



UniSart® Membranes Consistency by Design





Sartorius Stedim Biotech at a glance

Sartorius was founded in Goettingen, in 1870 by Florenz Sartorius and started initially manufacturing short-beam analytical balances.

In 1929, Sartorius started the first ever industrial production of cellulose nitrate membranes. The Sartorius group has become an internationally leading laboratory and process technology provider with core areas of expertise in biotechnology and mechatronics.

Today, the recent combination of the Sartorius Biotechnology Division and Stedim, the pioneer in disposable aseptic bag systems, creates a global biopharmaceutical supplier. Sartorius Stedim Biotech is a leading provider of cutting-edge equipment and services for the development, quality assurance and production processes of the biopharmaceutical industry. Our integrated solutions covering fermentation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry around the world to develop and produce drugs safely, timely and economically. For next generation processes, we focus on single-use technologies and added-value services to meet upcoming requirements of the industry we serve. Strongly rooted in the scientific community and closely allied with customers and technology partners, we are dedicated to our philosophy of "Turning science into solutions".

Headquartered in Aubagne, France, and with main operations in Germany and the US, Sartorius Stedim Biotech owns production and sales companies worldwide and employs over 2,200 people. In the diagnostic field, based on its long experience of microporous membrane and its tradition of high quality, Sartorius Stedim Biotech has developed large pore size cellulose nitrate membrane, which are now a reference for consistency.

Introduction

Our mission

To develop and manufacture diagnostic membranes with excellent performance and outstanding intra- and inter-lot consistency. To produce and deliver membranes on time to satisfy our customer requests. To collaborate with our customers and provide them support based on their application needs. To be not only a supplier to the IVD industry, but a loyal manufacturing partner.

The assay

First developed in the mid-80's for pregnancy testing, the Lateral Flow Immunoassay (LFIA) has since experienced rapid growth with more than 800 million pregnancy tests produced per year. Currently over 60 markers can be analyzed on the LFIA platform. The simplicity of the one-step, self-contained LFIA test explains why it has gained popularity. All LFIA tests have the same multi-component construction incorporating the diagnostic membrane on the center of it. These tests are produced in cards or in continuous rolls and then slit into strip. The LFIA strip can vary from a few millimeters in width to a few centimeters in length; it is often encased in a plastic housing. Test results can be qualitatively assessed visually or quantitatively by a reader. Recently, more and more quantitative assays have been developed and marketed.

The membrane

The membrane plays a key role in LFIA strips. It binds antibodies or capture molecules maintaining their immunoreactivity. It provides capillary action to drive the test. This membrane exhibits a large inner surface area that concentrates detector particles to generate a readable signal line. Therefore, cellulose nitrate with its unique microporous properties is the material of choice for all LFIAs.

Consistency, the most important parameter

Tuning the sensitivity and line shape of a LFIA is common practice today. Parameters like antibody and conjugate concentration, type of buffer, drying regimen and dispensing conditions, can be adjusted. The use of membrane material with consistent inter- and intra-lot properties will reduce the need for such adjustments during production. New assay development can be undertaken with more confidence especially with regard to the development of quantitative assays. The use of consistent membrane yield higher productivity and reduces scrap rates, time to market as well as overall cost.



Consistency by design



The team

A group of skilled scientists, technicians, production workers, product and marketing managers, all dedicated to the science of membrane technology for the LFIA market. The team develops new diagnostic membranes and production processes, gathers application know-how, and interacts closely with customers. The goal is to improve membrane consistency and performance, to support the customer with trouble shooting and to better correlate membrane properties to test performance.

Our R&D and application laboratories are located nearby production, giving birth to creative interaction loops.

The application lab

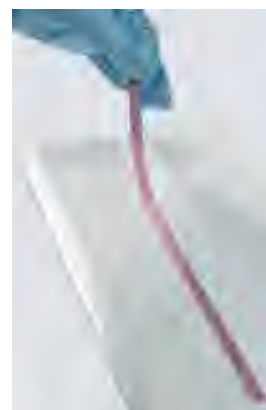
Our diagnostic membrane and LFIA application lab is fully equipped with innovative instruments and materials. That enable us to characterize diagnostic membranes and build LFIA tests. Common LFIA chemistries are used to evaluate membrane performance with respect to test architecture and production parameters.

Our capabilities include

- Jet or contact line printing
- Strip assembly
- Quantitative reading of colorimetric or fluorescent signal line intensities
- Evaluation of overall strip performance and consistency

Manufacturing facilities

Being the first ever manufacturer of cellulose nitrate membranes, Sartorius has many decades of experience in the formulation of the lacquer as well as in the building of state-of-the-art casting equipment and respective production facilities. In our new Plant 2001 in Germany we have rigid environmental controls in place to provide a stable and clean manufacturing process.



How lateral flow membranes are made

Membranes are cast from their respective lacquers, which is a complex mixture of cellulose nitrate polymers, additives and solvents. Each of the lacquer is directly applied in a thin layer onto a stainless steel belt or a clear polyester film for backed material. During the casting process, solvents evaporate forming the characteristic membrane structure needed for the lateral flow test. The membrane is impregnated, dried and wound into master rolls.

Membrane development

Right at the start of a new membrane development like for the new CN95, we look not only for membrane performance, but also for consistency. Both properties are equally important and guide the development process from formulation of the cellulose nitrate lacquer to the casting process. The equipment, raw materials and processes are selected with a focus on excellent performance and the ability to provide consistent results.

Selection of raw materials

In the development phase, raw materials are carefully selected and evaluated from the respective suppliers. This selection process is one of the key success factors in manufacturing consistent membranes. The reliable supply of consistent raw materials enables consistent membranes with excellent performance characteristics to be manufactured.

Membrane production process

The lacquer mixing and the casting processes are designed and controlled to provide outstanding inter- and intra-lot consistency. All of our UniSart® membranes feature a dust-free and exceptionally smooth surface due to a patented process. They are all manufactured according to DIN/ISO 9001:2000.

QA/QC

A comprehensive quality assurance system is a prerequisite for manufacturing consistent membrane. Our QA encompasses all the membrane manufacturing steps. Detailed quality controls tests are performed, ranging from incoming materials, to casting processes to the final release of a batch. Complete traceability of each UniSart® membrane lot down to the final slit roll is assured.



Challenge the consistency of our UniSart® membranes

Experience the unmatched consistency of our UniSart® membranes. In order to help you implement the membrane into your process, Sartorius offers the following:

- Membrane validation packages representing cross- and down-web, as well as inter-lot samples.
- Troubleshooting support using the expertise of our application lab
- Opportunities for visits and audits at the manufacturing plant in Germany

New UniSart® CN95

This new cellulose nitrate membrane has been specifically developed in order to have a very large and open pore structure and still show an unmatched consistency. This new membrane is the ideal substrate for lateral tests running on viscous or particle loaded samples with either cells or bacteria or other particles. The fast lateral speed will allow getting a very quick clearing of conjugate particles leading to a very clean background.

Due to its improved consistency, this new membrane will become essential for the development and production of quantitative assays. Indeed the UniSart® membrane family is already the membrane of choice for the majority of quantitative assay systems on the market.

The continuous improvements for better consistency that have been made during the development of this new UniSart® CN95 have also benefited to the existing CN140 membranes. These improvements have been achieved mainly by narrowing further down process parameters in our membrane manufacturing.

A critical parameter

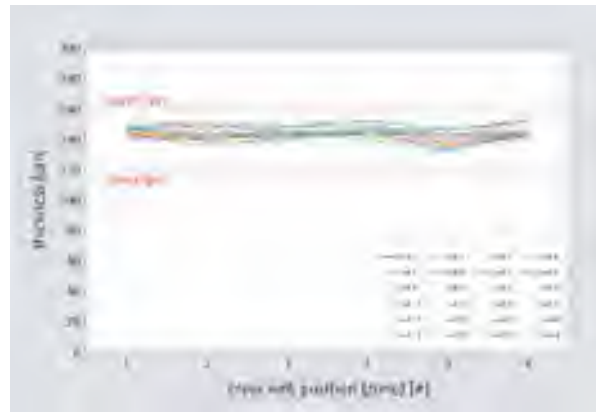
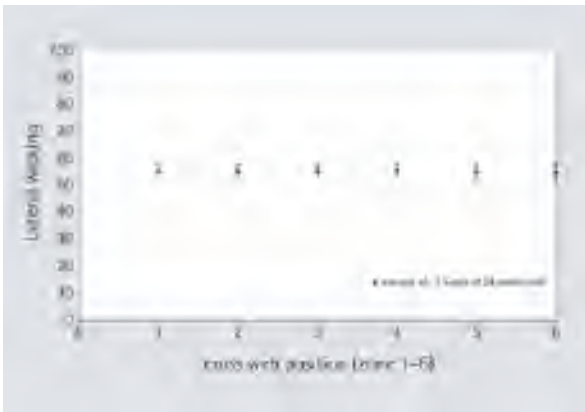
Consistency is the most important parameter for IVD manufacturers. Tuning the reagents in order to get the desired intensity and width on the test line is essential. But these developments are often compromised by the intra- and inter- lot variability of the solid components of the test such as the pads and the membrane. Today, the new UniSart® CN95 as well as the standard CN140 membranes are benefiting from all of our latest developments and improvements in membrane manufacturing. Along with our stringent quality control, this will ensure that all UniSart® membrane you receive will always have the same characteristics.



Unique inter- and intra-lot consistency

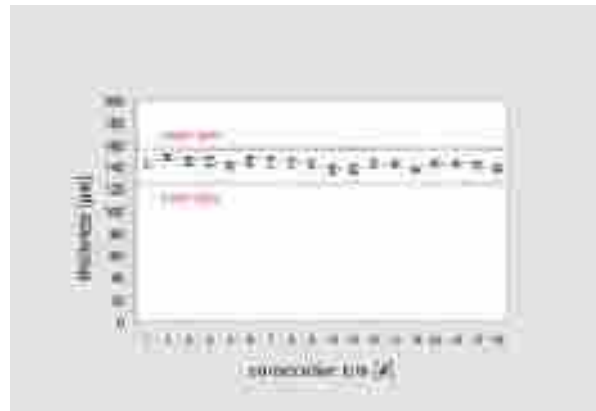
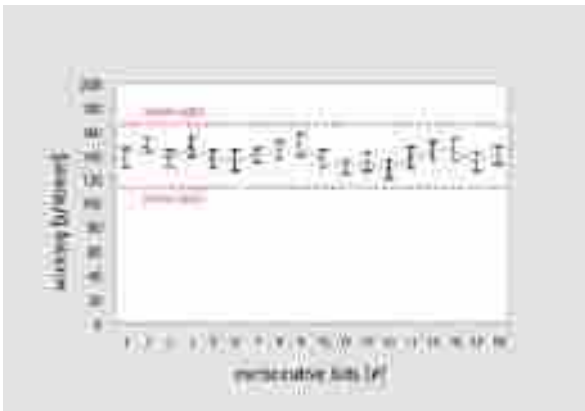
Intra-lot consistency

Down- and cross-web wicking data for an entire lot of the UniSart® CN140 unbacked.



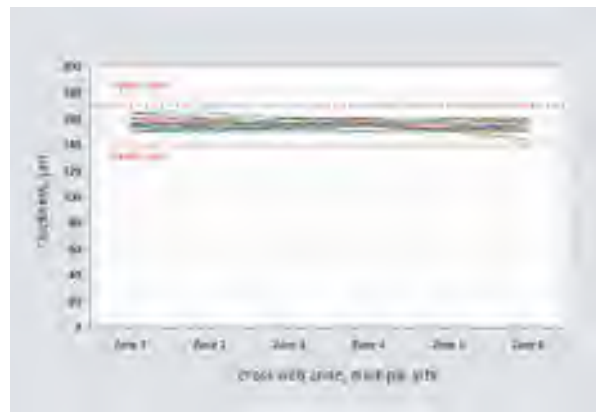
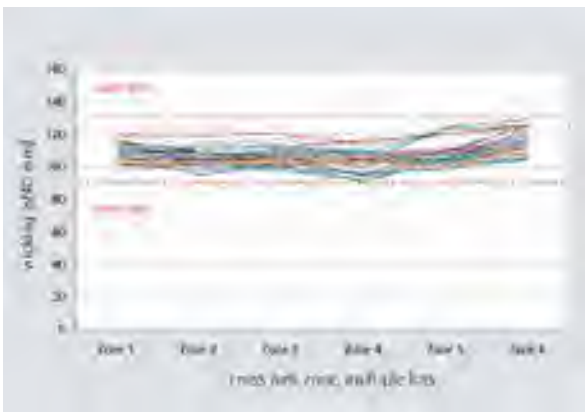
Inter-lot consistency

Wicking and thickness data of 18 consecutive lots of UniSart® CN140 backed.



New UniSart® CN95

Wicking and thickness data of UniSart® CN95



UniSart® membranes

Available membranes

UniSart® membranes are cellulose nitrate membranes with large pore size. Every step in the membrane manufacturing process, has been optimized in order to give a reproducible and clean structure. The defined pore structure of these membranes yield a controlled and fast lateral wicking of samples and reagents. The UniSart® family comprises 3 different standard membranes which are produced in large volume:

CN140 unbacked is a non supported cellulose nitrate membrane. Its good tensile strength still allows for an easy handling.

CN140 backed is a supported cellulose nitrate membrane. It is produced through direct casting onto a 100 µm clear polyester film.

CN95 is a supported cellulose nitrate membrane. it is produced through direct casting onto a 100 µm clear polyester film. The CN95 has much larger pore than the CN140 type and so a faster wicking speed.

Applications

Like the ELISA but developed in a one-step strip format, the LFIA allows for the rapid detection of an analyte through the powerful and sensitive immuno reaction.

The UniSart® membranes are designed to be the ideal solid phase for all these new assays either in the direct sandwich or competitive format. The new CN95 membrane is particularly adapted for lateral tests running on viscous or particle loaded samples with either cells or bacteria. The fast lateral speed of the UniSart® CN95 allows getting a very quick clearing of conjugate particles, either gold or larger latex beads. The CN140 membranes are the ideal substrate for LFIA requesting slower wicking for higher sensitivity.

Uniform and smooth surface

The UniSart® membranes are formed by an air casting process, where solvents are evaporated from different cellulosic polymers. A new improved patented manufacturing process allows us to always produce the UniSart® CN membranes with a clean and defect-free surface, which allow a clear signal reading at the end of the assay.

Consistent wettability

Although cellulose nitrate polymers are naturally hydrophobic, all UniSart® membranes are treated with a specific anionic surfactant to have immediate and long term uniform wettability.

High consistent protein binding

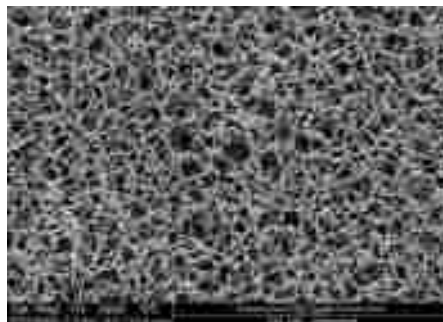
Cellulose nitrate membranes exhibit high non-specific binding of proteins due to the unique electrostatic and hydrophobic surface properties. Through its highly porous, sponge-like 3-D structure, the UniSart® membranes have an important surface area leading to high protein binding capacity per membrane area. More capture proteins on the test line will provide the basis for higher signal intensity on test and control lines.

Quality

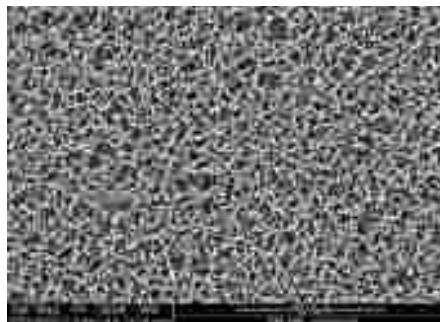
A certificate of Quality is delivered with every box of membrane. On the certificate of UniSart® CN140 and CN95, you find the exact mean value of the capillary speed and thickness of the complete batch from which the slit rolls originate. The variance inside this specific lot is also calculated, giving you a precise idea of the intra-lot homogeneity. A label on each membrane roll, provides the number of the master roll and the position of the final slit roll, allowing for precise tracking.



UniSart® CN140 unbacked



1.1. Air side CN140 Unbacked
(SEM @ 500x; bar = 100 µm)



1.2. Belt side CN140 Unbacked
(SEM @ 500x; bar = 100 µm)

This unbacked cellulose nitrate membrane is available in different sheet or roll format. Its good tensile strength allow for an easy handling and fixing onto any plastic support with non solvent pressure sensitive glue. The use of the belt side as reagent application side generate clean and sharp signal lines.

Ordering information

Product number

1UN14AR050020--B	UniSart® CN140 unbacked 20 mm on 50 m roll, box of 5 rolls
1UN14AR050025--B	UniSart® CN140 unbacked 25 mm on 50 m roll, box of 5 rolls
1UN14AR100025WS	UniSart® CN140 unbacked 25 mm on 100 m roll, box of 1 roll
11301-----118TD	UniSart® CN140 unbacked 20 mm on 50 m roll, box of 5 rolls
1UN14AS25020001	UniSart® CN140 unbacked 250 mm × 200 mm sheet, pack of 2 sheets

Specifications and characteristics

Membrane

Material	cellulose nitrate polymers
Thickness specification	120–160 [µm]
Capillary speed specification	≥52 [mm/5 min]*
Surfactant	anionic (sulfonate)
Protein binding	≈30 [µg IgG/cm ²]

Roll specifications

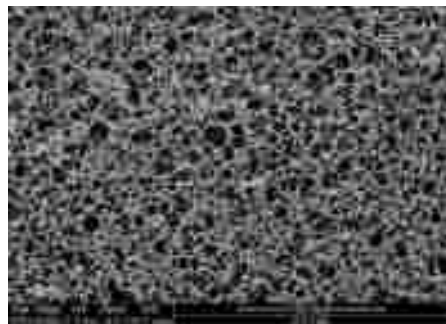
Roll core	76.8 [mm] ± 3" (inner diameter)
Core	plastic material
Available membrane width**	20, 25 [mm] (+/- 0.5 mm) 270 [mm]
Available membrane length**	50 [m] (+1/-0 m) 100 [m] (+1/-0 m)

Membrane wound with yellow interleaving papers

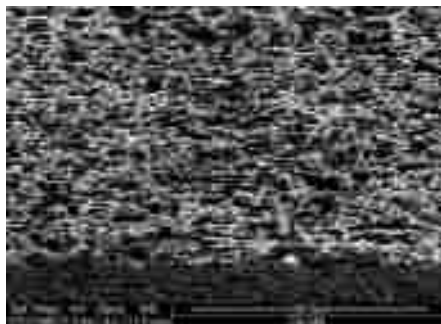
* corresponds to ≈150 [s/40 mm]

** custom dimensions are available upon request

UniSart® CN140 backed



1.1. Air side CN 140 Backed
(SEM @ 500x; bar = 100 µm)



1.2. Cross section CN140 Backed
(SEM @ 440x; bar = 100 µm)

This cellulose nitrate membrane is direct cast onto a transparent polyester film allowing a very easy handling and cutting. It is available in different sheet or roll format.

Ordering information

Product number

1UN14ER050017NT	UniSart® CN140 backed 17 mm on 50 m roll, box of 5 rolls
1UN14ER100018NT	UniSart® CN 140 backed 18 mm 100 m roll
1UN14ER050020-B	UniSart® CN140 backed 20 mm on 50 m roll, box of 5 rolls
1UN14ER050025--B	UniSart® CN140 backed 25 mm on 50 m roll, box of 5 rolls
1UN14ER100040	UniSart® CN140 backed 40 mm on 100 m roll, box of 1 roll

Specifications and characteristics

Membrane

Material	cellulose nitrate polymers
Thickness specification	125–155 [µm] (membrane layer)
Capillary speed specification	110–165 [s/40mm] (across casting direction)
Surfactant	anionic (sulfonate)
Protein binding Backing	≈30 [µg IgG/cm ²] 100 [µm] thick clear polyester film

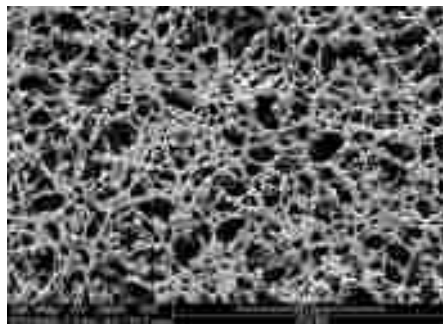
Roll specifications

Roll core	76.8 [mm] ± 3" (inner diameter)
Core	plastic material
Available membrane width*	20, 25, 40 [mm] (+/- 0.5 mm)
Available membrane length*	50 meters (+1/-0 m) 100 meters (+1/-0 m)

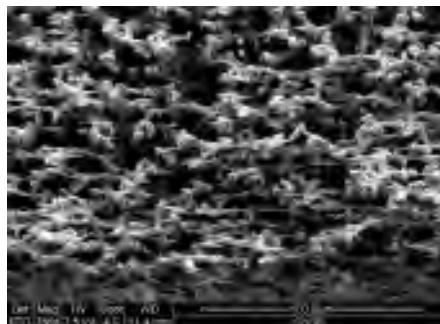
Membrane wound with yellow interleaving paper

* custom dimensions are available upon request

UniSart® CN95

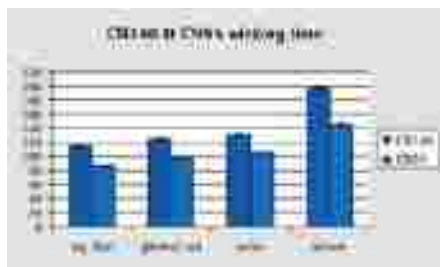


1.1. Air side CN95
(SEM @ 500x; bar = 100 µm)



1.2. Cross section CN95
(SEM @ 800x; bar = 100 µm)

The new CN95 membrane has a more open structure compared to the CN140 and a much faster capillary speed. It will generate much less background with a fast clearing time of the conjugate particles and a shorter time to signal on the test line. It is the ideal membrane for blood or serum test as well as for tests, which does not require the sensitivity of a slower membrane.



Ordering information

Product numbers

1UN95ER050020WSB	UniSart® CN95 backed 20 mm on 50 m roll, box of 5 rolls
1UN95ER050025WSB	UniSart® CN95 backed 25 mm on 50 m roll, box of 5 rolls
1UN95ER100020NT	UniSart® CN95 backed 20 mm on 100 m roll, box of 1 roll
1UN95ER100025NT	UniSart® CN95 backed 25 mm on 100 m roll, box of 1 roll

Specifications and characteristics

Membrane

Material	cellulose nitrate
Thickness specification	140–170 [µm] (membrane layer)
Capillary speed specification	90–135 [s/40 mm] (across casting direction)
Surfactant	anionic (sulfonate)
Typical protein binding	≈28 µg of IgG per cm ²
Backing	100 µm thick clear polyester film

Roll specifications

Roll core	76.8 mm (3") internal diameter
Core	plastic material
Available membrane width*	20 mm, 25 mm (+/- 0.5 mm)
Available membrane length	50 meters (+1/-0 m), 100 meters (+1/-0 m)

Membrane wound with yellow interleaving paper

* custom dimension are available on request

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com
For further information on diagnostics e-mail us at unisart@sartorius-stedim.com

Europe

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen

Phone +49.551.308.0
Fax +49.551.308.3289

unisart@sartorius-stedim.com
www.sartorius-stedim.com

Sartorius Stedim Systems GmbH
Schwarzenberger Weg 73-79
34212 Melsungen

Phone +49.5661.71.3400
Fax +49.5661.71.3702

www.sartorius-stedim.com

France

Sartorius Stedim Biotech S.A.
ZI Les Paluds
Avenue de Jouques – BP 1051
13781 Aubagne Cedex

Phone +33.442.845600
Fax +33.442.845619

Sartorius Stedim France SAS
ZI Les Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex

Phone +33.442.845600
Fax +33.442.846545

Austria

Sartorius Stedim Austria GmbH
Franzosengraben 12
A-1030 Vienna

Phone +43.1.7965763.18
Fax +43.1.796576344

Belgium

Sartorius Stedim Belgium N.V.
Leuvensesteenweg, 248/B
1800 Vilvoorde

Phone +32.2.756.06.80
Fax +32.2.756.06.81

Denmark

Sartorius Stedim Nordic A/S
Hoerskaetten 6D, 1.
DK-2630 Taastrup

Phone +45.7023.4400
Fax +45.4630.4030

Italy

Sartorius Stedim Italy S.p.A.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41
Fax +39.055.63.40.526

Netherlands

Sartorius Stedim Netherlands B.V.
Edisonbaan 24
3439 MN Nieuwegein

Phone +31.30.6025080
Fax +31.30.6025099

Spain

Sartorius Stedim Spain SA
C/Isabel Colbrand 10-12,
Planta 4, Oficina 121
Polígono Industrial de Fuencarral
28050 Madrid

Phone +34.91.3586102
Fax +34.91.3588804

Switzerland

Sartorius Stedim Switzerland GmbH
Lerzenstrasse 21
8953 Dietikon

Phone +41.44.741.05.00
Fax +41.44.741.05.09

U.K.

Sartorius Stedim UK Limited
Longmead Business Park
Blenheim Road, Epsom
Surrey KT19 9 QQ

Phone +44.1372.737159
Fax +44.1372.726171

America

USA

Sartorius Stedim North America Inc.
5 Orville Drive
Bohemia, NY 11716

Toll-Free +1.800.368.7178
Fax +1.631.254.4253

Sartorius Stedim SUS Inc.
1910 Mark Court
Concord, CA 94520

Phone +1.925.689.6650
Toll Free +1.800.914.6644
Fax +1.925.689.6988

Sartorius Stedim Systems Inc.
201 South Ingram Mill Road
Springfield, MO 65802

Phone +1.417.873.9636
Fax +1.417.873.9275

Argentina

Sartorius Argentina S.A.
Int. A. Avalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505
Fax +54.11.4762.2333

Brazil

Sartorius do Brasil Ltda
Av. Dom Pedro I, 241
Bairro Vila Pires
Santo André
São Paulo
Cep 09110-001

Phone +55.11.4451.6226
Fax +55.11.4451.4369

Mexico

Sartorius de México S.A. de C.V.
Circuito Circunvalación Poniente No. 149
Ciudad Satélite
53100 Naucalpan, Estado de México

Phone +52.5555.62.1102
Fax +52.5555.62.2942

Asia | Pacific

India

Sartorius Stedim India Pvt. Ltd.
10, 6th Main, 3rd Phase Peenya
KIADB Industrial Area
Bangalore – 560 058

Phone +91.80.2839.1963|0461
Fax +91.80.2839.8262

Japan

Sartorius Stedim Japan K.K.
KY Building, 8-11
Kita Shinagawa 1-chome
Shinagawa-ku
Tokyo 140-0001

Phone +81.3.3740.5407
Fax +81.3.3740.5406

Malaysia

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

Phone +60.3.8996.0622
Fax +60.3.8996.0755

Singapore

Sartorius Stedim Singapore Pte. Ltd.
10, Science Park Road, The Alpha
#02-25, Singapore Science Park 2
Singapore 117684

Phone +65.6872.3966
Fax +65.6778.2494

Australia

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

Phone +61.3.8762.1800
Fax +61.3.8762.1828

China

Sartorius Stedim Beijing
Representative Office
No. 33, Yu'an Road,
Airport Industrial Zone B, Shunyi District
Beijing 101300

Phone +86.10.80426516
Fax +86.10.80426580

BTChina@sartorius-stedim.com

Sartorius Stedim Shanghai
Representative Office
Room 618, Tower 1, German Centre,
Shanghai, PRC., 201203

Phone +86.21.28986393
Fax +86.21.28986392.11

BTChina@sartorius-stedim.com

Sartorius Stedim Guangzhou Office
Room 704, Broadway Plaza,
No. 233-234 Dong Feng West Road
Guangzhou 510180

Phone +86.20.8351.7921
Fax +86.20.8351.7931

BTChina@sartorius-stedim.com