

# 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 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2013-05-20

Latest Revision Date: 2022-06-02

Effective Date: 2022-02-26

Expiry Date: 2025-02-25



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