EU Quality Management System Certificate FI23/1008002

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: CN-MF-000002236

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products
Neonatal and Pediatric Ventilators, Ventilators, Defibrillator monitors

Certification is based on decision FI24/08139P0.
Previous certificate number: FI23/1008002 Issue 1.
Change in between this certificate and previous one: Addition of new addresses, addition of Defibrillator monitor models S2, S2A.
Devices covered, their intended purposes, risk classification as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 09 January 2024 until 05 September 2028 and remains valid subject to satisfactory surveillance audits.
Issue 2 Certified since 06 September 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo, NB

SGS FIMKO OY
Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S009 (EN ISO/IEC 17021-1)

EU Quality Management System Certificate FI23/1008002-2, continued

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 2
Sites
Main site 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 Headquarters
Floor 7 of EBOHR Building A & Floor 5 of EBOHR Building B, Timepieces Base, Guangming District, Shenzhen, Guangdong, 518106, P.R.China Engineering, Quality, Regulatory affairs, Purchasing and HR affairs
Floor 3&4, Unit A, Building 9, Guancheng Sanliang Industrial Park, No.2 of Xingguangchenxing Road, Huangjiang Town, Dongguan, Guangdong Province, 523000, P.R. China Warehouse
Room 301 and Room 302, No.86 of Xianneng Road, Tianliao Community, Yutang Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China Production, Warehouse
Floor 3 and North Side of Floor 4 of Ruihui Building, Intersection of Fuli South Road and Fangyuan Road, Matian Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China Warehouse, IQC

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Attachment 1 of Issue 2

Device or Device Group, EMDN Code	Risk Class	Identification Details and Intended Purposes
Z1203010504 Adult and Paediatric / Neonatal Pulmonary Ventilators	IIb	Ventilator Models: V6, V6A, V6B, V8, V8A, V8B Intended purpose: Assisted ventilation and respiratory support, SpO_2 and CO_2 monitoring for adult, paediatric and neonatal patients
Z1203010504 Adult and Paediatric / Neonatal Pulmonary Ventilators	IIb	Ventilator Models: NV70, NV70A, NV70B, NV60, NV60A, NV60B, NV50, NV50A, NV50B Intended purpose: Assisted ventilation and respiratory support, SpO_2 and CO_2 monitoring for adult, paediatric and neonatal patients
Z1203010504 Adult and Paediatric / Neonatal Pulmonary Ventilators	IIb	Ventilator Models: V2, V2A, V2B, V5, V5A, V5B Intended purpose: Assisted ventilation and respiratory support, SpO_2 and CO_2 monitoring for adult, paediatric and neonatal patients
Z1203010503 Neonatal / Paediatric Pulmonary Ventilators	IIb	Neonatal and Pediatric Ventilators Models: NV10, NV10A, NV10B Intended purpose: Assisted ventilation and respiratory support, SpO_2 and CO_2 monitoring for paediatric and neonatal patients
Z12030502 MANUAL DEFIBRILLATORS	IIb	Defibrillator monitor Models: S2, S2A Intended purpose: The monitor is used for manual defibrillation, noninvasive cardiac pacing and monitoring of ECG (3-ead, 5-lead, 6-lead or 12-lead selectable), Arrhythmia Analysis, ST Segment Analysis, 12-Lead Resting ECG Analysis, RESP, SpO2, RP, NIBP and EtCO2. The monitor can be used in professional healthcare environment and emergency medical services environment (including ambulance).

The certification decision is based on the following:

Report Identification and Date
Medical Device Certification Audit Report, MDR-2006_Shenzhen Comen_2023ES_FPMDREG3019 - MD Audit Report Ver E - Rev.1.1, dated 2024-01-10 Technical Documentation Assessment Report, MDR-2006_Comen_S2S2A_SC_FPMDREG3020 - MDR Technical Documentation Assessment Report Ver F - Rev.1.1, dated 2024-1-10

Conditions for or limitation to the validity of the certificate
N/A

EU Authorised Representative
Lotus NL B.V., Koningin Julianaplein 10, 1e Verd, 25955AA, The Hague, Netherlands SRN: NL-AR-000000121