ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

# Certificate

## No. Q8 070550 0015 Rev. 02

**Holder of Certificate:** **OSI Electronics Pte Ltd**
240 Macpherson Road
Pines Industrial Building #07-05
Singapore 348574
SINGAPORE

**Certification Mark:**

**Scope of Certificate:** **The provision of production services for Printed Circuit Board Assemblies, Pulse Oximetry Sensors and Related Accessories, Wire Harnesses and Cable Assemblies for Medical Devices, Headset and Related Assemblies, and Assemblies of Active Medical Devices**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 070550 0015 Rev. 02

**Report No.:** SIN_ 070550_RA_CC1_2024

**Valid from:** 2025-01-02
**Valid until:** 2027-10-31

**Date,** 2025-01-02

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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**Applied Standard(s):**

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

**Facility(ies):**

**OSI Electronics Pte Ltd**
240 Macpherson Road, Pines Industrial Building #07-05, Singapore 348574, SINGAPORE

The provision of production service for printed circuit board assemblies, pulse oximetry sensors and related accessories, wire harnesses and cable assemblies for medical devices, headset and related assemblies, and assemblies of active medical devices

**PT OSI Electronics**
Cammo Industrial Park Block F, No. 3A&No.5 Batam Center, 29431 Batam, INDONESIA

The provision of production service for printed circuit board assemblies, pulse oximetry sensors and related accessories, and assemblies of active medical devices

**PT OSI Electronics**
Cammo Industrial Park, Block F, No. 6 Batam Center, 29431 Batam, INDONESIA

The provision of production service for wire harnesses and cable assemblies for medical devices

**PT OSI Electronics**
Cammo Industrial Park Block G, No. 16, Batam Center, 29431 Batam, INDONESIA

The provision of production service for headset and related assemblies for medical devices

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