

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Newmarket Biomedical Ltd

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

Holds Certificate Number:

MD 679075

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

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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-01-05

Latest Revision Date: 2024-07-23

Effective Date: 2024-09-15

Expiry Date: 2027-09-14



Page: 1 of 1

...making excellence a habit.™