



# Certificate

No. Q6 080989 0004 Rev. 01

**Holder of Certificate:** **OSI Optoelectronics Sdn. Bhd.**

PTD 159386, KM 6.5  
 Jalan Kampung Maju Jaya  
 Kempas Lama  
 81300 Skudai, Johor  
 MALAYSIA

**Facility(ies):**

OSI Optoelectronics Sdn. Bhd.  
 PTD 159386, KM 6.5, Jalan Kampung Maju Jaya, Kempas Lama,  
 81300 Skudai, Johor, MALAYSIA

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:**

**Production of:**

- 1) Pulse Oximetry Systems and Sensors
- 2) Reusable A1C monitors
- 3) Printed Circuit Board Assemblies for Medical Devices

**Applied Standard(s):**

EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 080989 0004 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6 080989 0004 Rev. 01)

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**Valid until:** 2025-02-17

**Date,** 2022-01-11

Christoph Dicks