

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

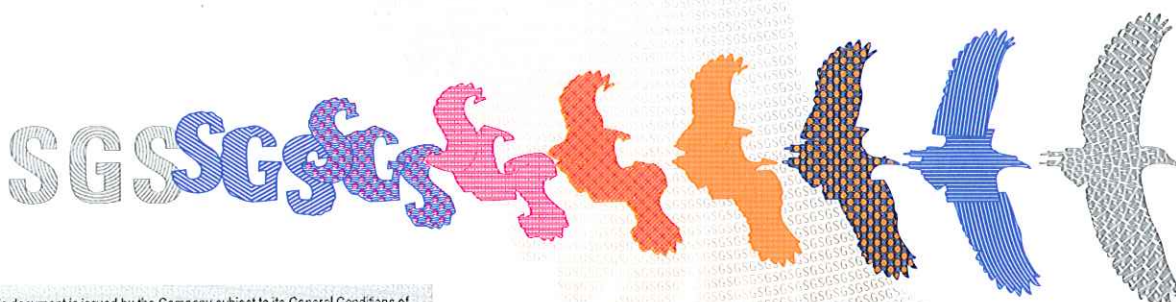


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LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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# 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, CO<sub>2</sub>, NIBP, SpO<sub>2</sub>, 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, SpO<sub>2</sub>, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS i3, NC5A)

Vital Signs Monitor for routine check of NIBP, SpO<sub>2</sub>, 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.



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## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

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This certificate is valid from 22 March 2021 until 05 February 2023  
and remains valid subject to satisfactory surveillance audits.  
Issue 3. Certified since 30 April 2015.

Certification is based on reports numbered CN/SZX 50010

Authorised by



Global Medical Devices Head of Notified Body

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# Shenzhen Comen Medical Instruments Co., Ltd.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

- **Electrocardiograph (Model: CM300, CM300A, 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, K12 pro, K12A pro, K15 pro, K15A pro, K18 pro, K18A pro, K22 pro, K22A pro, K1, K1A)
  - **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, C10, C11)**
  - **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 (Model: AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A, AX-400, AX-500, AX-600, AX-700)**
    - Infant Radiant Warmer (Model: BQ80, BQ80A)
    - Catheter-positioning guiding system (Model: U8, U8A)
    - Syringe Pump (Model: M300, M500)
    - Infant Phototherapy equipment (Model: BL70, BL70A, BL70B)
  - **Temperature Control System for management patient body temperature and vital physiological parameters Monitor (Model: P3, P6)**
  - **Sequential Compression System for prevention of deep vein thrombosis and pulmonary embolism (Model: SCD600)**
    - Defibrillator Monitor (Model: S8, S6, S5, S3)
- Sterility aspect only Restricted to the Aspect of manufacture concerned with securing and maintaining sterile conditions:**
- Sterile disposable laryngoscope blade (Model: CVL-2-1, CVL-3-1)
  - Sterile disposable electrode with extension wire used for Catheter-positioning guiding system (Model: 98ME01AC019)

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.





Certificate CN15/30545

The management system of

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Guangming 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 22 January 2020 until 29 April 2021  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 04 February 2021  
Issue 6. Certified since 30 April 2015

Authorised by

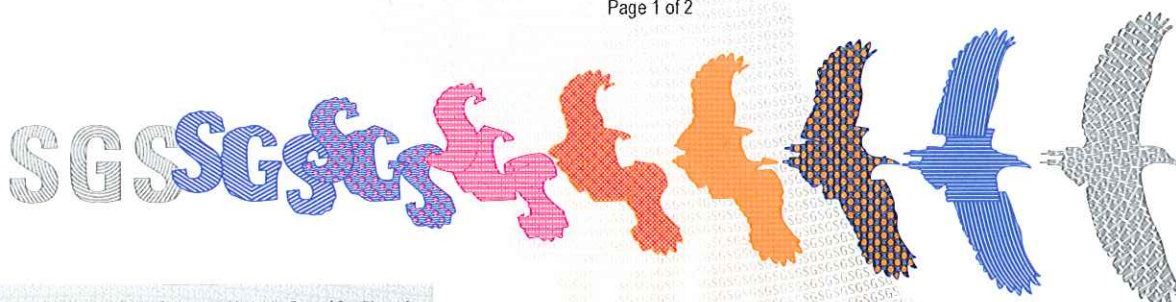


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# Shenzhen Comen Medical Instruments Co., LTD.

## ISO 13485:2016 EN ISO 13485:2016



Issue 6

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.



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COMEN Share with the World



Shenzhen Comen Medical Instruments Co., Ltd.

P/N: EN-S3-8P-20210528-V1.0

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Tel: +86-755-2640 8879 400-700-9488 Fax: +86-755-2643 1232 Website: en.comen.com E-mail: info@szcomen.com

**S3** Defibrillator Monitor





### Defibrillation

Manual defibrillation modes include synchronous cardioversion and asynchronous defibrillation.

4 in 1

### AED

The model applies patented analysis algorithm and automated analysis as well as convenient setting to guide clinical emergency personnel in providing defibrillation and basic life support.

### Pacing

Having on-demand pacing and fixed pacing mode, for patients with cardiac arrest and acute severe slow arrhythmia, in vitro non-invasive pacing mode is rapid, easy to master, time-saving and improve recovery success rate.

### Monitor

5-lead ECG monitoring as standard, optional monitoring functions include SpO<sub>2</sub>, NIBP, PR are also available for continuous monitoring of patient vital signs.

## Fast Defibrillation

### 1 knob

Mode can be switched among manual defibrillation, pacing and AED. In manual defibrillation, the user can complete the energy selection within 1 second.

### 3s

Defibrillator charge to 200J and shock in 3 seconds, rescue time is guaranteed fully.

### 3 steps

Fulfill defibrillating operation (Energy selection – Charging – Discharging).



# Emergency and transportation



## EN 1789 certificated

S3 designed for ambulance and emergency transportation, after rigorous testing, it acquired EN 1789 certification.



## Compact yet lighter

The S3 is perfect design of small size and lightweight(down to 5.6kg) defibrillator/monitor so as to be readily portable in the pre-hospital and hospital environment effectively.



## Longest lifespan

Two kinds of battery capacity, both of them provide excellent performance, support fast charging up to 210 times of maximum discharges, satisfy clinical requirements.



## Better protection

With the protection of IP44, S3 offers reliable performance in a variety of adverse conditions.



# Advanced BTE Technology

Higher efficiency with Advanced Biphasic Truncated Exponential (BTE) waveform technology and automatic impedance compensation.

Up to 360J energy selection, for patients with high defibrillation thresholds such as myocardial infarction, obesity, high impedance, higher energy selection indicates greater defibrillation success rate.

## Multifunctional Paddles

### 1 for 2

Electrode paddles can be divided into large and small electrode paddles which can defibrillate for both adult and child respectively.

### 1 pair

Defibrillating operation can be completed on a pair of electrode paddles.