

EC Certificate Full Quality Assurance System: Certificate CN15/30546

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

## 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 06 March 2019 until 05 February 2023  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 February 2021

Issue 10. Certified since 30 April 2015

Certification is based on reports numbered CN/SZX 50010

Authorised by

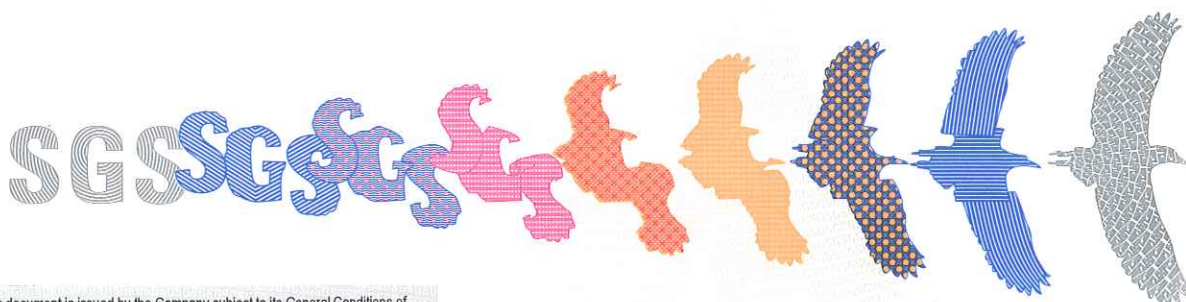
*Jonathan M. Hall*

**SGS United Kingdom Ltd, Notified Body 0120**

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 [www.sgs.com](http://www.sgs.com)

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# Shenzhen Comen Medical Instruments Co., LTD.

## Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 10

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)
- 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