



sartorius stedim
biotech

Discover our Freezing Capabilities: Celsius® Product Lines



turning science **into solutions**

Overview of the Freezing and Thawing Operations



Celsius®-Pak
(Volumes: 30 mL,
100 mL, 1 L, 2 L, 8.3 L and 16.6L)

Celsius® Controlled Freeze Thaw (CFT)



Celsius® FFT
(Volumes: 2 L, 4 L, 6 L and 12 L)

Celsius® Flexible Freeze Thaw (FFT)

Controlled Thawing Operation



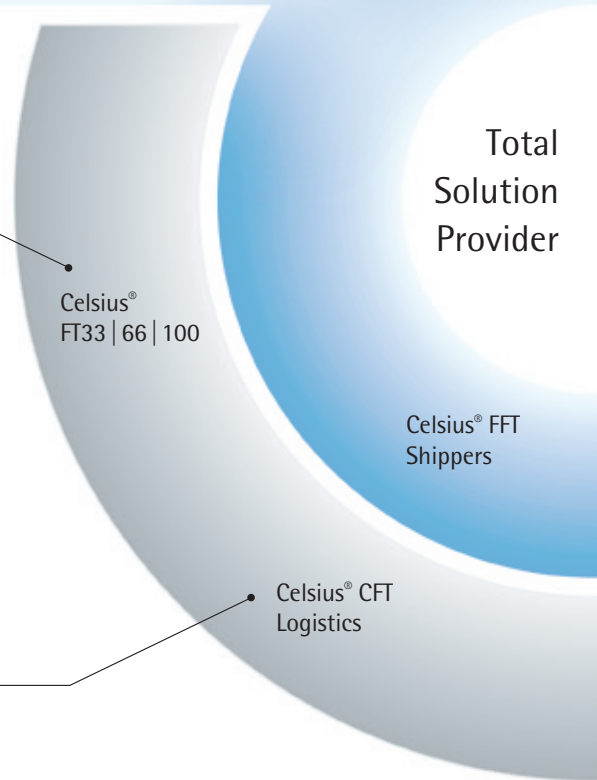
Storage & Logistics



Celsius® Shippable
Storage Module (SSM)



Celsius® SSM Shipper



Total
Solution
Provider

Celsius® FFT
Shippers

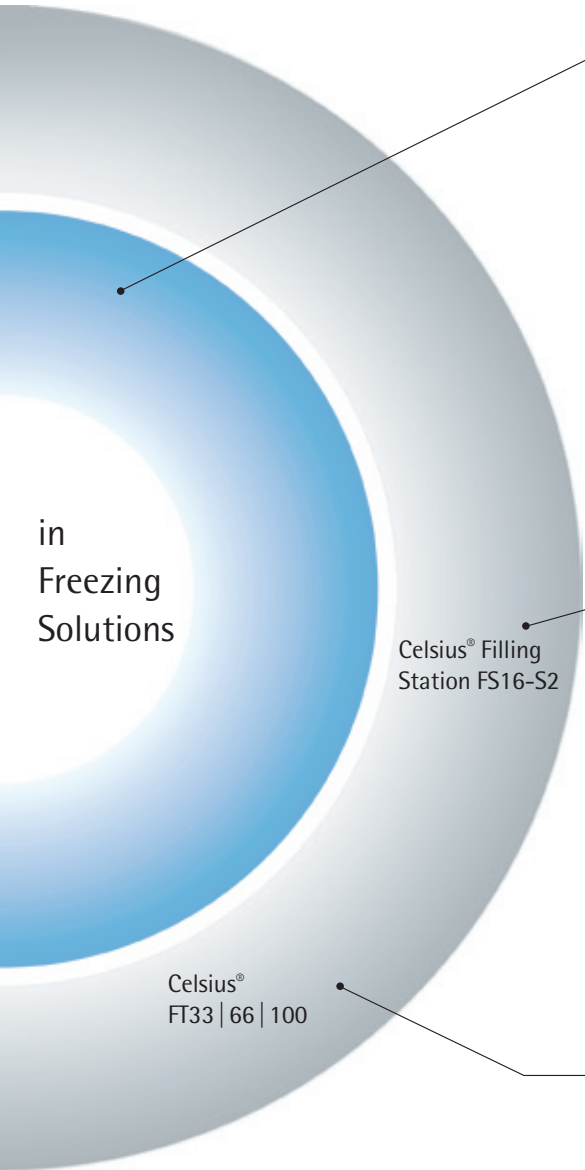
Celsius® CFT
Logistics

Celsius®
FT33 | 66 | 100

Sartorius Stedim Biotech offers comprehensive solutions, using either patented freeze-thaw technologies or conventional freezers, for the handling, storage, transfer and shipping of biopharmaceuticals.

The Celsius® CFT systems use a proprietary heat transfer technology to freeze and thaw biopharmaceutical solutions, scalable from process development to commercial scale production products.

The Celsius® FFT single-use assemblies are designed to provide the freezing container used in conventional freezer. The associated logistics for frozen storage and shipping of biopharmaceuticals is also available.



Freezing & storage in conventional freezer



Filling Operation

Celsius® Filling Station FS16-S2



Celsius® FT33 | 66 | 100

Controlled Freezing Operation



The Celsius® S3 Benchtop system is the only laboratory instrument available on the market to evaluate the Freeze and Thaw processes of new drug candidates in single-use containers with full scalability to production scale.

This tool allows generation of consistent samples library useful for evaluating stability, storage conditions and formulations.

Samples frozen in the Celsius® S³ Benchtop system may be stored at different temperatures to investigate the drug substance stability, using final scale-like conditions.

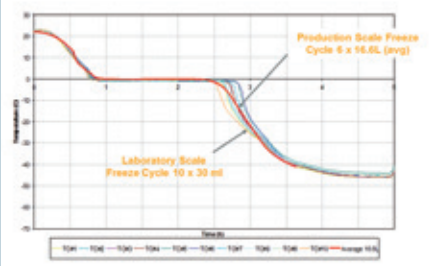


Celsius® CFT





16.6 L Process Scale vs. 30 mL S³



Celsius[®] S³ Overview





We Provide Our Support in Your Freezing Operations

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance

Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Validation

Celsius® Bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows sterility assurance level validation of 10^{-6} for each Single-Use System over its entire shelf life.

Application Support Development Studies

Feasibility studies are enabled using Sartorius Stedim Biotech Laboratory Scale Freeze and Thaw Technologies to assess the characteristics (quality, activity, robustness) of a drug substance.

The studies are designed to replicate the freeze | hold | thaw profiles of the Production Scale Controlled Freeze-Thaw Systems.

Biological entities have their own intrinsic characteristics that call for the development of product specific studies. Our applications group will work with clients to develop studies that will address the unique requirements of their biological entity.

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 A. Meucci, 4
50012 Grassano – 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

Africa

Republic of South Africa

Sartorius South Africa (Pty) Ltd
Unit 4, Alphen Square South
853 16th Road
Midrand 1685, RSA

Phone +27.11.315.5444

Americas

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
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

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