

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Leica Biosystems Newcastle Ltd
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom

Holds Certificate No:

FM 595827

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 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, immunological typing and therapeutic drug monitoring.

This certificate is traceable to this company's original registration Certificate Number LRQ 0961307/D dated May 7, 1999 and issued by Lloyd's Register Quality Assurance, Inc.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 02/15/2013

Effective Date: 05/27/2014

Expiry Date: 05/26/2017



CMDCAS
Recognized
Registrar



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