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) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

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

This certificate is valid from 03 September 2026 until 31 March 2028 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 30 September 2027

Issue 21. Certified since 31 March 2023

Authorised by
Virginie Siloret
Head of Certification and Compliance

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EU Quality Management System Certificate
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Shenzhen Comen Medical Instruments Co., Ltd.

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Class IIa devices
MDA0316
Anaesthetic Gas Scavenging System: AGSS-H, AGSS-L (Basic UDI-DI:69454290AG001GT)

MDA0302, MDS1009, MDS1010
Infant Phototherapy equipment:
BL70, BL70A, BL70B (Basic UDI-DI: 69454290BL001J9)
BL60, BL60A (Basic UDI-DI: 69454290BL003JD)

MDA0302, MDS1009
Neonatal Phototherapy Bed: BL20, BL20A, BL20B, BL20C (Basic UDI-DI: 69454290BL002JB)

MDA0203, MDS1009
Electrocardiograph is intended to acquire, analyze, display, and record resting electrocardiographic information:
CM1200, CM1200A, CM1200B, H3, H12, H12A (Basic UDI-DI: 69454290EL001KA)
H300, H301 (Basic UDI-DI: 69454290EL003KE)
H1200, H1200A, H1200B (Basic UDI-DI: 69454290EL002KC)

MDA0305, MDS1009
Sequential Compression System for preventing deep vein thrombosis and pulmonary embolism and eliminate limb edema
-Model: SCD600 (Basic UDI-DI: 69454290SC001N5)
-Model: SCE100, SCE100A, SCE300, SCE300A (Basic UDI-DI: 69454290SC002N7)

Class IIb devices
MDA0203, MDS1009, MDS1010 - EMDN: Z120302
Active non-implantable device for monitoring of vital physiological parameters including ECG, TEMP, SpO2, PR, NIBP, RESP and EtCO2, and associated incorporated software.

Multi-parameter Patient Monitor:
- Models 1: C30, C30A (Basic UDI-DI: 69454290PM001PA)
- Models 4: K12Pro, K12APro, K15Pro, K15APro, K18Pro, K18APro, K22Pro, K22APro (Basic UDI-DI: 69454290PM007PN)
- Models 5: K1, K1A (Basic UDI-DI: 69454290PM008PQ)

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- 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)
- Models 11: ND10, ND10A, ND10C, ND10S, ND12, ND12A, ND12C, ND12S, ND15, ND15A, ND15C, ND15S (Basic UDI-DI: 69454290PM013PH)
- Models 12: MR-M60, MR-M60E, MR-M60S, MR-M60T, MR-M80, MR-M80E, MR M80S, MR-M80T (Basic UDI-DI: 69454290MR001PC)
- Models 13: ND30, ND60, ND70, ND80, ND100, ND120, ND150, UD30, UD60, UD70, UD80, UD100, UD120, UD150 (Basic UDI-DI: 69454290PM015PM)
-Models 14: VC100, VC100E (Basis UDI-DI: 69454290PM018PT)
-Models 15: VC300, VC300E, VC300X, VC300T, VC600, VC600E, VC600X, VC600T, VC800, VC800E, VC800X, VC800T, VC300 Pro, VC300E Pro, VC300X Pro, VC300T Pro, VC600 Pro, VC600E Pro, VC600X Pro, VC600T Pro, VC800 Pro, VC800E Pro, VC800X Pro, VC800T Pro (Basis UDI-DI: 69454290PM017PR)
-Models 16: VK10, VK20 (Basic UDI-DI: 69454290PM008PQ)
-Models 17: VK120, VK130, VK150, VK160, VK180, VK190) (Basic UDI-DI: 69454290PM007PN)

Specialized Fetal & Maternal Monitor:
C21, C21A, C22, C22A, C20, C26, C29 (Basic UDI DI:69454290FM001KU)
CF5, CF5A, CF50, CF50A, CF5R, CF5AR, CF50R, CF50AR, CF8, CF8A, CF80, CF80A, CF8R, CF8AR, CF80R, CF80AR (Basic UDI-DI: 69454290FM002KW)
CF3, CF3A, CF30, CF30A, CF3 R, CF3A R, CF30 R, CF30A R (Basic UDI-DI: 69454290FM003KY)

COMEN Telemetry
(models: CT30, CT50, CT60, CT70, CT80) (Basic UDI-DI: 69454290CT001LC)

MDA0315, MDS1009, EMDN: Z120302
Central Monitoring System Software:
STAR8800 (Basic UDI-DI:69454290MS001PK)
eCenter-OB (Basic UDI-DI: 69454290MS005PT)

MDA0315, MDS1009, MDS1010 - EMDN: Z120302
Central Monitoring System Software:
eCenter-CMS (Basic UDI- DI:69454290MS003PP)

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

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NC6, NC6A, NC6C, NC6Neo, NC7, NC7A, NC7C, NC7Neo (Basic UDI-DI: 69454290SM002QD)

Specialized Neonatal Monitor:
K60, K60A, K80, K80A, K90, K90A (Basic UDI-DI: 69454290SN001QJ)

MDA0303, MDS1009, MDS1010 EMDN: Z12080407
Infant radiant warmer:
BQ80, BQ80A-The infant radiant warmer is an open care unit for warming, phototherapy, resuscitation and monitoring for infant, neonate (including premature babies) and paediatric patients with a weight less than 10 kg. (Basic UDI-DI: 69454290BQ002KE)

Class III devices
MDA0305, MDS1009, MDS1010
Defibrillator Monitor System (Models: S3, S5, S6, S8) for Manual or AED Defibrillation; Pacing; ECG, SpO2, EtCO2, TEMP, NIBP, IBP, RESP, PR monitoring; Arrhythmia and ST Segment Analysis. The system includes accessory Defibrillation Paddles (model: CM3901) (Basic UDI-DI: 69454290DM001K6)

MDA0303, MDS1009, MDS1010
Temperature Control System for the treatment of HIE (Hypoxicischemic Encephalopathy) during neonatal surgery or therapeutic hypothermia (Model: P3, P6) (Basic UDI-DI: 69454290TC001NG)

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
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

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Change in between this certificate and previous one: 1. remove Models 2,3, 8 of device Multi-parameter patient monitor & Specialized Cardiovascular Monitor: C100, C100B & Specialized Neonatal Monitor: C60, C66, C68, Datalys 760 and Syringe Pump: M300, M500 on the MDR certificate; Specialized Fetal & Maternal Monitor: C10, C11
2. add models 14, 15, 16, 17 of device Multi-parameter Patient Monitor and COMEN Telemetry (models: CT30, CT50, CT60, CT70, CT80) on the MDR certificate

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Shenzhen Comen Medical Instruments Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Sites

Shenzhen Comen Medical Instruments Co., Ltd.
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Shenzhen Comen Medical Instruments Co., Ltd.
Floor 1-4 & Floor 10, No. 3 Factory, Building 2, Phase 4 of No.4 Industrial Zone (formerly known as Hengshou Science and Technology Park), Heshuikou Community, Martian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China

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