MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 083929 0005 Rev. 00

Certificate Holder: **OSI Optoelectronics, Inc.**
12525 Chadron Avenue
Hawthorne CA 90250
USA

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate: **Design and Manufacture of Pulse Oximetry Sensors and Cables**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **61-277-0974**

Effective Date: **2018-07-19**

Expiry Date: **2021-07-18**

Date of Issue: 2018-07-31

(Arie Henkin)

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: Audit/Certification Criteria

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

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