

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



BSI Group America Inc. is an MDSAP recognised auditing organization