

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Trimedyne, Inc.

Main Site: 530 Technology Drive, Suite 275

Irvine, California, 92618, United States (FIN F002612)

Additional Site: 519 North Smith Avenue, units 105 and 106

Corona, California 92880 United States (FIN F004706)

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

### ISO 13485:2016

**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)

### The management system is applicable to:

*Design and Development, Production, Servicing, Installation and Distribution of Solid State Surgical Laser Systems and Laser Delivery Systems.*

*Additional Site: incoming inspection, manufacturing, service, storage, handing and shipping.*

**Certificate Number:**

0098950-01

**Initial Certification Date:**

2020-02-17

**Certification Effective Date:**

2020-03-04

**Certification Expiry Date:**

2023-02-16



Intertek

**Calin Moldovean**

President, Business Assurance

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