

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Trimedyne, Inc.

Main Site: 519 North Smith Avenue, Units 104 – 106

Corona, California, 92878, United States

(FIN F002612)

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.

Certificate Number:

0098950-03

Initial Certification Date:

2020-02-17

Certification Effective Date:

2023-02-16

Certification Expiry Date:

2026-02-16



Calin Moldovean

President, Business Assurance

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