



The management system of

Sartorius Stedim North America, Inc.

5 Orville Drive, Suite 200
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 12: 18 February 2019. Certified since September 2002.

The audit leading to this certificate commenced on 15/01/2019. Previous issue certificate validity date was until 04/03/2019.

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

Authorized by:

Christopher Malone

Christopher Malone
Vice President, 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





Sartorius Stedim North America, Inc.

ISO 9001:2015

Issue 12: 18 February 2019

Additional facilities:

5 Orville Drive, Suite 200, 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 Lluberas

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 US09/5619.02



The management system of

Sartorius Stedim Filters, Inc.

Barriada Arturo Lluberas

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Yauco, 00698, Puerto Rico

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

Authorized by:

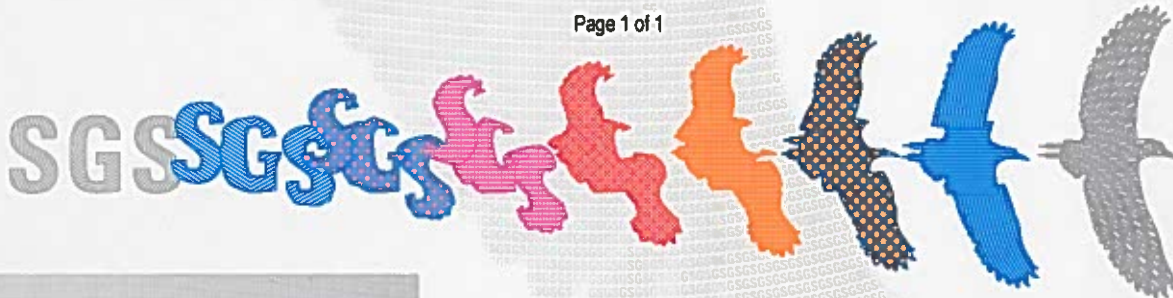
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Page 1 of 1



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Bo Susua Baja, Susua Industrial Park
Road 128 Intersection 368
km 2.1 Lot 6. Yauco. Puerto Rico

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