Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

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

Digitally signed by Jighili Tatiana
Date: 2021.07.05 17:50:08 EEST
Reason: MoldSign Signature
Location: Moldova

Valid from: 2020-01-07
Valid until: 2024-05-26

Date, 2020-01-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

Benannt durch/Designated by
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TÜV SÜD Product Service

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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 049076 0015 Rev. 01

Holder of Certificate: **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

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of 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**

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1915310

Valid from: 2019-10-10
Valid until: 2022-10-02

Date, 2019-10-10

Stefan Preiß
Head of Certification/Notified Body

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 050440 0030 Rev. 00

Holder of Certificate: **Shenzhen Carewell Electronics Co., Ltd.**
Floor 4, BLD 9
Baiwangxin High-Tech Industrial Park
Songbai Road, Xili Street
Nanshan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Carewell Electronics Co., Ltd.
Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Infusion Pumps, Syringe Pumps, Electrocardiographs, AI-ECG Platform, AI-ECG Tracker**

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1926517

Valid from: 2019-11-11
Valid until: 2022-10-30

Date, 2019-11-11

Christoph Dicks
Head of Certification/Notified Body

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A4 / 07.17

UP-7000

Multi-parameter Patient Monitor

NIBP

Technique	Oscillometric	
Typical measuring time	<30 seconds (typical adult cuff)	
Initial cuff inflation pressure	Adult Pediatric Neonate	<175mmHg <135mmHg <65mmHg
Overpressure protection limit	Adult Pediatric Neonate	300mmHg 240mmHg 150mmHg
Measuring range		
Systolic pressure	Adult Pediatric Neonate	40mmHg~275mmHg 40mmHg~200mmHg 40mmHg~135mmHg
Diastolic pressure	Adult Pediatric Neonate	10mmHg~210mmHg 10mmHg~150mmHg 10mmHg~95mmHg
Mean arterial pressure	Adult Pediatric Neonate	20mmHg~230mmHg 20mmHg~165mmHg 20mmHg~110mmHg
Measurement accuracy	Maximum mean difference: ±5 mmHg Maximum standard deviation: 8 mmHg	
Measurement mode	Manual, Auto, STAT	
Automatic measuring intervals	1~480min	

TEMP

Measuring range	21.0°C~50.0°C
Measuring accuracy	±0.2°C for range from 25.0°C~45.0°C

SpO_2

Transducer	Dual-wave length LED
SpO_2 measuring range	0%~100%
SpO_2 measuring accuracy	2% for range from 70% to 100%
Low perfusion performance	As low as 0.4%
PR measuring range	0bpm~250bpm
PR measuring accuracy	±2bpm or ±2%, whichever is greater

ECG

Input dynamic range	±0.5mVp~±5mVp
HR measuring range	15bpm~350bpm
HR measuring accuracy	±1% or ±2bpm, whichever is greater
HR alarm delay time	≤10s
Sensitivity selection	×1/4, ×1/2, ×1, ×2, ×4 and Auto
Sweeping speed	6.25mm/s,12.5mm/s, 25mm/s, 50mm/s
ECG noise level	≤30μVp-p
ECG input loop current	≤0.1μA
Differential input impedance	≥10Mohm
Common-mode rejection ratio (CMRR)	≥105dB (Monitoring mode) ≥89dB (Diagnostic mode)
Time constant	≥0.3s (Monitoring mode) ≥3.2s (Diagnostic mode)

RESP

RR measuring range	0rpm~120rpm
RR measuring accuracy	±5% or ±2rpm, whichever is greater

Others

Power supply	100~240Vac, 50/60Hz
Built-in battery	4400mAh Lithium battery
Display	12.1 inch TFT display
Alarming mode	Audible-visual alarm
Networking port	Ethernet port

Standard Configuration

ECG, RESP, SpO_2, NIBP, TEMP, PR

Option

2-IBP, $EtCO_2$, Nellcor SpO_2 , SunTech NIBP, Cardiac Output, Built-in printer, Cerebral State Monitoring, Central monitoring system, Touch screen

CREATIVE MEDICAL TÜV SÜD CE 0123 FDA510(k)

Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street
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Tel: +86 755 2643 3514 Fax: +86 755 2643 0390
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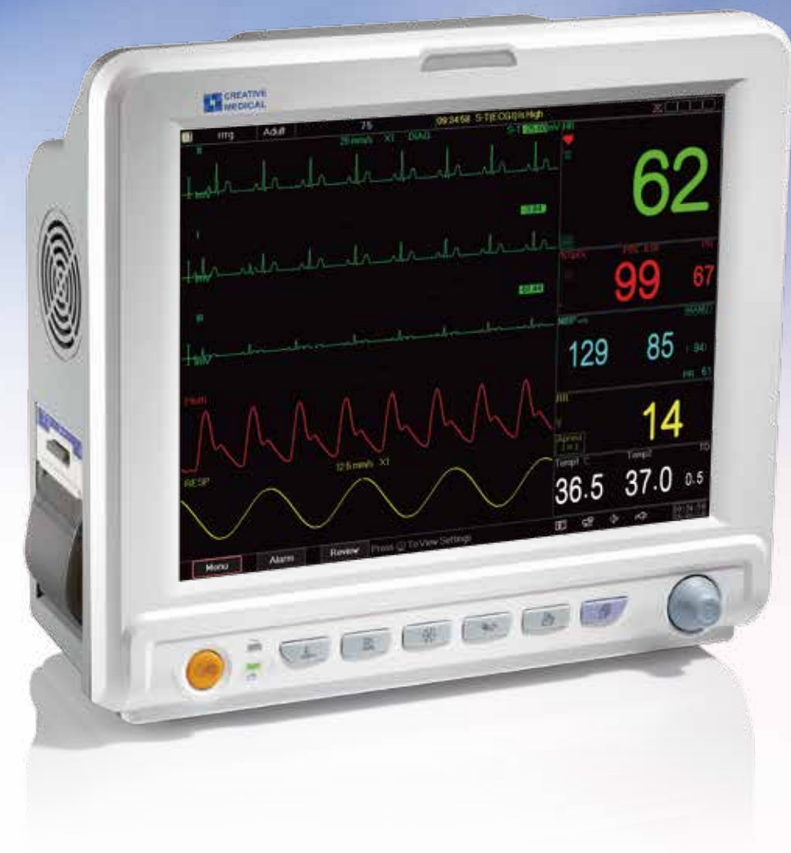
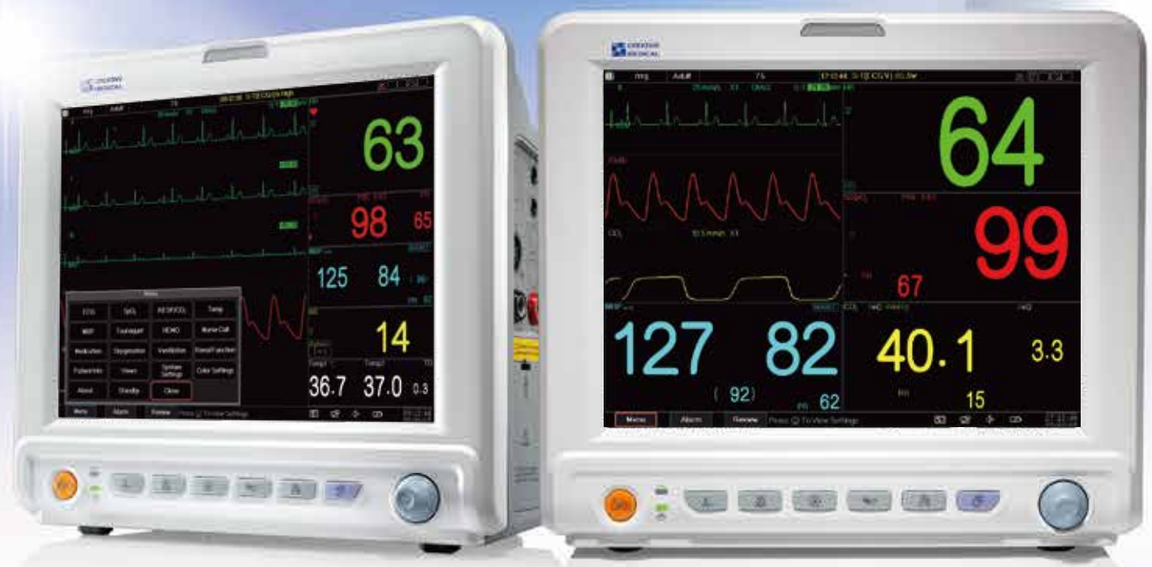
UP-7000

Multi-parameter Patient Monitor



CREATIVE MEDICAL



UP-7000

Multi-parameter Patient Monitor

FEATURES

- 12.1" high resolution TFT display with LED backlight
- Arrhythmia analysis and S-T segment measurement
- Protection against defibrillator discharge
- Adult/Pediatric/Neonate measurement modes
- Visual and audible alarms; Networking capability
- Up to 9 waveforms simulteneously display
- 72-hour ECG waveform data storage and recall
- 2000-hour data trends with graphic and tabular view
- 2000 groups event, ARR and SpO2 storage
- Built-in lithium battery; Touch screen optional

PRODUCT ACCESSORIES

Skin temperature | NIBP cuff | ECG leadwire | SpO_2 sensor

Dual IBP with EtCO2

Dual IBP with cardiac output

Cerebral state monitoring

9 waveform display