



EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

G1 049076 0016 Rev. 02

Manufacturer:

Shenzhen Creative Industry Co., Ltd.

Floor 5, BLD 9

BaiWangxin High-Tech Industrial Park

Songbai Road, Xili Street

Nanshan District 518110 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter **Monitors for Capnography and Pulse Oximetry**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

GZ1915302

Valid from:

2020-01-07

Valid until:

2024-05-26

Date.

2020-01-07

Christoph Dicks

Head of Certification/Notified Body



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Facility(ies):

Shenzhen Creative Industry Co., Ltd.

Floor 5, BLD 9, BaiWangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S

REPUBLIC OF CHINA

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Features

- 2.2 inch TFT display for SpO2, PI, Plethysmogram, PR
- MoveOxy[™]SpO2 technology with artifact removal and anti-motion performance
- Various choice of SpO2 probe for Adult, Pediatric and Neonate particularly
- Inbuilt lithium battery or AA battery for continuous monitoring
- Up to 384 hours SpO2 date storage for review
- Adjustable alarm limit, pitch tone level and key tone



Technical Specifications

SpO2

Technique: Dual-wavelength LED Measuring range: 35%~100%

Measuring accuracy: ±3% (range from 70% to 100%)

Pulse Rate

Measuring range: 30bpm~250bpm
Measuring accuracy: ±2bpm or ±2%

Perfusion Index

PI Range: 0.2%~20%

Data Storage

Up to 384 hours

Display

2.2 TFT display

Power Supply

AA disposable battery or Lithium battery

Charging

USB cable with adapter

Dimension

145 mm x 74 mm x 29 mm

Net Weight

210g

Data Upload

USB cable

Operating Environment

Operating Temperature: 5°C ~40°C
Operating Humidity: 30%~80%



Adult Clip Sensor



dult Soft Sensor



Pediatric Clip Sensor



Pediatric Soft Sensor



Neonate/Infant wrap sensor





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