

# 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: 2023-01-20

Expiry Date: 2024-05-05



BSI Group America Inc. is an MDSAP recognised auditing organization