

Certificate US09/5619.00

The management system of

Sartorius Stedim North America, Inc.

565 Johnson Avenue
Bohemia, NY 11716, United States

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities:

Design, development, sale and support of products used in bioprocessing. Manufacture of membrane filters, single use bags and sampling systems.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid from 4 March 2019 until 4 March 2022 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 13: 3 September 2019. Certified since September 2002.

The audit leading to this certificate commenced on 26/07/2019. Previous issue certificate validity date was until 04/03/2022

This is a multi-site certification. Additional site details are listed on subsequent pages.

Authorized by:

Dan Seal

Dan Seal

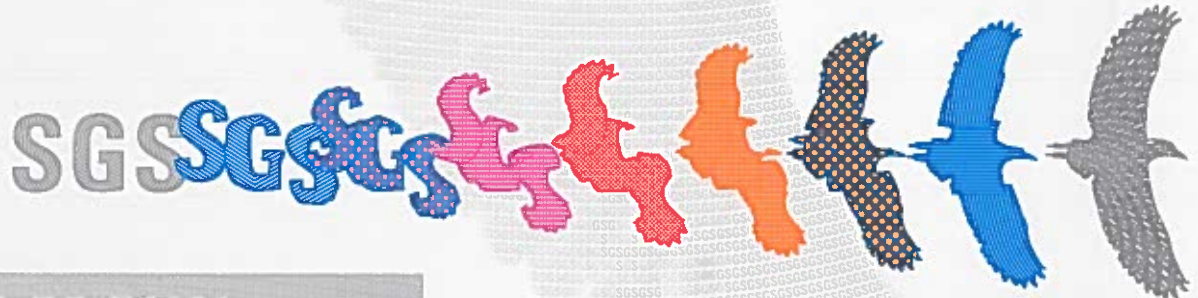
Technical Accreditation Manager, Certification & Business Enhancement North America
SGS North America, Inc.

201 Route 17 North, Rutherford, NJ 07070, USA
t (201) 508-3000 f (201) 935-4555 www.us.sgs.com

This certificate remains the property of SGS and shall be returned upon request

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Sartorius Stedim North America, Inc.

ISO 9001:2015

Issue 13: 3 September 2019

Additional facilities



565 Johnson Avenue, Bohemia, NY 11716, United States
Scope: Management and sales of bioprocessing components and systems. Management of the design and development of engineered to order bioprocessing systems. Management of field service, repair, and calibration of Sartorius Stedim bioprocessing equipment and installation. Design and development of products used in bioprocessing.

545-1 Johnson Avenue, Bohemia, NY 11716, United States
Scope: Management and sales of bioprocessing components and systems. Management of the design and development of engineered to order bioprocessing systems. Management of field service, repair, and calibration of Sartorius Stedim bioprocessing equipment and installation. Design and development of products used in bioprocessing.

Sartorius Stedim Filters, Inc., Barriada Arturo Lluberias
Road 128, Intersection 376, Yauco 00698, Puerto Rico
Scope: Production of membrane for filters, production of flat filters, injection molding, product validation laboratory.

Sartorius Stedim Filters, Inc., Bo Susua Baja, Susua Industrial Park
Road 128 Intersection 368, km 2.1 Lot 6, Yauco, Puerto Rico
Scope: Production of membrane filters and bag assemblies including the Quality, purchasing, receiving, kitting and shipping for Puerto Rico Operations.

Sartorius Stedim North America, Inc. New Oxford
80 Progress Avenue, New Oxford, PA 17350, United States
Scope: Manufacture of single use sampling systems including the Quality, purchasing, receiving, kitting and shipping operations.



Certificate US09/5619.04



The management system of

Sartorius Stedim North America, Inc.

Sartorius Stedim North America, Inc. New Oxford
80 Progress Avenue
New Oxford, PA 17350, United States

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities:

Manufacture of single use sampling systems including the Quality, purchasing, receiving, kitting and shipping operations.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.

This certificate is valid from 4 March 2019 until 4 March 2022 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 13: 3 September 2019. Certified since September 2002.

The audit leading to this certificate commenced on 26/07/2019. Previous issue certificate validity date was until 04/03/2022.

Multiple certificates have been issued for this scope
The main certificate is numbered US09/5619.00

Authorized by:

Dan Seal

Dan Seal

Technical Accreditation Manager, Certification & Business Enhancement North America
SGS North America, Inc.

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