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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 067303 0021 Rev. 00

Manufacturer:

Shenzhen Med-link Electronics Tech Co., LTD.
2nd, 4th and 5th Floor, Building Two
Hualian Industrial Zone
Xinshi Community, Dalang Street
Longhua District
518109 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000011145

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 067303 0021 Rev. 00

Report No.: GZ2313601

Valid from: 2024-03-14
Valid until: 2029-03-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIb
Device Group:	C900301 - PULSE OXIMETER SENSORS
Intended Purpose:	Disposable Pulse Oximeter Probe is to be used for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Classification:	Class IIb
Device Group:	C900301 - PULSE OXIMETER SENSORS
Intended Purpose:	Reusable Pulse Oximeter Probe is to be used for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Classification:	Class IIb
Device Group:	C900301 - PULSE OXIMETER SENSORS
Intended Purpose:	Sterile Pulse Oximeter Probe is to be used for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Classification:	Class IIa
Device Group:	V03010201 - TEMPERATURE MONITORING CUTANEOUS PROBES V03010299 - BODY TEMPERATURE MONITORING PROBES - OTHER
Intended Purpose:	/

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-03-14	GZ2313601	Initial issuance

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