

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

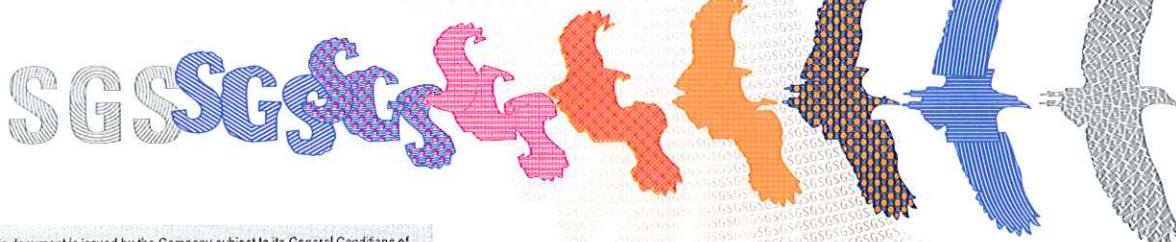


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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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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, 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.



Certificate CN15/30545

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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

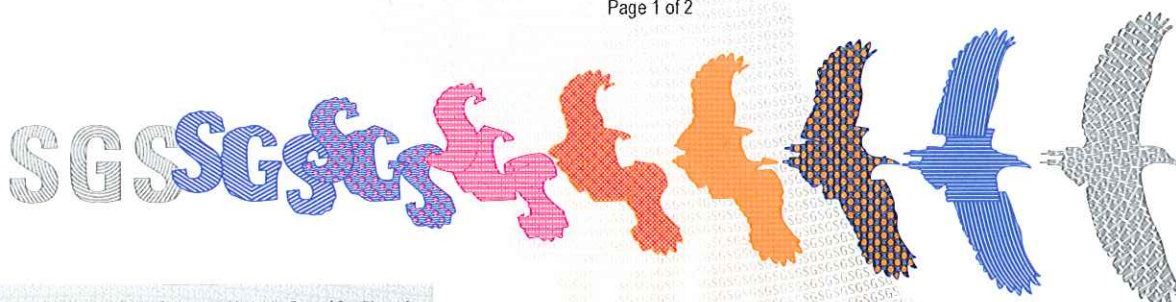


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extent of the law.

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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