Certificate CN15/30544
CN Number F00126Q00885R302

The management system of

Shenzhen Comen Medical Instruments Co., Ltd.

Unified Social Credit Code: 91440300738806174Y
Business Registration Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China (one license for multiple addresses)
Business Operation Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

has been assessed and certified as meeting the requirements of

ISO 9001:2015

Quality management systems - Requirements

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 28 April 2026 until 29 April 2027 and remains valid subject to satisfactory surveillance audits.
Issue 15. 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
t +44 (0)151 350-6666 - www.sgs.com

The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

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Certificate CN15/30544, continued
CN Number F00126Q00885R302

Shenzhen Comen Medical Instruments Co., Ltd.

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Issue 15

Design, development, manufacture and sales of Electronic endoscope, Functional Supply of Medical Endoscopy, Operating Table, Ceiling Pendant, Surgical Light Devices, Temperature Control Systems/ Devices, T piece Infant Resuscitation System, Infant Radiant Warmer, Medical Infant Bessinet, Infant/Neonatal Incubator, High Frequency Chest Wall Oscillator, Anaesthetic machine, Auxiliary Devices of Anaesthetic, Ventilator, Auxiliary Devices of Ventilator, Diagnostic Ultrasound System, Automatic CPR (Cardiopulmonary Resuscitation) Machine, Infusion Pump, Syringe Pump, Infusion Workstation System, Phototherapy Devices, External Defibrillator Devices, Patient Monitor Devices, Accessories of Patient Monitor Devices, Specialized Fetal & Maternal Monitor and Accessories, Electrocardiograph, Infrared Ear Thermometer, Central Monitoring System, Sequential Compression System and Accessories
Design, development and sales of iWork - Clinical Information Management System, Smart - Medical IoT Information Management System
Design and development of ICP (Intracranial pressure monitor) Monitor and Accessories

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Certificate CN15/30544, continued
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Shenzhen Comen Medical Instruments Co., Ltd.

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Quality management systems - Requirements

Issue 15

Sites

Shenzhen Comen Medical Instruments Co., Ltd.
Unified Social Credit Code: 91440300738806174Y
Business Registration Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China (one license for multiple addresses)
Business Operation Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Design, development and sales of Electronic endoscope, Functional Supply of Medical Endoscopy, Operating Table, Ceiling Pendant, Surgical Light Devices, Temperature Control Systems/Devices, T piece Infant Resuscitation System, Infant Radiant Warmer, Medical Infant Bessinet, Infant/Neonatal Incubator, High Frequency Chest Wall Oscillator, Anaesthetic machine, Auxiliary Devices of Anaesthetic, Ventilator, Auxiliary Devices of Ventilator, Infusion Pump, Syringe Pump, Infusion Workstation System, Phototherapy Devices, External Defibrillator Devices, Patient Monitor Devices, Accessories of Patient Monitor Devices, Specialized Fetal & Maternal Monitor and Accessories, Electrocardiograph, Infrared Ear Thermometer, Central Monitoring System, Sequential Compression System and Accessories, iWork-Clinical Information Management System, Smart-Medical IoT Information Management System, Automatic CPR (Cardiopulmonary Resuscitation) Machine and Diagnostic Ultrasound System.
Design and development of ICP (Intracranial pressure monitor) Monitor and Accessories

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Issue 15

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Business Operation Address: 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

Warehouse management and Incoming inspection process management in support of the Design, development, manufacture and sales of Electronic endoscope, Functional Supply of Medical Endoscopy, Operating Table, Ceiling Pendant, Surgical Light Devices, Temperature Control Systems/Devices, T piece Infant Resuscitation System, Infant Radiant Warmer, Medical Infant Bessinet, Infant/Neonatal Incubator, High Frequency Chest Wall Oscillator, Anaesthetic machine, Auxiliary Devices of Anaesthetic, Ventilator, Auxiliary Devices of Ventilator, Infusion Pump, Syringe Pump, Infusion Workstation System, Phototherapy Devices, External Defibrillator Devices, Patient Monitor Devices, Accessories of Patient Monitor Devices, Specialized Fetal & Maternal Monitor and Accessories, Electrocardiograph, Infrared Ear Thermometer, Central Monitoring System, Sequential Compression System and Accessories, Automatic CPR (Cardiopulmonary Resuscitation) Machine and Diagnostic Ultrasound System and design, development and sales of iWork–Clinical Information Management System, Smart–Medical IoT Information Management System and design and development of ICP (Intracranial pressure monitor) Monitor and Accessories

Shenzhen Comen Medical Instruments Co., Ltd.
Unified Social Credit Code: 91440300738806174Y
Business Registration Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China (one license for multiple addresses)
Business Operation Address: Room 403, Room 402, Room 302 and Room 301, No. 86 of Xianneng Road, Tianliao Community, Yutang Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

Manufacture of Electronic endoscope, Functional Supply of Medical Endoscopy, Operating Table, Ceiling Pendant, Surgical Light Devices, Temperature Control Systems/ Devices, T piece Infant Resuscitation System, Infant Radiant Warmer, Medical Infant Bessinet, Infant/Neonatal Incubator, High Frequency Chest Wall Oscillator, Anaesthetic machine, Auxiliary Devices of Anaesthetic, Ventilator, Auxiliary Devices of Ventilator, Diagnostic Ultrasound System

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Business Operation Address: Floor 302 Unit B, Floor 3&4 Unit A, Building 1, Guancheng Sanliang Industrial Park, No. 2 of Xingguangchenxing Road, Huangjiang Town, Dongguan, Guangdong Province, 523000, P.R. China

Warehouse management in support of the Design, development, manufacture and sales of Electronic endoscope, Functional Supply of Medical Endoscopy, Operating Table, Ceiling Pendant, Surgical Light Devices, Temperature Control Systems/Devices, T piece Infant Resuscitation System, Infant Radiant Warmer, Medical Infant Bessinet, Infant/Neonatal Incubator, High Frequency Chest Wall Oscillator, Anaesthetic machine, Auxiliary Devices of Anaesthetic, Ventilator, Auxiliary Devices of Ventilator, Infusion Pump, Syringe Pump, Infusion Workstation System, Phototherapy Devices, External Defibrillator Devices, Patient Monitor Devices, Accessories of Patient Monitor Devices, Specialized Fetal & Maternal Monitor and Accessories, Electrocardiograph, Infrared Ear Thermometer, Central Monitoring System, Sequential Compression System and Accessories, Automatic CPR (Cardiopulmonary Resuscitation) Machine and Diagnostic Ultrasound System and design, development and sales of iWork–Clinical Information Management System, Smart–Medical IoT Information Management System and design and development of ICP (Intracranial pressure monitor) Monitor and Accessories

Shenzhen Comen Medical Instruments Co., Ltd.
Unified Social Credit Code: 91440300738806174Y
Business Registration Address: 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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China (one license for multiple addresses)
Business Operation Address: 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 Infusion Pump, Syringe Pump, Infusion Workstation System, Phototherapy Devices, External Defibrillator Devices, Patient Monitor Devices, Accessories of Patient Monitor Devices, Specialized Fetal & Maternal Monitor and Accessories, Electrocardiograph, Infrared Ear Thermometer, Central Monitoring System, Sequential Compression System and Accessories, Automatic CPR (Cardiopulmonary Resuscitation) Machine

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

Manufacture of Ultrasonic transducer used for Diagnostic Ultrasound System

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