



Certificate of Registration

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

This is to certify that:

Leica Biosystems Newcastle Ltd Balliol Business Park West

Benton Lane

Newcastle upon Tyne

NE12 8EW United Kingdom

Holds Certificate Number:

MD 595830

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 and manufacture of in-vitro diagnostic reagents and test kits used in the diagnosis of cancer, cardiac markers, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents and immunological typing.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2013-05-20

Latest Revision Date: 2022-02-15

Effective Date: 2022-02-26 Expiry Date: 2022-08-25

Page: 1 of 1

bsi.



...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory