

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

Holds Certificate Number:

FM 702913

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, distribution, installation and servicing of digital image capture devices, digital image management and analysis software.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2009-08-10

Latest Revision Date: 2025-02-25

Effective Date: 2025-03-28

Expiry Date: 2028-03-27

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