

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - 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

Facility ID Number: F000261

Holds Certificate No:

**MDSAP 696855**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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: 2019-03-04

Effective Date: 2022-02-26

Expiry Date: 2023-02-25



BSI Group America Inc. is an MDSAP authorized auditing organization

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