By Royal Charter

EU Quality Management System Certificate

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

MDR 795750 R002

Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd

Address:
Floor10,Floor11 and Section C of Floor12 of Building 1A &
Floor 1 to Floor 5 of
Building 2, FIYTA Timepiece
Building, Nanhuan Avenue
Matian Subdistrict
Guangming District, Shenzhen
Guangdong
518106
China

Single Registration Number: CN-MF-000002236

EU Authorised Representative: Lotus NL B.V.

Address:
Koningin Julianaplein 10
1e Verd, 2595AA
The Hague
Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-03-21**

Current Issue Date: **2026-07-24**

Starting Validity Date: **2026-07-24**

Expiry Date: **2030-03-20**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Automatic External Defibrillator	See MDR 795754
Automatic External Defibrillator	See MDR 795752
Defibrillator Monitor	See MDR 795753
Internal Defibrillation Paddles	See MDR 795753

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	Intended purpose
Anesthesia Machine	The Anesthesia Machine is intended for inhaling anesthesia and respiratory management.
Syringe Pump	The syringe pump is intended for use on adult, pediatric and neonatal patients for intermittent or continuous delivery of medications through clinical intravenous route of administration.

Device Schedule: Class IIa, Custom-made and other devices	
Device(s)	**Risk Classification**
CO_2 Insufflator	Class IIa
Endoscopic Flushing Pump and Irrigation Tubes	Class IIa
Diagnostic Ultrasound System	Class IIa
Lower Gastrointestinal Video Endoscope	Class IIa
Medical Endoscopic Light Source	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2025-03-21	30005209	Issued
2025-10-09	30469967	Supplemented – Addition of Anesthesia Machine
2025-12-02	30273169	Supplemented – Addition of Automatic External Defibrillator and Defibrillator Monitor Amended – Revision of the Action on 2025-10-09 from Amended to Supplemented
2026-06-12	30596251	Supplemented – Addition of Syringe Pump
Current	30470026	Supplemented – Addition of CO_2 Insufflator, Endoscopic Flushing Pump and Irrigation Tubes, Diagnostic Ultrasound System, Lower Gastrointestinal Video Endoscope, Medical Endoscopic Light Source, and Internal Defibrillation Paddles.

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