Certificate CN15/30545

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

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 31 March 2026 until 31 March 2029 and remains valid subject to satisfactory surveillance audits.

Issue 16. Certified since 30 April 2015

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by
Liz Moran
Business Manager

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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Shenzhen Comen Medical Instruments Co., Ltd.

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Design, Manufacture, Installation and Service 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, T piece Infant Resuscitation System, Anesthesia Machine, Infant Radiant Warmer, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Temperature Control System for management patient body temperature and vital physiological parameters monitor, Video Laryngoscope, Sterile Disposable Laryngoscope blade, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Compression Cuff, Neonatal Incubator, Automatic External Defibrillator, High Frequency Chest Wall Oscillator, Medical Infant Bassinet, Neonatal/Pediatric Ventilator, Infusion workstation system, Infant Transport Incubator, Infusion pump, Patient Warming Blanket, Mobile Surgical Light, Neonatal phototherapy bed, Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Mobile Surgical Light, Infusion Management System, Electric bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, Operating Table, Respiratory Humidifier, ICP monitor, Anesthesia Vaporizer, Automatic CPR Machine, CPR sensor, 4K Endoscopic Camera System, Infant Incubator, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active) and Disposable Breathing Circuit Kit (Active), Ceiling Pendant.

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Shenzhen Comen Medical Instruments Co., Ltd.

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Medical devices - Quality management systems - Requirements for regulatory purposes

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Sites

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

Design, Installation, Service and Management Support 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, T piece Infant Resuscitation System, Anesthesia Machine, Infant Radiant Warmer, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Temperature Control System for management patient body temperature and vital physiological parameters monitor, Video Laryngoscope, Sterile Disposable Laryngoscope blade, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Compression Cuff, Neonatal Incubator, Automatic External Defibrillator, High Frequency Chest Wall Oscillator, Medical Infant Bassinet, Neonatal/Pediatric Ventilator, Infusion workstation system, Infant Transport Incubator, Infusion pump, Patient Warming Blanket, Mobile Surgical Light, Neonatal phototherapy bed, Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Mobile Surgical Light, Infusion Management System, Electric bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, Operating Table, Respiratory Humidifier, ICP monitor, Anesthesia Vaporizer, Automatic CPR Machine, CPR sensor, 4K Endoscopic Camera System, Infant Incubator, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active) and Disposable Breathing Circuit Kit (Active), Ceiling Pendant.

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Shenzhen Comen Medical Instruments Co., Ltd.

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Sites

Shenzhen Comen Medical Instruments Co., Ltd.
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

Warehousing Support of Design and Manufacture 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, T piece Infant Resuscitation System, Anesthesia Machine, Infant Radiant Warmer, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Temperature Control System for management patient body temperature and vital physiological parameters monitor, Video Laryngoscope, Sterile Disposable Laryngoscope blade, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Compression Cuff, Neonatal Incubator, Automatic External Defibrillator, High Frequency Chest Wall Oscillator, Medical Infant Bassinet, Neonatal/Pediatric Ventilator, Infusion workstation system, Infant Transport Incubator, Infusion pump, Patient Warming Blanket, Mobile Surgical Light, Neonatal phototherapy bed, Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Mobile Surgical Light, Infusion Management System, Electric bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, Operating Table, Respiratory Humidifier, ICP monitor, Anesthesia Vaporizer, Automatic CPR Machine, CPR sensor, 4K Endoscopic Camera System, Infant Incubator, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active) and Disposable Breathing Circuit Kit (Active).

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Shenzhen Comen Medical Instruments Co., Ltd.

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Sites

Shenzhen Comen Medical Instruments Co., Ltd.
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

Manufacture of Anaesthetic Gas Scavenging System, T piece Infant Resuscitation System, Anesthesia Machine, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Neonatal Incubator, High Frequency Chest Wall Oscillator, Neonatal/Pediatric Ventilator, Infant Transport Incubator, Respiratory Humidifier, Anesthetic Vaporizer, Infant Incubator, Infant Radiant Warmer, Temperature Control System for management patient body temperature and vital physiological, Medical Infant Bassinet, Patient Warming Blanket, Neonatal phototherapy bed, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, LED Surgical Light, Mobile Surgical Light, Mobile Surgical Light, Operating Table, Electric Bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, 4K Endoscopic Camera System, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active) and Disposable Breathing Circuit Kit (Active).

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Shenzhen Comen Medical Instruments Co., Ltd.

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Sites

Shenzhen Comen Medical Instruments Co., Ltd.
Room 302, Unit B & Floor 3-4, Unit A, No.1 Factory, Guanchang Sanliang Industrial Park, No.2, Chenxing Road, Huangjiang Town, Dongguan City, Guangdong Province, 523000, P.R. China
Warehousing Support of Design and Manufacture 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, T piece Infant Resuscitation System, Anesthesia Machine, Infant Radiant Warmer, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Temperature Control System for management patient body temperature and vital physiological parameters monitor, Video Laryngoscope, Sterile Disposable Laryngoscope blade, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Compression Cuff, Neonatal Incubator, Automatic External Defibrillator, High Frequency Chest Wall Oscillator, Medical Infant Bassinet, Neonatal/Pediatric Ventilator, Infusion workstation system, Infant Transport Incubator, Infusion pump, Patient Warming Blanket, Mobile Surgical Light, Neonatal phototherapy bed, Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Mobile Surgical Light, Infusion Management System, Electric bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, Operating Table, Respiratory Humidifier, ICP monitor, Anesthesia Vaporizer, Automatic CPR Machine, CPR sensor, 4K Endoscopic Camera System, Infant Incubator, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active) and Disposable Breathing Circuit Kit (Active).

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Sites

Shenzhen Comen Medical Instruments Co., Ltd.
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
Manufacture 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, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, Compression Cuff, Automatic External Defibrillator, Infusion workstation system, Infusion pump, ICP monitor, Automatic CPR Machine, CPR sensor; Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Infusion Management System, Video Laryngoscope, Sterile Disposable Laryngoscope blade.

Warehousing and Management Support of Design and Manufacture 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, T piece Infant Resuscitation System, Anesthesia Machine, Infant Radiant Warmer, Infant Phototherapy equipment, Catheter-positioning guiding system (including Sterile Disposable electrode with extension wire), Syringe Pump, Temperature Control System for management patient body temperature and vital physiological parameters monitor, Video Laryngoscope, Sterile Disposable Laryngoscope blade, Sequential Compression System for Prophylaxis of Vein Thrombosis and for alleviation of limb venous edema and pain, Defibrillator Monitor, High flow heated respiratory humidifier, Emergency and Transport Ventilator, Ventilator, Compression Cuff, Neonatal Incubator, Automatic External Defibrillator, High Frequency Chest Wall Oscillator, Medical Infant Bassinet, Neonatal/Pediatric Ventilator, Infusion workstation system, Infant Transport Incubator, Infusion pump, Patient Warming Blanket, Mobile Surgical Light, Neonatal phototherapy bed, Temperature Sensor, Reusable SpO2 sensor, Disposable SpO2 sensor, ECG cable, CO2 Dehumidification Tubing, CO2 Water Filter Assembly, CO2 Airway Adapter, NIBP CUFF, Mobile Surgical Light, Infusion Management System, Electric bronchoscope, Upper Gastrointestinal Video Endoscope, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Video Processor, Medical Endoscopic Light Source, Operating Table, Respiratory Humidifier, ICP monitor, Anesthesia Vaporizer, Automatic CPR Machine, CPR sensor, 4K Endoscopic Camera System, Infant Incubator, Medical Oxygen-air Blenders, Medical Air Compressors, Neonatal ventilator, nCPAP generator with accessories, Heated Breathing Tube and Chamber Kit, Diagnostic Ultrasound System, Disposable Breathing Circuit Kit (Non-active), Disposable Breathing Circuit Kit (Active) and Ceiling Pendant.

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Shenzhen Comen Medical Instruments Co., Ltd.

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Medical devices - Quality management systems - Requirements for regulatory purposes

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Sites

Shenzhen Comen Medical Instruments Co., Ltd.
C301 of EBOHR Building, Timepieces Base, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Manufacture of Diagnostic Ultrasound System.

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