

广东外办



21009953

2100005320

土耳其 1 / 2 (SH) Y

深圳市科曼医疗设备有限公司
深圳国立商事认证中心

证明书

CERTIFICATE



中国国际贸易促进委员会暨中国国际商会
China Council for the Promotion of International Trade is China Chamber of International Commerce

00002838

中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



214403A0/024833

号码 No.

兹证明：在所附声明上的深圳市科曼医疗设备有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. on the annexed DECLARATION is genuine.

China Council for the Promotion
of International Trade

商事证明专用章

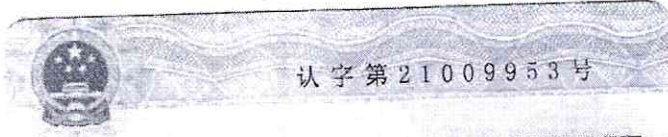
授权签字:

Authorized
Signature: LIU JUN

日期: 2021年04月26日
(Date: Apr. 26, 2021)

证书查询网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>





兹证明前面文书上中国国际
贸易促进委员会商事证明专用章
CCPIT (24) 的印章和授权签
字人 刘俊 的签字属实。



中华人民共和国外交部 (440)
二〇二一年四月二十八日 广州

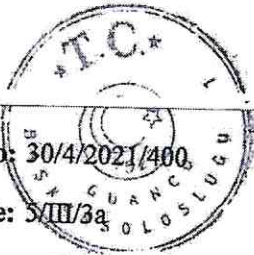
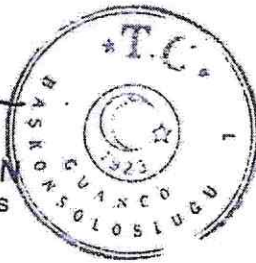
[Handwritten signature]



00783376

T.C.
GUANCO BAŞKONSOLOSLUĞU
İşbu belge üzerindeki imza ve mührün
Guangdong Dışişleri Ofisi'ne
ait bulunduğu, metne şamil olmamak
üzere onaylanır.

[Handwritten signature]
Selçuk ALKAN
Muavin Konsolos
Vice Consul



No: 30/4/2021/400

Tarife: 5/III/3a

Harç: 124 Yuan

Makbuz No: 28708424





SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD

Add: No.2 of FIYTA Timepiece Building, Nanhuan Avenue,
Gongming sub-district, Guangming District, Shenzhen, P.R China.
Tel: +86-755-26408879 Fax: +86-755-26431232
www.szcomen.com info@szcomen.com

声明 Declaration

兹证明我公司确已经取得 SGS 所颁发的 CE 证书;
WE HEREBY CERTIFY THAT WE HAS ACQUIRED CE CERTIFICATE, WHICH
IS ISSUED BY SGS;

证书编号: CN19/41057
CERTIFICATE REGISTRATION NO: CN19/41057

颁发时间: 2021-03-22
DATE OF ISSUE: 2021-03-22

有效期至: 2023-02-05
VALID UNTIL: 2023-02-05

证书影印件如下页, 且此影印件与原件相符。
THE FOLLOWING PAGE IS A PIECE OF THE CERTIFICATE AND THE
PHOTOCOPIER IS IN CONFORMITY WITH THE ORIGINAL.



Mac 汪胜飞/Turkey General Manager 土耳其总经理
Authorized Signature

深圳市科曼医疗设备有限公司
SHENZHEN COMEN MEDICAL INSTRUMENTS CO.,LTD.

2021 年 04 月 21 日
April 21th, 2021





EC Certificate Full Quality Assurance System: Certificate CN19/41057

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

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 22 March 2021 until 05 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 30 April 2015.

Certification is based on reports numbered CN/SZX 50010

Authorised by

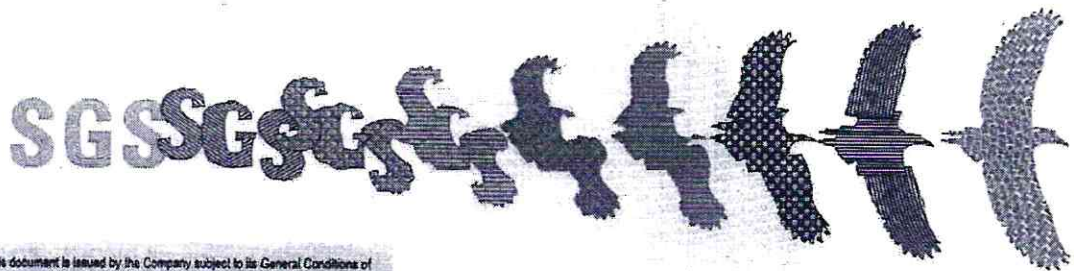
Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545 48 48 f +32 (0)3 545 48 49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 2



This document is issued by the Company subject to its General Conditions of
Certification Services, unless otherwise agreed, 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 <https://www.sgs.com/en/verified-clients-and-products/verified-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.



Certificate CN19/41057 continued

Shenzhen Comen Medical Instruments Co., Ltd. Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

- Electrocardiograph (Model: CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A)
 - Multi-parameter Patient Monitor for vital physiological parameters (Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A, STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, STAR8000F, OPUS i8, OPUS i10, OPUS i10 Expert, OPUS i12, OPUS i12 pro, OPUS i15, K12 pro, K12A pro, K15 pro, K15A pro, K18 pro, K18A pro, K22 pro, K22A pro, K1, K1A)
 - Fetal & Maternal Monitor for vital physiological parameters (Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)
 - Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A, C10, C11)
 - Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters (Model: C100, C100B)
 - Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system (Model: STAR8800)
 - Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS i3, NC5A)
 - Vital Signs Monitor for routine check of NIBP, SpO2, ECG, Temperature and Pulse rate (Model: NC5)
 - Specialized Neonatal Monitor for vital physiological parameters (Model: C60, C66, C68, Datalys 760)
 - Infrared Ear thermometer (Model: IRT10, IRT10A)
 - Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)
 - Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)
 - T piece Infant Resuscitation System (model: BQ70, BQ70A)
 - Anaesthesia Machine (Model: AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A, AX-400, AX-500, AX-600, AX-700)
 - Infant Radiant Warmer (Model: BQ80, BQ80A)
 - Catheter-positioning guiding system (Model: U8, U8A)
 - Syringe Pump (Model: M300, M500)
 - Infant Phototherapy equipment (Model: BL70, BL70A, BL70B)
 - Temperature Control System for management patient body temperature and vital physiological parameters Monitor (Model: P3, P6)
 - Sequential Compression System for prevention of deep vein thrombosis and pulmonary embolism (Model: SCD600)
 - Defibrillator Monitor (Model: S8, S6, S5, S3)
- Sterility aspect only Restricted to the Aspect of manufacture concerned with securing and maintaining sterile conditions:
- Sterile disposable laryngoscope blade (Model: CVL-2-1, CVL-3-1)
 - Sterile disposable electrode with extension wire used for Catheter-positioning guiding system (Model: 98ME01AC019)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

