



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 Effective Date: 2021-03-23 Latest Revision Date: 2021-06-08 Expiry Date: 2024-03-22

Page: 1 of 2

©GEM ...making excellence a habit."
...making excellence a habit."

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.

Certificate No: **FM 615523**

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



Original Registration Date: 2015-03-23 Effective Date: 2021-03-23 Latest Revision Date: 2021-06-08 Expiry Date: 2024-03-22

Page: 2 of 2