



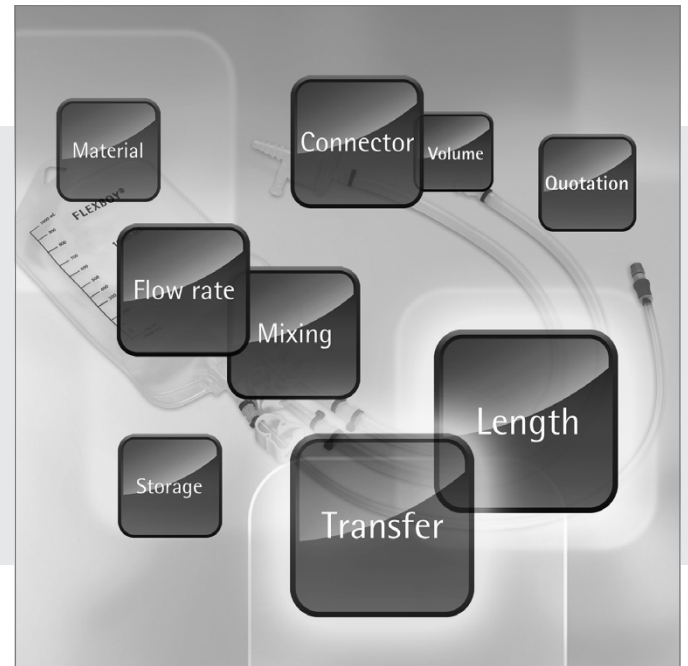
Configurable Flexsafe® 2D

Bags from 20 mL to 50 L

Product Information

Flexsafe® 2D Bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products.

Configurable Flexsafe® 2D Bags are designed from a database of pre-qualified components and proven functionalities using a web-based and interactive Product Configurator tool.



Description

The user friendly Product Configurator tool provides the flexibility needed for the application-based single-use configuration whilst improving design and quotation turnaround times, manufacturing lead times, security of supply and product reliability, safety and robustness.

They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. The broad chemical compatibility of Flexsafe® 2D Bags assures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications.

Applications

The multi-layer, PE and EVOH based S80 film provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

- Buffers and Media sterile
- Filtration & storage
- Bulk Harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate hold
- Final Product handling

Flexibility

Configurable Flexsafe® 2D Bags are configured from pre-qualified components and proven functionalities including a variety of tubing, connectors, filter and sampling methods for a streamlined incorporation into your process. Multiple configurations are available with bag volumes from 20 mL to 50 L with TPE tubing, compatible with BioWelder® and BioSealer® for aseptic connection | disconnections, silicone TuFlux® tubing compatible with Clipster® Aseptic Disconnecter and qualified for peristaltic pumping and TPE tubing for RF sealing with Vante™ Sealers. Sartopore® 2 Gamma MidiCaps® are proposed with an optional flush bag. Needle free sampling port or sampling bag may be used for easy and convenient sampling. Quick couplers, triclamps, Luer® fittings, Steam thru™ valves and Sterile-to-sterile connectors are provided for optimal connection compatibility flexibility in a production environment.

Easy Implementation

Configurable Flexsafe® 2D Bags are available in bag chamber volumes between 20 mL and 50 L. They are supplied sterilized and ready to use. This allows an easy and convenient process implementation. A series of associated systems such as Trays and Racks facilitate an easy bag handling. Sartorius Stedim Biotech supports users already at the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Features	Benefits
Pre-qualified component database and proven functionalities	Quality by design for improved product reliability
Standard components & manufacturing methods	Save on development and engineering costs
Instant design with a web-based Product Configurator	Shorten lead time for drawing & quotes
CTO dedicated supply chain and manufacturing capability	Shorten lead-time for products
Offer a large range of standardized configurable products	Reduce complexity and risks by Standardization
Product Configurator tool with preconfigured options & functionalities	Flexibility for optimal design tailored to the application needs
Most commonly used components and solutions in the market	Compatibility with end user process requirements

Robust Performance and Assurance of Supply

Flexsafe® 2D bags are designed for safe storage and shipping of biopharmaceutical solutions. Flexsafe® bags ensure consistent cell growth robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.

Configurable Transfer line

Bag Chamber	Multiple layer film, including EVOH gas barrier layer and TPE contact layer S80 film
Volumes	20 mL – 50 L
Tubing	Silicone TuFlux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnecter, TPE compatible with BioWelder® and BioSealer®
End Connectors	Quick Couplers Triclamp and Mini-Triclamp Luer® Locks Steam thru™ valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2 µm Gamma MidiCaps® size 4 Sartopore® 2 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4 Sartopore XLM 0.1 µm size 7 with optional flush bag for volume 1 L to 50 L
Sampling	Needleless sampling site Sampling with bag
Number of Lines	2 lines for bags from 20 mL to 500 mL 3 lines for bags from 1 L to 50 L

Validation

Flexsafe® 2D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Configurable Flexsafe® 2D Bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10⁻⁶ over the shelf life.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-use products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

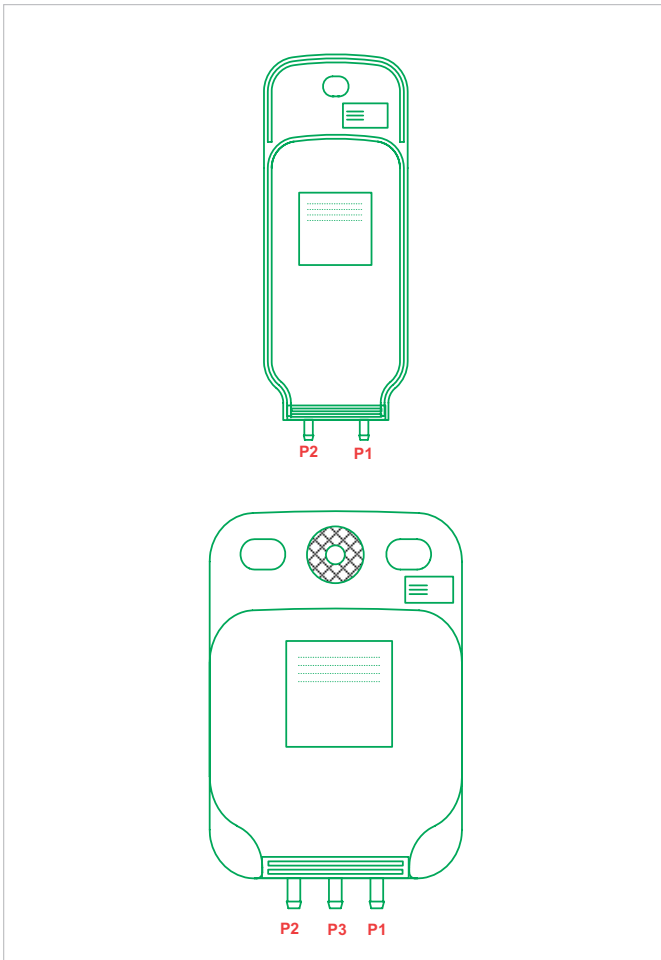
Flexsafe® 2D Bags are tested for compliance to:

- USP <85>: Bacterial Endotoxins Test
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulates
- ISO 11737: Bioburden
- ISO 11137: Sterilization of Medical Devices

Supply Chain

Configurable Flexsafe® 2D Bags are available as Configured to Order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

Technical Data



Functionalities
– Storage application

Specifications

Volume

20 mL, 50 mL, 150 mL, 250 mL, 500 mL,
1 L, 3 L, 5 L, 10 L, 20 L, 50 L

Number of Ports | Lines

– 3 lines where P1 is assimilated to the filling line,
P2 to the draining line or sampling line and
P3 to the sampling line

Tubing Diameters

ID × OD = 1/4" × 7/16" for P1, P2, P3
1/4" × 3/8" for P1, P2, P3
3/8" × 5/8" for P1, P2

Tubing Materials

Silicone Tubing, Silicone TuFlux®, TPE Tubing, Silicone TuFlux® +
TPE Tubing, Silicone + TPE tubing

Tubing Lengths

150 mm, 300 mm, 500 mm, 1000 mm, 1500 mm, 2000 mm,
no tubing

Type of Lines

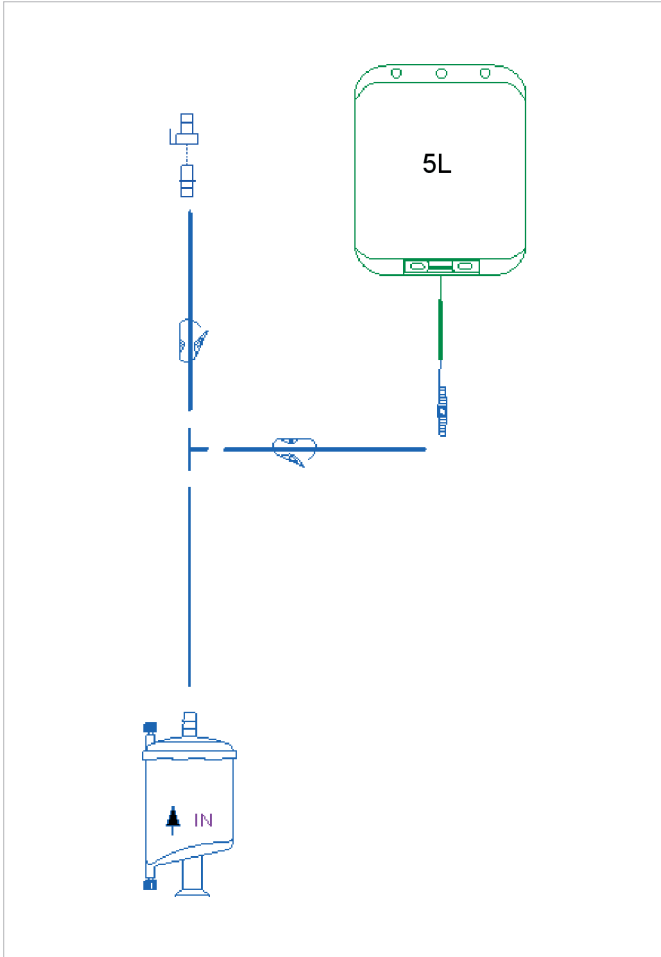
Port	P1	P2	P3
Line	Line 1	Line 2	Line 3
Function	Fill	Drain Sampling	Sampling
Normal Flow Rate with Filter	●		
High Flow Rate with Filter	●		
Normal Flow Rate	●	●	
High Flow Rate	● ⁽¹⁾	● ⁽¹⁾	
Sampling		●	●
Not Used		● ⁽¹⁾	● ⁽²⁾

⁽¹⁾ For Flexsafe® 2D from 3 L to 50 L

⁽²⁾ For Flexsafe® 2D from 20 mL to 500 mL

Line Type Normal Flow Rate with Filter and High Flow Rate with filter: port 1

Generic Description



Specifications

Tubing Diameters

ID × OD = 1/4" × 7/16" (6.4 mm × 11.1 mm)
or 3/8" × 5/8" (9.5 mm × 15.8 mm)

Tubing Materials

- Silicone TuFlux® or Si(Pt)
(filter removal with CPC Quick Coupler
or no filter disconnection)
- TPE tubing (filter removal with tube sealing)

Tubing Lengths

- 150 mm
- No Tubing

Type of filters

- Sartopore® 2 0.2 µm Gamma MidiCaps® size 4
- Sartopore® 2 0.2 µm Gamma MidiCaps® size 7
- Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4
- Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7
- Sartopore® XLM 0.1 µm size 7

Option

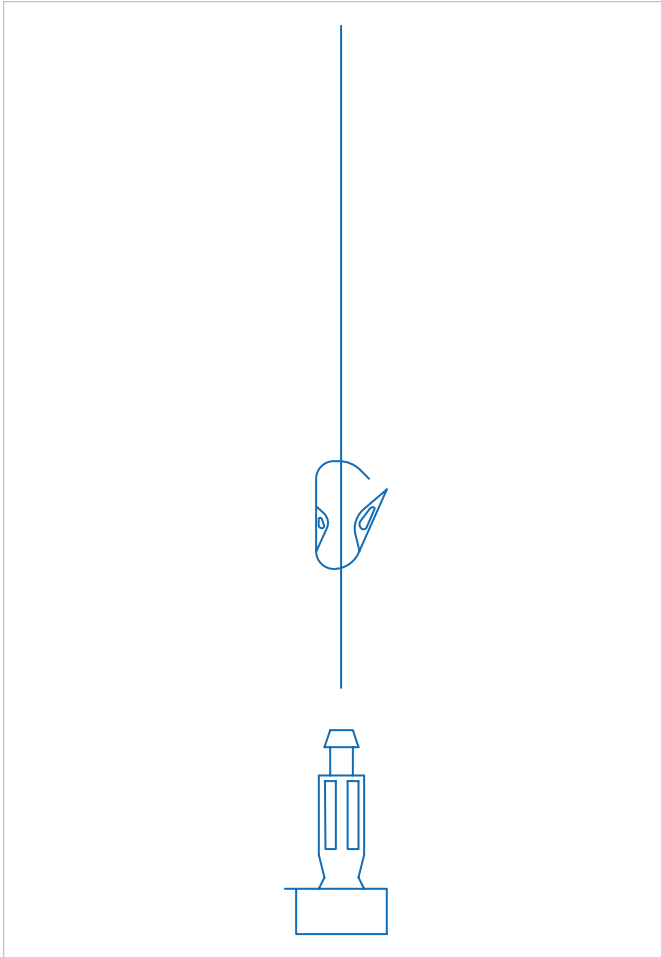
- No flush bag for volume 20 mL to 1 L
- 1 L Flexboy® Flush Bag (only with Normal Flow Rate)
- 5 L Flexboy® Flush Bag

Functionalities

- Filling through a sterilizing grade filter
- Optional filter flush bag only for volume > 1 L
- Optional filter disconnection with a Quick Coupler
or with tube sealing (TPE)

Line Type Normal Flow Rate: port 1 & 2 and High Flow Rate: port 1 & 2

Generic Description



Functionalities

- Bag filling or bag drainage
- Transfer with a peristaltic pump or by gravity
- Tube to tube welding
- Tube sealing
- Aseptic connection
- Generic connection with a TriClamp or a Quick Coupler

Specifications

Tubing Diameters

- ID × OD = 1/4" × 7/16" (6.4 mm × 11.1 mm)
- or 1/4" × 3/8" (9.5 mm × 15.8 mm)
- or 3/8" × 5/8" (9.5 mm × 15.8 mm)

Tubing Materials

- Silicone TuFlux[®] or Si(Pt) for 10 hr maximum operation with a peristaltic pump
- TPE (thermoplastic tubing) for tube sealing and welding operations
- Silicone TuFlux[®] or Si(Pt) with a TPE extension for 10 hr maximum operation with a peristaltic pump and for tube sealing and welding applications

Tubing Lengths

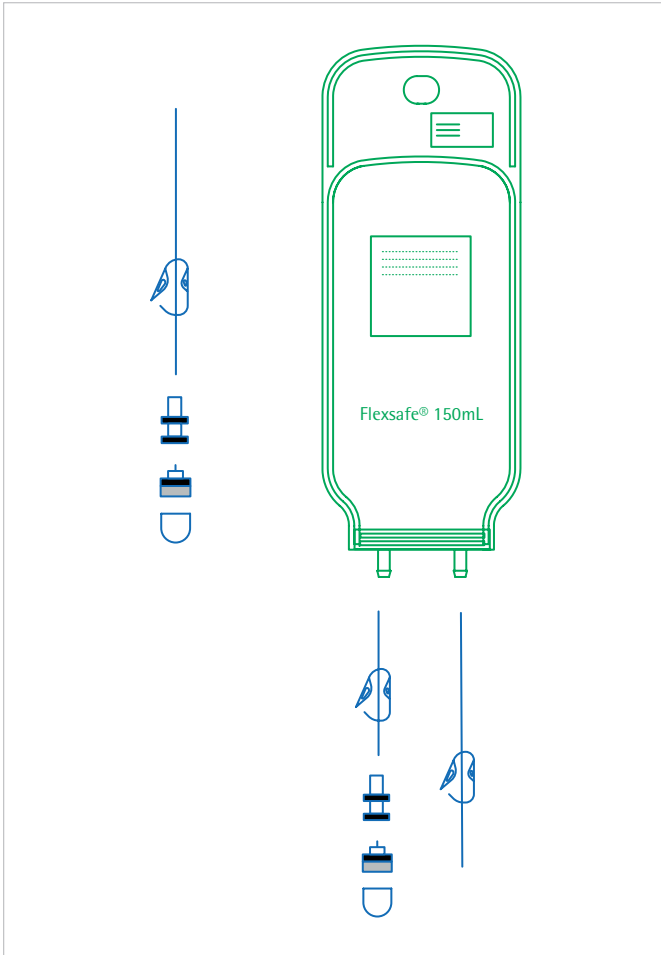
- 150 mm (6") for Si(Pt) TuFlux[®] or Si(Pt)
- 300 mm (12") for Si(Pt) TuFlux[®] or Si(Pt)
- 500 mm (20") for Si(Pt) TuFlux[®], Si(Pt) or TPE tubing
- 1,000 mm (39") total line length: 500 mm (20") Si(Pt) TuFlux[®] or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 1,500 mm (59") total line length: 1,000 mm (39") Si(Pt) TuFlux[®] or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 2,000 mm (79") total line length: 1,500 mm (59") Si(Pt) TuFlux[®] or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension

Distal Connectors

- SSB TriClamp (1-1/2" or 3/4" flange) with optional triclamp cap, plug, gasket and union
- Quick Coupler with plug - MPC (Male or Female)
- MPC PSU (Male or Female)
- OPTA[®] SFT - aseptic connection (Male or Female)
- STC I - CPC Steamthru™ connection (3/4" × 3/4" triclamp flanges)
- STC II - CPC Steamthru™ connection (3/4" × 3/4" triclamp flanges)
- KPC HT - Male or Female
- Luer Male or Female with cap (only with Normal Flow Rate)
- Aseptiquick genderless
- Lynx Valve ST 1/4" or 3/8"

Line Type "Sampling" P2 – P3⁽¹⁾ Normal Flow Rate

Generic Description



Specifications

Tubing Diameters

ID × OD = 1/4" × 7/16" (6.4 mm × 11.1 mm)

Tubing Materials

- Silicone TuFlux[®] or Si(Pt) for needleless sampling port
- TPE (thermoplastic tubing) for welding and sealing operations (sampling bag disconnection)

Tubing Lengths

- 150 mm

Connector

- Clave

Sampling Bag

- Flexsafe[®] 2D bag 150 mL

Functionalities (Sampling)

- Clave Connector
- Sampling Bag

⁽¹⁾ P2 For volume 20 mL to 500 mL
P3 for volume 1 L to 50 L

Line Type "Not Used" P2 – P3⁽²⁾

Functionality

- Not Used
- Obstructed port

⁽²⁾ P2 only for volumes > 1 L

Functionalities of the Flexsafe® 2D Bag from 20 mL to 50 L

	Normal Flow Rate with filter or High Flow Rate with filter	Normal Flow Rate	High Flow Rate	Sampling Transfer
Function	Sterile Fill	Fill Drain Addition	Fill Drain Addition	Sampling
Port	P1	P1 – P2	P1 – P2	P2 – P3
Tube Dim.	1/4" × 7/16" (6.4 mm × 11.1 mm) 3/8" × 5/8" (9.5 mm × 15.8 mm)	1/4" × 7/16" (6.4 mm × 11.1 mm)	3/8" × 5/8" (9.5 mm × 15.8 mm)	1/4" × 7/16" (6.4 mm × 11.1 mm)
Tube Length mm	150 (6")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6")
Tubing Materials	Si(Pt) TuFlux® Si(Pt) TPE	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) + TPE Si(Pt) TuFlux® + TPE	Si(Pt) TuFlux® Si(Pt) TPE Si(Pt) TuFlux® + TPE Si(Pt) + TPE	Si(Pt) TuFlux® Si(Pt) TPE
Standard Connectors		Luer M-F SSB TC 1 1/2" or 3/4" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick coupling PSU-M/F	Luer M-F SSB TC 1 1/2" or 3/4" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Clave
Aseptic Connectors		Opta® SFT-M/F AseptiQuik® Genderless	Opta® SFT-M/F AseptiQuik® Genderless STC I 3/4" × 3/4" STC II 3/4" × 3/4"	
Other Connectors		KPC HT-M/F Lynx ST 1/4"	KPC HT-M/F Lynx ST 3/8"	
Filters	Sartopore® 2 0.2 µm Gamma MidiCaps® size 4 Sartopore® 2 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 7 Sartopore® Platinum 0.2 µm Gamma MidiCaps® size 4 Sartopore® XLM 0.1 µm size 7			
Flush Bag	Flexboy® 1 or 5 L ⁽¹⁾			
Sampling Bags	Flexsafe® 2D Bag Bags 1 × 150 mL ⁽²⁾			

⁽¹⁾ Only for volume > 1 L

⁽²⁾ Only for volume 1 L to 50 L

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5-7
34302 Guxhagen
Phone +49.5665.407.0

France

Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques - CS 91051
13781 Aubagne Cedex
Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques - CS 71058
13781 Aubagne Cedex
Phone +33.442.845600

Austria

Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna
Phone +43.1.7965763.18

Belgium

Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles
Phone +32.2.756.06.80

Hungary

Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi
Phone +36.23.457.227

Italy

Sartorius Stedim Italy S.r.l.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)
Phone +39.055.63.40.41

Netherlands

Sartorius Stedim Netherlands B.V.
Phone +31.30.60.25.080
filtratie.nederland@sartorius-stedim.com

Poland

Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn
Phone +48.61.647.38.40

Russian Federation

LLC "Sartorius Stedim RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg
Phone +7.812.327.53.27

Spain

Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)
Phone +34.913.586.098

Switzerland

Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen
Phone +41.52.354.36.36

U.K.

Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ
Phone +44.1372.737159

Ukraine

LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine
Phone +380.44.411.4918

Americas

USA

Sartorius Stedim North America Inc.
5 Orville Drive, Suite 200
Bohemia, NY 11716
Toll-Free +1.800.368.7178

Argentina

Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires
Phone +54.11.4721.0505

Brazil

Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil
Phone +55.11.4362.8900

Mexico

Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605
Phone +52.55.5562.1102
leadsmex@sartorius.com

Peru

Sartorius Peru S.A.C.
Avenue Alberto del Campo 411
Floor 12 - The Office
15076 - San Isidro, Lima
Phone +51.1.441 0158

Asia | Pacific

Australia

Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175
Phone +61.3.8762.1800

China

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China
Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Beijing Branch Office
No. 33 Yu'an Road
Airport Industrial Park Zone B
Shunyi District, Beijing 101300
Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Guangzhou Branch Office
Room 1105
Xing Guang Ying Jing Building
No. 119, Shui Yin Road
Yue Xiu District, Guangzhou 510075
Phone +86.20.3836.4193

India

Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India
Phone +91.80.4350.5250

Japan

Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan
Phone +81.3.4331.4300

Malaysia

Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia
Phone +60.3.8996.0622

Singapore

Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684
Phone +65.6872.3966

South Korea

Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, Bundang-Gu
SeongNam-Si, GyeongGi-Do, 463-400
Phone +82.31.622.5700



▶ www.sartorius-stedim.com