

Single-use bags for the orbital shaken bioreactor (OSB)



The design of the orbital shaken bioreactors is to keep the mixing hydrodynamics from the μL stage to scales as large as 2500L. Due to the simplicity of the technology, the speed of scale-up is fast with a lower cost of implementation compared to stirred systems. Kuhner offers single-use bags for the whole range of orbital shaken bioreactors.

Different types of single-use bags are available to meet all our user's needs. The gamma-irradiated bags for the Kuhner shaken bioreactor require no impeller or invasive mixer. It enables quick setup times and eliminates elaborate cleaning and sterilization procedures or other more complex approaches.



Figure 1: 3D Bag design of the Standard single-use bag for the SB10-X

- 3D single-use bags
- Gamma irradiated
- Leachable and extractables study
- Integrated optical-chemical pH and DO sensors
- Option for customized bag

Scale-Up

The bioreactors are available in four different sizes with varying working volumes: 4-12L (SB10-X), 15-50L (SB50-X), 50-200L (SB200-X), and 500-2500L (SB2500-X).

Efficient scale up from lab scale to production scale – scan the QR code for more information.



Overview of all bag type

OSB type	Bag size and type (total volume)	Working volume / Bag volume	Article
SB10-X with 3L-Vessel module	Standard 3L	1.5 – 4.5L / 6L	105332
SB10-X	Standard 10L		105327 (SMX760001)
	Basic 10L	4 – 12L / 24L	105328 (SMX760002)
	Perfusion 10L		105329 (SMX760003)
SB50-X or SB200-X with 50L adapter	Standard 50L	15 – 50L / 100L	105330 (SMX750002)
SB200-X	Standard 200L	50 – 200L / 400L	105331 (SMX710002)
SB2500-Z	Standard 2500L	500 – 2500L / 4000L	105909 (SMX72004)

Features of the bag type

	3L		10L		50L	200L	2500L
	Standard	Basic	Standard	Perfusion	Standard	Standard	Standard
Optical sensor pH and DO	x		x	x	x	x	x
Additional Optical sensor pH and DO						x	x
Suitable for ATF* Perfusion	x	x	x	x	x	x	
Two exhaust filters				x	x***	x***	x***
Dip tube				x	x	x	
Additional tubes and ports for TFF** perfusion				x			

*Alternating Tangential Flow Filtration

**Tangential Flow Filtration

***Optional

Application areas

The orbital shaken bioreactor is suitable for cell cultivation, especially for shear-sensitive cells. Mechanical stress on the cells is reduced thanks to bubble-free surface gassing with almost no frothing. Following applications are suitable in the orbital shaken bioreactors.

Stem cells	<p>Stem cells are mostly adherent cultures and are very sensitive to shear stress. Orbital shaken bioreactors are ideally for stem cell cultivations since they have a low local power input, therefore, significantly reducing the mechanical shear stress on the cultivated stem cells.</p> <p>Example: Induced pluripotent stem cells (IPS)</p>
Animal / Human cells	<p>Animal or human cell cultures running for several days or a few weeks. They are usually cultured in suspension for different applications of vaccine development. For example, virus production in the bioreactor provides a low shear force which can be an advantage after the infection because the cells are more sensitive to shear stress.</p> <p>Examples: CHO, CHO-K1, HEK 293, Hybridoma, duck cells</p>
Insect cells	<p>Insect cells can be used for recombinant protein production.</p> <p>Examples: Spodoptera frugiperda Sf9, H-5</p>
Plant cells	<p>Plant cell cultures provide an attractive route to obtain precious plant-derived products, such as flavors, fragrances, alkaloids, pigments and pharmaceuticals that are expensive to synthesize chemically and naturally occur only at low concentrations.¹</p> <p>Examples: <i>Nicotina tabacum</i> L.CV BY2, Algea</p>
Processes with Microcarriers	<p>Microcarriers are used to cultivate adherent cells under dynamic conditions. The gentle process is suitable for the cultivation of stem cells.</p>

¹ <https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/plant-cell-culture>

Components and material

Our single-use bags are made from multi-layered USP Class VI plastic material. The product contact material is polyethylene (LDPE), which is routinely used for biological processes. The gas barrier is made of ethylene vinyl alcohol (EVOH), which provides extremely low gas permeability. The outer layer is made of Polyethylene (PE). For the 3L there are only two layers, and the product contact material is polyethylene (LDPE) and outer layer Polyethylene (PE).

Component	Material
Contact Layer	LDPE
Gas barrier	EVOH***
Outer layer	Polyethylene (PE)
C-Flex® tubing	Thermoplastic elastomer
Injection port	Polycarbonate/ Polyethylene (PC/PE)
Luer Lock connector	Polypropylene (PP)
Polyethylene (PE)	Polyethylene (PE)
MPC connectors	Polycarbonate (PC)
Sensor cap pH	Polyethylene (PE)
Sensor cap DO	Polyethylene (PE)
Y-connector	Polypropylene (PP)
Filter Acro 50 *	Nylon Membrane
Dipport **	Polyethylene (PE)
Steridyne Filter 0.2 **	PP/PVDF
Clamps	Polypropylene (PP)
AseptiQuik 1/2" Sterilkupplung, G-Serie**	Polycarbonate (PC)
Cable tie	Polyamide (PA)

*10L Standard/ Basic/ Perfusion bag

**50L and 200L bag

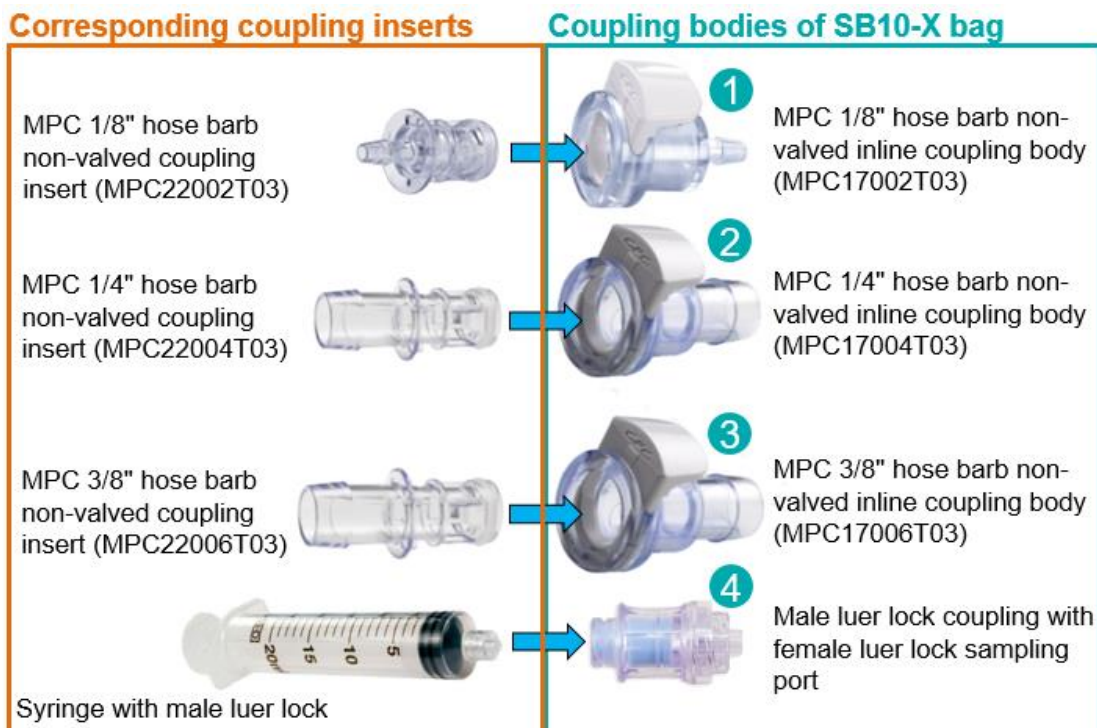
***not for the 3L bag

Connectors

The single-use bags have well known standard couplings (MPC and Luer lock). The coupling inserts shown in the orange rectangle are required to connect feeding bags, vessels, etc., to the corresponding SB10-X bag coupling bodies (shown in the green rectangle). The difference between the coupling inserts and the coupling bodies is just the diameter of the hose barb (1/8", 1/4" and 3/8") which is pushed into the tube. The insert diameters are all the same. That means that all coupling inserts can be connected to all coupling bodies. The only difference is the diameter of the tube which must be connected at the back of the coupling body/ insert. The bags/ vessels you wish to connect to the SB10-X bag need coupling inserts shown in the orange rectangles.

As well as the ports, connections can also be made by welding external tubes to the SB10-X bag. All the tubes on the bag are made of a thermoplastic material, so every line on the bag is weldable. This gives the user total flexibility when connecting other bags, filters, or additional tubes to the bag using a tube welder.

Below is an example for the connections on the SB10-X bags.



Optical Sensors

The standard bags have integrated optical sensors for pH/DO, allowing online measurements and control of pH and DO of the culture. They are already pre-calibrated and sterilized. The calibration data is found on the package of the bags. There are 2x pH and 2x DO sensors on the 200L and 2500L bags.

Measuring range

pH	5.5 – 8.5
DO	0 – 100%



Accessories

SB10-X: MagFix

There are 8 magnetic tube holders to help secure and guide all the tubing together with the cable and tubing management module. The MagFix can be attached to various steel surfaces on the vessel module, cable management module, and shaker module (orange marked in the picture).



SB10-X: Light protection jacket

This light protection jacket is easily placed over the vessel module. It protects light-sensitive media or products from UV, artificial light, as well as daylight.



SB50-X and SB200-X: Tubing support bar

A tubing support bar is available for attaching the various tubes (feeding, medium, air and pH regulation) and keeping them tidy.



SB200-X: Adapter 50L single-use bag

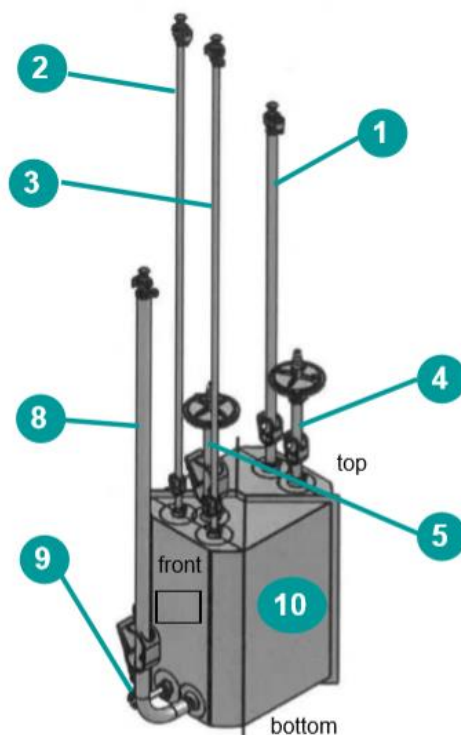
The stainless-steel adapter enables the use of a 50L bag in the orbitally shaken bioreactor SB200-X. This option gives users the flexibility to cultivate with either a 50L or a 200L single-use bag in the same orbitally shaken bioreactor footprint.



Bag configuration

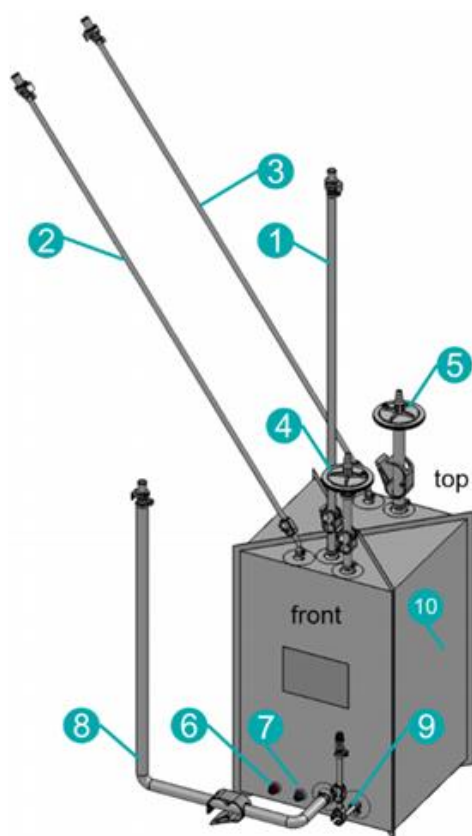
S10-X with 3L-Vessel module – 3L Standard single-use bag

Pos.	Function (proposed)	Description
1	infilling	port 1/4" ► thermoplastic tube 1/4"x7/16"x800mm ► MPC coupling 1/4" with cap
2	feeding / fresh medium	port 1/8" ► thermoplastic tube 1/8"x1/4"x1200mm ► luer lock female 1/8" with cap
3	additional acid/base	port 1/8" ► thermoplastic tube 1/8"x1/4"x1200mm ► luer lock female 1/8" with cap
4	gas flow in	port 1/4" ► thermoplastic tube 1/4"x7/16"x250mm ► bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON® II)
5	exhaust gas	Port 3/8" ► thermoplastic tube 3/8"x5/8"x320mm ► bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON®)
6	pH sensor	● optical chemosensor pH (PreSens)
7	DO sensor	● optical chemosensor DO (PreSens)
8	harvest	port 3/8" ► thermoplastic tube 3/8"x5/8"x800mm ► MPC coupling 3/8" with cap
9	sampling	port 1/4" ► thermoplastic tube 1/8"x1/4"x180mm ► luer lock female ► injection port with cap
10	bag material	outer layer: PE fluid contact layer: LDPE



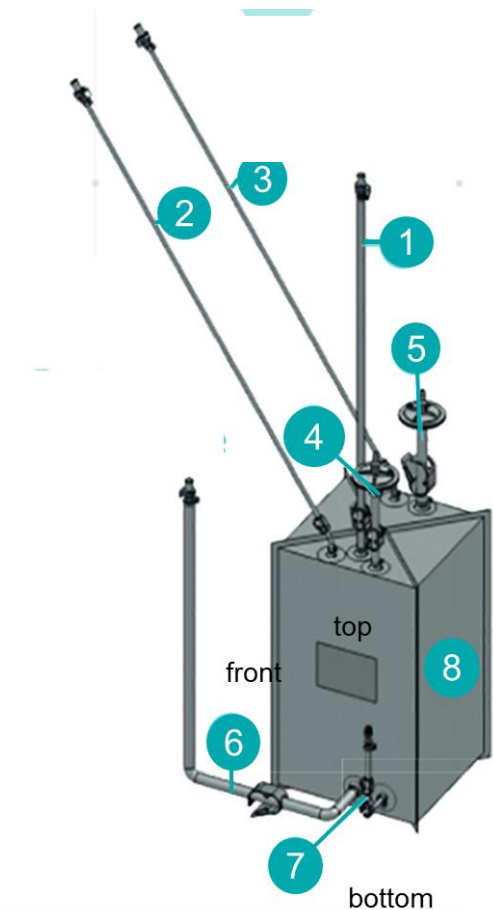
SB10-X – 10L Standard single-use bag (SMX760001)

Pos.	Function (proposed)	Description
1	infilling	port 1/4" ▶ thermoplastic tube 1/4"x7/16"x600mm ▶ MPC coupling 1/4" with cap
2	feeding / fresh medium	port 1/8" ▶ thermoplastic tube 1/8"x1/4"x800mm ▶ MPC coupling 1/8" with cap
3	additional acid/base	port 1/8" ▶ thermoplastic tube 1/8"x1/4"x800mm ▶ MPC coupling 1/8" with cap
4	gas flow in	port 1/4" ▶ thermoplastic tube 1/4"x7/16"x140mm ▶ bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON® II)
5	exhaust gas	Port 3/8" ▶ thermoplastic tube 3/8"x5/8"x140mm ▶ bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON® II)
6	pH sensor	optical chemosensor pH (PreSens) ●
7	DO sensor	optical chemosensor DO (PreSens) ●
8	harvest	port 3/8" ▶ thermoplastic tube 3/8"x5/8"x1000mm ▶ MPC coupling 3/8" with cap
9	sampling	port 1/4" ▶ thermoplastic tube 1/8"x1/4"x180mm ▶ luer lock female ▶ injection port with cap
10	bag material	outer layer: PE gas barrier: EVOH fluid contact layer: LDPE



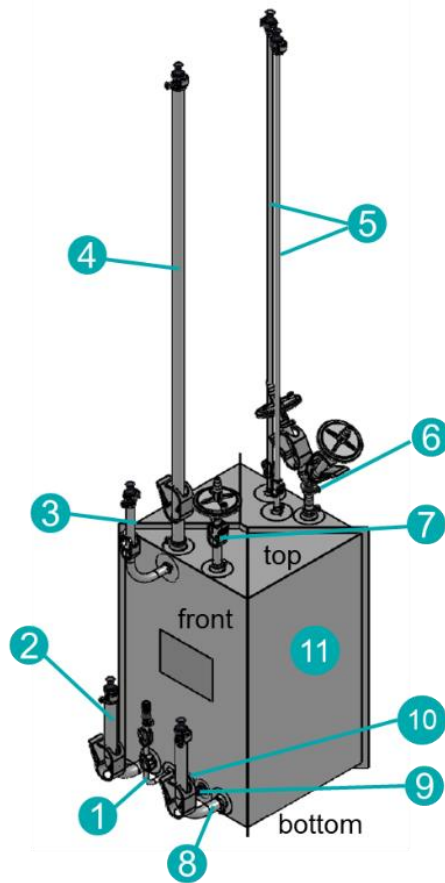
SB10-X – 10L Basic single-use bag (SMX760002)

Pos.	Function (proposed)	Description
1	infilling	port 1/4" ► thermoplastic tube 1/4"x7/16"x600mm ► MPC coupling 1/4" with cap
2	feeding / fresh medium	port 1/8" ► thermoplastic tube 1/8"x1/4"x800mm ► MPC coupling 1/8" with cap
3	additional acid/base	port 1/8" ► thermoplastic tube 1/8"x1/4"x800mm ► MPC coupling 1/8" with cap
4	gas flow in	port 1/4" ► thermoplastic tube 1/4"x7/16"x140mm ► bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON® II)
5	exhaust gas	Port 3/8" ► thermoplastic tube 3/8"x5/8"x140mm ► bidirectional filter 0.2 µm (PALL ACRO® 50 EMFLON®)
6	harvest	port 3/8" ► thermoplastic tube 3/8"x5/8"x1000mm ► MPC coupling 3/8" with cap
7	sampling	port 1/4" ► thermoplastic tube 1/8"x1/4"x180mm ► luer lock female ► injection port with cap
8	bag material	outer layer: PE gas barrier: EVOH fluid contact layer: LDPE



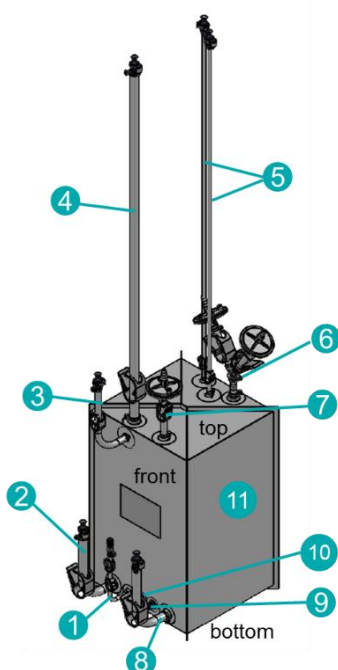
SB10-X – 10L Perfusion single-use bag (SMX760003)

Pos.	Function (proposed)	Description
1	sampling	port 1/8" ▶ thermoplastic tube 1/8" x 1/4" x 180mm ▶ luer lock female ▶ injection port ▶ protection cap
2	TFF out / ATF / fresh medium/ draining	port 3/8" ▶ thermoplastic tube 3/8" x 5/8" x 120mm ▶ MPC coupling 3/8" with cap
3	TFF in / fresh medium/ feeding	thermoplastic dip tube 1/4" x 7/16" x 330mm ▶ port 1/4" ▶ thermoplastic tube 1/4" x 7/16" x 120mm ▶ MPC coupling 1/4" with cap
4	infilling	port 3/8" ▶ thermoplastic tube 3/8" x 5/4" x 800mm ▶ MPC coupling 3/8" with cap
5	acid / base	port 1/8" ▶ thermoplastic tube 1/8" x 1/4" x 800mm ▶ MPC coupling 1/8" with cap
6	exhaust gas	port 3/8" ▶ thermoplastic tube 3/8" x 5/8" x 40mm ▶ Y-Part 3/8" ▶ 2 x thermoplastic tube 3/8" x 5/8" x 80mm ▶ filter 0.2 μm
7	gas flow in	port 1/4" ▶ thermoplastic tube 1/4" x 7/16" x 100mm ▶ filter 0.2 μm
8	harvest / 2nd ATF	port 3/8" ▶ thermoplastic tube 3/8" x 5/8" x 120mm ▶ MPC coupling 3/8" with cap
9	pH sensor	optical chemosensor pH (PreSens) ●
10	DO sensor	optical chemosensor DO (PreSens) ●
11	bag material	outer layer: PE gas barrier: EVOH fluid contact layer: LDPE



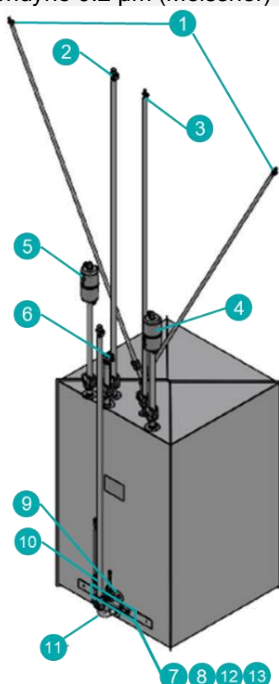
SB50-X – 50L Standard single-use bag (SMX750002)

Pos.	Function (proposed)	Description
1	Inoculation	silicone dip tube 1/4" x 7/16" x 550mm, end cut diagonal ► Bag ► flange with opposable barbs for tube ID 1/4" ► C-flex tube 1/4"x 7/16" x 80mm ► Y-connector for tube ID 1/4" ► C-flex tube ID 1/4" x 7/16" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/4" ► MPC sealing plug C-flex tube ID 1/4" x 7/16" x 80mm with pinch clamp ► straight connector for tubes ID 1/4" and 3/8" ► C-flex tube ID 3/8" x 5/8" x 1420mm ► MPC coupling body for tube ID 3/8" ► MPC sealing plug ►
2	exhaust gas	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 450mm with pinch clamp ► Sterile filter Steridyne 0.2µm (Meissner)
3	Back up exhaust gas	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 200mm with pinch clamp ► sterile coupling for tube 1/2" (CPC AseptiQuik G connector body AQG17008) ► filter kit
4	Adding Supplements 1	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/8" ► MPC sealing plug
5	Adding Supplements 2	flange with barb for tube ID 3/8" ► C-flex tube 3/8"x 5/8" x 1500mm with pinch clamp ► MPC coupling body for tube ID 3/8" ► MPC sealing plug
6	gas flow in	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 750mm with pinch clamp ► Sterile filter Steridyne 0.2µm (Meissner) ►
7	pH sensor	optical chemosensor pH (PreSens)
8	DO sensor	optical chemosensor pH (PreSens)
9	Sampling 1	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 400mm with 2 pinch clamps ► injection port for luer lock connector for tube ID 1/8" ► luer lock connector female ► protection cap for luerlock connector female
10	Sampling 2	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 180mm with 2 pinch clamps ► injection port for luer lock connector for tube ID 1/8" ► luer lock connector female ► protection cap for luerlock connector female
11	Harvest	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/2" ► MPC sealing plug
FK	Filter kit	Port 3 ► sterile coupling for tube 1/2" (CPC AseptiQuik G connector body AQG17008) ► C-flex tube 1/2" x 3/4" x 230mm with pinch clamp ► Sterile filter Steridyne 0.2 µm (Meissner)



SB200-X – 200L Standard single-use bag (SMX710002)

Pos.	Function (proposed)	Description
1	Inoculation	silicone dip tube 1/4" x 7/16" x 850mm, end cut diagonal ► Bag ► flange with opposable barbs for tube ID 1/4" ► C-flex tube 1/4"x 7/16" x 80mm ► Y-connector for tube ID 1/4" ► C-flex tube ID 1/4" x 7/16" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/4" ► MPC sealing plug ► C-flex tube ID 1/4" x 7/16" x 80mm with pinch clamp ► straight connector for tubes ID 1/4" and 3/8" ► C-flex tube ID 3/8" x 5/8" x 1420mm ► MPC coupling body for tube ID 3/8" ► MPC sealing plug ►
2	Adding Supplements 1	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/8" ► MPC sealing plug
3	Adding Supplements 2	flange with barb for tube ID 3/8" ► C-flex tube 3/8"x 5/8" x 1500mm with pinch clamp ► MPC coupling body for tube ID 3/8" ► MPC sealing plug
4	gas flow in	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 750mm with pinch clamp ► Sterile filter Steridyne 0.2µm (Meissner) ►
5	exhaust gas	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 450mm with pinch clamp ► Sterile filter Steridyne 0.2µm (Meissner)
6	Back up exhaust gas	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 200mm with pinch clamp ► sterile coupling for tube 1/2" (CPC AseptiQuik G connector body AQG17008) ► filter kit
7	pH sensor 1	optical chemosensor pH (PreSens)
8	DO sensor 1	optical chemosensor pH (PreSens)
9	Sampling 1	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 400mm with 2 pinch clamps ► injection port for luer lock connector for tube ID 1/8" ► luer lock connector female ► protection cap for luerlock connector female
10	Sampling 2	flange with barb for tube ID 1/8" ► C-flex tube 1/8" x 1/4" x 180mm with 2 pinch clamps ► injection port for luer lock connector for tube ID 1/8" ► luer lock connector female ► protection cap for luerlock connector female
11	Harvest	flange with barb for tube ID 1/2" ► C-flex tube 1/2" x 3/4" x 1500mm with pinch clamp ► MPC coupling body for tube ID 1/2" ► MPC sealing plug
12	pH sensor 2	optical chemosensor pH (PreSens)
13	DO sensor 2	optical chemosensor pH (PreSens)
FK	Filter kit	Port 3 ► sterile coupling for tube 1/2" (CPC AseptiQuik G connector body AQG17008) ► C-flex tube 1/2" x 3/4" x 230mm with pinch clamp ► Sterile filter Steridyne 0.2 µm (Meissner)



Manufacturer



Hegewald Medizinprodukte GmbH is our certified partner for the development and cleanroom production of our single-use bags. They are an experienced partner for the development and production of flexible containers made of films. They manufacture our 3L – 200L single-use bags and offer individual solutions for products in the medical, paramedical, pharmaceutical, and biotechnological applications.

Certificates

On request we provide quality certificates for the single-use bags.



Entegris is our partner for the development and production of our 2500L Bag. Quick-turn around custom configurations to deliver a total solution for your upstream and downstream needs. Entegris will be able to provide a complete portfolio of single-use bioprocessing solutions for development, scale-up, and bulk production, helping to solve our customers' most complex biomanufacturing challenges.

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