

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## LightScalpel, LLC

(FIN F000881)

Main Site: 11818 North Creek Parkway N, Suite 100,

Bothell, Washington, 98011, 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)

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)

## The management system is applicable to:

Design, Manufacturing and Servicing of surgical lasers, laser systems, and accessories.

**Certificate Number:** 

0080472-02

**Initial Certification Date:** 

2018-10-03

**Date of Certification Decision:** 

2021-10-01

**Certification Effective Date:** 

2021-10-02

**Certification Expiry Date:** 

2024-10-02



MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean

President, Business Assurance

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



