bsi.

By Royal Charter

Certificate of Registration

QUALITY 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.

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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™