



Certificate of Registration

OUALITY 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

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 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-28

Effective Date: 2022-03-28

Expiry Date: 2025-03-27

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BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.