



Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Newmarket Biomedical Ltd Unit 1 Lanwades Business Park Kentford Suffolk CB8 7PN United Kingdom

Facility ID Number: F000332

Holds Certificate No:

MDSAP 689887

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

> The design, development, manufacture and distribution of immunoassay and haemagglutination assay Invitro diagnostic reagents and kits for the detection of transmissible agents in donor screening and clinical laboratories.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-02-04

Effective Date: 2021-09-15

Expiry Date: 2024-09-14

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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.