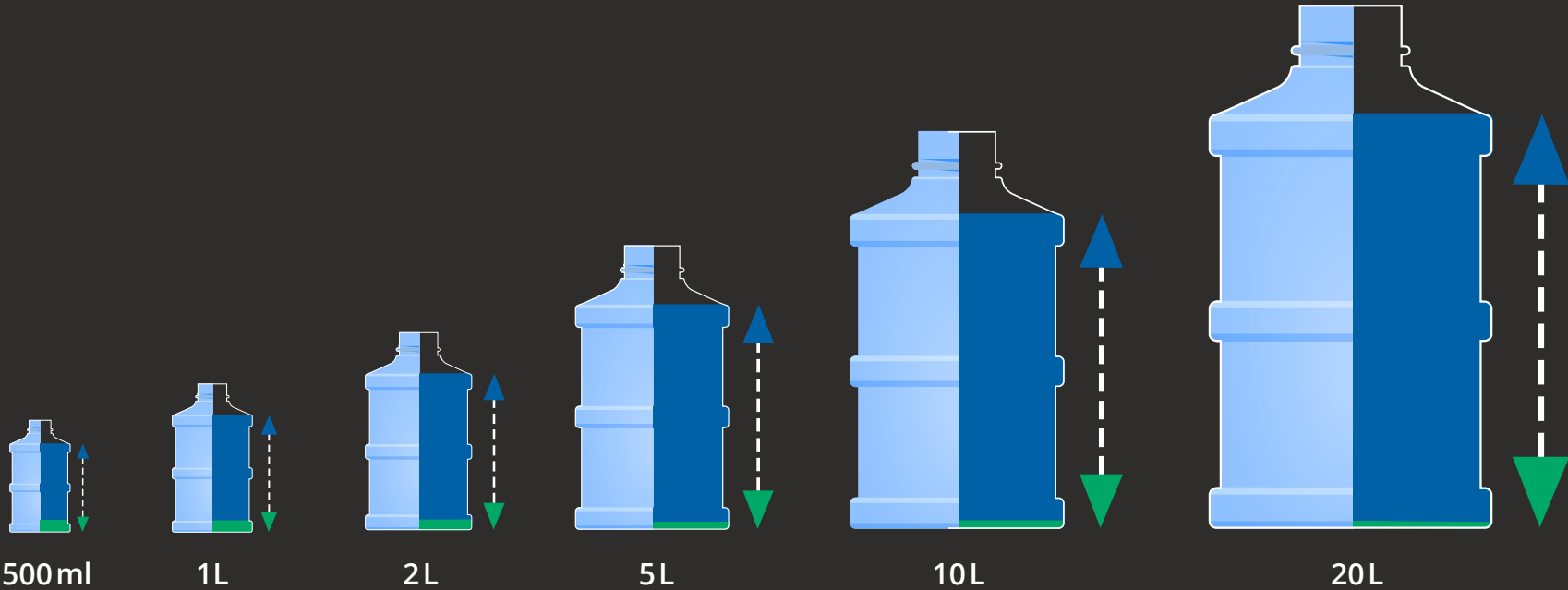


# Minimum Mixing Volume

Continuous Volume 50ml-20L

Maximum Mixing Volume per bottle size:

0,5L	1L	2L	5L	10L	20L
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Minimum Mixing Volume per bottle size:

60 ml	85 ml	123 ml	217 ml	302 ml	560 ml
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2-10% nominal volume

Minimum Mixing Volume <4%

# Mixed4Sure™ Bottom Mount



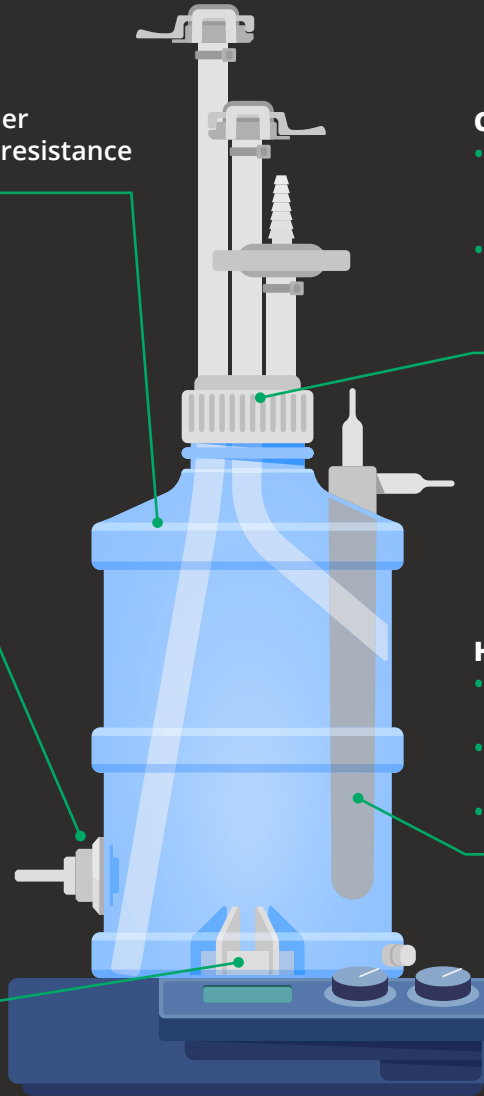
- Pharmatainer™ (PC/PET)**
- 500ml-20L
  - PET for superior gas barrier
  - PC for improved thermal resistance



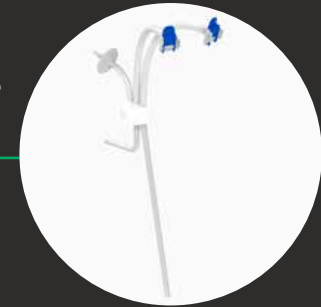
- Sensor in mount**
- Single-use sensor in polycarbonate housing
  - pH and conductivity with integrated PT1000



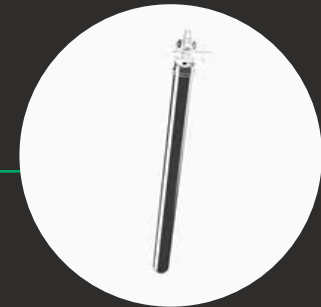
- 4 Blade Impeller**
- PEEK & PPSU
  - 200-600rpm



- Cap2v8®**
- Continuous, uninterrupted fluid pathway
  - Last Drop™ and high precision polypropylene dip tubes



- Heating/Cooling Finger**
- Passivated 316L stainless-steel
  - Length sized according to the bottle volume
  - 20°C > 2°C in 90 min



# Mixed4Sure™ Bottom Mount-Extractables

MATERIAL LIST			
ITEM	QTY	DESCRIPTION	LONG TERM FLUID CONTACT SURFACES
1	1	20L PHARMATAINER BOTTLE, POLYCARBONATE	PC or PET
2	1	CAP2V8-70-Y-3DC W/ 2 PORTS @ 3/8" ID X 5/8" OD TUBING	
		1/4" ID X 1/2" OD TUBING, CELLGYN	
3	1	50mm 0.2µm HYDROPHOBIC VENT FILTER, GAMMA STABLE	
4	2	3/8" HB X ASEPTIQUIK S CONNECTOR, POLYCARBONATE	Polycarbonate
5	1	MLS X SWABABLE VALVE, POLYCARBONATE	Polycarbonate
6	1	LUER CAP, POLYCARBONATE	
7	1	PG 13.5 ADAPTER, POLYCARBONATE	
8	1	PG 13.5 PLUG, POLYPROPYLENE	
9	1	014 O-RING, RED SILICONE	
10	1	1.9" BOTTOM MIXER KIT, PEEK/RADEL	PEEK & PPSU
11	1	10-32-3/8" SCREW, POLYCARBONATE	
12	1	111 O-RING, PLATINUM CURED SILICONE	Silicone
13	1	COOLING FINGER HEAD, POLYCARBONATE	
14	2	1/4" BONDABLE BARBS, POLYCARBONATE	
15	1	O-RING, RED SILICONE	
16	1	.924" ID X 1" OD COOLING FINGER TUBE, 316L 20RA EP SS	Stainless Steel 316L Passivated
17	4	COOLING FINGER COIL, POLYCARBONATE	
18	2	6mm RIGID TUBE, POLYPROPYLENE	Polypropylene
19	3	STD. CABLE TIE, NYLON	
20	1	HAMILTON SENSOR PORT KIT, POLYCARBONATE	Polycarbonate, Polyethylene & Silicone
21	2	SMALL CAP PLUG, VINYL	

Extractables for all long-term fluid contact surfaces

USP <665> compliant

## Ordering Information

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64004S	PC	500ml	✓			
SS64020S	PC	1L	✓			
SS64021S	PC	2L	✓			
SS64039S	PET	500ml	✓			
SS64049S	PET	1L	✓			
SS64050S	PET	2L	✓			
SS64000S	PC	5L	✓			
SS64005S	PC	10L	✓			
SS64010S	PC	20L	✓			
SS64035S	PET	5L	✓			
SS64040S	PET	10L	✓			
SS64045S	PET	20L	✓			

<b>Product code</b>	<b>MOC</b>	<b>Volume</b>	<b>Check valve/ sample port</b>	<b>Powder Port</b>	<b>Heating/ Cooling Finger</b>	<b>Sensors (pH &amp; Conductivity)</b>
SS64001S	PC	5L	✓	✓		
SS64006S	PC	10L	✓	✓		
SS64011S	PC	20L	✓	✓		
SS64036S	PET	5L	✓	✓		
SS64041S	PET	10L	✓	✓		
SS64046S	PET	20L	✓	✓		

## Ordering Information

Product code	MOC	Volume	Check valve/ sample port	Powder Port	Heating/ Cooling Finger	Sensors (pH & Conductivity)
SS64003S	PC	5L	✓		✓	✓
SS64008S	PC	10L	✓		✓	✓
SS64013S	PC	20L	✓		✓	✓
SS64038S	PET	5L	✓		✓	✓
SS64043S	PET	10L	✓		✓	✓
SS64048S	PET	20L	✓		✓	✓



<b>Product code</b>	<b>MOC</b>	<b>Volume</b>	<b>Check valve/ sample port</b>	<b>Powder Port</b>	<b>Heating/ Cooling Finger</b>	<b>Sensors (pH &amp; Conductivity)</b>
SS64002S	PC	5L	✓	✓	✓	✓
SS64007S	PC	10L	✓	✓	✓	✓
SS64012S	PC	20L	✓	✓	✓	✓
SS64037S	PET	5L	✓	✓	✓	✓
SS64042S	PET	10L	✓	✓	✓	✓
SS64047S	PET	20L	✓	✓	✓	✓

# Mixed4Sure™ – 4 Key Components

SaniSure® Manufactures 4 Key Components to Provide an Unparalleled Level of Quality and Assurance of Supply for our Assemblies



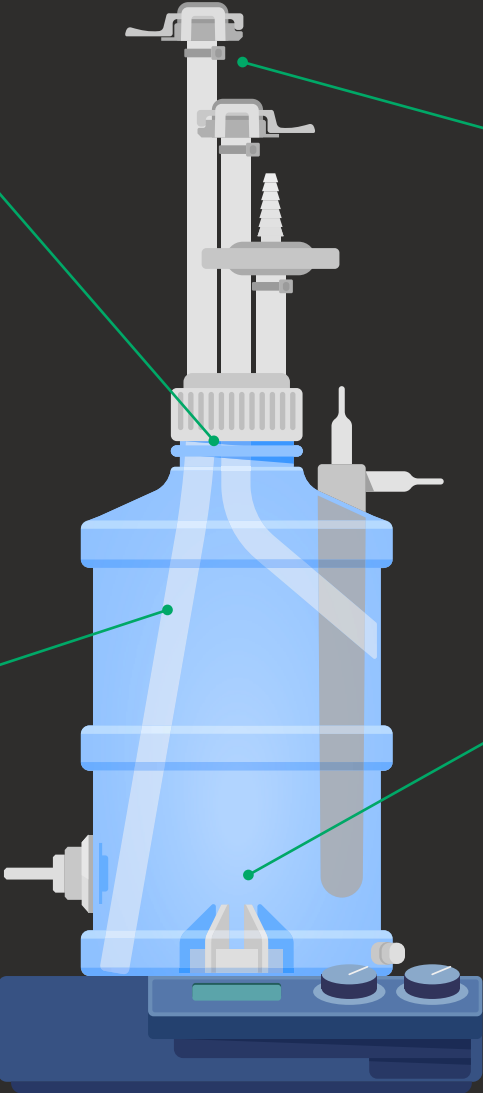
### Bottle/Caps

- We are one of the leading manufacturers of 10ml to 20L bottles. PET is the best gas barrier and PC is ideal for freezing and/or high temperatures.



### Tubing

- Stocked tubing sizes with many formulations to fit your specific application. Our portfolio includes platinum-cured silicone, CellGyn® (TPE), and Pharm-A-Line™ (TPV).



### Fittings

- Single-use Sanitary connectivity – aSURE® with built-in gasket, Bio-Ease® clamps, instrument fittings, sanitary reducers, barbs, threaded adapters, fusion, site tubes, over-molded hoses, and more.



### Mixing

- How do you mix at 20L and below? SaniSure® manufactures a range of novel mixing products to meet your bioprocessing needs.



# **SaniSure® is simplifying single-use technologies for sterile manufacturing in the single-use bioprocessing industry.**

We are a global leader in the design and manufacturing of single-use systems and components for drug and vaccine manufacturing and other biotech applications.

Our core manufacturing capabilities include

- injection molding,
- injection-stretch blow molding,
- cleanroom assembly,
- tubing extrusion,
- fabrication,
- and other proprietary technologies.

We have a global footprint of 5 manufacturing sites worldwide to provide our customers with an unrivaled level of vertical integration and supply-chain security.

For more details, visit us at [sanisure.com](https://sanisure.com) or [linkedin/sanisure.com](https://linkedin.com/sanisure.com)



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Please visit our  
website to learn more  
[sanisure.com](http://sanisure.com)

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