



# CERTIFICATE OF REGISTRATION

This is to certify that

## FluxErgy Inc.

13766 Alton Pkwy Suite 150; 30 Fairbanks Suite 114; 15 Musick Irvine, California 92618 USA

**D-U-N-S: 05-976-5569**

Refer to Attachment to Certificate of Registration dated November 16, 2020 for additional certified sites operates a

## Quality Management System

which complies with the requirements of

## ISO 13485:2016 and the requirements of the following regulatory authorities

**Australia:**

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

**Brazil:**

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

**Canada:**

- Medical Device Regulations SOR/98-282, Part 1

**United States:**

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

**Design, development, manufacturing, servicing and installation of printed circuit board and IVD devices to make low-cost lab testing consumables.**

Certificate No.: CERT-0135621

File No.: 1719187

Issue Date: 2020-11-16

Original Certification Date: 2020-11-13

Certification Effective Date: 2020-11-13

Certificate Expiry Date: 2023-11-12

Heather Mahon

Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an authorized MDSAP auditing organization.



Registered by:  
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request. To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register: [https://www.saiglobal.com/en-us/assurance/auditing\\_and\\_certification/certification\\_register/](https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_register/)



# ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0135621 issued on November 16, 2020

**File No.**

**Effective Date**

1719187

**FluxErgy Inc.**

November 13, 2020

**13766 Alton Pkwy Suite 150; Irvine, California 92618 USA:**  
D-U-N-S: 05-976-5569

Research and development, Test card manufacturing, Device assembly,  
HR, Marketing and Finance.

**30 Fairbanks Suite 114; Irvine, California 92618 USA:**

Research and development, Assay manufacturing, Quality, Sales, IT,  
Purchasing, Receiving/shipping/servicing, Inventory, Warehouse,  
Installation/servicing.

**15 Musick, Irvine, California 92618 USA:**

Device assembly.