

Certificate of Registration

QUALITY 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 their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2013-05-20

Latest Revision Date: 2025-02-05

Effective Date: 2025-02-26

Expiry Date: 2028-02-25

Page: 1 of 2



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Certificate No: MD 595830

Location	Registered Activities
Leica Biosystems Newcastle Ltd Balliol Business Park West Benton Lane Newcastle upon Tyne NE12 8EW United Kingdom	The design, development, and manufacture of in-vitro diagnostic reagents and their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.
Leica Biosystems Newcastle Ltd 2 Gosforth Park Way Newcastle NE12 8ET United Kingdom	The design and development of in-vitro diagnostic reagents and their associated ancillaries, consumables, and test kits used in the diagnosis of cancer, disease status, endocrine disorders, genetic testing, protein metabolism, transmissible agents, and immunological typing.



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Page: 2 of 2

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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