EC Certificate Full Quality Assurance System: CN15/30546

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

South of Floor 7, Block 5, 4th Industrial Area of Nanyou,
Nanshan District, Shenzhen, 518052, Guangdong, 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 February 2018 until 05 February 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 February 2021
Issue 7. Certified since 30 April 2015

Certification is based on reports numbered CN/SZX 50010

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

Authorised by

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EC Certificate Full Quality Assurance System: CN15/30546, continued

Shenzhen Comen Medical Instruments Co., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 7

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)
- 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)
- 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)

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

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