

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that: **LUMEDX Corporation**
110, 110th Ave NE
Bellevue
Washington
98004
USA

DUNS Number: 62-697-4505

Holds certificate No: **MDSAP 659125**

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 4 – Production Quality Assurance Procedure [if design controls are excluded from the certification]; 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

Designs, develops, manufactures, distributes, installs and services 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:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2017-08-01

Effective Date: 2019-01-17

Expiry date: 2021-05-05

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