



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LUMEDX Corporation Also doing business as LumedX -An Intelerad Company 305 Church at N Hills Street Floor 6 Raleigh North Carolina 27609 USA

Facility ID Number: F000270

Holds Certificate No:

**MDSAP 659125** 

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 4 - Production Quality Assurance Procedure

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282 **USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, servicing, installation, and distribution of software-only based Cardiovascular Information System products, including import and export interfaces, PACS systems, and an ECG Management system.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-08-01

Effective Date: 2024-05-06

Expiry Date: 2027-05-05

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MEDICAL DEVICE SINGLE AUDIT PROGRAM BSI Group America Inc. is an MDSAP recognised 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 <u>online</u>. 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.