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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 065652 0012 Rev. 00

**Manufacturer:**

**Shenzhen Launch Electrical Co., Ltd.**
Building F
Zhonggangxing Industrial Estate
Zhangge Community, Guanlan Street
Longhua New District
518110 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000028780

**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 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:G10 065652 0012 Rev. 00

**Report No.:** GZ2212902

**Valid from:** 2023-12-19
**Valid until:** 2028-12-18

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2023-12-19


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

## No. G10 065652 0012 Rev. 00

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z1203020285 - MULTI-PARAMETER MONITORS - CONSUMABLES |
| **Intended Purpose:** | The reusable SpO2 sensor are intended used for non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). Products is indicated for use with Adults and neonate who requires the monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), the sensors are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel. |

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|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z1203020285 - MULTI-PARAMETER MONITORS - CONSUMABLES |
| **Intended Purpose:** | The Temperature Probe is a reusable cable intended for use for adult patients who require continuous temperature monitoring when used with temperature monitoring equipment, Use is limited by the indications for use of the connected monitoring equipment. Products are intended to be used by trained operators in a medical professional's environment or under the direction of a trained medical professional. |

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

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-12-19 | GZ2212902 | Initial issuance |



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