CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Elliquence, LLC

(FIN F000807)

Main Site: 2455 Grand Avenue

Baldwin, New York 11510 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

The design, manufacture and service of RF Generators, sterile, non sterile, disposable and reusable electrodes and forceps for surgical cutting and coagulation. Applications include general surgical, minimally invasive spine, interventional radiology (radiofrequency ablation), pain management and neurosurgical procedures.

Certificate Number:
0096191

Initial Certification Date:
2019-11-20

Certification Effective Date:
2019-11-20

Certification Expiry Date:
2022-11-19

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851