

Certificate CN15/30544  
The management system of

## Shenzhen Comen Medical Instruments Co., Ltd.

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, Matian  
Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China  
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, Matian  
Sub-district, Guangming District, Shenzhen, 518106, Guangdong, P.R. China

Unified Social Credit Code 91440300738806174Y  
has been assessed and certified as meeting the requirements of

### ISO 9001:2015

For the following activities

Design, Production and Sales of Fetal& Maternal Monitor, Multi-parameter Patient Monitor,  
Specialized Cardiovascular Monitor, Vital Signs Monitor, Specialized Neonatal Monitor,  
Specialized Fetal & Maternal Monitor, Defibrillator Monitor, Central Monitoring System  
Software, Anaesthetic Gas Scavenging System, Infant Incubator, T-piece Infant Resuscitation  
System, Electrocardiograph, Infrared Ear Thermometer, Anaesthesia Machine, Infusion Pump,  
Infusion Workstation, Syringe Pump, Neonatal Ventilator, Medical Oxygen-air Blender, Medical  
Air Compressor, Ceiling Pendant, LED Surgical Light, Infant Radiant Warmer, Infant  
Phototherapy Equipment, Catheter-positioning Guiding System, Temperature Control System,  
Video Laryngoscope, Sequential Compression System, High Flow Heated Respiratory  
Humidifier, Emergency and Transport Ventilator, Ventilator  
Design and Sales of Sterile disposable laryngoscope blade

This certificate is valid from 30 April 2021 until 29 April 2024  
and remains valid subject to satisfactory surveillance audits.  
Recertification audit due a minimum of 60 days before the expiration date.  
Issue 7. Certified since 30 April 2015

Authorised by

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
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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](http://www.cnca.gov.cn)



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of the law.

此为证书 CN15/30544 译本

下述组织

# 深圳市科曼医疗设备有限公司

注册地址: 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

经营地址: 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

统一社会信用代码 91440300738806174Y

的管理体系已经过审核, 并被证明符合下述要求

## ISO 9001:2015

所涉及的活动范围覆盖

母亲/胎儿/病人多参数监护仪, 多参数病人监护仪, 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, 除颤监护仪, 中央监护系统, 麻醉废气传输回收系统, 培养监护系统, T-组合婴儿复苏系统, 心电图机, 红外耳式体温计, 麻醉机, 输液泵, 输注工作站, 注射泵, 新生儿呼吸机, 医用空氧混合器, 医用空气压缩机, 吊塔, 手术无影灯, 婴儿辐射保暖台, 新生儿蓝光治疗仪, 置管引导定位系统, 医用控温系统, 视频喉镜, 间歇脉冲加压抗栓系统, 高流量呼吸湿化治疗仪, 急救转运呼吸机, 呼吸机的设计、生产和销售, 一次性灭菌喉镜片的设计和制造



该证书的有效期自 2021 年 04 月 30 日至 2024 年 04 月 29 日  
组织必须定期接受监督审核并经审核合格此证书方继续有效  
持续认证至少在证书失效前 60 天执行  
版本号 7. 初始注册日期 2015 年 04 月 30 日

签署



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Rossmore Business Park Ellesmere Port Cheshire CH65 3 EN UK  
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本证书信息可在国家认证认可监督管理委员会官方网站[www.cnca.gov.cn](http://www.cnca.gov.cn)上查询

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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

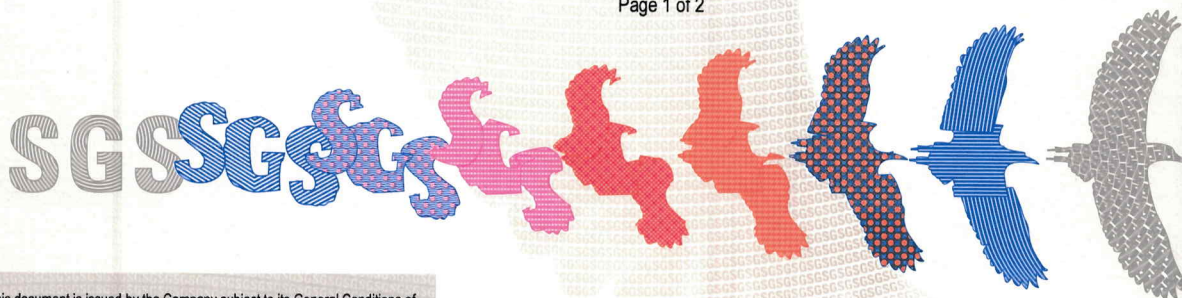


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# Shenzhen Comen Medical Instruments Co., Ltd.

## 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



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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

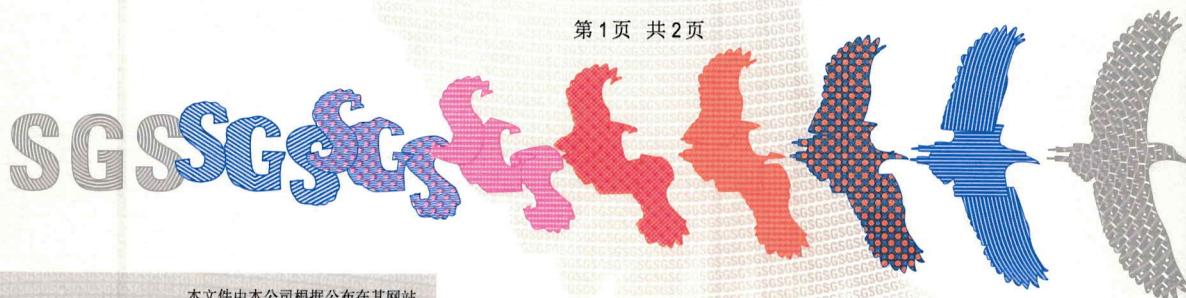


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此为证书 CN15/30545 译本，续  
This is an SGS translation of CN15/30545 Issue8, Continued

## 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



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