

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
Tyne and Wear
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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-05-20

Latest Revision Date: 2019-02-26

Effective Date: 2019-02-26

Expiry Date: 2022-02-25



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