Digitally signed by Maxim Victor
Date: 2023.05.01 15:21:04 EEST
Reason: MoldSign Signature
Location: Moldova

Shenzhen Comen Medical Instruments Co., Ltd
Floor 10, Floor 11 and section C of Floor 12 of Building 1A &
Floor 1 to 5 of Building 2,
FIYTA Timepiece Building,
Nanhuan Avenue
Matian Sub-District, Guangming District
Shenzhen, Guangdong 518106
P.R. China

Date: 09.01.2023

To Whom it may Concern

This is to confirm that the company Shenzhen Comen Medical Instruments Co., Ltd has started, its transition from MDD 93/42/EC to MDR 2017/745 with SGS Belgium Nv NB 1639. Please see below the expected plan for MDR certification of Shenzhen Comen Medical Instruments Co., Ltd

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- Contract signed with SGS Belgium NV for CE mark under MDR EU 2017/745: 08.07.2022
- On site audit Stage 1 has been conducted during 2,75 days on the: 12 & 13Th of July 2022
- On site audit Stage 2 has been conducted during 30.5 days staring on 28Th of November 2022 leading to 9 nonconformities .
- Initial technical documentation assessments for devices have started in August 2022 for entire range of devices from class Is to III (MDN1207,MDN1214, MDA0202, MDA0203, MDA0302, MDA0303, MDA0305, MDA0306, MDA0307, MDA0315, MDA0316)
- Follow up review and nonconformities closing for TDA: expected in September 2023 (depending of Shenzhen Comen Medical Instruments Co., Ltd capacity to provide relevant evidence to close the nonconformities)
- Final review and certification decision: expected for the October 2023.

These dates are provided based on actual knowledge of compliance status and may be extended depending on the severity of the non-conformities and capacities of the company to provide evidence in a timely manner.

Regarding requirements associated implementation of MDCG2022-18, we will not emit condition certificate as we consider we need additional guidance from MDCG on way to implement this conditional certification.

Regarding the fact the devices are meeting General Safety and Performance Requirements we can't confirm it now as the assessment is ongoing, but the devices were compliant with MDD 93/42/EC Essential Requirements.

However, I confirm that Shenzhen Comen Medical Instruments Co., Ltd is maintaining compliance with ISO13485:2016 requirements that are assessed thank to regular on-site audit and they have demonstrated compliance with MDR QMS on site requirements.

I will be your contact point in SGS Belgium Nv (NB1639).

Yours sincerely

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

广东外办

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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

CCPIT
中国国际贸易促进委员会

ÖZERAY TERCÜME BÜROSU
ÖZERAY TRANSLATION OFFICE
NOTER YEMİNLİ MÜTERCİM

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

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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

214403A0/024831

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 CCPIT

授权签字：

Authorized Signature: LIU JUN

日期：2021年04月26日

(Date: Apr. 26, 2021)

证明书查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

ÖZERAY TERCÜME BÜROSU ÖZERAY TRANSLATION OFFICE YEMİNLİ MÜTERCİM

认字第210099449号

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

00783372

中华人民共和国外交部证使专用章 (440)

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

Selçuk ALKAN
Muavin Konsolos
Vice Consul

T.C. BAŞKONSOLOSLUĞU GUANCO 1923

No: 30/4/2021/398

Tarife: 5/III/3a

Harç: 124 Yuan

Makbuz No: 28708422

ÖZERAY TERCÜME BÜROSU ÖZERAY TRANSLATION OFFICE NOTER YEMİNLİ MÜTERCİM

COMEN
Share With The World.

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 UNITIL: 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

ÖZERAY TERCÜME BÜROSU
ÖZERAY TRANSLATION OFFICE
YEMİNLİ MÜTERCİM

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

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.