



America

CERTIFICATE

No. QS6 083929 0005 Rev. 03

Certificate Holder:

OSI Optoelectronics, Inc.
12525 Chadron Avenue
Hawthorne CA 90250
USA

Certification Mark:



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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 083929 0005 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:QS6_083929_0005_Rev.03)

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

REPs Facility ID:

F005270

Report No.:

72195290

Effective Date:

2024-02-24

Expiry Date:

2027-02-23

Page 1 of 2

Date of Issue: 2024-02-27

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS6 083929 0005 Rev. 03

Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

OSI Optoelectronics, Inc.

12525 Chadron Avenue, Hawthorne CA 90250, USA

OSI Optoelectronics, Inc.

12515 Chadron Avenue, Hawthorne CA 90250, USA

Facility Scopes:

OSI Optoelectronics, Inc.

12525 Chadron Avenue, Hawthorne CA 90250, USA

Design and Manufacture of Pulse Oximetry
Sensors and Cables
REPs Facility ID: F005270

OSI Optoelectronics, Inc.

12515 Chadron Avenue, Hawthorne CA 90250, USA

Design and Manufacture of Pulse Oximetry
Sensors and Cables
REPs Facility ID: F005270

Page 2 of 2

Date of Issue: 2024-02-27

(Renee Walker)
Director, US Certification Body, MHS