

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 No:

FM 615523

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

The Design and Development and Manufacturer of Immunological Reagents including Monoclonal and Polyclonal Antibodies, Calibrators and Controls to the Healthcare Industry (i.e. In-Vitro Diagnostic, Biotechnology, Pharmaceutical).

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-03-23

Latest Revision Date: 2021-02-04

Effective Date: 2021-03-23

Expiry Date: 2021-09-22

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Certificate No: **FM 615523**

Location	Registered Activities
SDIX, LLC 111 Pencader Drive Newark Delaware 19702 USA	The Design and Development and Manufacturer of Immunological Reagents including Monoclonal and Polyclonal Antibodies, Calibrators and Controls to the Healthcare Industry (i.e. In-Vitro Diagnostic, Biotechnology, Pharmaceutical).
SDIX, LLC 52 Anderson Road Windham Maine 04062 USA	Manufacturer and supplier of Immunological reagents including monoclonal and polyclonal antibodies, calibrators and controls to the healthcare industry (i.e. in-vitro diagnostic, biotechnology, pharmaceutical).



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.