

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

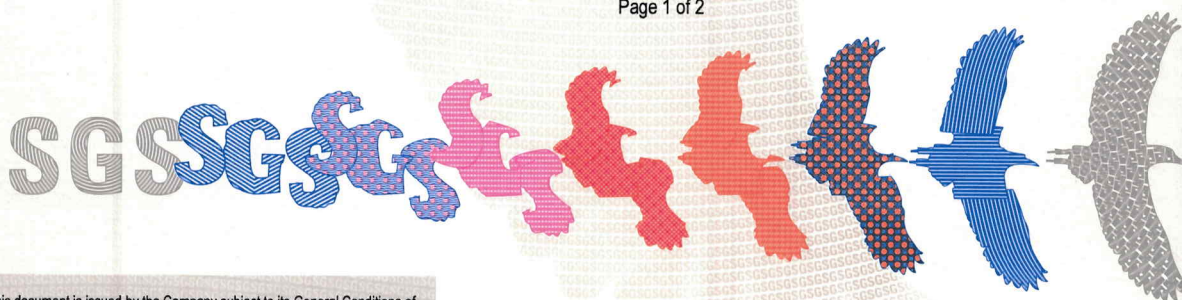


0005

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



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-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 extent of the law.

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 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



0005



此为证书 CN15/30545 译本
This is an SGS translation of CN15/30545 Issue 8

下述组织

深圳市科曼医疗设备 有限公司

中国广东省深圳市光明区马田街道南环大道飞亚达钟表大厦 1A
栋 10-11 层, 12C, 2 栋 1-5 层



的管理体系已经过审核, 并被证明符合下述要求

ISO 13485:2016 EN ISO 13485:2016

所涉及的活动范围覆盖

所涉及的活动范围显示在第二页

该证书的有效期自 2021-03-02 至 2024-04-29
并须经过符合要求的监督审核保持有效
持续认证需在 2024-02-04 之前执行
版本号 8. 初始注册日期 2015-04-30

签署

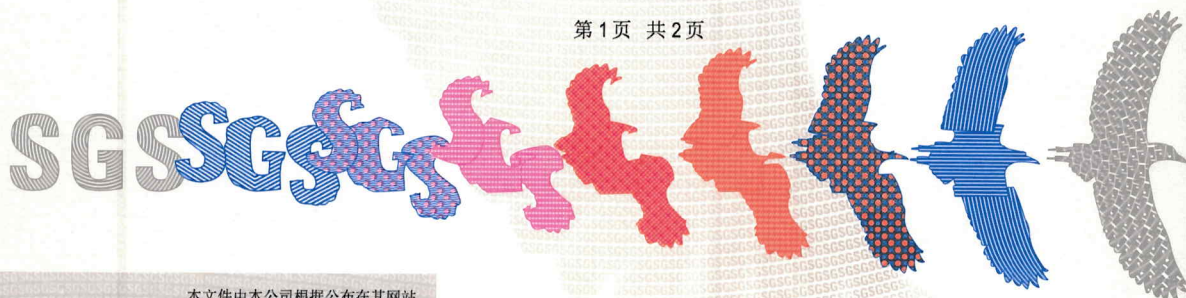


0005

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

第 1 页 共 2 页



本文件由本公司根据公布在其网站
www.sgs.com/terms_and_conditions.htm 中的认证服务通用条款颁发。提
请注意其中已确定的责任范围, 赔偿和司法管辖事项。本文件的真
实性可在网站 <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory> 中核实。任何未经授权的对此文件的内容或外观的变
更、伪造或篡改皆属非法, 违反者将会被依法追究。

此为证书 CN15/30545 译本，续
This is an SGS translation of CN15/30545 Issue8, Continued

深圳市科曼医疗设备 有限公司

ISO 13485:2016 EN ISO 13485:2016

Issue 8

所涉及的活动范围覆盖

- 设计、生产和销售
 - 心电图机
- 母亲/胎儿/病人多参数监护仪
 - 病人监护仪
- 心血管专用监护仪
 - 生命体征监测仪
- 新生儿专用监护仪
 - 产科专用监护仪
- 中央监护系统
- 红外耳式体温计
- 麻醉废气传输回收系统
 - 手术灯
 - 吊塔
- T 组合婴儿复苏系统
 - 麻醉机
 - 辐射保暖台
- 新生儿蓝光治疗仪
- 置管引导定位系统（包括一次性灭菌的带延长线的电极）
 - 注射泵
- 医用控温系统，用于管理病人体温和监护重要的生理参数
 - 视频喉镜
- 一次性灭菌喉镜片
- 间歇脉冲加压抗栓系统，用于预防静脉血栓形成和减轻肢体
 - 静脉水肿和疼痛
 - 除颤监护仪
 - 呼吸湿化治疗仪
 - 急救转运呼吸机
 - 呼吸机
 - 病床

