

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Bovie Medical Corporation

(F000758)

Main Site: 5115 Ulmerton Road

Clearwater, Florida, 33760, USA

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

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)

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

### The management system is applicable to:

*The design, development, manufacture and service of electrosurgical generators and accessories; and the contract manufacture of lighted orotracheal intubation stylets and eye bubbles, cauteries, disposable nerve locators, surgical light, electrosurgery equipment including accessories, ophthalmology burrs and power handles.*

**Certificate Number:**

01101146

**Initial Certification Date:**

02 February 2021

**Date of Certification Decision:**

02 February 2021

**Issuing Date:**

02 February 2021

**Valid Until:**

01 February 2022



**Intertek**

**Calin Moldovean**

President, Business Assurance

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