

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

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 March 2021 until 29 April 2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 February 2024
Issue 8. Certified since 30 April 2015



Authorised by



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ISO 13485:2016 EN ISO 13485:2016



Issue 8

Detailed scope

- Design, Manufacture and Distribution 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
 - Ceiling Pendant
 - 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
 - Operating table



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