

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SDIX, LLC
111 Pencader Drive
Newark
Delaware
19702
USA

Holds Certificate Number:

FM 615523

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacturing of Immunological Reagents including Monoclonal and Polyclonal Antibodies, Calibrators, other Proteins for In-Vitro Diagnostics and Medical Devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-03-23

Latest Revision Date: 2024-02-26

Effective Date: 2024-03-23

Expiry Date: 2027-03-22

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Certificate No: FM 615523

Location	Registered Activities
SDIX, LLC 111 Pencader Drive Newark Delaware 19702 USA	Manufacturing of Immunological Reagents including Monoclonal and Polyclonal Antibodies, Calibrators, other Proteins for In-Vitro Diagnostics and Medical Devices.
SDIX, LLC 52 Anderson Road Windham Maine 04062 USA	Manufacturing of Immunological Reagents including Monoclonal and Polyclonal Antibodies, Calibrators, other Proteins for In-Vitro Diagnostics and Medical Devices.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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