EU Quality Management System Certificate FI23/1008002

The quality 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 and III)

for the following:
Neonatal and Pediatric Ventilators, Ventilators, Defibrillator monitors, Endoscopic devices, Respiratory humidifiers, Automatic CPR, Temperature control system, Patient Warming Blanket and Infusion pump, Infusion Workstation System, Syringe Pump and Reusable SpO2 Sensor

Issue 11
Previous certificate's number and issue: FI23/1008002 Issue 10
Change in between this certificate and the previous one: Supplemented of product range.

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 30 October 2026 until 05 September 2028 and remains valid subject to satisfactory surveillance audits.
Certified since 06 September 2023
Certified activities performed by additional sites are listed on the subsequent pages.

Authorised by
Jani Högman, Certifier

SGS FIMKO OY
Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 - www.sgs.fi - Business ID 0634247-4

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Issue 11
Sites
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 Management, Design and development, Sales, Service provision, Regulatory affairs,
Room 301 and Room 302, Room 402 & Room 403, No.86 of Xianneng Road, Tianliao Community, Yutang Sub-district, Guangming District, Shenzhen, Guangdong Province, 518106, P.R. China Production, IQC, Warehouse
Room 302, Unit B & Floor 3-4, Unit A, No.1 Factory, Guancheng Sanliang Industrial Park, No.2, Chenxing Road, Huangjiang Town, Dongguan City, Guangdong Province, 523000, P.R. China Warehouse
Floor 3 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
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 Production, procurement, Raw material warehouse, incoming material inspection, engineering, quality, purchasing

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIa
MDA 0204
EMDN: Z12020511 Video gastroscopes
Upper Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE001PL, Models: EG-200, EG-200T, EG-201, EG-201T
Upper Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE007PY, device models: EG-300Z, EG-150Z
Upper Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE016PZ, device models: EG-100, EG-101, EG-100T, EG-101T, EG-100XT, EG-101XT, EG-150, EG-151, EG-150T, EG-151T, EG-150XT, EG-151XT
Upper Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE010PM, device models: EG-200N, EG-100N,

EMDN: Z12020606 Video colonoscopes
Lower Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE002PN, Models:EC-200, EC-200L, EC-201, EC-201L
Basic UDI-DI: 69454290LG001LL, Models:EC-300, EC-300L, EC-A30, EC- A30L, EC-A20, EC- A20L, EC-300P, EC-300PL, EC- A30P, EC- A30PL, EC-A20P, EC- A20PL, EC-300T, EC-300TL, EC- A30T, EC- A30TL, EC- A20T, EC- A20TL

Lower Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE008Q2, device models: EC-300Z, EC-300ZL, EC-150Z, EC-150ZL, EC-300ZP, EC-300ZPL, EC-150ZP, EC-150ZPL
Lower Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE017Q3, device models: EC-150, EC-151, EC-150L, EC-151L
Lower Gastrointestinal Video Endoscope, Basic UDI-DI: 69454290VE018Q5, device models: EC-301, EC-301L, EC-A31, EC-A31L, EC-301P, EC-301PL, EC-A31P, EC-A31PL, EC-301T, EC-301TL, EC-A31T, EC-A31TL.
Lower Gastrointestinal Video Endoscope,Basic UDI-DI: 69454290VE009Q4, device models: EC-300XP, EC-300XPL, EC-300SP, EC-300SPL

EMDN: Z12020802 Video bronchoscopes
Electric Bronchoscope, Basic UDI-DI: 69454290EB001H4, Models: E1000, E2000, E3000, E4000, EB28, EB38, EB52, EB58

EMDN: Z12020402 Light sources for endoscopy and minimally invasive surgery
Medical Endoscopic Light Source, Basic UDI-DI: 69454290VE004PS, Models: ELS-2000C, ELS-2000U, ELS-2010C, ELS-2010U

Medical Endoscopic Light Source, Basic UDI-DI:69454290VE011PP, Models: ELS-1000C, ELS-1000U,
Medical Endoscopic Light Source, Basic UDI-DI:69454290VE014PV, software version: V1, device models: ELS-1500C, ELS-1500U.
Medical Endoscopic Light Source, Basic UDI-DI:69454290VE019Q7, software version: V1, device models: ELS-3000C, ELS-3000U

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIa

MDA 0202
EMDN: Z12020406 Video processors,
Medical Endoscopic Video Processor, Basic UDI-DI: 69454290VE003PQ, software version: V1, Models: EIS-2000U, EIS-2000Pro, EIS-2000C, EIS-2000E, EIS-2000S, EIS-2000X,
Medical Endoscopic Video Processor, Basic UDI-DI:69454290VE012PR, software version: V1, device models: EIS-1000U, EIS-1000Pro, EIS-1000X, EIS-1000E,
Medical Endoscopic Video Processor, Basic UDI-DI:69454290VE015PX, software version: V1, device models: EIS-1500U, EIS-1500Pro, EIS-1500X, EIS-1500E,
Medical Endoscopic Video Processor, Basic UDI-DI:69454290VE020PQ, software version: V1, device models: EIS-3000U, EIS-3000Pro, EIS-3000X, EIS-3000E

MDA 0303
EMDN Z12040208, Body Thermoregulation Equipment
Patient Warming Blanket, Basic UDI-DI 69454290TC004NN, device models: P5, P5A, P5B, P5C

EMDN Z1203020299, Multi–Parameter Monitors-Other (For TEMP monitoring part)
Temperature Control System, Basic UDI-DI 69454290TC002NJ, software version V1, P1, P1A, P1B, P1C
Temperature Control System, Basic UDI-DI 69454290TC003NL, software version V1, P2, P2A, P2B, P2C

MDA 0307
EMDN R060201 Active Ventilation Humidification System
Respiratory Humidifier, Basic UDI-DI: 69454290RH001NV, software version: V1, Models: HT50, HT30

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIb
MDA 0307

EMDN: Z1203010504 Adult and paediatric/neonatal pulmonary ventilators
Basic UDI-DI: 69454290GV002N8, software version: V1, Models: V6, V6A, V6B, V8, V8A, V8B
Intended purpose: Assisted ventilation and respiratory support, SpO2 and CO2 monitoring for adult, paediatric and neonatal patients

Basic UDI-DI: 69454290GV003NA, software version: V1, Models: NV70, NV70A, NV70B, NV60, NV60A, NV60B, NV50, NV50A, NV50B
Intended purpose: Assisted ventilation and respiratory support, SpO2 and CO2 monitoring for adult, paediatric and neonatal patients

Basic UDI-DI: 69454290GV004NC, Models: V2, V2A, V2B, V5, V5A, V5B
Intended purpose: Assisted ventilation and respiratory support, SpO2 and CO2 monitoring for adult, paediatric and neonatal patients

EMDN: Z1203010504 Adult and paediatric/neonatal pulmonary ventilators
Basic UDI-DI: 69454290GV001N6, Models V3, V3A, V3B, V3C, V3D, V3 Pro, V3A Pro, V3B Pro
Intended use: The ventilator provides assisted ventilation and respiratory support, SpO2, and CO2 monitoring for adult, pediatric and neonatal patients. The ventilator is intended to be used in professional healthcare facilities. The ventilator should only be operated by healthcare professionals. The device cannot be used in MR environments.

EMDN: Z1203010504 Adult and paediatric/neonatal pulmonary ventilators
Emergency and transport ventilator Basic UDI-DI: 69454290EV001MG, Models: V1, V1A, V1B, V1C, V1D, V1 Pro
Intended use: The emergency and transport ventilator provides positive pressure ventilation, SpO2 and CO2 monitoring for adult, pediatric and neonate patients. The ventilator is intended to be used in professional healthcare facilities and emergency medical services environments by health professionals with varying levels of training and education. The ventilator is transit-operable during transport inside and outside the healthcare facility. The device cannot be used in MR environments.

EMDN: Z1203010503 Neonatal/pediatric pulmonary ventilators
Neonatal and Pediatric Ventilators
Basic UDI-DI: 69454290NV002QM, Models: NV10, NV10A, NV10B
Intended purpose: Assisted ventilation and respiratory support, SpO2 and CO2 monitoring for paediatric and neonatal patients

Neonatal and Pediatric Ventilators
Basic UDI-DI: 69454290VN001RK, Models: VN6S, VN6, VN6S HFO, VN8S, VN8, VN8S HFO
Intended purpose: To provide neonates (including premature infants) and pediatrics (weighing<30kg) with different levels of support for ventilation in either invasive or non-invasive ways, as well as the SpO2 and CO2 monitoring, in professional healthcare facilities. The ventilator should only be operated by healthcare professional operators

EMDN: Z1203010503 Neonatal/pediatric pulmonary ventilators
Basic UDI-DI: 69454290NV001QK, Neonatal Ventilator, Models: NV7, NV8, NV9
Intended use: Neonatal/Pediatric Ventilator is intended to provide non-invasive ventilation support for neonates and pediatric patients with spontaneous breath in professional healthcare facilities. The Ventilator can also provide heated humidified high-flow nasal cannula (HFNC) and SpO2 monitoring for patients under ventilation. The ventilator should only be operated by healthcare professionals. The device cannot be used in MR environments

EMDN: Z12030102 Continuous positive pressure equipment
Basic UDI-DI: 69454290NV001QK, Neonatal Ventilator, Models: NV6
Intended use: Integrates the medical air-oxygen blender/humidifier/pressure generating device to provide bubble NCPAP ventilation therapy for neonates

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIb
MDA0307
EMDN: Z12030104 Portable pulmonary ventilators
Emergency Transport Ventilator, Basic UDI-DI: 69454290EV002MJ, software version: V1, Models: EV5, EV5A
Intended purpose: The device is intended to provide adult or pediatric patients weighing ≥10 kg with different levels support of artificial ventilation in invasive or non-invasive way, as well as the SpO2 and CO2 monitoring, in the emergency medical services environment or transport to or between the professional healthcare facilities. This device cannot be used in MR environment.

Emergency Transport Ventilator, Basic UDI-DI: 69454290EV002MJ, Models: EV3, EV3A
Intended purpose: The device is intended to provide adult or pediatric patients weighing ≥10 kg with different levels support of artificial ventilation in invasive or non-invasive way in the emergency medical services environment or transport to or between the professional healthcare facilities. This device cannot be used in MR environment.

Z1203019099 Various instruments for anaesthesia and pulmonary ventilation support other
Medical Oxygen-air blenders, Basic UDI-DI: 69454290KL001MC, Model: KL-20
Intended purpose: This product is a respiratory device used to mix the input medical oxygen and air at a set concentration and output the mixed gas for clinical use. It is intended to provide oxygen therapy to patients. It can be used by healthcare professionals in professional healthcare facilities.

Emergency and Transport Ventilator, Basic UDI-DI:69454290EV004MN, software version: V1, Models: EV20, EV20A, EV20B, EV20C
Intended use: The device is intended to provide adult, pediatric and infant patients with different levels support of ventilation in invasive or non-invasive way, as well as the SpO2 and CO2 monitoring, in professional healthcare facilities and emergency medical services environments, or during transport to or between these facilities. The ventilator should only be operated by healthcare professionals. This device cannot be used in MR environment.

MDA0305
EMDN: Z12030502 Manual defibrillators
Defibrillator monitor, Basic UDI-DI: 69454290DM003KA, software version: V1, 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)

EMDN: C020499 External cardioversion and defibrillation devices - other
Automatic CPR machine, Basic UDI-DI: 69454290AC001FX, software version: V1, Model: ES3, ES3A, ES3B, ES5, ES5A, ES5B
Intended purpose: The Automatic CPR machine, when applied to an adult patient who have acute circulatory arrest, defined as the absence of spontaneous breathing and pulse as well as loss of consciousness, is intended to: ▪ Provide consistent depth and rate chest compressions. ▪ Provide EtCO2 monitoring function.

EMDN C900301 PULSE OXIMETER SENSORS
Reusable SpO2 sensor, Basic UDI-DI 69454290CM005K3, Models:CM-M02-001, CM-M02-003, CM-M02-004, CM-M02-006, CM-M02-007, CM-M02-009, CM-M02-010, CM-M02-012, CM-M02-013, CM-M02-014, CM-M02-015
Intended use: The reusable SpO2 sensor in this series are intended to measure the patient's non-invasive SpO2 value. It collects the patient's SpO2 signal and PR signal and transmits them to the SpO2 module for analysis. This product is suitable for adult, pediatric and neonate and intended to be operated only by healthcare professionals, in professional healthcare facilities.

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIb
MDA0306
EMDN code: Z12030301, INFUSION PUMPS
Infusion pump, model: ME900, ME900A Software version: Ver.1.(x), Basic UDI-DI: 69454290IP002ML
Intended purpose: The infusion pump is suitable for adults, pediatrics, and neonates patients for the intermittent or continuous delivery of gastrointestinal nutrients, medications, blood, and blood products in intravenous or gastrointestinal route.

Infusion pump, model: ME900-L, ME900A-L Software version: Ver.1.(x), Basic UDI-DI: 69454290IP005MS
Intended purpose: The infusion pump is intended for adults, pediatrics, and neonates for the intermittent or continuous delivery of gastrointestinal nutrients, medications, blood, and blood products in intravenous or gastrointestinal route.

Infusion pump, model: ME660, ME660A Software version: Ver.1.(x) Basic UDI-DI: 69454290IP004MQ
Intended purpose: The infusion pump is suitable for adults, pediatrics, and neonates for the intermittent or continuous delivery of gastrointestinal nutrients, medications, blood, and blood products in intravenous or gastrointestinal route.

MDA0318, MDS1009
EMDN: Z12030306, INFUSION AND SYRINGE PUMP CONTROL SYSTEMS
Infusion Workstation System, model: MX8900, MX8900A, Basic UDI-DI: 69454290IW003P7
Intended purpose: The MX8900/MX8900A infusion workstations system is a system rack used to supply power to and collect alarm and infusion information from the installed infusion pumps or syringe pumps.

MDA0306, MDS1009
EMDN: Z12030302, SYRINGE PUMP
Syringe Pump, model: M800, M800A, M800-TCI, Basic DUI-DI: 69454290SP002R2
Intended purpose: The syringe pump is intended for use on adult, pediatric and neonatal for intermittent or continuous delivery of medications through clinical intravenous route of administration.

Syringe Pump, model: M260A, M260 Basic UDI-DI 69454290SP004R6, software version V1,
Intended use: The syringe pump is intended for use on adult, pediatric and neonate for intermittent or continuous delivery of medications through clinical intravenous route of administration.

Syringe Pump, model: M500A, M500B Basic UDI-DI 69454290SP006RA, software version V2,
Intended use: The syringe pump is intended for use on adult, pediatric and neonate for intermittent or continuous delivery of medications through clinical intravenous route of administration.

Syringe Pump, model: M800-L, M800A-L, Basic UDI-DI 69454290SP003R4, software version V1,
Intended use: The syringe pump is intended for use on adult, pediatric and neonatal for intermittent or continuous delivery of medications through clinical intravenous route of administration.

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Shenzhen Comen Medical Instruments Co., Ltd.

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 11

The certification decision is based on the following:

Report Identification and Date:
FPMDREG1008 - MDR Notification of Product Changes Ver F -FL 250522, dated 2025-10-10
FPMDREG1008 - MDR Notification of Product Changes Ver F -SyringePump(delete M200A), dated 2026-09-07
Audit report: MDR-2006_Shenzhen Comen_2026ES_FPMDREG3019 - MD Audit Report Ver H - Rev.1.0, dated 2026-07-15
Technical Documentation Assessment reports: MDR-2006_2026ES_M800_FPMDREG3020 - MDR TDA Report Ver J Rev.1, dated 2026-09-28; MDR-2006_2026ES_MX8900_FPMDREG3020 - MDR TDA Report Ver J Rev.1, dated 2026-9-28; COMEN SpO2 sensor FPMDREG3020 - MDR Technical Documentation Assessment Report Ver G_Revision 1_2026-10-21, dated 2026-10-21

Applied Standards / Common specifications:
EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports

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

EU Authorised Representative:
Lotus NL B.V., Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
SRN: NL-AR-000000121

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.