IEC QUALITY ASSESSMENT SYSTEM (IECQ)

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IECQ Certificate of Conformity
Hazardous Substance Process Management

IECQ Certificate No.: **IECQ-H SGSCN 20.0027-08** Issue No.: **9** Status: **Current**

Additional Site to Certification: IECQ-H SGSCN 20.0027 Initial Date: 2015-05-14

Supersedes: IECQ-H SGSCN 20.0027-08 Issue 8 Issue date: **2026-05-14** Site Added: **2024-05-27**

CB Reference No.: CN22/00000729.08 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 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

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:

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.

-- 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This Certificate of Conformity may be suspended or cancelled (withdrawn) in accordance with the Rules of Procedure of the IECQ System.
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The Status and authenticity of this certificate may be verified by visiting www.iecq.org

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 20.0027-08** 颁发次数: **9** 状态: **Current**

Additional Site to Certification: IECQ-H SGSCN 20.0027 初次决定日期: 2015-05-14

取代: IECQ-H SGSCN 20.0027-08 Issue 8 发证日期: **2026-05-14** 新增场所: **2024-05-27**

认证机构文件号码: CN22/00000729.08 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

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:

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

-- 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

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