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 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

Digitally signed by Cobzari-Ţurcan Rodica
Date: 2023.11.16 17:00:10 EET
Reason: MoldSign Signature
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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.

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