COPIA CORESPUNDE
ORIGINALULUI

EC Certificate Full Quality Assurance System: Certificate CN19/41057

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 22 January 2020 until 05 February 2023 and remains valid subject to satisfactory surveillance audits. Issue 2. Certified since 30 April 2015 and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN-SZX 50010

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPM/D5097 - Certificate CE1639 ... EN rev. 02

S.R.L.
"...MEDCOM"
IDNO 1004600066975

Shenzhen Comen Medical Instruments Co., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
Issue 2

Detailed scope

- Electrocardiograph
(Model: CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3, H12, H12A)

- Multi-parameter Patient Monitor for vital physiological parameters
(Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A,STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, Star8000F, OPUS i8, OPUS i10, OPUS i10 Expert, OPUS i12, OPUS i12 pro, OPUS i15)

- Fetal & Maternal Monitor for vital physiological parameters
(Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)

- Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A)

- Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters
(Model: C100, C100B)

- Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system
(Model: STAR8800)

- Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS i3, NC5A)

Vital Signs Monitor for routine check of NIBP, SpO2, ECG, Temperature and Pulse rate
(Model: NC5)

- Specialized Neonatal Monitor for vital physiological parameters
(Model: C60, C66, C68, Datalys 760)

- Infrared Ear thermometer (Model: IRT10, IRT10A)

- Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)

- Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)

-T piece Infant Resuscitation System (model: BQ70, BQ70A)

- Anaesthesia Machine (AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A)
- Infant Radiant Warmer (BQ80, BQ80A)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

S.R.L. "ROMEDCOM" IDNO 1004600066075 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

COPIA CORESPUNDE ORIGINALULUI

Certificate CN15/30544

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

F1~5, No. 2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen city, Guangdong province, P.R. China

Unified Social Credit Code 91440300738806174Y

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, Manufacture and Distribution of Fetal & Maternal Monitor, Multi-parameter Patient Monitor, Specialized Cardiovascular Monitor, Vital Signs Monitor, Specialized Neonatal Monitor, Specialized Fetal& Maternal Monitor, Defibrillator/Monitors, Central Monitoring System Software, Anaesthetic Gas Scavenging System, Infant Incubators, T-piece Infant Resuscitation System, Electrocardiograph, Infrared Ear Thermometer, Anaesthetic Systems, Syringe Pumps, Infusion Workstation, Infusion Pumps, Neonatal Ventilators, Medical Oxygen-air Blenders, Medical Air Compressors, Ceiling Pendant, LED Surgical Light, Infant Radiant Warmer

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 31 August 2018 until 29 April 2021 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 5. Certified since 30 April 2015

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001 2015 0118

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ROMEDCOM" S.R.L. REPUBLICA MOLDOVA IDNO 1004600060075

UKAS MANAGEMENT SYSTEMS 0005

COPIA CORESPUNDE ORIGINALULUI

Certificate CN15/30545

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

No. 2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 October 2018 until 29 April 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 February 2021
Issue 5. Certified since 30 April 2015

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

S.R.L. "ROMEDCOM"

Shenzhen Comen Medical Instruments Co., LTD.

ISO 13485:2016
EN ISO 13485:2016

Issue 5

Detailed scope

Design, Manufacture and Distribution of
- -Electrocardiograph,
- -Fetal & Maternal Monitor,
- -Multi-parameter Patient Monitor,
- -Specialized Cardiovascular Monitor,
- -Vital Signs Monitor,
- -Specialized Neonatal Monitor,
- -Specialized Fetal/Maternal Monitor,
- -Central Monitoring System Software
- -Infrared Ear thermometer
- -Anaesthetic Gas Scavenging System
- -LED Surgical Light
- -Ceiling Pendant
- -T-piece Infant Resuscitation System
-Anesthesia Machine,
-Infant Radiant Warmer.

UKAS MANAGEMENT SYSTEMS
0005

COPIA CORESPUNDE ORIGINALULUI

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Fiab SpA
Via P. Costoli, 4
Vicchio (FI)
50039
Italy

Holds Certificate Number: **MD 77846**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, servicing and retail of the following medical devices and accessories:
- Electronic devices for electrophysiology and temporary cardiac stimulation.
- Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads).
- Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG).
- Introducer kits for percutaneous use.
- Devices for the extraction of permanent intravenous and subcutaneous leads.

The stockholding and supply of medical devices, with lot traceability.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-02-25
Latest Revision Date: 2019-04-18

Effective Date: 2018-08-01
Expiry Date: 2021-07-31

...making excellence a habit.

S.R.L. "ROMEDCOM" IDNO 1006400068975 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

Certificate No: **MD 77846**

Location	Registered Activities
Fiab SpA Via P. Costoli, 4 Vicchio (FI) 50039 Italy	The manufacture of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). - Introducer kits for percutaneous use. - Devices for the extraction of permanent intravenous and subcutaneous leads. The stockholding and supply of medical devices, with lot traceability.
Fiab SpA Via Passerini 2,3,4,6 Vicchio (FI) 50039 Italy	The design, development, manufacture, servicing and retail of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). - Introducer kits for percutaneous use. - Devices for the extraction of permanent intravenous and subcutaneous leads. The stockholding and supply of medical devices, with lot traceability.
Fiab SpA Via Della Resistenza, 18 Vicchio (FI) 50039 Italy	The manufacture of the following medical devices and accessories: - Electronic devices for electrophysiology and temporary cardiac stimulation. - Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads). - Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG). - Introducer kits for percutaneous use. - Devices for the extraction of permanent intravenous and subcutaneous leads. The stockholding and supply of medical devices, with lot traceability.

Original Registration Date: 2004-02-25
Effective Date: 2018-08-01
Latest Revision Date: 2019-04-18
Expiry Date: 2021-07-31

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

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)

No. G1 070143 0004 Rev. 00

Manufacturer: **SAN-O-SUB Italia S.r.l.**
Via L. da Vinci, 168
20090 Trezzano sul Naviglio (MI)
ITALY

Facility(ies): SAN-O-SUB Italia S.r.l.
Via L. da Vinci, 168, 20090 Trezzano sul Naviglio (MI), ITALY

Product Category(ies): **Pressure regulators, pressure regulators with integrated cylinder valves, flowmeters, humidifiers for medical gases**

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.: ITA1277216

Valid from: 2019-09-16
Valid until: 2024-05-26

Date, 2019-07-10

Stefan Preiß
Head of Certification/Notified Body

"ROMEDCOM" SRL

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

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

TÜV®

A4 / 07.17

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

COPIA CORESPUNDE ORIGINALULUI

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 9045/B - Rev.003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

SAN-O-SUB ITALIA S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA L. DA VINCI 168
I - 20090 TREZZANO SUL NAVIGLIO (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI CEI EN ISO 13485:2016

SISTEMI QUALITÀ – DISPOSITIVI MEDICALI
QUALITY SYSTEMS – MEDICAL DEVICES

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, fabbricazione e immissione in commercio di dispositivi medici attivi per la regolazione di gas in alta pressione. Commercializzazione di accessori per ossigenoterapia di altri fabbricanti

Design and development, manufacturing and placing on the market of active medical devices for regulation of high pressure gases. Trade of accessories for oxygen therapy by third part manufacturer

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità / *Validity*
Dal / From: 2018-11-20
Al / To: 2021-11-17

Data emissione / *Printing Date*
2018-11-20

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2009-11-17
DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE / EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE
2018-11-17

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

S.R.L. "ROMEDCOM"

TID 1401

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

COPIA CORESPUNDE ORIGINALULUI

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 9045/A - Rev.003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

SAN-O-SUB ITALIA S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA L. DA VINCI 168
I - 20090 TREZZANO SUL NAVIGLIO (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione, fabbricazione e commercializzazione di prodotti per la regolazione di gas in alta pressione per il settore industriale, subacqueo e per il settore sanitario. Assemblaggio e commercializzazione di bombole per gas ad alta pressione
(IAF 19, 17, 18)

***Design, production and trade of high pressure gas regulator for industrial, diving and health care sector. Assembly and trade of cylinders for high pressure gas** (IAF 19, 17, 18)*

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità / *Validity*	
Dal / From:	2018-11-20
Al / To:	2021-11-17
Data emissione / *Printing Date*	2018-11-20

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2009-11-17
DATA DI SCADENZA DEL PRECEDENTE CERTIFICATO ISO 9001:2008: 2018-09-14
EXPIRATION DATE OF THE PREVIOUS CERTIFICATE ISO 9001:2008: 2018-09-14

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

"ROMEDCOM" S.R.L.

TÜV®

TI01 14.01

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

COPIA CORESPUNDE
ORIGINALULUI

TÜV SÜD
Product Service

CERTIFICATE

No. Q5 18 04 03389 001

Holder of Certificate: Silbermann Technologies Ltd.
5 HaRakevet Street
4900715 Petach Tikva
ISRAEL

Facility(ies):
Silbermann Technologies Ltd.
5 HaRakevet Street, 4900715 Petach Tikva,
ISRAEL

Silbermann Technologies Ltd.
6 Ravnitzki Street, 4900617 Petach Tikva,
ISRAEL

Certification Mark:

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

Scope of Certificate: Design and development, production, distribution, service and installation of medical gas supply systems, oxygen and vacuum therapy units, components and accessories

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.: 713122903

Valid from: 2018-07-10
Valid until: 2021-07-09

Date, 2018-07-10

Stefan Preiß

Page 1 of 1

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

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

COPIA CORESPUNDE ORIGINALULUI

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Silbermann Technologies Ltd.

5 Harakevet Street st POB 4605
4900715 Petah-Tikva
Israel

for the scope of application

Design and development, production, distribution, service and installation of medical gas supply systems, oxygen and vacuum therapy units, components and accessories

6 Ravnitzki St.
4900715 Petach Tikva
Israel

for the scope of application

Production of medical gas supply systems, oxygen and vacuum therapy units, components and accessories

has established and applies
a Quality Management System.

An audit was performed, Report No. **707088644**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2018-07-12** until **2021-03-19**.

Certificate Registration No.: **12 100 56103 TMS**.

Product Compliance Management
Munich, 2018-07-16

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

S.R.L. "ROMEDCOM" IDNO 1018600066975 SOCIETATEA PE RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

COPIA CORESPUNDE ORIGINALULUI

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)

No. G1 18 04 03389 002

Manufacturer:
Silbermann Technologies Ltd.
5 HaRakevet Street
4900715 Petach Tikva
ISRAEL

EC-Representative:
Medes Limited
5 Beaumont Gate
Shenley Hill, Radlett
Hertfordshire WD7 7AR
UNITED KINGDOM

Product Category(ies):
Medical Gas Supply Systems and Oxygen and Vacuum Therapy Units, Components and Accessories

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.: 713122903

Valid from: 2018-07-10
Valid until: 2023-07-09

Date, 2018-07-10

Stefan Preiß

"ROMEDCOM" S.R.L. IDNO 1004600066975 SOCIETATEA PE RASPUNDERE LIMITATA REPUBLICA MOLDOVA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

COPIA CORESPUNDE
ORIGINALULUI

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)

No. G1 18 04 03389 002

Facility(ies):

Silbermann Technologies Ltd.
5 HaRakevet Street, 4900715 Petach Tikva, ISRAEL

Silbermann Technologies Ltd.
6 Ravnitzki Street, 4900612 Petach Tikva, ISRAEL

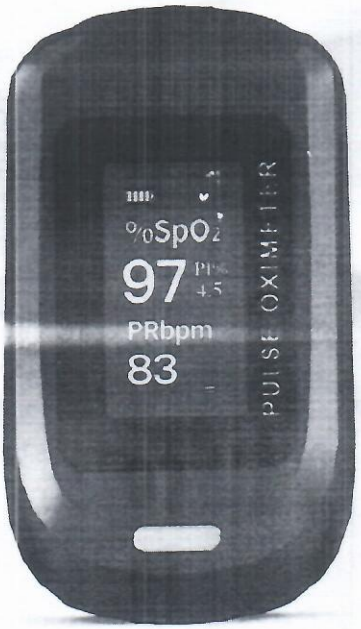
"ROMEDCOM" IDNO 1004600066975 SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA

Konsung

COPIA CORESPUNDE ORIGINALULUI

Fingertip pulse oximeter

SONOSAT-F02W



One button measurement

Flexible finger chamber

Three-proof design

Pulse bar graph

Durable and Reliable

Audible & visual alarm

Features:

- Parameter: SPO2, HR, PI
- TFT color screen with four direction display
- One button operation, simple and easy
- 8s auto power off without operation
- Compact body and portable to carry

Specification:

Product model: F03T

Dimensions: 59*34*30mm

Screen type: OLED bi-color display

Battery: 2 X AAA 1.5V alkaline batteries

SpO2 measuring accuracy:
70-100%: ±2%, ≤ 70% unspecified

PR measuring accuracy:
±2BPM or ±2% (select larger)

Body weight: 50g (Include 2 X AAA batteries)

Security type: class 2 BF type application equipment

Product Specification: finger clip type

SpO2 measuring range: 0~100%(the resolution is 1%)

PR measuring range:
30~250BPM(the resolution is 1BPM)

Package:
Oximeter, hanging rope, user manual, warranty card

ROMEDCOM

SGS

CORESPUNDE
GINALULUI

EC Certificate Full Quality Assurance System: CN14/31039

The management system of

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

NO. 8, Shengchang West Road, Danyang Development Zone,
Jiangsu Province, 212300, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 20 June 2017 until 19 June 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 3 July 2020
Issue 4. Certified since 8 September 2014

Certification is based on reports numbered CN/SZX 49730

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

"ROMEDCOM" S.R.L.

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 4

Detailed scope

Fingertip Pulse Oximeter used for home care and medical outpatient department;
Wrist Pulse Oximeter used for home care and medical outpatient department;
Patient Monitor used for vital physiological parameters
Models: AURORA 8; AURORA 10; AURORA 12; AURORA 8s; AURORA 10s; AURORA 12s;
Handheld Monitor used for Measuring Multiple Physiological Parameters
Models: SONOSAT-H01A, SONOSAT-H01B, SONOSAT-H01C

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

Room A01, 14th floor, 1st Hall, Gaoxinqi Strategic Emerging Industrial Park, Plan 2, LiuXianYi Road, No. 67, Baoan District, Shenzhen City, Guangdong Province, 518101, P.R. China

COPIA CORESPUNDE ORIGINALULUI

Certificate CN14/31038

The management system of

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

NO. 8, Shengchang West Road, Danyang Development Zone,
Jiangsu Province, 212300, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 04 April 2019 until 07 September 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 03 July 2020
Issue 3. Certified since 08 September 2014

Expiry date of last certificate: 31 March 2019
End date of last recertification audit: 18 March 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 3

Detailed scope

Design and manufacture of Fingertip Pulse Oximeter, Wrist Pulse Oximeter, Handheld Monitor, Patient Monitor and Urine Analyzer

Additional facilities

Room A01, 14th Floor, 1st Hall, Gaoxinqi Strategic Emerging Industrial Park, Plan 2, LiuXianYi Road, No. 67, Baoan District, Shenzhen City, Guangdong Province, 518101, P.R. China

UKAS MANAGEMENT SYSTEMS
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