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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: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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, as applicable

The management system is applicable to:

The design, manufacture and service of RF generators; sterile, non-sterile, disposable and reusable electrosurgical instruments; including electrodes, forceps and procedure packs for surgical cutting, coagulation, and radiofrequency ablation. The design and manufacture of surgical instruments, including endoscopes and sterile and non-sterile reusable accessories. Applications include general surgical, minimally invasive spine, pain management and neurosurgical procedures.

Certificate Number:
0096191

Revision Level: 04

Initial Certification Date:
2019-11-20

Certification Effective Date:
2025-11-19

Certification Expiry Date:
2028-11-19

ISO 13485:2016 CERTIFICATION TM intertek

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Rathin Grover
President, Business Assurance

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