EU Quality Management System Certificate CN23/00001577

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
SRN Number: CN-MF-000002236
has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 02 August 2023 until 31 March 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 September 2027

Issue 3. Certified since 31 March 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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t +32 (0)3 545-48-48 - www.sgs.com

Shenzhen Comen Medical Instruments Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

Active non-implantable device for monitoring of vital physiological parameters including (but not limited to) ECG, TEMP, SpO2, PR, NIBP, RESP and EtCO2, and associated incorporated software.

Class IIb - MDA0203, MDS1009, MDS1010 - EMDN: Z120302

Multi-parameter Patient Monitor:
- Models 1: C30, C30A (Basic UDI-DI: 69454290PM001PA)
- Models 2: C50, C500, C80, C800, C86, C860, Datalys 750, Datalys 780, OPUSi15 (Basic UDI-DI: 69454290PM002PC)
- Models 3: C70, C90, Datalys 770, Datalys 790, C70A, C90A (Basic UDI-DI: 69454290PM003PE)
- Models 4: K12Pro, K12APro, K15Pro, K15APro, K18Pro, K18APro, K22Pro, K22APro (Basic UDI-DI: 69454290PM007PN)
- Models 5: K1, K1A (Basic UDI-DI: 69454290PM008PQ)
- Models 6: NC8, NC8A, NC10, NC10A, NC12, NC12A, STAR8000A, STAR8000B, STAR8000C, OPUS i8, OPUS i10, OPUS i12, OPUSi10 Expert (Basic UDI-DI:69454290PM005PJ)
- Models 7: NC19, NC19A, STAR8000D (Basic UDI-DI: 69454290PM012PF)
- Models 8: STAR8000, STAR8000E, STAR8000F, STAR8000H, OPUS i12 pro (Basic UDI-DI: 69454290PM004PG)
- Models 9: C100A (Basic UDI-DI: 69454290PM006PL)"
- Models 10: N10M, N10MA, N10MC, N12M, N12MA, N12MC, N15M, N15MA, N15MC, N10, N10A, N10C, N12, N12A, N12C, N15, N15A, N15C, N10MPro, N10MAPro, N12MPro, N12MAPro, N15MPro, N15MAPro (Basic UDI-DI:69454290PM011PD)

Fetal & Maternal Monitor: STAR5000, STAR5000C, STAR5000D, STAR5000E, STAR5000A, STAR5000B, STAR5000F, STAR5000H (Basic UDI-DI:69454290FM001KU)

Specialized Fetal & Maternal Monitor: C10, C11 (Basic UDI- DI:69454290FM001KU)

Specialized Fetal & Maternal Monitor: C21, C21A, C22, C22A (Basic UDI-DI:69454290FM001KU)

Specialized Fetal & Maternal Monitor: C20, C26, C29 (Basic UDI-DI:69454290FM001KU)

Specialized Cardiovascular Monitor: C100, C100B (Basic UDI-DI:69454290PM010PB)

Central Monitoring System Software: STAR8800 (Basic UDI-DI:69454290MS001PK)

Vital Signs Monitor: NC3, NC3A, NC3B, OPUSi3, NC5, NC5A (Basic UDI-DI:69454290SM001QB)

Specialized Neonatal Monitor: C60, C66, C68, Datalys 760 (Basic UDI-DI:69454290PM009PS)

Class IIb - MDA0306, MDS1009, MDS1010 - EMDN: Z12030302
Syringe Pump: M300, M500 (Basic UDI-DI:69454290SP001QY)

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Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: - CN/SZX/50010 - CTC 1.35
Authorized representative name and address (if relevant): Lotus NL B.V., Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Previous certificate number: N/A

Change in between this certificate and previous one: Addition of the new “models 10” for certified device Multi-parameter Patient Monitor

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Issue 3
Sites
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
Shenzhen Comen Medical Instruments Co., Ltd. Floor 7 of EBOHR Building A & Floor 5 of EBOHR Building B, Timepieces Base, Guangming District, Shenzhen, Guangdong, P.R. China
Shenzhen Comen Medical Instruments Co., Ltd. Floor 2, Building 108B, 7th Industrial Zone, Mashantou, Matian Street, Guangming District, Shenzhen, Guangdong, P.R. China
Shenzhen Comen Medical Instruments Co., Ltd. Unit 501, West Side of the Fifth Floor of the Machinery Factory (No. 2 Area of Chuangxiang), Yanxiang Technology Industrial Park, No.11 of Gaoxin West Road, Guangming Street, Shenzhen, Guangdong, P. R. China
Shenzhen Comen Medical Instruments Co., Ltd. Floor 3 and 4 of Ruihui Building, Intersection of Fuli South Road and Fangyuan Road, Matian Street, Guangming District, Shenzhen, Guangdong, P.R. China