

# 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



**Intertek**

**Calin Moldovean**

President, Business Assurance

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