IEC QUALITY ASSESSMENT SYSTEM (IECQ)

For rules and details of the IECQ visit www.iecq.org

IECQ Certificate of Conformity
Hazardous Substance Process Management

IECQ Certificate No.: **IECQ-H SGSCN 20.0027** Issue No.: **9** Status: **Current**
Supersedes: IECQ-H SGSCN 20.0027 Issue 8 Issue date: **2026-05-14** Initial: **2015-05-14**
CB Reference No.: CN22/00000729 Expiration: **2028-05-13**

Applicable to:

- **EU Directive 2011/65/EU** ("RoHS – Restriction of the use Of certain Hazardous Substances") in electrical and electronic equipment. Including all published amendments

Applicant: **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, Mashatou Community, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, China

The organization has established and implemented restricted/hazardous substances process management procedures and related processes, which have been assessed by an IECQ Conformity Assessment Body, in accordance with IECQ 03-1 and IECQ 03-5, for the issuance of this certificate, and found to be in conformity with the applicable requirements to the IECQ Hazardous Substances Process Management Scheme, and in respect of the IECQ Specification:

- **IECQ QC 080000:2017** Hazardous Substance Process Management (HSPM) System Requirements

This Certificate is applicable for the following scope of activity:

Overall scope:
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.
Design and development of ICP (Intracranial pressure monitor) Monitor and Accessories.
Master site scope:
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, Automatic CPR (Cardiopulmonary Resuscitation) Machine and Diagnostic Ultrasound System.
Design and development of ICP (Intracranial pressure monitor) Monitor and Accessories.

-- Attached schedule(s): none

Issued by: **SGS-CSTC Standards Technical Services Co. Ltd.**
F16 Century YuHui Mansion, 73 Fucheng Rd.
Beijing, China

Authorised person: David Xin

The validity of this certificate is maintained through on-going surveillance audits by the IECQ CB issuing this certificate.
This Certificate of Conformity may be suspended or cancelled (withdrawn) in accordance with the Rules of Procedure of the IECQ System.
This certificate and any schedule(s) may only be reproduced in full and is not transferable and remains the property of the issuing IECQ CB.
The Status and authenticity of this certificate may be verified by visiting www.iecq.org

IEC QUALITY ASSESSMENT SYSTEM (IECQ)

For rules and details of the IECQ visit www.iecq.org

Additional Sites Covered by this IECQ Certification

IECQ Certificate No.: IECQ-H SGSCN 20.0027 Issue No.: 9

IECQ-H SGSCN 20.0027-02 Site Added: **2023-05-10**

Shenzhen Comen Medical Instruments Co., Ltd.
Floor 3 of Ruihui Building, Intersection of Fuli South Road and Fangyuan Road, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, China

Scope of activity at this site:

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 and development of ICP (Intracranial pressure monitor) Monitor and Accessories.

IECQ-H SGSCN 20.0027-05 Site Added: **2024-05-27**

Shenzhen Comen Medical Instruments Co., Ltd.
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, China

Scope of activity at this site:

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.

IECQ-H SGSCN 20.0027-06 Site Added: **2024-05-27**

Shenzhen Comen Medical Instruments Co., Ltd.
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, China

Scope of activity at this site:

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 and development of ICP (Intracranial pressure monitor) Monitor and Accessories.

IECQ-H SGSCN 20.0027-08 Site Added: **2024-05-27**

Shenzhen Comen Medical Instruments Co., Ltd.
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, China

Scope of activity at this site:

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.

IECQ-H SGSCN 20.0027-09 Site Added: **2026-05-13**

Shenzhen Comen Medical Instruments Co., Ltd.
C301 of EBOHR Building, Timepieces Base, Guangming District, Shenzhen, Guangdong Province, 518106, China
Scope of activity at this site:
Manufacture of Ultrasonic transducer used for Diagnostic Ultrasound System.

IEC 质量评定体系 (IECQ)

IECQ有关规则及详情，请访问 www.iecq.org

IECQ 符合性证书
有害物质过程管理

IECQ 证书号码: **IECQ-H SGSCN 20.0027**
颁发次数: **9**
状态: **Current**
取代: IECQ-H SGSCN 20.0027 Issue 8
发证日期: **2026-05-14**
初次决定日期: **2015-05-14**
认证机构文件号码: CN22/00000729
有效期: **2028-05-13**

适用于:

- **EU Directive 2011/65/EU** ("RoHS – Restriction of the use Of certain Hazardous Substances") in electrical and electronic equipment. Including all published amendments

申请人: **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马山头社区南环大道飞亚达钟表大厦1栋A10层-11层，12C，2栋1-5层 518106

该组织已建立并实施受限/有害物质过程管理程序及相关过程，经IECQ符合性评定机构依据IECQ 03-1和IECQ 03-5进行评定，确认其符合IECQ有害物质过程管理方案的适用要求及下列IECQ规范，特颁发此证书。

- **IECQ QC 080000:2017** Hazardous Substance Process Management (HSPM) System Requirements

本证书适用于以下活动范围:

总范围:
电子内窥镜，医用内窥镜功能供给，手术台，吊塔，手术照明设备，温热（冷）治疗设备/器具，T-组合婴儿复苏系统，婴儿辐射保暖台，医用婴儿床，婴儿培养箱，排痰机，麻醉机，麻醉辅助装置，呼吸设备，呼吸设备辅助装置，输液泵，注射泵，输液信息采集系统，蓝光治疗设备，体外除颤设备，病人监护设备，病人监护设备附件，产科专用监护仪及附件，心电图机，红外耳式体温计，中央监护系统，间歇脉冲加压抗栓系统及附件, 心肺复苏机，便携式彩色多普勒超声系统的设计开发、生产和销售
颅内压监护仪及附件的设计开发
主地址范围:
电子内窥镜，医用内窥镜功能供给，手术台、吊塔、手术照明设备，温热（冷）治疗设备/器具，T-组合婴儿复苏系统，婴儿辐射保暖台，医用婴儿床，婴儿培养箱，排痰机，麻醉机，麻醉辅助装置，呼吸设备，呼吸设备辅助装置，输液泵，注射泵，输液信息采集系统，蓝光治疗设备，体外除颤设备，病人监护设备，病人监护设备附件，产科专用监护仪及附件，心电图机，红外耳式体温计，中央监护系统，间歇脉冲加压抗栓系统及附件，心肺复苏机，便携式彩色多普勒超声系统的设计开发和销售
颅内压监护仪及附件的设计开发

-- 附件附表: 无

发证机构: **SGS-CSTC Standards Technical Services Co. Ltd.**
F16 Century YuHui Mansion, 73 Fucheng Rd.
Beijing

授权人: David Xin

本证书效力由颁发此证的IECQ符合性评定机构进行持续监督审核来予以维持。
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IEC 质量评定体系 (IECQ)

IECQ有关规则及详情，请访问 www.iecq.org

本 IECQ 认证所涵盖的附加场所

IECQ 证书号码: IECQ-H SGSCN 20.0027 颁发次数: 9

IECQ-H SGSCN 20.0027-02 新增场所: **2023-05-10**

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富利南路与芳园路交汇处瑞辉大厦3楼 518106

本场所的活动范围:

支持电子内窥镜，医用内窥镜功能供给，手术台，吊塔，手术照明设备，温热（冷）治疗设备/器具，T-组合婴儿复苏系统，婴儿辐射保暖台，医用婴儿床，婴儿培养箱，排痰机，麻醉机，麻醉辅助装置，呼吸设备，呼吸设备辅助装置，输液泵，注射泵，输液信息采集系统，蓝光治疗设备，体外除颤设备，病人监护设备，病人监护设备附件，产科专用监护仪及附件，心电图机，红外耳式体温计，中央监护系统，间歇脉冲加压抗栓系统及附件，心肺复苏机，便携式彩色多普勒超声系统的设计开发、生产和销售；颅内压监护仪及附件的设计开发的仓库管理和来料检验过程管理

IECQ-H SGSCN 20.0027-05 新增场所: **2024-05-27**

深圳市科曼医疗设备有限公司
中国广东省深圳市光明区玉塘街道田寮社区先能路86号301、302、402、403 518106

本场所的活动范围:

电子内窥镜，医用内窥镜功能供给，手术台，吊塔，手术照明设备，温热（冷）治疗设备/器具，T-组合婴儿复苏系统，婴儿辐射保暖台，医用婴儿床，婴儿培养箱，排痰机，麻醉机，麻醉辅助装置，呼吸设备，呼吸设备辅助装置，便携式彩色多普勒超声系统的生产

IECQ-H SGSCN 20.0027-06 新增场所: **2024-05-27**

深圳市科曼医疗设备有限公司
中国广东省东莞市黄江镇星光辰星路2号冠城三良智慧工业园一号厂房A单元3楼-4楼、B单元302 523000

本场所的活动范围:

支持电子内窥镜，医用内窥镜功能供给，手术台，吊塔，手术照明设备，温热（冷）治疗设备/器具，T-组合婴儿复苏系统，婴儿辐射保暖台，医用婴儿床，婴儿培养箱，排痰机，麻醉机，麻醉辅助装置，呼吸设备，呼吸设备辅助装置，输液泵，注射泵，输液信息采集系统，蓝光治疗设备，体外除颤设备，病人监护设备，病人监护设备附件，产科专用监护仪及附件，心电图机，红外耳式体温计，中央监护系统，间歇脉冲加压抗栓系统及附件，心肺复苏机，便携式彩色多普勒超声系统的设计开发、生产和销售；颅内压监护仪及附件的设计开发的仓库管理

IECQ-H SGSCN 20.0027-08 新增场所: **2024-05-27**

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合水口社区第四工业区第四期第二栋（原名恒寿科技园）3号厂房第1-4层、10层 518106

本场所的活动范围:

输液泵，注射泵，输液信息采集系统，蓝光治疗设备，体外除颤设备，病人监护设备，病人监护设备附件，产科专用监护仪及附件，心电图机，红外耳式体温计，中央监护系统，间歇脉冲加压抗栓系统及附件，心肺复苏机的生产

IECQ-H SGSCN 20.0027-09 新增场所: **2026-05-13**

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马山头社区钟表基地依波大厦C301 518106

本场所的活动范围:

便携式彩色多普勒超声系统探头的生产