

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



SGS United Kingdom Ltd Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



0005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms\_and\_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-d-clients-and-products/certified-client-directory.

Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest

SGS

Certificate CN15/30545, continued

## Shenzhen Comen Medical Instruments Co., Ltd.

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

- Sterile Disposable Laryngoscope blade

High flow heated respiratory humidifier
 Emergency and Transport Ventilator



- Operating table

- Sequential Compression System for Prophylaxis of Vein Thrombosis

temperature and vital physiological parameters Monitor

and for alleviation of limb venous edema and pain

Page 2 of 2

- Ventilator

- Video Laryngoscope

- Defibrillator Monitor