

# 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**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**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 in vitro diagnostic reagents and kits for the detection of transmissible agents in donor screening and clinical laboratories.

For and on behalf of BSI:

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Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-02-04

Effective Date: 2024-09-15

Expiry Date: 2027-09-14



BSI Group America Inc. is an MDSAP recognised auditing organization