Certificate CN20/608235

The quality 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 City, Guangdong Province, 518106, P.R. China
Facility number: F004371

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820, Quality Management System Regulation, 21 CFR Part 821 - Device Tracking

For the following activities
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from Effective date 2026-06-07 until Expiry date 2029-06-07 and remains valid subject to satisfactory surveillance audits.
Issue 9. Certified since 2020-08-04
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Head of Certification and Compliance
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.

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Shenzhen Comen Medical Instruments Co., Ltd.

MDSAP (ISO 13485:2016)

Issue 9

Design, Manufacture and Service of
Specialized Fetal & Maternal Monitor for the area of obstetrics & gynaecology;
Multi-parameter Patient Monitor for the area of cardiovascular and anaesthesiology;
Vital Signs Monitor, Electrocardiograph, Defibrillator Monitor, Semi-Automatic External Defibrillator, Automated External Defibrillator, Automatic CPR (Cardiopulmonary Resuscitation) Machine, CPR (Cardiopulmonary Resuscitation) Sensor and Central Monitoring System Software for the area of cardiovascular;
Anesthesia Machine, High flow heated respiratory humidifier, Respiratory Humidifier, Emergency and Transport Ventilator, Ventilator, T-piece Infant Resuscitation System, Medical Air Compressor, High Frequency Vibration Sputum Excretion System and Neonatal and Pediatric Ventilators for the area of anaesthesiology;
Medical Infant Bassinet, Infant Radiant Warmer, Neonatal Incubator, Infant Phototherapy Equipment, Infant Transport Incubator, Infant Incubator, Medical Examination Light and Neonatal Phototherapy Bed for the area of General Hospital;
Syringe Pump, Infusion Pump, Infusion workstation system, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, 4K Endoscopic Camera System for the area of General Hospital;
Sequential Compression System, Temperature Control System for the area of Physical Medicine;
Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, CO2 Insufflator and Endoscopic Flushing Pump for the area of gastroenterology/urology;
Diagnostic Ultrasound System for the area of Radiology;
Operating Table and Mobile Surgical Light for the area of general & plastic surgery;
Video Laryngoscope and Electric Bronchoscope for the area of Ear, Nose, and Throat devices;
Design and manufacture of Sterile Disposable Laryngoscope Blade for the area of Ear, Nose, and Throat devices;
Design, manufacture, Installation and Service of LED Surgical Light and Ceiling Pendant for the area of general & plastic surgery

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Certificate CN20/608235, continued

Shenzhen Comen Medical Instruments Co., Ltd.

MDSAP (ISO 13485:2016)

Issue 9

Sites

Campus:
Floor 3 of Ruihui Building, Intersection of Fuli South Road and Fangyuan Road, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Campus:
Room 301 and Room 302, Room 402 & Room 403, No.86 of Xianneng Road, Tianliao Community, Yutang Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Campus:
Room 302, Unit B & Floor 3-4, Unit A, No. 1 Factory, Guancheng Sanliang Industrial Park, No.2, Chenxing Road, Huangjiang Town, Dongguan City, Guangdong Province, 523000, P.R. China

Campus:
Floor 1-4 & Floor 10, No. 3 Factory, Building 2, Phase 4 of No. 4 Industrial Zone (formerly known as Hengshou Science and Technology Park), Heshuikou Community, Martian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Campus:
C301 of EBOHR Building, Timepieces Base, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

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