

# Professional & convenient



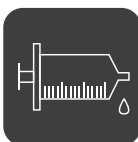
## Extensive drug library

M300 provides a drug library with capacity of 2100 and is customizable for new entries, giving medical personnel essential drug options for infusion records to ensure medication safety.



## Multiple working modes

Features rate mode, time mode, weight mode, interval mode, trapezia mode, sequence mode, micro mode, TIVA mode, loading dose mode and night mode, which meet a variety of clinical needs and matched well with other ICU equipment.



## Continuous titration

The infusion parameters setting can be changed without stopping it.

COMeN



M300 Syringe Pump



## Screen within easy reach

The M300 syringe pump has a large 4.3-inch screen with a 20 degree tilt, touch screen operation, visualized numerical display and lifelike colors, which render the injection curve display more vividly.

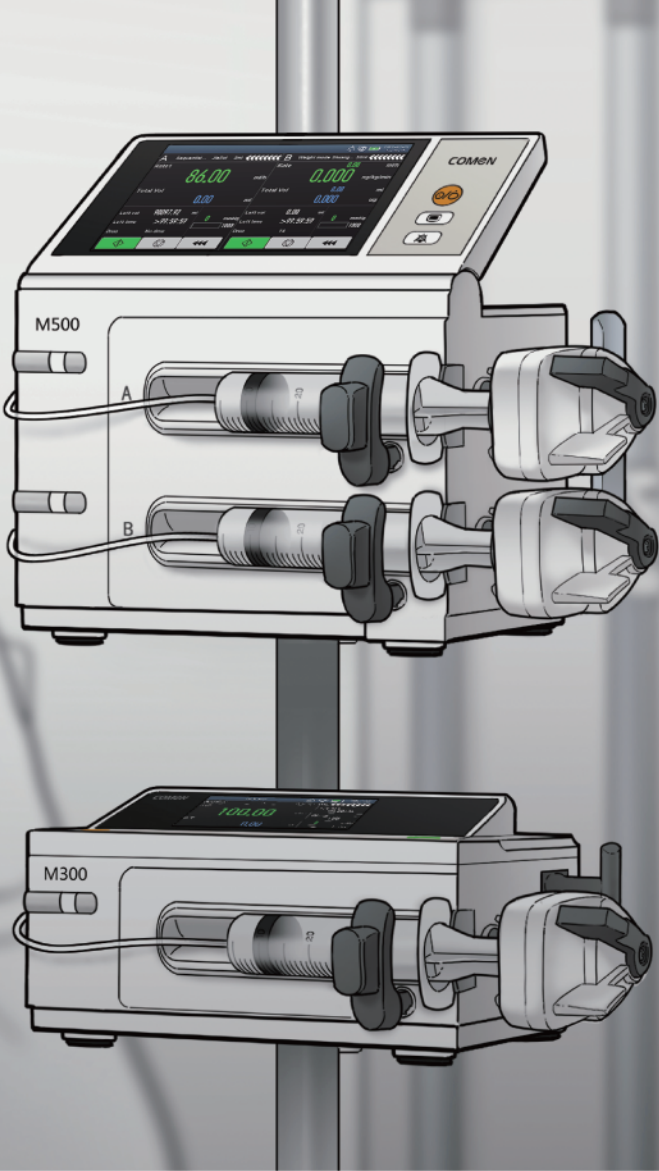
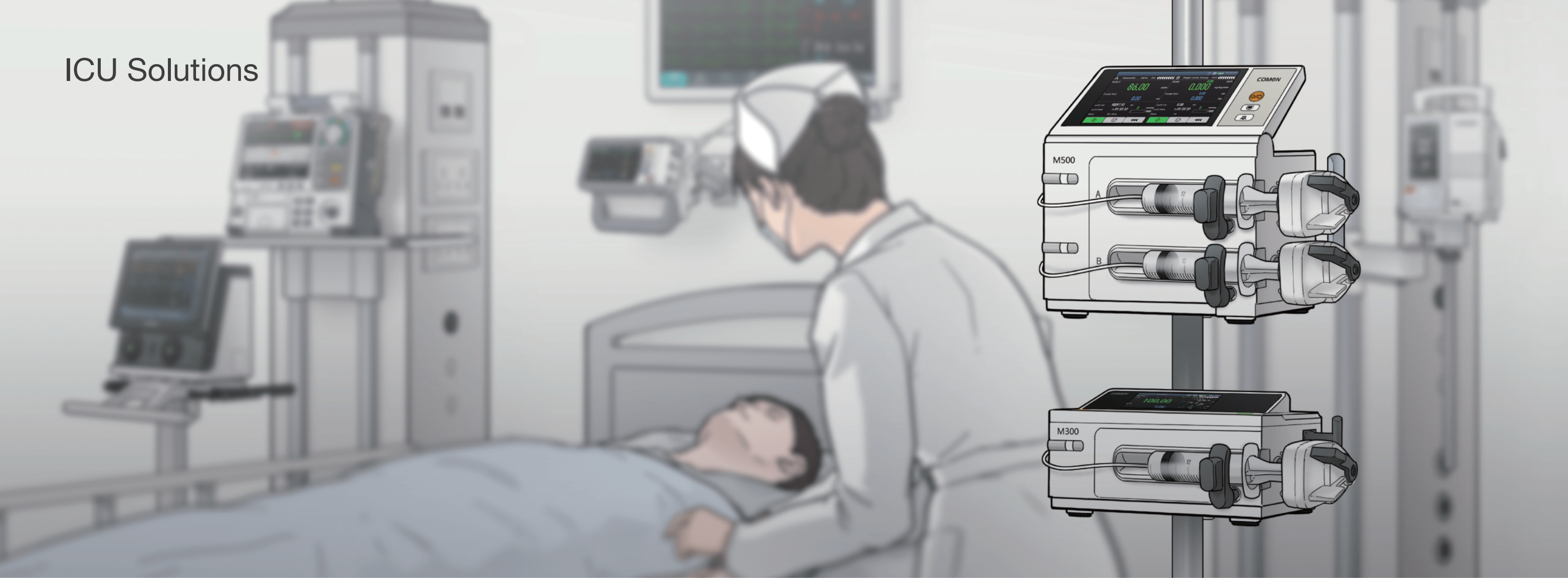


Shenzhen Comen Medical Instruments Co., Ltd.

P/N: EN-M300-4P-20200618-V1.0

Add: No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district,Guangming New District, Shenzhen, 518106, P.R.China  
Tel:+86-755-2640 8879 400-700-9488 Fax:+86-755-2643 1232 Website: en.comen.com E-mail: info@szcomen.com

# ICU Solutions



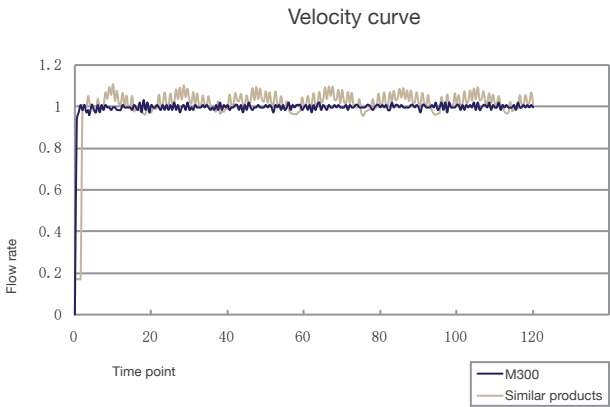
## Multi-CPU monitoring High precision injection

### CPU matrix

M300 adopts multiple CPUs to monitor each other and form a coordinated alarm system to ensure the safety of injection and prevent accidents.

### High-performance motor

The high-performance stepper motor and transmission system allow the M300 to inject without generating pulse waves even at low speeds.



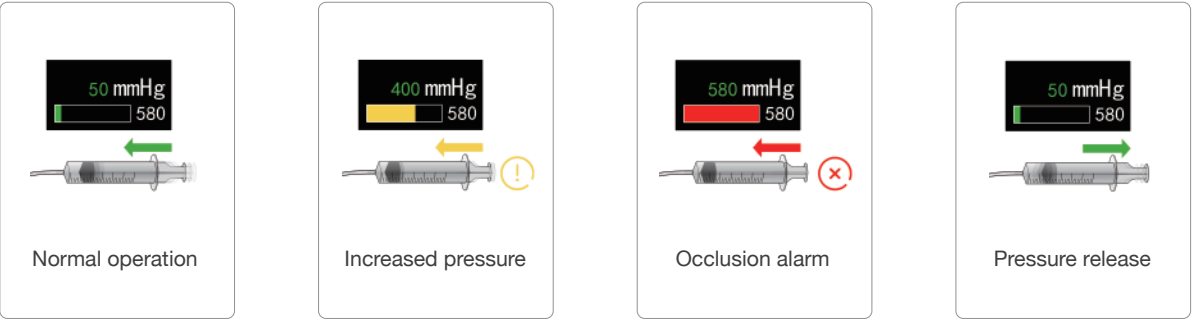
## Smart Occlusion Management System

### Anti- Bolus

Auto pressure release and Real time pressure monitoring.  
In the presence of bolus obstruction, the pressure is automatically released, and an audible and visual alarm is issued to prompt the medical staff to deal with it.

### Dynamic pressure monitoring

Real-time alarm for abnormal pressure is specially designed in response to dramatic changes in syringe pressure. The pressure value of the syringe is monitored with both digital and graphical displays.





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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

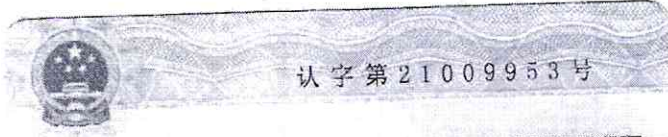
日期: 2021年04月26日

(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。



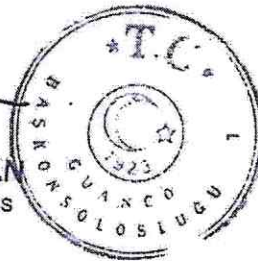
中华人民共和国外交部 (440)  
二〇二一年四月二十八日 广州

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

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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

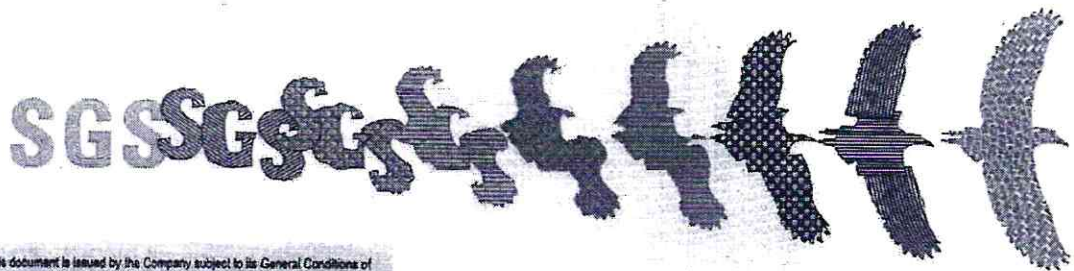
Global Medical Devices Head of Notified Body

**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](http://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.







## EC Declaration of Conformity

**Manufacturer:**

 Shenzhen Comen Medical Instruments Co., Ltd  
**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, Guangdong, 518106, P.R. China.

**Whose Single Authorized Representative:**  
 Lotus NL B.V.

**Address:**

 Koningin Julianaplein 10, 1e Verd, 2595AA,  
 The Hague, Netherlands.

We, the manufacturer, declare at our sole responsibility that following products

Product name	Model
Electrocardiograph	CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A
Vital Signs Monitor	NC3, NC3A, NC3B, OPUS i3, NC5, NC5A
Infrared Ear thermometer	IRT10, IRT10A
Anesthetic Gas Scavenging System	AGSS-L, AGSS-H
Ceiling Pendant	D5, D7, D6, D8, D9, D9A, D9B
Sequential Compression System	SCD600
Phototherapy Unit	BL70, BL70A, BL70B
Defibrillator monitor	S8, S6, S5, S3

meet the provisions of Directive 93/42/EEC.

Those medical devices have been assigned to class IIa according to rules of the Directive 93/42/EEC (The rule for each device are shown in the following annex I). It bears the mark

# CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section 4) of Directive 93/42/EEC has been assessed and certified by the Notified Body

**SGS Belgium NV**  
**SGS House Noorderlaan**  
**87 2030 Antwerp Belgium**  
 Certificate No.: CN19/41057  
 Issue date: 2021.03.22  
 Expiry date: 2023.02.05

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of  
 Company: Shenzhen Comen Medical Instruments Co., Ltd  
 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, Guangdong,  
 518106, P.R. China.

Shenzhen, 2021.4.28  
 Place, date



深圳市科曼医疗设备有限公司  
 Legally binding signature, Function

