IEC QUALITY ASSESSMENT SYSTEM (IECQ)

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IECQ Certificate of Conformity
Hazardous Substance Process Management

IECQ Certificate No.: **IECQ-H SGSCN 20.0027-05** Issue No.: **9** Status: **Current**

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

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

CB Reference No.: CN22/00000729.05 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.**
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

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 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.

-- 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This Certificate of Conformity may be suspended or cancelled (withdrawn) in accordance with the Rules of Procedure of the IECQ System.
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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 20.0027-05** 颁发次数: **9** 状态: **Current**

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认证机构文件号码: CN22/00000729.05 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玉塘街道田寮社区先能路86号301、302、402、403 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:

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

-- 附件附表: 无

发证机构: **SGS-CSTC Standards Technical Services Co. Ltd.**
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Beijing

授权人: David Xin

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