By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Leica Biosystems Imaging, Inc.
1360 Park Center Drive
Vista
California
92081
USA

Facility ID Number: F000262

Holds Certificate No: **MDSAP 689425**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-03-28 Effective Date: 2025-03-28 Expiry Date: 2028-03-27

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 689425**

Registered Scope:

The design and development, manufacture, distribution, installation, and servicing of in vitro diagnostic digital image capture devices and digital image viewing, management and analysis software for use in clinical pathology as an aid to cancer diagnosis.

Original Registration Date: 2019-03-28 Effective Date: 2025-03-28 Expiry Date: 2028-03-27